

# HTAi 2016 Annual Meeting

Abstract Book



# Contents

<b>Oral Presentations</b>	<b>13</b>
OS.07 Should RCT Search Filters Account For The Phases Of Clinical Trials In Addition To Study Design? Results from an explanatory case-study	13
OS.10 Derivation Of Cost-Effectiveness Thresholds Based On Per Capita Health Expenditures & Life Expectancy	14
OS.11 Are Three Days Enough To Capture The Key Evidence For HTA Documents?	15
OS.13 Are Current Approaches To HTA Keeping Up With The Evolution And Pace Of Change In Medical Technology	16
OS.15 What Does The Current Research Evidence Tell Us About Searching For The Various Aspects Of HTA?	17
OS.18 A Novel Framework For Guiding Evidence Generation Strategies To Support Evaluation Of New Drugs	18
OS.21 Deconstructing Rapid Reviews: When Is Evidence Good Enough?	19
OS.22 Understanding Cost Drivers For Health Technology Assessment In Low-Income Countries	20
OS.23 Thrombectomy In The Treatment Of Acute Ischemic Stroke	21
OS.28 Engagement Of Older Adults In Aging-Related Health Technology Innovation	22
OS.35 An Integrated Perspective On The Value Of Health Technology. Results Of The Integrate-HTA Project	23
OS.38 Post Policy Implementation Review: The Case Of Rapid Fetal Fibronectin Testing For Preterm Labour	24
OS.47 The Impact Of Quality Of Life Data In Relative Effectiveness Assessments Of New Anticancer Drugs	25
OS.48 Platelet rich plasma: a case study for the identification of disinvestment using horizon scanning	26
OS.49 Caring Wisely: Optimising Patient Care In Australia And New Zealand	27
OS.50 Establishing The Value Of Diagnostic Technology In Terms Of Patient Outcome	29
OS.54 Impact On Capability As An Alternative Framework For Assessing The Value Of Healthcare Interventions	30
OS.56 Reconciling Public And Patient Preferences In Healthcare Decision Making. Belgium Pilots New Models	30
OS.60 Informing Acceptable Icers: What Is The Validity And Role Of Empirical Estimates Of A Cost-Effective	32
OS.61 Did Patient Care Meet Clinical Pathways In China?	33
OS.64 Different Approaches For Priority Setting In HTA: Methods, Criteria And Strategic Frameworks	34
OS.65 The Development Of A Priority-Setting Framework For Health Technology Assessment In Spain	35
OS.66 Pharmaceutical HTA And Drug Reimbursement Process In Mongolia	36
OS.68 Potential Savings In Healthcare Spending On Low Value Interventions In Massachusetts, US	37
OS.69 Joining Forces To Enhance Evidence. Informed Decision-Making In Eurasian Countries: A Swot Analysis	38
OS.72 Assessment Of Hair Protheses For Cancer Patients Using An Adapted HTA Method	39
OS.77 Is Patent 'Evergreening' Restricting Access To Medicine/Device Combination Products?	40
OS.80 Room With A Patient View, Engaging Patients In Health Care Decision Making. Insights From Australia	41
OS.83 The Scottish Medicines Consortium's New Process For End Of Life And Orphan Medicines	42
OS.90 Use Of Text-Mining Tools For Systematic Reviews	43
OS.93 Developing An Evaluation Framework To Measure Research Impact Of PPPHealth Research Programme	44
OS.94 Integrating Drugs Budget Impact And Drugs Market Uptake Models In Horizon Scanning: The C-Tobia Mode	45
OS.99 Cost Analysis Of Particle Radiotherapy In Comparison To Photon Therapy In China	47
OS.108 Updating HTA Guidelines Using HTA Methodology Research: The Dutch Experience	47
OS.109 Providing Information On New And Emerging Health Technologies:A User Survey	48
OS.114 Lack Of HTA: An Obstacle For Development Through Drug Repurposing	49
OS.124 Economic Evaluation Of Transcatheter Aortic Valve Implantation Treated By Medical Management	50
OS.125 Cost Effectiveness Of Antidepressants And Anticonvulsants For Treatment Of Chronic Low Back Pain	51
OS.127 Medical Devices In The Brazilian Public Health System (SUS), Technology Evaluation And Incorporation	52
OS.136 The Role Of Experiential Knowledge In Research Prioritisation, Regulation And Technology Appraisal	54

OS.137 Budget Impact Analysis Of Using Dihydroartemisinin Piperaquine To Treat Uncomplicated Malaria.....	55
OS.140 Reproductive Information Quality And The Probability Of Unplanned Pregnancies.....	56
OS.141 NICE Medtech Innovation Briefings: Informing Decisions About Innovative Technologies.....	57
OS.142 What Impact Have Drug Replacement On Hospital Treatment? A Health Technology Assessment Discussion.....	58
OS.144 Benchmark In Clinical Pathway Of Stroke Therapy On The Basis Of 534 Acute Hospitalized Patients.....	59
OS.149 Real-World Evidence (RWE) And The Value For Health Care Decision-Making In Rare Diseases.....	59
OS.151 Assessment Of Health Technology Usage In Family Group Practices Of Ulaanbaatar City.....	61
OS.155 Evaluation Of Guidelines With Automated Educational Messages For Improving Use Of LaboratoryTests.....	61
OS.165 Value In The Making In Medical Technology Introduction: An Interactive HTA.....	62
OS.167 The Patient Reported Outcomes, Burdens And Experiences (PROBE) Phase 1.....	63
OS.173 IMI GetReal: Stakeholder Views On The Early Use Of Pragmatic Trials During Medicine Development.....	64
OS.180 Publically Available Patient-Oriented Research Methods Guidance Materials: A Horizon Scan.....	65
OS.189 Optimization Of The General Surgery Service Of The University Hospital Pedro Ernesto.....	67
OS.194 Social Preferences For Rare Diseases In Spain.....	68
OS.201 Health Technology Assessment Of Medical Devices For Rare Diseases.....	69
OS.203 Where Are We With The Challenge Of High-Cost Medicines? Global Comparison Of The Reimbursement.....	70
OS.204 At What Point In The Life Cycle Of Technologies Are HTA Reports Requested?.....	71
OS.210 Horizon Scanning Alerts In Brazil: Informing Society.....	72
OS.211 Options For Formulary Development In Middle-Income Countries.....	73
OS.212 Economic Evaluations: Tendencies In Southern Africa.....	74
OS.214 How Long Does HTA Take?.....	75
OS.217 Public Consultation Of Guidelines In Brazil: Patient Involvement, Transparency, Implementation Tool.....	76
OS.225 Horizon Scanning Alerts With Sofosbuvir And Ledipasvir (Harvoni®) For The Treatment Of Hepatitis C.....	77
OS.230 The Road Map For HTA Development In Kazakhstan: For Well Informed Health-Care Decisions.....	78
OS.240 What Is The Value Of Low-Level Research Evidence For Decision-Making?.....	79
OS.241 Efficacy, Safety And Cost-Effectiveness Of Aripiprazole For Schizophrenia: A Systematic Review.....	80
OS.243 Exploring Unwarranted Variations In Clinical Healthcare Practice: Implications For De-Implementation.....	82
OS.244 Realist Exploration Of Unwarranted Variation In Clinical Healthcare Practice.....	83
OS.247 Use Of Bayesian Multi-Parameter Evidence Synthesis To Inform Health Care Decision Making.....	84
OS.248 Use Of Multivariate Network Meta-Analysis To Combine All Available Evidence For Predicting Outcome.....	85
OS.251 Immunosuppressive Therapy For Renal Transplantation In Adults: A Systematic Review.....	87
OS.254 Are HTAs Biased When Evaluating High-Cost Drug Combinations?.....	88
OS.255 Does HTA Share Their Clinical Evidence Sources?.....	89
OS.258 Assessment Of The Value Of Telemedical Monitoring Of Diabetic Foot Ulcer Patients.....	90
OS.261 Priority Setting In HIV/AIDS Control In Indonesia.....	92
OS.268 Priority Setting For Universal Health Coverage In Thailand.....	92
OS.269 Future Elderly Care In China, How Should It Be? Aspects From The Chinese Youngsters In Guangzhou.....	93
OS.275 Coverage With Evidence Development: Routine Activities Needed To Improve Quality Of Data Gathered.....	95
OS.279 Bronchial Thermoplasty (BT).....	96
OS.288 The Consideration Of Values In Developing Quality Standards: Emerging Issues And Challenges.....	97
OS.289 Safety And Effectiveness Of Irreversible Electroporation In Pancreatic Cancer: A Systematic Review.....	98
OS.294 Drivers Of Value In Medical Device Evaluation. What Makes For A Positive Recommendation?.....	100

OS.299 Strategic Reorganization Of A 10 Year Old Hospital-Based HTA Unit.....	101
OS.302 State Of Rare Disease Management In Southeast Asia.....	102
OS.312 Comparative Efficacy Of Antimicrobial Central Venous Catheter In Reducing Bloodstream Infections.....	105
OS.315 Challenges To Undertaking A Systematic Review Of Rapid Diagnostic Tests In Sepsis.....	106
OS.318 Updated NICE technology appraisals patient submission template; informing health care decisions.....	106
OS.321 New Methods For Early Diagnostic Of Cancer.....	107
OS.332 Broadening The Perspective In Economic Evaluation—A Case Study Of Dementia Interventions.....	108
OS.333 Hospital HTA: A Tool For Improving Nursing Practice.....	109
OS.341 Rapid Health Technology Assessment For Proton And Heavy Ion Therapy In China.....	110
OS.350 Prioritisation Of Emerging Medical Devices In Health Technology Assessment.....	112
OS.351 Cost-Effectiveness Of Sequential Use Of ELF Test/ARFI And ELF Test Alone Versus Biopsy.....	113
OS.355 Study On Benefit Of New Medical Reform In Primary Health Institutions?.....	114
OS.375 Is Partial Knowledge Adequately Considered In Uncertainty Analysis For Economic Evaluation.....	115
OS.378 Force Field Analysis Of HTA Introduction At National Level In China.....	116
OS.379 Publication Bias And Selective Reporting: Are Summary Online Trial Reports Sufficient?.....	116
OS.382 Beyond EQ-5D: What Patients Say Is Important.....	118
OS.394 The Scottish Health Technologies Group’s Innovative Medical Technology Overview (IMTO) Process.....	119
OS.396 Measuring The Value Of HTA Cooperation In Europe: The Example Of EUnetHTA.....	120
OS.398 Cost-Utility And Decision-Making At A National, Regional And Local Level: A Matter Of Perspective.....	121
OS.400 High Satisfaction And Implementation Rates For HTA Performed By Clinicians With Support And Quality.....	122
OS.401 Managing Uncertainty In Reimbursement Decisions Through Risk Share Agreements.....	124
OS.404 Applying Multi-Criteria Decision Analysis (MCDA) Simple Scoring As An Evidence-Based HTA Methodology.....	124
OS.414 Assessing Value-For-Money For Orphan Drugs; Mismatch Of Applied Methods, Economic Theory And Data.....	126
OS.420 Implementation Status And Governmental Regulation Of Non-Invasive Prenatal Testing In China.....	127
OS.424 Robotic Surgery: Meteor Or Supernova? Results From A Web-Based Survey.....	128
OS.425 Providing Value: Patients Experiences,Perceptions Of Professional Care, Support.....	129
OS.426 HTA In Practice: An Australian Example.....	130
OS.433 The Relationship Between Surgeon And Hospital Volume And Outcomes In Lower Limb Vascular Surgery.....	131
OS.439 Divergent Views Of Healthcare Professionals And The Adoption Of Home Based Dialysis Therapies.....	133
OS.440 Estimating The Size Of Advanced Gastroenteropancreatic Neuroendocrine Tumour Sub-Populations To Supp.....	135
OS.456 Systematic Review Of The Economic Burden In Patients With Pulmonary Arterial Hypertension.....	136
OS.458 Cost-Effectiveness Of Saxagliptin Versus Glimepiride As Second-Line Therapy Added To Metformin.....	137
OS.459 Cost-Effectiveness Of HLA-DQB1 And HLA-B Alleles Testing For Clozapine-Induced Agranulocytosis.....	138
OS.466 The Impact Of Magnitude Of Clinical Benefit On HTA Recommendations For New Anticancer Drugs.....	139
OS.469 Determinants Of Health Technology Assessment Knowledge Translation: Triangulation Of Data in China.....	140
OS.474 Using International HTAs In Local Settings - Have We Reached Our Goal?.....	141

<b>Posters.....</b>	<b>143</b>
Poster 1A Comparison Between Reimbursement Decisions On Oncology Drugs: CONITEC, NICE, CADTH And PBS.....	143
Poster 2A Factors Influencing Reimbursement Decisions On Medical Devices.....	144
Poster 4A Trends In Between-Country Health Equity In Sub-Saharan Africa From 1990 To 2011: Improvement, Convergence and Reversal.....	145

Poster 5A Budget Impact Analysis Of Insulin Aspart In The Treatment Of Type 2 Diabetes Mellitus In Patients Treated With Insulin In Malaysia.....	147
Poster 6A Factors Influencing Reimbursement Decisions On Medical Devices.....	148
Poster 7A Experimenting A Process To Involve Patients Associations And Gathering Context-Specific Patients' Views To Be Added To The Review Of Literature In An HTA Report On Dialysis Modalities.....	149
Poster 8A Decision Criteria Used In Multi-Criteria Decision Analysis For Health Insurance Reimbursement: A Systematic Review And Development Of Decision Criteria Framework.....	150
Poster 9A Review Of HTA Submissions In The UK: Are There Lessons To Be Learnt?.....	151
Poster 10A NMA In HTA: Novel Approaches For Searching For Indirect Evidence.....	151
Poster 11A Can "Open Data" Help The Drug Policy?.....	153
Poster 12A Clinical Outcomes With Bioresorbable Vascular Scaffold Versus Zotarolimus And Everolimus Drug Eluting Stent : Evidence From A Bayesian Approach Network Meta-Analysis.....	154
Poster 13A Methods And Processes To Update Patient Decision Aids Supporting Patient Values And Preferences In Health Care Decision Making.....	155
Poster 14A Modelling The Incremental Cost Of Adopting Neoadjuvant Pertuzumab In A Singaporean HER2+ Breast Cancer Population.....	156
Poster 15A The Social Cost Of Major Depressive Disorder.....	157
Poster 16A An Example Of HTA International Data Sharing Influencing National Decisions For Innovation Adoption: Consistency Of FDG-PET Accuracy And Cost-Effectiveness In Initial Staging Of Patients With Hodgkin Lymphoma Across Jurisdictions.....	158
Poster 17A Using Mobile Phone Technology Strengthens Follow Up Of TB Patients Who Are Co-Infected With HIV Infection In TASO Mulago.....	159
Poster 18A Role Of Pictorial Warning On Cigarette Packets In Tobacco Cessation - A Questionnaire Survey Among Cigarette Smokers In Chennai, India.....	160
Poster 19A Patient Participation In Health Decision Making: An Overview Of Current State In Indonesia.....	161
Poster 20A Pregnant Women's Willingness-To-Pay For Noninvasive Prenatal Screening For Fetal Down Syndrome In China.....	162
Poster 22A Study On Patient-reported Outcomes In Ulcerative Colitis Treatment: A Systematic Review Of The Literature.....	163
Poster 23A A Systematic Review Of Economic Evaluations Of Pneumococcal Vaccination In Children In Low And Middle Income Countries.....	164
Poster 24A Developing Integrated Care Pathways For Stroke And Chronic Obstructive Pulmonary Disease Linked With Payment Reform In Rural China.....	165
Poster 25A Characterization Of Patient's Perceptions On The Treatment Of Ankylosing Spondylitis And Rheumatoid Arthritis: A Patient-Centric Approach.....	166
Poster 26A Development Of A Conceptual Disease Model For Use In Economic Modelling Of An Orphan Disease Sporadic Inclusion Body Myositis (sIBM).....	167
Poster 27A Development And Validation Of A System Of Identification Of Fever Cases.....	169
Poster 28A Translation Of Patient-Reported Outcomes In East Asia.....	171
Poster 30A Assessment Of The Clinical Efficacy Of Pure Intradiscal Technique For Treatment Of Spinal Disc Herniation.....	172
Poster 31A Hyper Immunoglobulin D Syndrome (HIDS): Patients' Views Of Their Disease Journey.....	173
Poster 32A How To Develop Patient Perspective In Our Rapid HTA Process At The French National Authority For Health?.....	174
Poster 33A Adding Value To Health Research: The Dutch Experience.....	175
Poster 34A The Setting Up Of An International Patient Panel To Guide The HTAi Patient And Citizen Involvement In HTA Interest Group In Its Work.....	176
Poster 35A Patient Reported Outcome Measures To Assess Benefit In Patients With Symptomatic Cardiac Arrhythmia Treated With Catheter Ablation.....	177
Poster 36A Patient Submissions To HTA: Comparing Experiences In Asia, Latin America, And Canada.....	178
Poster 37A Healthcare Issues And Social Consensus In Korea: Report Of The Round Table Conference Of National Evidence-Based Collaborating Agency.....	179

Poster 38A A Systematic Review Of Self-Management Interventions To Improve Coping And Resilience In Common Long Term Conditions.....	180
Poster 39A On A "Fair" Price Of A Medical Device.....	182
Poster 40A Integration Of Evidence And Values To Support Reimbursement Decision-Making On Diabetes: Experiences From HTA Agencies And Implications For Developing Countries.....	183
Poster 41A The Review Of Price Decisions For Recently Listed Pharmaceutical Drugs In Japan.....	184
Poster 42A Modelling Cost-Effectiveness Of Antiretroviral Treatments In HIV: Incorporating Adherence And Non-AIDS Related Morbidities.....	185
Poster 43A The Transition Of Patients From Curative To Palliative Care: A Systematic Review Of Ethical Issues And Applied Methods.....	186
Poster 45A Implementation Strategy For Evidence-Based Decision Making In HIRA.....	189
Poster 46A Acceptability Of Health Technology Innovations: Involvement Of HIV Positive Patients In Decision Making TASO Uganda Experience.....	190
Poster 48A Cost-Benefit Of Panoramic Radiographs Total Spine And Lower Limbs Achieved By Systems With The Use Of Films And Computed Radiology (CR) At University Center In Brazil.....	191
Poster 49A Added value of end of life and orphan medicines: a thematic analysis from the patient/carer perspective.....	192
Poster 50A Spiritual Therapy For Mental Disorders.....	193
Poster 51A The Barriers Of Health Technology Assessment At Iran.....	194
Poster 52A Comparison Of The Effect Of Treatments For Rotator Cuff Tears: Systematic Review And Meta Analysis Of Articles Analyzed By Intention-To-Treat (ITT) Method.....	196
Poster 53A The Role Of Observational Data Gathering In Health Technology Assessment Of New Procedures.....	197
Poster 54A Development Of Web Application For Assessment Of Cognitive Functions And Detection Of Aphasias In Patients With Stroke And Traumatic Brain Injury.....	198
Poster 55A Tuak Consumption Analysis Of Tuak Drinkers In Lumban Siagian Jae Siatas Barita District Of North Tapanuli, North Sumatra 2015 (Quantitative And Qualitative Approaches).....	199
Poster 56A By Applying The Double Bottle Drain System To Improve The Expansive Function On The Hemo-pneumothorax.....	200
Poster 57A Ethical Standards In Reporting Research From Healthcare-Related Retrospective Databases.....	201
Poster 58A The Harmonization Of HTA Methods: A Way Forward?.....	202
Poster 59A Should PrEP Be Part Of The Dutch HIV Strategy: A Stakeholder Analysis.....	202
Poster 60A The Current Evidence On Blood Gas Analysis For Patients With Intensive Care.....	204
Poster 61A Are Drug-coated Balloons Cost-Effective For Femoropopliteal Occlusive Disease? A Comparison Of Bare Metal Stents And Uncoated Balloons With Regard To The Target Lesion Revascularization Rate.....	205
Poster 62A Comparative Effectiveness Between Long Acting Injection And Atypical Oral Antipsychotics In Schizophrenia Patients: A Systematic Review And Meta-Analysis.....	206
Poster 63A Using Of Analysis Of Evidence Data In The Development Of New Combined Drugs And Study Of Their Pharmacological Activity.....	206
Poster 64A From HTA To Service Provision: Example; Continuous Intrathecal Baclofen (ITB) Infusion For Severe Spasticity And Dystonia.....	208
Poster 65A The Use Of Exploratory Analyses By Evidence Review Groups In The NICE Single Technology Appraisal Process.....	209
Poster 66A The Beneficial Effects Of Renin-angiotensin System Inhibitors In Chronic Liver Disease: A Systematic Review.....	210
Poster 67A Quality Evaluation Of Exclusive Medical Devices.....	210
Poster 69A The Heart Failure Caregiver Questionnaire In Caregivers Of Chronic Heart Failure Patients: Potential Of A Validation Study On The Japanese Population.....	212
Poster 70A Live Long Or Suffer? Willingness To Pay Among College Students.....	213
Poster 71A Coming To A Common Approach In The Health Economic Modelling Of Opioid Addiction: An Open Source Reference Model Approach.....	214

Poster 72A Using A Method Of Indirect Comparison In Network Meta-Analysis To Compare Efficacy In Randomized Clinical Trials That Include Patient Groups With Different Attributes.....	216
Poster 73A Acceptability Of The Comparator Used In Global Development In The Local HTA Submission Across 7 Diverse Jurisdictions.....	217
Poster 74A Health Technology Performance Assessment: Real-World Evidence Guiding Disinvestment.....	218
Poster 75A Impact Of Integral Team For High-Risk-High-Complexity-High-Cost Material Management.....	219
Poster 76A Smoking Cessation: A Case Study Of A Pilot Integrated Programme In Qingdao, China.....	221
Poster 77A Development Of HTA Implementation Strategy In Tunisia.....	222
Poster 78A Experience Of Using The EUnetHTA Core Model For National HTA Production 'Implantable Left Ventricular Assist Device (LVAD) In Addition To Guideline Directed Medical Therapy (GDMT) In End Stage Heart Failure': Experience And Lessons Learned.....	223
Poster 79A The Evaluation Of Da Vinci Surgical System.....	224
Poster 80A Assessing Therapy Versus Enhancement - Does It Matter At All?.....	225
Poster 81A Committee For Health Technology Incorporation Into The SUS And The Legalization Of Access To Health Care.....	226
Poster 82A The Results Of Educational Workshop On Health Technology Assessment In The Russian Federation And CIS Countries.....	227
Poster 83A RENEM - National List Of Equipments And Permanent Materials For The SUS.....	228
Poster 84A The Impact On Health Services Of Mobile Applications In The Context Of Transaction Costs.....	229
Poster 85A Estimation Of Needs Of Immune Suppressant Medicines Financed By The Government Budget For Patients With Organ Transplants.....	230
Poster 88A Analysis Of Drug Related Problems In Hypertension Treatment.....	231
Poster 89A A Comparison Of Critical Disease Insurance Schemes In Different Areas Of China.....	232
Poster 90A Assessment Of Detecting Number Of Individuals And Medical Costs By CKD Severity Using Annual Health Checkup Data And Medical Claims Data In Japan.....	233
Poster 91A Amniopatch Procedure For The Treatment In Preterm Premature Rupture Of The Membranes: Systematic Review.....	234
Poster 92A Network Meta-Analysis For HTA: Review Of HTA Body Guidelines Globally.....	235
Poster 93A The Use Of Non-Randomised Evidence In Health Technology Assessments: A UK Perspective.....	235
Poster 94A Overview Of The Cardiac Implant Registry In The Last Decade.....	236
Poster 95A Added Direct Inpatient Costs Of Antimicrobial Resistant (AMR) Infections In China.....	237
Poster 96A Moving Towards Better Outcomes In Multiple Sclerosis By Addressing Policy Change.....	238
Poster 99A HTA In Rare Diseases: A Snapshot Of Current Approaches, Implications And Recommendations.....	239
Poster 101A International Variability Of Factors Influencing The Reimbursement Decisions In Asia Pacific: A Case Study Of Targeted Oncology Medicines.....	240
Poster 102A Effects Of China's Essential Medicine System On Improving Rational Drug Use In Village Clinics: An Empirical Study In Shandong Province, China.....	241
Poster 103A Defensive Retreat And Function Differentiation - An Empirical Study On Operation Models Of Township Health Centers Under The New Health Care.....	242
Poster 104A The Efficacy Of Fluoride Toothpastes To Reduce Dental Caries In Preschool Children.....	243
Poster 105A Assessing The Incremental Cost Of TAVR And SAVR Complications In Contemporary, Real-World Clinical Practice.....	244
Poster 106A Data Governance For Real-World Evidence: Cross-Country Differences And Recommendations For A Governance Framework.....	245
Poster 107A Assessment Of Pneumococcal Vaccines For The Immunization Of Elderly In Germany.....	247
Poster 108A Clinical Effectiveness Of Immunosuppressive Therapy For Renal Transplantation In Children And Adolescents: A Systematic Review.....	248
Poster 109A Cost-Effectiveness Of Sequential Use Of ELF Test/ARFI And ELF Test Alone Versus Biopsy To Assess Liver Fibrosis In Chronic Alcoholic Liver Disease (ALD).....	249

Poster 110A Missing The Value Of Herd Immunity In Cost-Effectiveness Analyses Of Vaccines. A Systematic Review.....	250
Poster 111A Hyperbaric Oxygen Therapy As Adjuvant Treatment Of Diabetic Foot: A Systematic Review.....	251
Poster 112A Using Health Technology Assessment To Design And Evaluate Clinical Pathways: The Essential HTA Template For Clinical Pathways.....	252
Poster 113A Social Demographic Characteristics And Direct Medical Costs For Patients With Fecal Incontinence In Korea: Big Data Analysis From The National Health Insurance Claims Dataset.....	253
Poster 114A Cost Effectiveness Of Pulmonary Artery Pressure Guided Management Of Chronic Heart Failure In The Australian Healthcare Setting.....	254
Poster 115A Breast Cancer Risk Prediction Model For Identifying Those At Risk: The Malaysian Context.....	255
Poster 116A Quantifying The Burden Of Pain: A Tool For Assessing Pain Severity Burden In Those Diagnosed With Pain.....	257
Poster 117A Costs On Procedures And Health Technologies Used By Patients Diagnosed With Schizophrenia During Eleven Years Of Follow-Up.....	258
Poster 145A Mapping The Disability Assessment Scale To Preference-Based Health Utilities In Patients With Upper Limb Spasticity.....	259
Poster 146A A Cost-Utility Analysis Of Bevacizumab For Treatment Of Recurrent Ovarian Cancer In Canada.....	260
Poster 1B A Comparative Cost Analysis Of Robotic-Assisted Surgery Versus Laparoscopic Surgery And Open Surgery Considering A Set Of Urologic Surgical Procedures.....	261
Poster 2B Vitamin D And Atopic Dermatitis: A Systematic Review And Meta-Analysis.....	263
Poster 3B High-Dose-Rate Brachytherapy As Monotherapy In Localized Prostate Cancer: A Systematic Review Of Its Safety And Efficacy.....	264
Poster 5B Health Technology Assessment For The Reorganization And Automation Of The Medical Laboratory Of Bambino Gesù Children's Hospital.....	265
Poster 6B Efficacy Of The MICA Antibody For Transplant Patients.....	266
Poster 7B Revisiting Role Of HTA In Drug Pricing And Reimbursement In China: A Government Perspective.....	267
Poster 8B Effectiveness Of Interventions To Solve Emergency Department Overcrowding.....	268
Poster 9B Liposomal Amphotericin B Or Amphotericin B Lipid Complex: Which Is The Best Alternative Among Patients With Previous Renal Impairment Or Unacceptable Toxicity To Conventional Amphotericin B Treatment?.....	269
Poster 11B Volume-Outcome Relationships In Peripheral Vascular Surgery: An Overview Of Reviews Introduction.....	270
Poster 13B Impact Of Emerging Medical Evidence On Clinician Behaviour: A Pilot Study Of Low Risk Prostate Cancer Treatments Over a 10-Year Period.....	271
Poster 14B Cost-Effectiveness Analysis Of DAA Based Treatment For Untreated Patients With Genotype 1 Chronic Hepatitis C In China.....	272
Poster 15B Growing Trend Analysis Of New And Emerging Health Technologies: Based On Euroscan Database.....	273
Poster 16B The Efficacy And Safety Of Scopolamine For The Treatment Of Adult Depression: A Mini-HTA.....	274
Poster 17B The Patient Experience Of Colchicine Resistant-Familial Mediterranean Fever (Cr-FMF): Patients' Views Of Their Disease Journey.....	275
Poster 18B The Influence Of The Medical Insurance Payment Policy In Health Technology Assessment and The Empirical Analysis Based On China's Rural Residents Borrowing Medical Disease.....	276
Poster 19B Infant Mortality, Risk Factors And Causes.....	277
Poster 20B Cost Effectiveness Analysis On Universal Hearing Impairment Screening (UHS) Associated With DNA Screening (UHS-DNA), Compared To UHS.....	278
Poster 21B Determining The Time Of Sending Appointment SMS Text Messaging Reminders To Patients On Antiretroviral Therapy (ART): Pilot Study At TASO Jinja, Uganda.....	278
Poster 22B Budget Impact And Cost-Effectiveness Of An Innovative Blood Glucose Measurement Device Using Pattern Alert Technology In Insulin-Treated Diabetics In Japan.....	279
Poster 23B The Factors Affecting Hospitalization Cost Analysis Of Acute Myocardial Infarction.....	280
Poster 24B Measuring Caregiver Quality Of Life: Which Aspects Really Matter?.....	281

Poster 27B Growth Factors For Angiogenesis In Peripheral Arterial Disease (PAD): A Cochrane Review.....	282
Poster 28B Anti-TNF Drugs For The Treatment Of Rheumatoid Arthritis In The Public Health System, Brazil: A Prospective Cohort.....	283
Poster 29B Hepatitis C Infection Drugs Pricing: Evolution Over Time.....	284
Poster 30B Building Efficient Healthcare Systems Through Integrated Health Care Decision Making In Low And Middle Income Countries.....	285
Poster 31B A Cost-Effectiveness Analysis Of Islet Transplantation Compared With Intensive Insulin Therapy For The Treatment Of Type 1 Diabetes.....	286
Poster 32B Professional And Health Technology Assessment Core Development By The Paulista HTA Network - REPATS - Of The São Paulo State Health Secretariat Brazil.....	287
Poster 33B Indirect Cost Of Rheumatoid Arthritis In Poland: How Value Is Societal Perspective.....	289
Poster 34B Measuring The Impact Of Positive HTA Assessments: Investigating The Factors That Affect Implementation.....	289
Poster 35B The Cost Of Severe Haemophilia In Five European Countries: The CHES Study.....	291
Poster 36B Pricing And Reimbursement Of Biosimilars In Kazakhstan.....	292
Poster 37B Conditional Coverage With Evidence Development In South Korea From 2009 To 2016: ESD In Early Gastric Cancer.....	293
Poster 39B Membership Retention In The National Health Insurance Scheme In Ghana.....	294
Poster 40B Safety And Effectiveness Of Thermal Pulsation Treatment For Obstructive Meibomian Gland Dysfunction: Systematic Review.....	295
Poster 41B Advancing The Development Of A General Practitioner System In Hainan Province, China: A Stakeholder Analysis Among Township Health Center Directors.....	295
Poster 42B Challenge For The Health Technology Assessment And The Evidenced-Based Decision Making In Korea.....	297
Poster 43B The Economic Evaluation About The Cost Estimation Of The Clinical Pathway In China.....	298
.....	298
Poster 44B Health Advice By Mobile Alerts Improves Management Of Diabetes Patients In Suburbs Of Kampala District, Uganda.....	299
Poster 45B An Assessment Of A Text Messaging-Based Disease Surveillance In Health Care In Vietnam.....	299
Poster 46B The Policy, Law And Legal Environment Related To Supplying, Distribution And Financing Of Medication And Medical Devices For Reproductive Health.....	300
Poster 47B Impact Of The InFormation On Shared Decision Making (SDM) In The Early Diagnosis Of Alzheimer's Disease.....	302
Poster 48B Factors Influencing Participation In The Screening And Detection Of Dementia (In Korean Adults).....	302
Poster 49B Conditional Coverage With Evidence Development In Spain.....	303
Poster 50B Multi Criteria Decision Analysis In Russian Healthcare System.....	304
Poster 51B Analysis Of Technological Innovation Produced Within The Italian NHS: An HTA Approach.....	305
Poster 52B The Impact Of Shared Decision Making On The Length Of Hospital Stay And The Health Expenditure.....	306
Poster 53B What Is Real World Data? A Review Of Definitions Based On Literature And Stakeholder Interviews.....	307
Poster 54B Real-World Data Use In Health Technology Assessment: A Policy Review.....	308
Poster 55B Coordinate System For Intercepting New Technologies Using App In AIIC HTA Network.....	309
Poster 56B Dealing With A Lack Of Data Relevant For Taking Decisions On Hospital Formularies.....	309
Poster 57B Medical Personnel's Demands For The InFormation Of New And Emerging Health Technologies: Based On A Pilot Survey In Shanghai And Gansu, China.....	310
Poster 58B Cost-Benefit Of Innovative Teleradiology Technology In Low-Resource Settings.....	312
Poster 59B Sutureless Aortic Valve Replacement For Aortic Valve Stenosis.....	314
Poster 60B High Prevalence Of Hypovitaminosis D In Patients With Chronic Low Back Pain: Evidence From Systematic Review And Meta-Analysis.....	315
Poster 61B Regulation Problems Of Pharmaceutical Price Control In Kazakhstan.....	316
Poster 62B Patient Profile From The First International Burden Of Illness Study In Inadequately Controlled Chronic Spontaneous	

Urticaria: ASSURE-CSU.....	317
Poster 63B Time Series Analysis Of Hospitalization And Material Cost Of Hip Replacement.....	318
Poster 64B Role Of Low Dose Naltrexone In Crohns Disease Condition: A Systematic Review And Meta-Analysis.....	319
Poster 65B What Are We Missing By Limiting The Outcome Of Cost Effectiveness Analyses Of Diagnostic Tests To Cost Per Correct Result?.....	319
Poster 67B Dealing With Structural Uncertainty In Model-based Submissions To National Funding Bodies?.....	320
Poster 68B Volume-Outcome Relationships In The Treatment Of Abdominal Aortic Aneurysm In Europe: A Systematic Review.....	321
Poster 70B Risperidone For Aggressiveness In Adults With Autism Spectrum Disorders In Brazil: A Budget Impact With Probabilistic Sensitivity Analysis.....	322
Poster 71B Assessment On The Benefits Of ALT Rapid Tests Before Blood Collection In Nonpaid Blood Donators Of Shanghai.....	323
Poster 72B A Health Care Of Elderly In Brazilian Emergency Services: An Integrative Review.....	324
Poster 73B Evaluation Of Residual Bacterial Content And Trace Elements In Different Brands Of Commercially Supplied Bottled Drinking Waters In Kerala, India - A Comparative Study.....	325
Poster 74B Advances In Diabetes: Technology On The Horizon.....	326
Poster 75B Review Of HTA Role In Drug Centralized Procurement In A Chinese Setting.....	332
Poster 76B Uncertainty In Health Utilities Elicited Through The EQ-5D-3L.....	333
Poster 77B Performance Of Second Trimester Maternal Serum Screening For Down Syndrome In China: Systematic Review And Meta-analysis.....	334
Poster 78B The 'Value' Of Safety-Engineered Medical Devices In Reducing Needlestick And Sharps Injuries.....	335
Poster 79B Presentation Of The SR/PS-Method For Use Of Data On Primary Studies From Systematic Reviews In Health Technology Assessment.....	336
Poster 80B Questionnaire Survey On Current Experiences And Knowledge On Health Economics Analysis In Data Science Division In Pharmaceutical Companies In Japan (2014).....	337
Poster 81B Evaluation Of Medical Service Efficiency Of Township Hospitals Before And After The Implementation Of The Essential Medicine System In Shandong Province, China.....	338
Poster 82B Social Values In Health Technology Assessment.....	339
Poster 83B The Trade-Off Between QALY Maximisation And Social Values: A Systematic Review Of Public Opinion Surveys.....	340
Poster 84B Lifetime Cost-Effectiveness Of Vildagliptin Versus Sulphonylurea As Add-On Therapy In Patients With Type 2 Diabetes Mellitus (T2Dm) Inadequately Controlled By Metformin Monotherapy In Thailand.....	341
Poster 85B Dealing With Uncertainties When The Decision Has To Be Made.....	342
Poster 86B Systematic Review Of Economic Evaluation Of NIPT For Down Syndrome.....	344
Poster 87B Mortality Reduction From Gastric Cancer By Endoscopic And Radiographic Screening.....	344
Poster 88B The Costs Of Short- And Long-Term Psychotherapies And Their Effectiveness On Work Ability In The Treatment Of Depression And Anxiety: A Randomized Trial With A 5-Year Follow-Up.....	345
Poster 89B Comparison On Diagnostic Value Between Serum CYFRA21-1 And CEA In Non-Small Cell Lung Cancer: A Meta Analysis.....	346
Poster 90B Cost-Effectiveness Analysis Of Neonatal Screening Of Critical Congenital Heart Defects In China.....	347
Poster 91B Economic Evaluation Of Automated External Defibrillators In Japan.....	348
Poster 92B What Is The Clinical Effectiveness Of Cetuximab And Panitumumab For Previously Untreated Metastatic Colorectal Cancer? A Systematic Review.....	350
Poster 93B Determinants Of High Technology Medical Equipment Utilization In Chinese Hospitals: A Panel Data Analysis.....	351
Poster 94B Experiences Of Lung Cancer Screening Using Low Dose CT: A Meta-Analysis.....	352
Poster 95B A Systematic Study Of Clinical Guidelines On Non-Invasive Prenatal Test: International Experience And Its Wider Implications.....	353
Poster 96B Cost Effectiveness Analysis Of Two Nucleotide Antiviral Therapies For Chronic Hepatitis B Patients With Hepatitis Be Antigen-positive In China: Tenofovir Disoproxil Fumarate Vs. Lamivudine.....	354

Poster 97B EUnetHTA JA2 WP7 Achievements In Improving Additional Evidence Generation.....	355
Poster 99B Organizational Readiness In Implementation Of EHR In Two South African Hospitals.....	356
Poster 100B Use Of Social Media In US And EU To Study Comparative Treatment Patterns In Multiple Sclerosis.....	357
Poster 105B Research And Application Of Policy Evaluation In Health Of China - Based On The Literature Review.....	358
Poster 106B Marginal Differences In Health-Related Quality Of Life Of People With Diabetes In China.....	359
Poster 107B Searching For Evidence For Systematic Reviews Of Volume-Outcome Relationships In Peripheral Vascular Surgery.....	359
Poster 109B The Methodological Guideline For Therapeutic Medical Devices Of The European Network For Health Technology Assessment (EUnetHTA).....	361
Poster 110B Toward More Pragmatism In HTA: How To Evaluate A Widely Disseminated Health Technology? Assessment Shortening Advantages And Limits. Illustration With PCR For Meningitis And Encephalitis Diagnosis.....	362
Poster 111B Critical Appraisal Tools: An International Collaboration.....	363
Poster 112B Health-Related Quality Of Life Questionnaires In Lung Cancer Patients Attending A Tertiary Care Hospital.....	364
Poster 113B Assistive Technologies For Ageing Populations In Low- And Middle-Income Countries: A Systematic Review.....	365
Poster 115B Scientific Literature Monitoring Of Brazilian Emergency Services.....	369
Poster 116B Situation Analysis Of Implementation Of HTA In Kazakhstan.....	370
Poster 118B Pharmaceutical Review Of Mongolia.....	371
Poster 120B Multi-Indication Pricing: Pros, Cons, And Applicability To The UK.....	372
Poster 121B The Road Map For HTA Development In Kazakhstan: For Well Informed Health-Care Decisions.....	373
Poster 122B Social Media: A New Tool For Collecting Effectiveness Data?.....	374
Poster 123B Health Technology Assessment Of Femtosecond Laser: A New Frontier In Cataract Surgery.....	375
Poster 124B Extending Provincial Health Coverage To Include Eye Examinations For Diabetic Retinopathy By Optometrists: Economic Evidence From Prince Edward Island, Canada.....	377
Poster 125B Study On Process Of China's Essential Medicine System Based On Smith-Model.....	377
Poster 126B Activities Of Center Of Health Technology Assessment In Hospital In Brazil: An Experience Report.....	378
Poster 127B Efficacy And Safety Of Beta Interferon-1A-30 G For Multiple Sclerosis: A Systematic Review.....	379
Poster 128B Study On Relative Price Of Current Traditional Medical Service Items In Shanghai - Based On A Standard Value Model.....	381
Poster 129B What Is The Problem In China's Medical Care Resources Allocation: Some Evidence From Data Envelopment Analysis (DEA).....	382
Poster 130B Omitting Routine Chest Radiograph (X-ray) In Routine Medical Examination (RME) In Malaysia: Potential Cost Saving.....	383
Poster 131B Pilot Study Of Establishing A Horizon Scanning System In China.....	385
Poster 132B Systematic Review Of Restrictive Transfusion Thresholds In Major Orthopedic Surgery.....	386
Poster 133B Survey On Patient Safety Climate In Public Hospitals In China: Psychometric Properties Of The Chinese Version Of The Patient Safety Climate In Healthcare Organizations Survey.....	387
Poster 134B Effectiveness Of Prophylaxis With Palivizumab In A Brazilian Real-World Setting.....	390
Poster 135B 'Pink Pill': Does It Add To Non-Pharmacological Treatment Of Hypoactive Sexual Desire Disorder?.....	391
Poster 136B HTA Capacity Building And Institutionalization: The Case Of Bulgaria.....	392
Poster 137B Medical Devices: From Licensing To Coverage. Highlights From Argentina, Brazil, Colombia, And Mexico.....	393
Poster 138B Dynamic Interactive Model For Capacity Building And Institutionalization Of An HTA Structure.....	394
Poster 139B Waiting Time In CT And MRI Scan Services In China.....	395
Poster 140B A New HTA System For Japan - Simulating Potential Effects On Drug Prices.....	396
Poster 141B Involving The Public In The Development Of An Horizon Scanning Website: Experiences From Two Focus Groups.....	397
Poster 142B Can Lack Of Clinical Utility Be Used As A Reason For Disinvestment Of Investigative Tests?.....	398

Poster 143B A Proposal To Improve Quality Indicators Assessment Of Managed Health Care In Health Insurance In Brazil.....	399
Poster 144B Quality Monitoring Program Of Service Providers In Health Insurance In Brazil.....	400
Poster 146B How Asia-Pacific Patients Perceive Impact Of UHC And HTA On Orphan Drug Access.....	402
Poster 147B Including The Poor In Indonesia's National Health Insurance In West Java Province: A Stakeholder Analysis.....	403
Poster 150B Budget Impact Of Long-Acting Insulin Analogues In Brazil.....	404

# Oral Presentations

## OS.07 Should RCT Search Filters Account For The Phases Of Clinical Trials In Addition To Study Design? Results from an explanatory case-study.

### DESCRIPTION:

In technologies that are newly released, Phase III trials are often sparse and the data is immature, and this presents a problem: decision makers must make decisions even in the absence of optimal trial evidence. Phase II trials (and trial data), including sub-group analyses, could be used to supplement Phase III trials, but do RCT search filters capture this data?

### PRESENTING AUTHOR:

Chris Cooper

### AUTHORS:

Chris Cooper, Simon Briscoe, Louise Crathorne

### BACKGROUND:

Study design literature search filters to identify RCTs are established and efficient but they do not distinguish between the phases of clinical trials. We have found that well known RCT search filters block the identification of trials that are referred to by their clinical phase (as opposed to being indexed as an RCT), they block identification of sub-group analyses, and they may block the identification of Phase II trials. This means that valuable studies and study data are being missed.

### OBJECTIVES:

Test an RCT search filter against a gold standard of: trials identified by clinical phase rather than RCT study design, phase II trials, and sub-group analyses; and

Develop and test search terms for the above scenarios, and appraise the effect of integrating these terms into search filters.

### METHODS:

A gold standard of Phase II trial abstracts, sub-group analyses, and studies known by their clinical phase, was developed by searching MEDLINE using a population and intervention search;

The same search strategy was run using a population and intervention and RCT structure: and

the RCT-filtered search was screened to identify the gold standard records.

And

- textual analysis and open-coding was applied on the gold standard to identify shared keywords and MeSH; and
- the terminology was developed into a search filter and tested against the gold standard. The sensitivity of this filter was appraised relative to the RCT filter.

### RESULTS:

Commonly used RCT filters miss Phase II trials, sub-group analyses, and studies that are known by their phase of clinical research as opposed to their relative study design.

Amending proven RCT search filters can identify both Phase III and Phase II trials.

### CONCLUSIONS:

Decision makers are required to make decisions even in the absence of optimal trial data. Phase II trials, trial data, and relevant sub-group analyses, could aid decision makers, if suitably accounted for;

RCT search filters do not typically distinguish between the phases of clinical trials and so do not commonly identify Phase II trials, sub-group analyses, and trials referred to by their clinical phase alone; and

Additional search terms should be included in RCT search filters to identify trials referred to by their clinical phase rather than their study design and sub group analyses.

---

## OS.10 Derivation Of Cost-Effectiveness Thresholds Based On Per Capita Health Expenditures & Life Expectancy

### DESCRIPTION:

We present a methodology to estimate cost-effectiveness thresholds (CET) based on per-capita health expenditures and life expectancy and the results of applying this methodology to derive guidance CET in 181 countries. This approach, based on widely available data, can be useful to inform decisions in countries using economic evaluations. Our results show significantly lower CET than those promoted by WHO.

### PRESENTING AUTHOR:

Sebastián García Martí

### AUTHORS:

Andres Pichon-Riviere, Federico Augustovski, Sebastián García Martí

### BACKGROUND:

Cost-effectiveness (CE) is increasingly used for resource allocation worldwide. One key hurdle for its widespread use is the lack of a widely accepted methodology to derive CE thresholds (CET) at the healthcare system or country levels.

### OBJECTIVES:

To propose a methodology and derive local CET based on per capita health expenditures (pcHE) and life expectancy (LE).

### METHODS:

Our approach was based on depicting how the ICER of new interventions affect the pace of increase of pcHE while population LE increases. We found that this relationship can be characterized as follows:

$$i = (\text{ICERu} + \text{LE}) / (\text{LE} + 1)$$

Where 'i' is the ratio of increase in pcHE once a one-year increase in LE of the population is achieved (e.g.  $i=1.1=10\%$  increase); and ICERu is the incremental CE ratio of the interventions expressed in units of annual pcHE (e.g. an ICERu of 8.5 indicates that the CE of the interventions is equal to 8.5 pcHE per life-year).

Consequently, if a health system can establish the maximum ratio of increase in pcHE it is willing to assume in the medium term once it has reached the goal of a one-year increase in population LE (iT), then the CET, measured in units of pcHE (CETu) that new interventions should not exceed in order to keep pcHE within the limits set by iT can be estimated as:

$$\text{CETu} = iT * (\text{LE} + 1) - \text{LE}$$

We used OLS to estimate in a series of countries the expected increase in pcHE ('i'), according to their level of income and life expectancy, associated with a one-unit increase in life expectancy (measured in years or healthy life years), following both a cross-sectional (2013 data) and a longitudinal approach (2003-2013) using World Bank data, and we applied predicted country 'i' estimates to derive country level CET.

### RESULTS:

In low-income countries, CET ranged between 5 and 7 annual pcHE per life-year gained and between 6 and 8 annual pcHE per QALY; while in high-income countries CET ranged between 7 and 10, and between 8 and 11 annual pcHE per life-year or QALY, respectively. These values (in thousands of US current dollars 2015) represent CET of 32-40 in the UK; 83-101 in the USA; 6-7 in Mexico and 0.6-0.7 in Uganda.

Only in 15 out of 178 countries the threshold exceeded one GDP per capita per life-year and in 34 of 181 exceeded one GDP per capita per QALY (8.4% and 18.8% of the countries respectively). In only one country the CET per life-year was above

1.5 GDP (USA), and only in two countries (USA and Lesotho) it was above 1.5 GDP per QALY. There was no case in which the estimated threshold was above two GDP per capita.

### **CONCLUSIONS:**

This approach, based on widely available data, can be useful to inform decisions in all countries using economic evaluations. Our results show thresholds significantly lower than those promoted by WHO.

---

## **OS.11 Are Three Days Enough To Capture The Key Evidence For HTA Documents?**

### **DESCRIPTION:**

Rapid reviews have emerged as an efficient approach to synthesizing evidence for informing decision makers in health care settings. The objective of this study is to compare the conclusions and analyze the amount and direction of the evidence included in HTA documents produced in an ultra-rapid way (produced in 2-3 days) compared to Rapid-HTA (produced in 4-8 weeks).

### **AUTHORS:**

Sebastián García Martí, Ariel Bardach, Demián Glujovsky, Lucila Rey Ares, Agustín Ciapponi

### **BACKGROUND:**

Rapid reviews have emerged as an efficient approach to synthesizing evidence for informing decision makers in health care settings. It is uncertain whether very shorter timeframes that are needed sometimes in specific healthcare decisions, e.g. two to three days elaboration-time, would still be adequate for capturing the key evidence that forms part of more elaborate Health Technology Assessment (HTA) documents.

### **OBJECTIVES:**

To compare the conclusions and analyze the amount and direction of the evidence included in HTA documents produced in an ultra-rapid way (produced in 2-3 days) compared to Rapid-HTA (produced in 4-8 weeks).

### **METHODS:**

IECS is an Argentinean HTA agency that produces both of the aforementioned types of documents according to the urgency and needs of decision-makers. The documents are based on focused search strategies in meta-search engines and online biomedical literature databases, to identify systematic reviews, clinical practice guidelines, HTAs, coverage policies, and selected primary research. The ultra-rapid HTAs are prepared by highly-trained staff who select the most important evidence according to their own judgement. The 'slower' HTAs allow a more exhaustive assessment of the evidence.

We selected pair of documents, one done in two days and the other in five weeks, oriented to the same research question. The longer document needed to be published later and within one year timeframe of the shorter one. The additional evidence identified by the newer document, published at a later date than the ultra-rapid HTA, was excluded and the conclusions modified wherever necessary. Pairs of independent researchers extracted the outcomes, and disagreements were solved by a third researcher.

### **RESULTS:**

We selected 32 pairs of documents and 24 that met inclusion criteria were finally included. 92% of rapid-HTAs included more evidence than ultra-rapid-HTAs.

ultra-rapid-HTAs (Mean  $\pm$  SD) rapid-HTAs (Mean  $\pm$  SD) Difference (95% CI) P value (t test)

Guidelines 2 5.5  $\pm$  5.5 3.5 (1.2 - 5.8) 0.0043

Systematic Reviews 1.7  $\pm$  1.5 3.4  $\pm$  3.5 2.2 (0.6 - 3.8) 0.0071

RCTs 0.2 ± 0.7 1.1 ± 1.2 0.9 (0.3 - 1.5) 0.0028

TABLE UPLOADED WITH THIS INFORMATION

The rapid-HTAs included 50% more safety and quality of life outcomes than ultra-rapid-HTAs in this sample.

Despite the more evidence included in rapid-HTAs, there was 96% (95% CI 78.9 to 99.9) of conclusion matching with ultra-rapid-HTAs.

In the only one mismatch the rapid-HTA considered the technology appropriate in selected cases and the ultra-rapid-HTA considered the same technology as experimental.

### CONCLUSIONS:

Despite the more evidence considered by rapid-HTAs, there was a 96% (95% CI 78.9 to 99.9) of conclusion matching with ultra-rapid-HTAs. Ultra-rapid-HTA approach can potentially be a useful tool for decision makers.

---

## OS.13 Are Current Approaches To HTA Keeping Up With The Evolution And Pace Of Change In Medical Technology

### DESCRIPTION:

Existing approaches to HTA may be inadequate to keep up with the evolution and pace of change in medical technology. Healthcare systems that cannot respond promptly to these changes may lose opportunities to optimize clinical outcomes and efficiency benefits arising from innovation. This presentation will consider how HTA could evolve to better unlock the full potential of medical technology.

### AUTHORS:

John Gillespie, Frederique Debrouker, Katsunori Fujita, Sang Soo Lee, Andrew Wiltshire

### BACKGROUND AND OBJECTIVES:

Health technology assessment (HTA) increasingly plays a pivotal role in determining patient access to new medical devices. However, medical technology evolves rapidly, raising questions of whether approaches to HTA have kept up with the pace of change. The adoption of innovative medical technology can require significant changes in the organisation of healthcare delivery (1). In addition, existing reimbursement arrangements may not apply to innovative health technologies. If these barriers to adoption are not appropriately considered in HTA of medical devices, and technology uptake is impacted, then opportunities to improve patient outcomes will not be fully realised.

### METHODS:

Major HTA organisation websites were searched in order to determine whether evaluation approaches (e.g. assessment scoping and methods guidelines) proactively consider 'real-world' barriers to technology adoption.

### RESULTS:

Preliminary analysis across several HTA agencies, found that guidance on the scope and evidence requirements for technology evaluations contains very limited explicit consideration of wider barriers for technology adoption. The absence of HTA implementation plans may explain this. This may also be part or wholly explained by the absence of differentiation in HTA methods used by agencies for medical devices compared with evaluation of drug technologies. This is consistent with the findings of a recent survey of non-European HTA agencies (2).

### CONCLUSIONS:

To unlock the full potential of innovation, HTA of medical technologies should continue to evolve. Revision of current evaluation approaches is required to ensure organisational needs and funding arrangements for medical technology are fully considered. Approaches to HTA - e.g. MaRS EXCITE (3) - which directly integrate

research on medical technology into 'real world' clinical practice may offer opportunities to better consider healthcare infrastructure needs. Mature and emerging HTA agencies must ensure that assessment approaches are 'future-proof', with processes and methodologies adaptable to technological change.

#### REFERENCES:

(1) Tarricone R, Drummond M (2011). Challenges in the clinical and economic evaluation of medical devices: The case of transcatheter aortic valve implantation. *Journal of Medical Marketing* 2011. 11(3) 221-229.

(2) Ciani O, Wilcher B, Blankart CR, Hatz M, Rupel VP, Erker RS, Varabyova Y, Taylor RS. Health technology assessment of medical devices: a survey of non-European union agencies. *Int J Technol Assess Health Care*. 2015 Jan;31(3):154-65

(3) MaRS. What is MaRS EXCITE? Available: [www.marsdd.com/systems-change/mars-excite/mars-excite/](http://www.marsdd.com/systems-change/mars-excite/mars-excite/) (Accessed 23rd December, 2015).

---

## OS.15 What Does The Current Research Evidence Tell Us About Searching For The Various Aspects Of HTA?

#### DESCRIPTION:

Increasing numbers of research papers about information retrieval for health technology assessments, systematic reviews and other evidence syntheses are being published, and it is time-consuming and demanding to keep up-to-date with the latest developments. Summarized Research in Information Retrieval for HTA (SuRe Info), an open access web resource, seeks to help in this task by providing easy access to current methods papers, and support research-based information retrieval practice.

#### AUTHORS:

Jaana Isojärvi, Sari Ormstad, Julie Glanville, David Kaunelis, Carol Lefebvre, Kath Wright, On behalf of the SuRe Info group 1. National Institute for Health and Welfare (THL), Finnish Office for Health Technology Assessment (Finohta), Finland 2. Norwegian Knowledge Centre for the Health Services (NOKC), Norway 3. York Health Economics Consortium (YHEC), University of York, UK 4. Canadian Agency for Drugs and Technologies in Health (CADTH), Canada 5. Lefebvre Associates Ltd, UK 6. Centre for Reviews and Dissemination (CRD), University of York, UK

#### BACKGROUND AND OBJECTIVES:

Increasing numbers of research papers about information retrieval for health technology assessments, systematic reviews and other evidence syntheses are being published, and it is time-consuming and demanding to keep up-to-date with the latest developments. Summarized Research in Information Retrieval for HTA (SuRe Info), an open access web resource, seeks to help in this task by providing easy access to current methods papers, and support research-based information retrieval practice.

#### METHODS:

To meet the challenge of keeping up-to-date with information retrieval research, the Health Technology Assessment international (HTAi) Interest Group on Information Resources (IRG) started a project entitled SuRe Info in 2011, aiming at developing a web resource that provides research-based information relating to information retrieval aspects of HTAs and systematic reviews condensed into an easily digestible format. SuRe Info is mainly targeted for information specialists and others who work with information retrieval. The international project group consists of experienced information specialists from various HTA agencies and research institutions.

Methods publications are identified by running topic-specific search strategies in selected relevant

databases. Included publications are critically appraised and synthesized into topic specific chapters.

## RESULTS:

SuRe Info was officially launched in June 2013, and it is published as a part of HTAi Vortal. It consists of two sections: 1) information on general search methods common across all health technologies and 2) methods to use when searching for specific aspects of health technologies, such as clinical effectiveness, safety and costs and economic evaluation. The latter is mainly based on the structure of the HTA Core Model®, a methodological framework for collaborative production and sharing of HTA information, developed by the European network for Health Technology Assessment (EUnetHTA). Within both sections, chapters summarize the current research findings concerning a particular information retrieval aspect. The chapters are reviewed and updated twice a year. Concise chapters provide guidance that help searchers in their everyday work. Searchers find answers to questions concerning general search methods, such as how to develop and structure a search strategy, where to find and how to apply search filters, and how to peer review a search strategy. They also find guidance which helps them to decide on which sources to search and how to structure a search strategy on a specific topic such as safety, costs and economic evaluation, ethical or legal issues.

## CONCLUSIONS:

SuRe Info is an open-access web resource, providing research-based information relating to the information retrieval aspects of health technology assessments and systematic reviews. It seeks to help searchers stay up-to-date in the latest developments by providing easy access to summaries of current methods publications, and in that way supports research-based information retrieval practice.

The HTA Core Model® already provides links to SuRe Info chapters for domain-specific guidance

on information retrieval issues. We look forward to future collaboration with other networks.

---

## OS.18 A Novel Framework For Guiding Evidence Generation Strategies To Support Evaluation Of New Drugs

### DESCRIPTION:

We present a decision-making framework, produced by the pan-European IMI GetReal project. The framework provides guidance on the use of real-world evidence for establishing relative effectiveness of new drugs. The content was developed with broad stakeholder engagement. The framework will assist in integrating real-world study designs in future drug development programmes and support further policy and scientific agenda.

### AUTHORS:

Pall Jonsson, Maciej Czachorowski, Mike Chambers, Chris Chinn, Rob Thwaites, Sarah Garner

### BACKGROUND AND OBJECTIVES:

Regulatory submissions aim to demonstrate the safety and efficacy of new drugs. However, decision makers such as payers and health technology assessors (HTAs) are increasingly interested in evidence of effectiveness outside the clinical trial setting. The demonstration of real-world effectiveness requires potential use of 'real-world' evidence (RWE) before marketing authorisation. However, this has many operational, methodological, regulatory, and ethical issues. We present the work of the Innovative Medicines Initiatives GetReal project, which is developing a decision-making framework aimed at guiding the potential use of RWE, informed by a broad stakeholder view of acceptability.

## **METHODS:**

Work package 1 of IMI GetReal ([www.imi-getreal.eu](http://www.imi-getreal.eu)) used a multi-stakeholder engagement approach to develop a decision-making framework intended to inform the design of development strategies that provide better information about relative effectiveness of new drugs. This work included case study workshops in five disease areas, and additional stakeholder engagement intended to elicit comprehensive views on the acceptability of evidence generation strategies that provide a greater focus on effectiveness of drugs in real-life settings. Stakeholders included patient organisations, clinicians, academic specialists, clinical trialists, pharmaceutical companies, European regulators, HTA bodies and payers.

## **RESULTS:**

The GetReal consortium presents a draft framework which is aimed at facilitating the assessment of different development options. The framework consists of five key components: 1) an overview of current policies related to RWE and key strengths and weaknesses of such evidence; 2) a catalogue of real-world study designs outlining key characteristics of study types; 3) a comprehensive review of sources of RWE; 4) a review of state-of-the-art methods for analysis of RWE; and 5) stakeholder perspectives on the use of RWD for decision making. A decision-making algorithm sits at the core of the framework and takes stakeholders through a series of probing questions examining the potential need for RWE and subsequent considerations regarding the suitability of potential RWE study designs.

## **CONCLUSIONS:**

The GetReal consortium has engaged stakeholders to generate comprehensive views on the value and acceptability of real-world evidence for establishing relative effectiveness of drugs in real-life settings. The resulting framework will enable pharmaceutical R&D to assess potential options for integrating real-world study designs in future drug development programmes. Additionally, the framework will

support further policy and scientific agenda on the use of real-world evidence.

---

## **OS.21 Deconstructing Rapid Reviews: When Is Evidence Good Enough?**

### **DESCRIPTION:**

Rapid reviews tailor methods to expedite the traditional knowledge synthesis process. They can provide evidence that is “good enough” when timeliness is crucial and the alternative may be no evidence at all. This oral presentation will describe the results of a master’s thesis research program on rapid reviews.

### **AUTHORS:**

Shannon Kelly, Tammy Clifford, David Moher

### **BACKGROUND AND OBJECTIVES:**

Policy-makers are continually challenged with having to wait for the ‘best evidence’ on health technologies when using traditional HTA reports or systematic reviews to inform their processes. Although attention to rigour and robust results are highly valued, the lengthy timelines associated often conflict with the urgent needs of decision-makers. Rapid reviews tailor methods to expedite the traditional knowledge synthesis process. They can provide evidence that is ‘good enough’ when timeliness is crucial and the alternative may be no evidence at all. This oral presentation will describe the results of a master’s thesis research program on rapid reviews.

### **METHODS:**

This research program was defined by 3 separate, but related research projects related to rapid reviews:

1. Defining rapid reviews and a consensus approach: Results from a modified Delphi study describing what key stakeholders considered

were the fundamental defining characteristics of rapid reviews.

2. Quality of conduct and reporting in rapid reviews: A literature search identified rapid reviews and the quality of conduct and reporting were assessed using PRISMA and AMSTAR checklists.
3. A Q-methodology study on rapid reviews: Results from a study employing qualitative and quantitative methods to query producers and knowledge users about their opinions on rapid reviews.

### RESULTS:

Results show that further refinement to the definition of rapid review may be required before it can be globally applied and that a classification of rapid review types may be more feasible and appropriate than a strict definition. Three salient viewpoints on rapid reviews were identified. Clear perspectives exist amongst evidence producers and knowledge-users and there is support for the role of rapid reviews in evidence-informed decision-making. Through an evaluation of rapid review samples, this study confirmed that compliance with recommended guidelines for reporting and conduct is limited at best, although this is not a problem unique to this approach.

### CONCLUSIONS:

This study established that rapid reviews are a valuable form of evidence synthesis and suggests that further investigation of residual knowledge gaps is warranted and desired by both evidence producers and knowledge users. Notably, future exploration into reporting or conduct guidelines specific to rapid reviews may be beneficial, but it is unclear if specific rapid review guidelines are necessary or desired by evidence producers and users, and whether these types of products would be applicable across the spectrum of rapid review approaches.

.....

## OS.22 Understanding Cost Drivers For Health Technology Assessment In Low-Income Countries

### DESCRIPTION:

Our research work underscores the importance of understanding contextual aspects of program implementation and associated costs related to health technology interventions in low-income countries.

### AUTHORS:

Asif Raza Khowaja, Craig Mitton, Rahat Qureshi, Stirling Bryan, Laura A Magee, Zulfiqar Bhutta, and Peter von Dadelszen

### BACKGROUND AND OBJECTIVES:

The CLIP Trial is a cluster randomized controlled trial (cRCT) of an integrated package of pre-eclampsia screening and mobile-health (m-health) platform-guided risk stratification and management in sub-Saharan African and South Asian countries. Understanding cost drivers and estimating societal costs is an important challenge for economic evaluation of similar m-health initiatives in low-income countries. This study aimed to assess cost drivers to inform design of the CLIP economic model from a societal perspective.

### METHODS:

Qualitative research was conducted alongside the CLIP cRCT in Pakistan. Nine focus groups were conducted, two with 19 pregnant women with pregnancy hypertension, two with 17 husbands/fathers-in-law, two with 20 community health care providers, two with 20 medical doctors at referral health facilities, and one with 11 district-level health decision/policy makers. Thematic analysis was performed using NVivo software.

### RESULTS:

The community perspective included out-of-

.....

pocket (OOP), health system, and program costs. Most pregnant women and male decision makers reported a large burden of OOP costs related to: in- and out-patient care, informal care from traditional healers, self-medications, childbirth, newborn care, transport to health facility, and in particular, missed wages by caretakers. Many health care providers identified health system costs associated with human resources for hypertension risk assessment at the household level, transport, and communication about patient referrals. Health decision makers recognized program implementation costs, such as the m-health platform (i.e., e-tablets, computers, and the internet), equipment (i.e., digital blood pressure devices, pulse-oximeters, and urine dipsticks), staff training, and monitoring and supervision costs. Almost all participants revealed factors rooted in cultural practices (i.e., delayed care-seeking), contextual limitations (i.e., geographical remoteness, lack of around-the-clock transport), and health system inefficiencies (i.e., delayed triage and provision of treatment) that could lead to catastrophic costs.

**CONCLUSIONS:**

Scale-up of m-health initiatives such as CLIP has the potential to bridge health service delivery gaps and improve maternal and perinatal health. A thorough understanding of cost drivers can be a useful approach in designing economic models suitable for the needs of decision makers in low-income countries and in understanding the policy implications related to program scale up should trial results prove favorable.

---

## OS.23 Thrombectomy In The Treatment Of Acute Ischemic Stroke

**DESCRIPTION:**

Five recently published RCTs showed positive effects of mechanical thrombectomy for treating

acute ischemic stroke patients. The objective of this study is to review the effect of methodological differences in these RCTs on their comparability and results. This study critically examines the main characteristics, and methodological heterogeneity of these studies affects the comparability of efficacy and safety results.

**AUTHORS:**

Peter L Kolominsky-Rabas, Shixuan Zhang, Julia Mayer, Claudia Wild

**BACKGROUND AND OBJECTIVES:**

The five recently published multicenter RCTs MR CLEAN, ESCAPE, EXTEND-IA, SWIFT-PRIME and REVASCAT showed positive effects of mechanical thrombectomy for treating acute ischemic stroke patients. These five RCTs prospectively randomised patients to standard care (usually thrombolysis) alone or standard care plus mechanical thrombectomy. The objective of this study is to review the effect of methodological differences in these trials on their comparability and results.

**METHODS:**

This study critically examines the main characteristics of the five RCTs including the trial design, inclusion criteria, intervention methods and related time factors on the assessment of mechanical thrombectomy trial results.

**RESULTS:**

The number of patients randomised ranged from 70 to 500, with three studies stopping early due to efficacy. MR CLEAN was notably the only 'pragmatic trial'. Two RCTs used intraarterial treatment where choice of therapy was left to a certain level of interventionists' discretion, with retrievable stents recommended. Three RCTs focused on thrombectomy with a specific device, the Solitaire FR stent retriever. Inclusion criteria differed in terms of imaging modalities used, thrombus location, and time intervals for treatment ranging between 4.5 - 12 hours after symptom onset. Further variations concerned

process times and measurement. In all studies, the outcome of modified Rankin Scale at 90 days favoured thrombectomy (adjusted odds ratio values ranged from 1.67 to 3.1). Higher rates of functional independence in favour of thrombectomy were noted in all RCTs, improvements ranged from 32.6% vs 19% to 71% vs 40%. MR CLEAN exclusively reported the safety variable 'new ischemic stroke in a different vascular territory within 90 days' as 5.6% and 0.4% in the thrombectomy and control groups, respectively.

### **CONCLUSIONS:**

The results of five recent RCTs focusing on thrombectomy are highly promising but methodological heterogeneity of these studies affects the comparability of efficacy and safety results. Caution is therefore needed when drawing overall conclusions for HTA reporting.

---

## **OS.28 Engagement Of Older Adults In Aging-Related Health Technology Innovation**

### **DESCRIPTION:**

Current trends of population aging, rapid technological innovation, deliberative dialogue, and the democratization of health support the need to understand engagement of older adults in processes of health technology assessment (HTA). This project aims to build on health engagement research to learn how older adults can be meaningfully engaged in regional partnerships that support innovation and HTA.

### **AUTHORS:**

Heather McNeil, Paul Stolee, Josephine McMurray, Dr. Don Juzwishin

### **BACKGROUND AND OBJECTIVES:**

There is growing recognition of the value of infrastructure that supports and drives

technological innovation in local clusters, or regional innovation ecosystems (RIEs). This innovation typically arises from collaboration between researchers, government and industry & the 'Triple Helix' (Etzkowitz & Leydesdorff, 2000). The population in many countries is rapidly aging, and technological innovation has considerable potential to support the health and well-being of older adults. Current trends towards transparency, citizen empowerment, deliberative dialogue, and the democratization of health all support the need to understand the engagement of end users in processes of health technology assessment (HTA), potentially through an expansion of the Triple Helix. Previous work conducted by our group (Stolee et al., 2015) identified principles for engaging older adults in the broad domain of health research and planning (McNeil, Elliott, Stolee, & Investigators, 2014). This project aims to build on this understanding to learn how older adults can be meaningfully engaged in regional partnerships that support innovation and health technology assessment.

### **METHODS:**

This project consists of three phases incorporating transdisciplinary participatory integrated mixed methods with a focus on knowledge exchange throughout. This presentation will focus on the results of the first two phases. Phase I was a systematic review of the available literature on Regional Innovation Ecosystems (RIEs) to inform hypothesized modifications to current collaborative models of innovation and learn from initiatives outside of health that currently incorporate end user engagement. In Phase II, interviews and focus groups were conducted with stakeholders to explore current practices for engaging older adults in health innovation and opportunities for their participation in RIEs and HTA.

### **RESULTS:**

The literature review identified themes important to engagement, including a variety of roles for end users. Older interviewees saw involvement as an opportunity for a meaningful contribution.

While older adults are often involved in aspects of technological innovation such as user-testing, opportunities for consistent engagement are limited. Consultations found that engagement of older adults in RIEs and HTA could yield insights into values, preferences, experiences and traditions that can enhance the value, acceptability and use of technologies. Barriers such as ageism and lack of awareness of opportunities to be involved affect older adult engagement in RIEs and HTA.

### CONCLUSIONS:

Results of the first phases of the project are informing the evolution of the Triple Helix to generate a model of engagement of older adults in RIEs and HTA. Results will be used to inform collaborative partnerships that support the development and appropriate adoption of health technology innovations that have the potential to improve the well-being of older adults. Continued relationships with stakeholders built during the project's knowledge exchange efforts will translate the results of this study to advance the potential role of older adults in decision-making in health technology innovation as meaningful partners in regional health innovation and HTA.

### REFERENCES:

Etzkowitz, H., & Leydesdorff, L. (2000). The dynamics of innovation: from National Systems and 'Mode 2' to a Triple Helix of university-industry-government relations. *Research Policy*, 29(2), 109-123. [http://doi.org/10.1016/S0048-7333\(99\)00055-4](http://doi.org/10.1016/S0048-7333(99)00055-4)

McNeil, H., Elliott, J., Stolee, P., & The CHOICE Investigators. (2014). Engaging older adults in healthcare research and planning: Guidelines from the CHOICE knowledge synthesis project. In IJIC. Sydney, Australia.

Stolee, P., Elliott, J., McNeil, H., Boscart, V., Heckman, G. A., Hutchinson, R., Judd, M. (2015). Choosing Healthcare Options by Involving Canada's Elderly: a protocol for the CHOICE realist synthesis project on engaging older persons

in healthcare decision-making: Table 1. *BMJ Open*, 5(11), e008190. <http://doi.org/10.1136/bmjopen-2015-008190>"

---

## OS.35 An Integrated Perspective On The Value Of Health Technology. Results Of The Integrate-HTA Project

### DESCRIPTION:

INTEGRATE-HTA, an innovative research project was co-funded by the European Union (EU) under the Seventh Framework Programme from January 2013 until December 2015. This project developed concepts and methods that enable a patient-centred, comprehensive, and integrated assessment of complex health technologies which were applied in a palliative care case study. The practical guidances are available through the project website [www.integrate-HTA.eu](http://www.integrate-HTA.eu).

### AUTHORS:

Wija Oortwijn, Gert Jan van der Wilt, Dario Sacchini, Ansgar Gerhardus on behalf of the INTEGRATE-HTA project team

### BACKGROUND AND OBJECTIVES:

In recent years there have been major advances in the development of HTA. However, HTA still has certain limitations when assessing health technologies which are context-dependent, as current HTA focusses on the technology, not on the (socio-cultural, healthcare) system within it is used; is performed differently depending on the way technology is implemented; and may have different effects on different patients. Furthermore, HTA usually assesses and appraises aspects side-by-side while decision-making needs an integrated perspective on the value of health technology. In the INTEGRATE-HTA project, we (a Consortium of seven partners from five different European countries: Germany, Italy, The Netherlands,

Norway, United Kingdom) developed concepts and methods to deal with these challenges. As the rise in chronic diseases in ageing populations has led to the development of increasingly complex technologies, we used palliative care as a case study to test the concepts and methods.

#### **METHODS:**

Different approaches were used to develop guidances on how to conduct integrated assessment of complex health technology. These include building on existing concepts and methods for single assessment aspects, i.e. effectiveness, ethical, socio-cultural, economic, and legal issues; Logic models were used to conceptualize the intervention in its context; Feedback from stakeholder advisory panels in seven different European countries to ensure public and patient involvement; and Application in a case study on palliative care. The applicability and relevance of the draft guidances were reviewed by an external panel of 31 experts, representing 14 nationalities and a variety of professional backgrounds.

#### **RESULTS:**

INTEGRATE-HTA resulted in six guidances: 1) Assessing effectiveness, economic, ethical, socio-cultural and legal aspects in complex health technologies; 2) Guidance on moderators, predictors and patient preferences for treatment outcomes, and their integration; 3) Assessment of context and implementation in systematic reviews and HTAs of complex interventions; 4) Use of logic models in systematic reviews and HTAs of complex interventions; 5) Integrated assessment of complex health technologies & The INTEGRATE-HTA model; and a case study report: 6) Integrated assessment of home based palliative care with and without reinforced caregiver support: 'A Demonstration HTA'. At the meeting, we present the added value of the guidances to HTA-doers and users.

#### **CONCLUSIONS:**

The INTEGRATE-HTA guidances can help unlock the value of health technology. It is not a matter

of collecting the facts, but a matter of collecting facts that are considered relevant, plausible to stakeholders and which are amenable to scientific inquiry. They therefore contribute to a transparent HTA process and a deeper understanding of complex health technologies. As already stated by Farrell et al.: Assessment processes are embedded in different sorts of institutional settings, within which scientists, decision-makers, and advocates communicate to define relevant questions for analysis, mobilize certain kinds of experts and expertise, and interpret findings in particular ways.

#### **REFERENCES:**

Farrell, A.; VanDeveer, S.D.; Jager, J. Environmental assessments: four under-appreciated elements of design. *Global Environmental Change*, 2001; 11 (4):311-333.

Website INTEGRATE-HTA: [www.integrate-hta.eu](http://www.integrate-hta.eu)

---

## **OS.38 Post Policy Implementation Review: The Case Of Rapid Fetal Fibronectin Testing For Preterm Labour**

#### **DESCRIPTION:**

To err on the side of caution, physicians place greater significance on positive than negative test results. The policy to adopt Fetal Fibronectin testing in Alberta did not achieve the intended aims of reducing unnecessary healthcare utilization to achieve health system cost-savings. It is imperative that further education and training be provided to ordering physicians on how to interpret test results.

#### **AUTHORS:**

Anderson W. Chuck, Nguyen X. Thanh, Radha S. Chari, Robert Douglas Wilson, Selikke Janes-Kelley, James C. Wesenberg

## **BACKGROUND AND OBJECTIVES:**

In 2006, the Alberta Ministry of Health issued a policy to implement fFN testing as a publicly funded service available to all Alberta women. The goals were to reduce healthcare utilization and unnecessary treatment (ambulance transfers, hospital admissions, and length of hospital stay), which would result in health system cost-savings, by more accurately diagnosing false preterm labour. This study is a post-policy implementation review to determine if the policy achieved its goals.

## **METHODS:**

We first assessed the impact of fFN testing on clinical decision-making on ambulance transfer, hospital admission, and average length of hospital stay by comparing between the tested and untested patients. This was conducted separately for in and outpatients, and for true and false preterm labour, using multilevel regressions with episodes/visits being nested within patients. We then assessed the impact of fFN testing on health system costs by using decision tree models populated with actual data and results from the regressions.

## **RESULTS:**

The additional information provided by fFN testing did influence clinical decision-making. However, physicians placing greater significance on positive test results compared to negative ones resulted in the inadvertent increase in healthcare utilization. One of possible explanations is that there is significant risk to the mother and infant if a case of true preterm labour is misdiagnosed. Thus, there would be an inherent tendency to err on the side of caution and be influenced more greatly by positive test results. When factoring the costs of fFN testing as well, the total cost for the health system between 2008 and 2013 increased up to \$4.2 million (2014 CA\$) with \$0.7 million for false and \$3.5 million for true preterm labour.

## **CONCLUSIONS:**

The policy to adopt fFN testing in Alberta did not achieve the intended aims of reducing unnecessary

healthcare utilization to achieve health system cost-savings. If the access to fFN testing services remains, it is imperative that further education and training be provided to ordering physicians on how to interpret test results along with a mechanism for ongoing management and assessment of fFN testing that can feed back to physicians as well as health system managers.

.....

## **OS.47 The Impact Of Quality Of Life Data In Relative Effectiveness Assessments Of New Anticancer Drugs**

### **DESCRIPTION:**

This study investigates the role of quality of life (QoL) data in relative effectiveness assessments (REAs) for new anticancer drugs in European countries. Whilst methods guidelines state that QoL is a relevant endpoint, this is not well-reflected in the current REAs of anticancer drugs. Further research is needed to improve the use of this patient-centered endpoint in future REAs.

### **AUTHORS:**

Sarah Kleijnen, Teresa Alves, Iga Lipska, Hubertus G Leufkens, Anthonius De Boer, Wim G Goettsch

### **BACKGROUND AND OBJECTIVES:**

The assessment of the relative effectiveness of a new drug compared to the standard treatment plays an important role when determining its reimbursement status of a new drug. Evidence shows that quality of life (QoL) is considered to be a relevant endpoint in relative effectiveness assessments (REAs) of new (anticancer) drugs [1,2], as patients at advanced stages of disease face daily challenges in all the dimensions of QoL [3,4]. However, it is unknown whether this perceived importance of QoL data is reflected in reimbursement decisions in Europe.

Objective: To investigate the inclusion of QoL data in REAs for new anticancer drugs in European countries as well as their impact on reimbursement recommendations.

### **METHODS:**

A comparative analysis was conducted studying publicly-available drug assessments for reimbursement decisions in six European jurisdictions (England, France, Germany, The Netherlands, Poland and Scotland). Anticancer drugs were selected that received market authorization in Europe between 2011-2013 and for which at least four drug assessments from different jurisdictions were available. Data were abstracted from the REA section of the reports using a standardised data collection form. A decision algorithm was used to determine the impact of included QoL data on the recommendation and to categorise it into positive, neutral, negative, unknown or no impact.

### **RESULTS:**

A total of 14 anticancer drugs were included, adding up to a total of 79 drug assessments. QoL data was included in 56% (n=44) of the REAs. Of these 44 REAs, the majority included disease specific QoL instruments, such as the EORTC and FACT questionnaires. The QoL data seemed to have a neutral impact in 32% (n=14) of the assessments; positive in 30% (n=13); negative in 7% (n=3) and for 2% of the evaluations the impact was unknown (n=1). No impact was identified (no statement included in recommendation on included QoL data) for 30% (n=13) of the assessment.

### **CONCLUSIONS:**

Whilst guidelines from various European countries state that QoL is a relevant endpoint for anticancer drugs, this is not well-reflected in the current REAs of new anticancer drugs. QoL data were included in just over half of the assessments and their impact on the recommendations was limited. Further research is needed to identify causes for the absence of QoL data and to map strategies to

improve the use of this patient-centered outcome in future reimbursement decisions.

### **REFERENCES:**

1. Kleijnen S, George E, Goulden S, et al. Relative Effectiveness Assessment of Pharmaceuticals: Similarities and Differences in 29 Jurisdictions. *Value in Health* 2012, 15, 954-960.
2. Nooten F van, Caro JJ. Use of relative effectiveness information in reimbursement and pricing decisions in Europe. *Journal of Comparative Effectiveness Research* 2013, 2(1) 33-44.
3. Wilson MK, Collyar D, Chingos DT, et al. Outcomes and endpoints in cancer trials: bridging the divide. *Lancet Oncology* 2015; 16: e43-52.
4. Grant M, Sun V. Advances in Quality of Life at the End of Life. *Seminars in Oncology Nursing*, Vol. 26, No 1 (February), 2010: pp 26-35.

---

## **OS.48 Platelet rich plasma: a case study for the identification of disinvestment using horizon scanning**

### **DESCRIPTION:**

Horizon scanning usually provides an early warning system, alerting health policy makers to new and emerging innovative healthcare technologies before they enter the health system. However, the same methodology identified platelet rich plasma for the treatment of osteoarthritis of the knee as a potential target for disinvestment as the evidence indicated that this was an ineffective and costly procedure.

### **AUTHORS:**

Linda Mundy

### **BACKGROUND AND OBJECTIVES:**

Horizon scanning is a methodology usually

designed to identify new and emerging innovative healthcare technologies before they enter the health system. However, there is the potential for horizon scanning to be used identify low-value, inappropriate clinical practices that deliver minimal benefit to patients and represent a considerable financial burden on the health system.

#### **METHODS:**

Intra-articular injections of platelet rich plasma (PRP) was identified by routine horizon scanning as a potentially innovative treatment alternative for osteoarthritis of the knee. It has been suggested that by addressing tissue damage early, the use of PRP may result in a reduced number of arthroscopy/arthroplasty procedures being conducted in the public hospital system. A rapid, non-systematic assessment of the evidence pertaining to the safety and effectiveness of PRP compared to non-steroidal anti-inflammatory drugs (NSAIDs) for the treatment of osteoarthritis of the knee was conducted.

#### **RESULTS:**

The evidence-base to support the use of intra-articular injections of PRP for the treatment of osteoarthritis of the knee was poor, informed by studies that used an inappropriate comparator for the Australian setting (hyaluronic acid) or by case series evidence. Although there was some evidence that PRP injections may provide some symptomatic relief, there was no evidence that PRP injections could alter the natural progression of osteoarthritis and it is unlikely that the use of PRP would result in changes to clinical practice in the treatment of osteoarthritis at the public hospital level.

At the time of assessment, the use of PRP for the treatment of patients with osteoarthritis of the knee was increasing in the private sector in Australia, particularly in the sports medicine field. Private PRP practitioners were performing these injections for both osteoarthritis and soft tissue injuries using public healthcare funds via an inappropriate Medicare Benefits Schedule (MBS) item number. In 2011-12, a total of 5,480 services were performed

using this MBS item number. During 2013-14, this figure rose to 30,452, an increase of over 450%, with public reimbursement fees totalling >\$3.6 million. In January 2015 the MBS reviewed and amended the wording of the item number to prevent its use for PRP injections. In the 9-month period since the amendment, only 4,173 services have been performed using this item number. If this number was extrapolated to a 12-month period, it would equate to 5,564 services, representing a decrease of 82% compared to the number of services performed in 2013-14, representing a saving of \$2.97 million to the public health system.

#### **CONCLUSIONS:**

This assessment highlights the potential use of HS to identify potential targets for disinvestment of ineffective, inefficient or harmful clinical practices. HS for disinvestment can run in parallel with HS for investment and represents an inexpensive yet effective methodology to identify high volume/low value healthcare practices.

---

## **OS.49 Caring Wisely: Optimising Patient Care In Australia And New Zealand**

#### **DESCRIPTION:**

In light of escalating healthcare costs driven by the investment in new healthcare technologies, health systems need to identify disinvestment opportunities, leveraging work of other agencies to reduce duplication of effort and find mechanisms of translating disinvestment policy into clinical practice. Australia and New Zealand have proposed a one-stop-shop to co-ordinate bi-national disinvestment resources.

#### **AUTHORS:**

Linda Mundy, Kaye Hewson, Brendon Kearney

**BACKGROUND AND OBJECTIVES:**

Australia and New Zealand are at the forefront of evidence-based decision making using health technology assessment (HTA) methodology for the investment of new healthcare technologies. Having worked hard at establishing best practice HTA to assist decision-makers with prioritising investments in new healthcare technologies, the health systems of Australia and New Zealand now, like most health systems around the world, face the challenge of controlling escalating costs in a resource-limited environment without compromising quality of care. Where health technologies continue to drive healthcare costs significantly, governments cannot continue to invest in health innovations without a concurrent process for disinvesting in outmoded, unsafe or ineffective healthcare services. When investing in new technologies, governments need to find a mechanism to evaluate whether or not these new technologies offer an opportunity to either fully or partially disinvest from existing technologies.

**METHODS:**

This presentation will summarise discussions around disinvestment in Australia and New Zealand, including current disinvestment work as well as the way forward.

HealthPACT was established to provide advance notice of significant new and emerging health technologies to policy makers in Australia and New Zealand. In the past HealthPACT’s remit was to focus on the identification and early assessment of healthcare technologies of national significance using a horizon scanning methodology. This approach has been broadened to include actively seeking technologies of potentially greatest impact within the health sector, including the serendipitous identification of disinvestment opportunities via horizon scanning.

As such, in December, HealthPACT held a forum, Caring Wisely: Optimising Patient Care in Australia and New Zealand, to stimulate discussion and address the challenges disinvestment presents

for public hospital systems in Australia and New Zealand. Participants and panellists included disinvestment researchers from the academic sector, clinicians, policy-makers and public reimbursement agencies.

**RESULTS:**

Discussions were wide-ranging and robust around issues of identifying and prioritising healthcare technologies for disinvestment, leveraging work of other agencies, and the difficulty of translating disinvestment policy into clinical practice. A number of initiatives were proposed including the establishment of a central repository and portal, which would enable rapid dissemination and exchange of information around disinvestment, reduce duplication of effort and increase awareness within the health sectors of Australia and New Zealand. Improved stakeholder engagement would assist consumers, clinicians, policy-makers and health service managers to understand the appropriate use of current technologies and clinical interventions.

**CONCLUSIONS:**

Participants agreed that a one-stop-shop should be established to co-ordinate bi-national disinvestment resources at all levels of the Australian and New Zealand health systems and external agencies, including clinical and academic institutions. It was agreed that HealthPACT, with established national, international, jurisdictional and clinical links, and experience in evidence-based HTA, is best placed to perform this task. It was agreed that HealthPACT should act as a central repository and clearing house for assessments of low/no value healthcare. As such, HealthPACT, in addition to being a Horizon Scanning agency, will become a bi-national disinvestment resource and hub with a dedicated web site.

## OS.50 Establishing The Value Of Diagnostic Technology In Terms Of Patient Outcome.

### DESCRIPTION:

Increasingly, diagnostic test characteristics such as sensitivity and specificity are considered surrogate end-points. To establish the value of diagnostic technologies in terms of patient outcomes requires an RCT. We report the design, analysis and results of an RCT assessing the clinical and cost-effectiveness of Adrenal Vein Sampling vs CT in the diagnosis of patients with hypertension resulting from aldosteronism.

### AUTHORS:

Gert Jan van der Wilt, Tanja Dekkers, Peter Makai, Jaap Deinum on behalf of the SPARTACUS trial consortium

### BACKGROUND AND OBJECTIVES:

Increasingly, the need for using patient outcomes as key endpoint is recognized when assessing the value of novel diagnostic technologies. Ideally, this requires prospective randomized controlled trials, comparing clinical and economic outcomes in patients who have been randomly allocated to different diagnostic regimens. Here, we report the design, analysis and results of an RCT assessing the clinical and cost-effectiveness of Adrenal Vein Sampling vs CT in the diagnosis of patients with hypertension resulting from aldosteronism. In such patients, aldosteronism may be due to unilateral adenoma or bilateral hyperplasia. Since the former requires surgery and the latter requires drug treatment, it is important to distinguish between the two etiologies. Conventionally, this is done using computed tomography (CT). Its performance is low, however, due to limited resolution and detection of non-productive adenomas. As an alternative, an interventional radiological procedure has been developed, Adrenal Vein Sampling (AVS). The aim of our study was to assess the clinical and

cost-effectiveness of AVS vs. CT in the diagnosis of aldosteronism.

### METHODS:

We included 200 patients with confirmed aldosteronism-induced hypertension in 13 centres in the Netherlands and Poland. They were randomly allocated to either CT or AVS. Primary endpoint was intensity of hypertensive treatment (Defined Daily Doses, DDD). Secondary endpoints included quality of life (SF-36, EQ-5D) and costs incurred to the health care system. Follow up was one year. The probability that AVS is a cost-effective diagnostic strategy was calculated, using different threshold values for Willingness to Pay for the gain of one QALY. Incremental Net Monetary Benefit regressions were performed to account for the multicenter nature of the study.

### RESULTS:

At one year follow up, no significant differences were found between the two groups in DDDs or systolic and diastolic blood pressures. On average, patients in the AVS group gained 0.05 (SD: 0.04) extra QALYs at a mean incremental cost of 2285 Euros (SE: 486). At a Willingness to Pay of 20.000 Euro per QALY, the probability that AVS, when compared to CT is a cost-effective diagnostic strategy is 2%.

### CONCLUSIONS:

Introducing novel diagnostic technologies may affect diagnostic accuracy, patient management and patient outcome. To assess whether a novel diagnostic technology truly offers advantages as compared to existing modalities, all three dimensions need to be taken into account. To obtain valid data on these dimensions requires a prospective RCT. The results of our study strongly suggest that AVS hardly confers added benefit to patients with aldosteronism-induced hypertension as compared to conventional imaging, and is very unlikely to be cost-effective.

## OS.54 Impact On Capability As An Alternative Framework For Assessing The Value Of Healthcare Interventions

### DESCRIPTION:

The capability approach might provide an interesting adjunct to the current measurement of the impact of healthcare technology on quality of life. It raises the fundamental question whether measurement of subjective wellbeing suffices, or should be complemented with an assessment of what real opportunities people have to do and be things they have reason to value.

### AUTHORS:

Gert Jan van der Wilt

### BACKGROUND AND OBJECTIVES:

It is increasingly recognized that the capability approach, developed by Nobel Prize laureate Amartya Sen, may provide a valuable framework to assess a health care intervention's value. Capability does not so much refer to what people do or be, but to what people are capable of doing or being. As such, it is closely related to the concept of freedom. It conceptualizes capability as a function of capacities, resources, and context. It recognizes that disease conditions can constrain an individual's capability, and that healthcare interventions may prevent this from happening or help to restore capability. It has been developed as an alternative to valuations that are based on utility or primary goods. We report initial results of the development of a questionnaire to measure capability in children.

### METHODS:

Development of a capability questionnaire requires definition of beings and doings that should be available to every member of a community ('capability set'), irrespective of their idiosyncratic preferences. A list of such beings and doings was developed on the basis of interviews and literature review and pilot-tested for clarity and relevance.

Children with cerebral palsy attending specialized education were asked to fill out the questionnaire. Peers who were not diagnosed with congenital disorders enrolled in main stream education were asked to fill out the questionnaire. For comparison, children also filled out the Kidscreen, a self-reported quality of life questionnaire.

### RESULTS:

The questionnaire covered items such as being able to make music, to engage in sports or dancing, to play with friends, to read, to dress oneself, to help in chores, to tinker, to assist in cooking, to understand people and to be understood, to fantasy, etc. Questions were phrased in terms of actual achievement, capability and preference. In a pilot study, three children with cerebral palsy and 22 peers filled out the questionnaire. In capability of doings, but not of beings, children with cerebral palsy reported lower outcomes than their peers.

### CONCLUSIONS:

The capability approach might provide an interesting adjunct to the current measurement of the impact of healthcare technology on quality of life. It raises the fundamental question whether measurement of subjective wellbeing suffices, or should be complemented with an assessment of what real opportunities people have to do and be things they have reason to value. Our preliminary data suggest that capability can be measured and offers information that complements current approaches to quality of life measurement.

---

## OS.56 Reconciling Public And Patient Preferences In Healthcare Decision Making. Belgium Pilots New Models

### DESCRIPTION:

Healthcare decision makers have to take care of society as good housefathers. This implies

balancing the values and preferences of the taxpayers, scientific evidence and preferences and wishes of individual patients with needs. This study presents the application of a decision framework that incorporates public and patient preferences and supports decision makers in making legitimate decisions.

#### **AUTHORS:**

Irina Cleemput, Stephan Devriese, Laurence Kohn, Raf Mertens

#### **BACKGROUND AND OBJECTIVES:**

Healthcare decision makers have to take care of society as good housefathers. This implies balancing the values and preferences of the taxpayers, scientific evidence and preferences and wishes of individual patients with needs. This study presents the application of a decision framework that incorporates public and patient preferences and supports decision makers in making legitimate decisions.

#### **METHODS:**

Belgium developed a decision model that integrates scientific evidence and both citizens' and patients' preferences in the decision making processes in an explicit and transparent way. Citizens and patients fulfil a different role: citizens' preferences help in setting general healthcare priorities. Patients contribute through their expertise by experience, in particular where scientific evidence is scarce.

Weighing all criteria that matter to coverage decisions transparently and coherently is a difficult exercise for a decision maker. The Belgian model splits complex coverage decisions into five sub-questions that each have a well-defined scope and fewer criteria to consider. A key question in the coverage decision process is whether patients with a particular disease are actually asking for a new treatment, i.e. do they perceive a therapeutic need? Assessment of therapeutic need requires patient input. But to remain consistent with the obligation towards society, scientific evidence and citizen

input is also required to weigh these needs against the needs of other patients.

The model uses multi-criteria decision analysis (MCDA) to help the decision makers answer the sub-questions in a transparent way, based on scientific evidence. MCDA involves weighting of relevant decision criteria according to their relative importance. The weights of the decision criteria for each question were obtained through a large survey of the general public (n=4800).

#### **RESULTS:**

The model has been pilot tested with Belgian decision makers for ranking medical needs. The pilot showed that using MCDA for this purpose is feasible and decision makers are open to it. Neutral presentation and validation of the scientific evidence included in the evidence tables are of key importance. Additional qualitative evidence obtained directly from patients is an important complement to the evidence from scientific literature for a well-informed appraisal.

#### **CONCLUSIONS:**

The Belgian model implies a paradigm shift in two ways: first, it starts from the principle that a healthcare system should be driven by needs, not by supply. Second, it combines the virtues of evidence-based medicine with increased legitimacy of decision processes towards the general public. The study shows that the generally supported principle of patient and citizen involvement can be brought into practice in a feasible and efficient way, making use of a transparent decision framework.

#### **REFERENCES:**

KCE has performed five studies (one ongoing) over the last 10 years contributing to the development of the tool that is now available and tested by decision makers:

1. Christiaens W, Kohn L, Léonard C, et al. Models for citizen and patient involvement in health care policy - Part I : exploration of their feasibility and acceptability. KCE Reports. Brussels: Belgian Health

Care Knowledge Centre (KCE), 2012.

2. Cleemput I, Devriese S, Kohn L, et al. Incorporating societal preferences in reimbursement decisions - Relative importance of decision criteria according to Belgian citizens KCE Reports. Brussels: Belgian Health Care Knowledge Centre (KCE), 2014.

3. Cleemput I, Neyt M, Thiry N, et al. Threshold values for cost-effectiveness in health care KCE Reports. Brussels: Belgian Health Care Knowledge Centre (KCE), 2008.

4. le Polain M, Franken M, Koopmanschap M, et al. Drug reimbursement systems: international comparison and policy recommendations. KCE Reports. Brussels: Belgian Health Care Knowledge Centre (KCE), 2010.

---

## OS.60 Informing Acceptable Decisions: What Is The Validity And Role Of Empirical Estimates Of A Cost-Effective

### DESCRIPTION:

Currently, value based pricing reflects subjective views of value, which may be reducing health system efficiency. This study applied a two-stage process to estimate incremental QALY gains from marginal increases in health care expenditure in Australia. The results are inherently uncertain. Should value based pricing continue, or should we seek alternative approaches to negotiating prices for new technologies?

### AUTHORS:

Laura Edney, Hossein Hajiali Afzali, Terence Cheng, Jonathan Karnon

### BACKGROUND AND OBJECTIVES:

There is growing acceptance of some form of value based pricing to inform reimbursement decisions

for new technologies.[1] In making judgments about whether a new technology's incremental benefits justify its incremental costs, Gafni and Birch have argued that the inability to estimate the true opportunity cost of new technologies has increased health care expenditure with little evidence of increases in population health.[2]

Alternative approaches to estimating opportunity cost have been proposed, including assessment of displaced services, of services that could be expanded, and of the expected effects of marginal increases in health care expenditure.

[3] This study aimed to develop and apply a two-stage estimation process to generate an empirical estimate of the incremental QALYs associated with marginal increases in government funded health care expenditure in Australia. In the first stage expenditure and mortality data were analysed to estimate the marginal increment cost per life year gained. In the second stage, population utility data were analysed to incorporate quality of life effects and so estimate the marginal incremental cost per QALY gained.

The validity and role of the resulting estimates were assessed in comparison to alternative empirical approaches to informing value based reimbursement decisions.

### METHODS:

For stage 1, government health care expenditure data were assembled at a statistical local area (SLA) level. Age and gender standardized years of life lost (YLL) and many sociodemographic variables were derived at an SLA level. Instrumental variables were used to estimate the expected incremental cost per life years gained.

For stage 2, AQoL and SF6D derived utility weights were mapped to self-assessed health, to generate utility weights from four rounds of the National Health Survey. These data were analysed to estimate the average annual effects of health care on population utility, and to convert life years to QALYs gained.

## RESULTS:

The statistical models used to estimate the marginal effects of health care expenditure on YLL included a health needs index and a combination of instrumental variables, which passed relevant validation tests. The estimated incremental costs per life year gained varied across years, but demonstrated face validity.

Analyses of population utility were complicated by the need to disentangle the effects of health care and social determinants of health on changes in population utility. The estimated expenditure effects on population utility are small, which increases the effects of uncertainty on the expected incremental cost per QALY gained.

## CONCLUSIONS:

Empirical estimates of the opportunity costs of decisions to fund new technologies are inherently incomplete and uncertain. Previous studies have reported difficulties in assessing displaced services as a basis for informing a cost-effectiveness threshold, and other estimates of the marginal ICER have also been subject to significant uncertainty.

In the absence of an empirical basis, value based pricing reflects subjective views of value, which may well be reducing health system efficiency, especially in an era of limited growth in health care expenditure. Should we continue to pursue value based pricing, or seek alternative approaches to negotiating prices for new technologies?

## REFERENCES:

- [1] Paris V, Belloni A, Value in Pharmaceutical Pricing, OECD Health Working Papers 2013; 63, DOI: 10.1787/18152015
- [2] Gafni A, Birch S, Incremental cost-effectiveness ratios (ICERs): the silence of the lambda. Soc Sci Med. 2006;62(9):2091-100
- [3] Claxton et al, Methods for the estimation of the National Institute for Health and Care Excellence

cost-effectiveness threshold, Health technology Assessment 2015; 19(14)

---

## OS.61 Did Patient Care Meet Clinical Pathways In China?

### DESCRIPTION:

This nationwide survey studied the status of medical care complied with clinical pathways in secondary and tertiary public hospitals in China, through auditing patient records using KPIs derived from national clinical pathways which issued by the NHFPC. The average compliance rate of pneumonia, AMI, heart failure, C-section and cholecystitis were 68.47%, 68.87%, 68.04%, 77.71% and 67.65% respectively.

### AUTHORS:

Jie Bai, Di Xue, Minqi Li, Ping Zhou

### BACKGROUND AND OBJECTIVES:

Studies have documented an association between the use of clinical pathways and positive outcomes including the provision of high-quality and cost-effective care, the improvement of patient and staff satisfaction, the reduction of length of stay and medical cost.

Since 2009, the National Health and Family Planning Commission of China (NHFPC) had issued more than 300 national clinical pathways so far, in order to improve the effectiveness and efficiency of medical care in China. After pilot program, every general secondary or tertiary public hospital was requested to implement at least 5 or 10 national clinical pathways respectively in 2012.

As three years have passed, it was necessary to study whether medicine patient care complied with national clinical pathways, and also the extent of compliance in general public hospitals.

The aim of our study is to check whether patient care are compliant with national clinical pathways

and also to figure out the compliance rates of each selected disease in general public hospitals in China.

## **METHODS:**

In consideration of economic and territorial distribution, three cities were picked up respectively from Shanghai, Hubei and Gansu. One tertiary and one secondary general public hospital were chosen from each city.

Additionally, we identified national clinical pathways of five most common conditions: community-acquired pneumonia, acute myocardial infarction (AMI), heart failure, cesarean section, and biliary calculus with acute cholecystitis. And we also created auditing charts containing key performance indicators (KPIs) based on the national pathways, which used to review patient records.

In every hospital, thirty patient records in 2014 were supposed to be selected randomly for each condition. And records in 2013 would be selected if records in 2014 were deficient.

## **RESULTS:**

The numbers of valid patient records audited across all 18 hospitals were 534, 487, 426, 538 and 536 for medicine care of pneumonia, AMI, heart failure, cesarean section, and biliary calculus with acute cholecystitis respectively.

The overall average compliance rate of five conditions was 69.98%. Regarding to each condition, the average compliance rates were 68.47% of pneumonia with thirteen KPIs, 68.87% of AMI with twelve KPIs, 68.04% of heart failure with twelve KPIs, 77.71% of cesarean section with eleven KPIs, and 67.65% of biliary calculus with acute cholecystitis with fifteen KPIs.

No record met all KPIs in biliary calculus with acute cholecystitis care.

## **CONCLUSIONS:**

There is a real gap between clinical practice in

public hospitals and national clinical pathways in China.

Further researches are necessary to dig the causes of the gap, especially from points of both the quality of clinic pathways and the contributions of public hospitals, including organization reasons and personnel reasons.

---

## **OS.64 Different Approaches For Priority Setting In HTA: Methods, Criteria And Strategic Frameworks**

### **DESCRIPTION:**

The development of rational and transparent approaches for HTA priority setting has become strategic for many organisations. The following paper, based on a systematic review of the literature, provides an inventory of all potentially relevant criteria and offers recommendations regarding practical considerations for implementing successful HTA prioritisation approaches.

### **AUTHORS:**

Leonor Varela Lema, Marisa López García, Gerardo Atienza Merino

### **BACKGROUND AND OBJECTIVES:**

Within Spain, HTA is mandatory to inform decision making regarding the inclusion, exclusion or modification of current use indications in the common NHS service portfolio. In this sense, the development of an explicit priority setting process that allows for a rational and transparent selection of the new technologies to be assessed has become strategic for health care policy makers, as it can contribute to the efficient allocation of resources in HTA. The aim of this paper is to describe and analyse the processes and decision criteria used for priority setting internationally in order to identify a comprehensive set of relevant

criteria and practical approaches that would serve as a starting point for the deliberations on the development of the Spanish prioritisation framework.

## **METHODS:**

We made an inventory of the criteria considered relevant for health care priority setting and identified strategic or conceptual frameworks based on a systematic review of the literature (medical databases, web pages of INAHTA and EUnetHTA agencies, scientific journals, grey literature). We categorized criteria based on existing classifications and analysed potential differences and similarities in the topic selection approaches used by different HTA agencies, evaluating the appropriateness and feasibility at the light of the goals of our organization.

## **RESULTS:**

The criteria and considerations were derived from 17 publications (8 relating to HTA agencies). Overall, a total of 63 potentially relevant priority setting criteria were identified, which could be grouped in 8 categories: 1) Need for intervention; 2) Outcomes of intervention; 3) Type of benefit; 4) Economic consequences; 5) Existing knowledge/quality of evidence and uncertainties; 6) Implementation complexity/feasibility; 7) Priority, justice and equity and 8) Context. HTA agencies considered from 4-12 criteria and used different formal approaches for informing topic selection (stakeholder involvement, information requirements, appraisal and judgment methods). Globally, processes were not fully transparent and papers were not fully explicit regarding how these criteria were ranked or how they were incorporated into decision making.

## **CONCLUSIONS:**

Although it is acknowledged that there are no standardised processes for priority setting, some general consensus and common trends have been identified regarding criteria, principles and procedures, models and strategies and stakeholder involvement. The following paper provides

important insights into these approaches and offers recommendations regarding considerations for implementing successful HTA prioritisation approaches. Findings are envisioned to be useful for many organisations that are aiming to implement or improve priority setting frameworks, with independence on whether they are coming from low-middle or high income countries.

---

## **OS.65 The Development Of A Priority-Setting Framework For Health Technology Assessment In Spain**

### **DESCRIPTION:**

Within Spain, HTA is required to inform decision making regarding the inclusion of new health care technologies in the common portfolio of the National Health System. The following paper describes the explicit priority setting framework that was developed for identifying and ranking technology proposals based on their potential benefits and the perceived utility and value for patients, professionals and public.

### **AUTHORS:**

Leonor Varela Lema, Marisa López García, Gerardo Atienza Merino

### **BACKGROUND AND OBJECTIVES:**

Within Spain, HTA is required to inform decision making regarding the inclusion of new health care technologies in the common portfolio of the National Health System. Acknowledging the need for comprehensive approaches for setting priorities on assessment proposals, the Ministry of Health of the Spanish NHS commissioned the development of an explicit priority setting framework to standardize the identification and selection processes so as to guide decision makers on the technologies that are likely to have an impact on the healthcare system and would bring the most

added value to the society. The current work aims to describe the development of the prioritisation framework that was established within our country for identifying and ranking technology proposals based on their potential benefits and the perceived utility and value for patients, professionals and public.

#### **METHODS:**

The development of the prioritisation framework comprised 3 phases; 1) systematic review to identify common priority setting criteria, methods and strategic approaches; 2) Consensus development (modified Delphi method) of the final list of criteria and domains consistent with the goals and vision of the Spanish priority setting framework and weighing of prioritisation domains by a multidisciplinary panel integrating health care decision makers from macro, meso and micro level, clinical experts, patients and representatives of other end users (medical societies, patient associations, consumer associations, etc.); 3) Development of the explicit implementation process (who, when and how).

#### **RESULTS:**

The prioritisation process developed incorporates a quantitative multi-criteria decision analysis approach, which builds upon the defined criteria and attributed weightings. The PriTec web application, routinely used in other prioritisation areas, provides the bases for technology analysis. Scoring is carried out using strict set of ranking rules and key evidence relating to each criterion (PriTec matrix). The tool calculates automatically the total weighted average score for each proposal (max :50) and provides decision makers with a brief report of the performance of each domain. Formal submission templates are delivered for technology application proposals with explicit data requirements for each of the criteria.

#### **CONCLUSIONS:**

The prioritisation process developed for the Spanish health care system, although consistent with

the goals of our organization, can constitute an innovative example of a rigorous, comprehensive and systematic approach for supporting decision making regarding HTA priorities. Although it is acknowledged that the criteria and practical approaches can be context-dependent, the methodological approach can be useful for all HTA agencies that are aiming to develop or improve current processes.

---

## **OS.66 Pharmaceutical HTA And Drug Reimbursement Process In Mongolia**

#### **DESCRIPTION:**

The Government of Mongolia approved the HTA program in 2002. The program is aimed to introduce the most effective and affordable technologies that can allocate resources appropriately to ensure the accessibility and affordability of essential medicines, especially in developing countries with limited funding. There is a lack of information in regards to pharmaceutical HTA and reimbursement decisions in Mongolia.

#### **AUTHORS:**

Gereltuya Dorj

#### **BACKGROUND AND OBJECTIVES:**

Health technology assessment (HTA) is regulated by the Ministry of Health and Sports of Mongolia (MOHS). The Government of Mongolia approved the National Program to improve HTA in 2002. The objectives of the program included introducing the most effective and affordable technologies that are suitable to the level of care provided; selecting and adopting appropriate technologies. The latest review completed by the MOHS revealed that misconceptions about technology selection and a poor understanding of HTA principles were common among health professionals. The objective of this study is to assess the pharmaceutical HTA and drug reimbursement process in Mongolia.

**METHODS:**

Experts and decision-makers involved in health technology assessment and drug reimbursement process were interviewed. Questionnaire was developed by using the HTA methodology and discussion with academics and pharmacists. Questionnaire was tested for reliability, accuracy and validity. Administrative documents and published statistics were reviewed.

**RESULTS:**

The drug reimbursement system and health insurance (HI) scheme have developed since 1994 in Mongolia. To date, insured ambulatory patients can get a total of 134 essential drugs partly reimbursed (up to 83% of retail price). A total of 5.6 million \$ was spent on reimbursement of essential drugs, and the half of the reimbursement was spent on cardiovascular agents (50%) in 2014. A decision to include the drug in the reimbursement list is based on mortality and morbidity rates for the last two years and drug consumption. Reimbursement of drugs is an important task shared by different authorities, including the MOHS and HI Fund.

**CONCLUSIONS:**

MOHS works towards delivering quality health care to all patients, whereas the Ministry of Finance is aimed to increase the HI coverage with a limited health funding. Periodical reports of drugs registration process, average duration for drug registration are available. However, there is a lack of publicly available information for reimbursement decision making processes. More research is required to re-assess the approval of drugs and develop more transparent and detailed guidelines for HTA and reimbursement process in Mongolia.

.....

## OS.68 Potential Savings In Healthcare Spending On Low Value Interventions In Massachusetts, US

**DESCRIPTION:**

Quantifying the resources spent on low value interventions can help decision makers gain insight on the potential healthcare savings that could be accrued if resources were reallocated away from these interventions. Our study aims to quantify the healthcare resources and expenditures spent on low-value interventions in Massachusetts across payers in an effort to better understand and allocate healthcare spending.

**AUTHORS:**

Natalia Olchanski, Pallavi Rane, Joshua T Cohen, Peter J Neumann

**BACKGROUND AND OBJECTIVES:**

Research indicates that waste and inefficiency consumes 10% to 30% of health care spending in the United States, but exactly what health care interventions are contributing the most to this misallocation is poorly understood. Some 'low-value' interventions that offer relatively low or no additional health benefits for their costs have been identified in comparative effectiveness and cost-effectiveness literature. Other initiatives by physician professional societies, such as the Choosing Wisely initiative, have identified ineffective interventions. Research to date has focused on specific interventions in Medicare populations. Our study aims to quantify the healthcare resources and expenditures spent on low-value interventions in Massachusetts (MA) across payers, including commercial payers and Medicaid, a program providing health care coverage to low income Americans, in an effort to better understand and allocate healthcare spending.

## METHODS:

We identified a list of low-value services based on published literature, which included cancer screening, diagnostic and preoperative testing, imaging, and surgical procedures. We used the 2012 MA All Payer Claims Database (APCD) for the population of 6,549,289 individuals to examine the proportion of individuals who received these services for populations age 18-65 and older than 65, and to calculate the state's associated annual healthcare expenditure. The APCD included medical and pharmacy claims from all commercial payers and certain public programs (Medicare Part C only and Medicaid), including patient out-of-pocket payments. We examined utilization and spending on selected low value services by commercial payers and Medicaid.

## RESULTS:

Our analysis included 14 low value services. For the population aged 18-65, on average 8% of individuals received low value services, ranging from 28.8 to 0 per 100 eligible individuals for each selected service type. Total annual expenditures on the selected low value services in individuals aged 18-65 were \$103.4M, with \$12M (12%) spent by Medicaid, and \$89.3M (86%) by commercial payers. Highest spending services included imaging for non-specific lower back pain, stress testing for stable coronary artery disease, and computed tomography of the sinuses for uncomplicated acute rhinosinusitis. Total annual expenditures on low value services across all age groups were \$155.7M overall (excluding traditional Medicare), with \$13.9M (9%) spent by Medicaid, and \$109.4M (70%) by commercial payers.

## CONCLUSIONS:

Quantifying the resources spent on low value interventions can help decision makers gain insight on the potential healthcare savings that could be accrued if healthcare resources were reallocated away from these interventions. Specific services can be identified and quantified using administrative

data, despite the limitations presented by the lack of clinical details.

---

## OS.69 Joining Forces To Enhance Evidence. Informed Decision-Making In Eurasian Countries: A Swot Analysis

### DESCRIPTION:

Health technology assessment (HTA) has shown remarkable growth over the last 30-40 years and has rapidly become widespread in regions such as Latin America and Asia. Countries contributed to the regional/global development of HTA by establishing networks according to their cultural and geographical proximity, or the commonality of systems. In 2015, Eurasian HTA Initiative was established with the leadership of Turkish Evidence Based Medicine Society and included the countries extending from Balkans to Central Asia. The objective of this study was to analyze common strengths, weaknesses, opportunities, and threats (SWOT) in the enhancement of evidence-informed decision making for the members of this initiative.

### AUTHORS:

Rabia Kahveci, Mirela Çela, Nabil Seyidov, Ahmed Novo, Sinisa Stevic, Temirkhan Kulkhan, Bermet Baryktabasova, Elizabeta Zisovska, Sanja Simovic, Bilgehan Karaday, Esra Meltem Koç

### BACKGROUND AND OBJECTIVES:

Rapid development in health technologies affects health policies of countries. Thus governments try to provide high quality, equal and accessible health care to public while managing health care budgets. Health technology assessment (HTA) has shown remarkable growth over the last 30-40 years and has been used as a basis for health care policy decisions in European and North American countries and in recent years it has rapidly become widespread in regions such as

Latin America and Asia. Countries also contributed to the regional/global development of HTA by establishing networks according to their cultural and geographical proximity, or the commonality of systems. In 2015, Eurasian HTA Initiative was established with the leadership of Turkish Evidence Based Medicine Society and included the countries extending from Balkans to Central Asia that are thought to be new, but promising for development of HTA. The objective of this study was to analyze common strengths, weaknesses, opportunities, and threats (SWOT) in the enhancement of evidence-informed decision making for the members of this initiative.

**METHODS:**

The initiative has organized two meetings in March and November, 2015, with participation of Albania, Azerbaijan, Bosnia and Herzegovina, Macedonia, Montenegro, Kazakhstan, Krygyzstan and Turkey with Tunisia as an observer country. Both meetings included workshops for facilitating interactive discussions and brain storming to facilitate a SWOT analysis.

**RESULTS:**

Lack of adequate number of certified/licensed EBM/HTA courses, absence of EBM related courses/lectures in curricula of undergraduate, graduate and post-graduate schools are some of weaknesses, but availability of web-based resources, and courses on critical appraisal, quality assessment and/or pharmacoinformatics-based courses for doctors, pharmacists, dentists, nurses in different countries in the region could be seen as some of the strengths. Although lack of regional expertise and some reliance on out of region expertise and/or professionals in EBM are major weaknesses, availability of trained personnel and some international educational activities on EBM in the region, potential for relevant information/experience exchange among the partners in the region are some of the opportunities.

**CONCLUSIONS:**

The SWOT analysis has shown common challenges and opportunities for the member countries towards evidence-informed decisionmaking and the initiative is thought to be a major opportunity for a permanent network and a knowledge-sharing platform in the region.

.....

## OS.72 Assessment Of Hair Protheses For Cancer Patients Using An Adapted HTA Method

**DESCRIPTION:**

The French HTA agency (HAS) was asked to assess wigs. Despite no data were available on these atypical medical products, we successfully performed the assessment by defining the most suitable hair protheses eligible for reimbursement. We also created open access data on their technical characteristics, especially to help patients with chemotherapy-induced alopecia in their choice.

**AUTHORS:**

Nadia NAOUR, Corinne Collignon, Jacques Belghiti

**BACKGROUND AND OBJECTIVES:**

Accurate reimbursement of hair protheses was integrated in the last national cancer plan in order to improve patients' quality of life and to alleviate financial consequences of malignancy. The French National Authority for Health [HAS] was designated to assess the most suitable hair protheses eligible for an upgraded reimbursement from 125\$ to 250\$.

Since clinical literature and recommendations are not available on hair protheses, considered everyday consumer products, they could not be assessed via a systematic review. Moreover, no trade mark notice was available and CE marking is not a prerequisite for their access to the market.

This work presents a new process of evaluation,

based on industry's data, patients' associations testimonies and covering data from other HTA agencies.

#### **METHODS:**

A questionnaire was sent to hair prostheses companies and cancer organizations to collect technical description of the products and patients demands, respectively. A request to International Network of Agencies for Health Technology Assessment was also sent, to compare the reimbursement in other countries. All information regarding the current healthcare system and reimbursed hair prostheses were collected and analyzed by health professionals. They belonged to a multidisciplinary working group which included a dermatologist, a surgical oncologist, a specialist cancer advisory nurse, a social worker, a psychologist, a social and educational worker and a health support worker.

#### **RESULTS:**

Industry data showed synthetic fibres were similar. Hair prostheses' cost was related to visual appearance, with superiority of hand sewing, and to lightness of the cap, for maximum comfort.

Patients revealed that they were not aware of the main characteristics of prostheses. They complained about commercial relationships with patients and quite systematic out-of-pocket charges.

Data from seven foreign national agencies reported a minimum coverage of around 250\$, including funding of accessories. Medical indications were well defined, however, no information was provided on technical specifications.

The working group advocated most patients requests and defined for a 250\$ hair prosthesis, minimal characteristics.

#### **CONCLUSIONS:**

Our work underlines the successful assessment of specific products, by adjusting standard HTA

methods. Despite the absence of literature and open access to technical knowledge, we also demonstrated that our assessment of hair prostheses produced data. Patients' associations pleaded for a satisfying visual aspect and lightness, leading us to define corresponding minimal technical requirements that meet the new funding tariff.

---

## **OS.77 Is Patent 'Evergreening' Restricting Access To Medicine/Device Combination Products?**

#### **DESCRIPTION:**

The continuous re-development and re-patenting of device components in medicine/device combination products (e.g., inhalers, pens) is prevalent. Such patenting activity on device components may outlast expired patents on the medicament itself and helps prevent direct marketplace competition. We measure the prevalence of such activity and question whether the value of these improvements is proportionate given the additional costs.

#### **AUTHORS:**

Reed Beall, Jason Nickerson, Warren Kaplan, Amir Attaran

#### **BACKGROUND AND OBJECTIVES:**

Not all new drug products are truly new. Some are the result of marginal innovation and incremental patenting of existing products, but in such a way that confers no major therapeutic improvement. This phenomenon, pejoratively known as 'evergreening', can allow manufacturers to preserve market exclusivity, but without significantly bettering the standard of care. Other studies speculate that evergreening is especially problematic for medicine/device combination products, because patents on the

device component, and therefore, may outlast expired patents on the medicine component, to keep competing, possibly less-expensive generic products off the market.

**METHODS:**

We focused on four common conditions that are often treated by medicine/device product combinations: asthma and chronic obstructive pulmonary disease (COPD), diabetes, and severe allergic reactions. The patent data for a sample of such products (n=49) for treating these conditions was extracted from the United States Food and Drug Administration’s Orange Book. Additional patent-related data (abstracts, claims, etc) were retrieved using LexisNexis TotalPatent. Comparisons were then made between each product’s device patents and medicine patents.

**RESULTS:**

Device patents exist for 90% of the 49 medicine/ device product combinations studied, and were the only sort of patent for 14 products. Overall, 55 percent of the 235 patents found by our study were device patents. Comparing the last-to-expire device patent to that of the last-to-expire active ingredient patent, the median additional years of patent protection afforded by device patents was 4.7 years (range: 1.3 - 15.2 years).

**CONCLUSIONS:**

Incremental, patentable innovation in devices to extend the overall patent protection of medicine/ device product combinations is very common. Whether this constitutes ‘evergreening’ depends on whether these incremental innovations and the years of extra patent protection they confer are proportionately matched by therapeutic improvements in the standard of care, which is highly debatable.

.....

## OS.80 Room With A Patient View, Engaging Patients In Health Care Decision Making. Insights From Australia

**DESCRIPTION:**

In most markets the patient voice is given little consideration in government or private payer decisions to reimburse medicines. This paper provides a summary of proceedings from an Australian patient forum with the aim of improving access to medicines by developing a formalised framework to incorporate a broader patient-driven perspective into the decision making process.

**AUTHORS:**

Simon Fifer, John Rose, Ian Olver, Nathan Walters, Todd Stephenson, Richard Vines

**BACKGROUND AND OBJECTIVES:**

In most markets the patient voice is given little consideration in government or private payer decisions to reimburse medicines. Quite often, even health professionals do not necessarily have a deep understanding of what it is like to experience a health condition. Furthermore, the attributes and outcomes that are important to the patient (and carer) may at times be different to what the health professional and payor perceive as important. This limited view may mean the medicine is undervalued by the system. Targeted and appropriate input from patient and carer groups might lead to a more balanced basis of HTA decision making.

**METHODS:**

In 2015 a group of stakeholders (from industry, academia and patient groups) came together to discuss methodologies and approaches for eliciting the patient perspective on the value of medicines. As a result of these meetings a conference was organised aimed at increasing patient engagement in health technology assessment (HTA) in Australia. The conference, called ‘Room with a Patient View: Engaging patients in health care decision making’,

is being hosted by the University of South Australia's Institute for Choice (I4C) and Sansom Institute for Health in February 2016. The aim of the conference is to discuss, develop and formalise a framework to incorporate a broader patient-driven perspective into the health care decision making processes. The conference includes presentations from a number of international and local experts in this field (including the Australian Department of Health and PBAC), workshops and a summary session to conclude with recommendations for change.

### **RESULTS:**

Relevant background information and forum proceedings will be collated in a Whitepaper. Highlights from the whitepaper will be presented in this paper.

### **CONCLUSIONS:**

Patient engagement in the HTA is a complex and widely discussed topic among concerned stakeholder groups, such as patients, patient groups policy makers and HTA decision-makers. This paper provides a summary of findings from an Australian patient forum with principal stakeholders, offering new perspectives, opinions and possible solutions to patient engagement in HTA. Insights will help further inform the debate by providing examples of how the patient perspective can be incorporated into HTA systems, including sharing global learnings and novel research initiatives.

In addition, this paper will also provide a summary of forum attendee preferences for patient input in the Australian HTA. Preferences will be elicited using a discrete choice model. Outputs from the model will be displayed as an online dashboard (i.e., interactive tool to perform scenario analysis) which will allow users to configure the optimal HTA patient engagement model by stakeholder group (patients, government, clinicians, researchers and industry).

.....

.....

## **OS.83 The Scottish Medicines Consortium's New Process For End Of Life And Orphan Medicines**

### **DESCRIPTION:**

In 2014, SMC introduced a new appraisal process for medicines used at the end of life and for very rare conditions. The purpose of this study is to review the first years experience in terms of the types of economic evaluation received, trends in the acceptance rates and the magnitude of QALY gains and cost-effectiveness ratios.

### **AUTHORS:**

Ailsa Brown, Corinne Booth, Brian O'Toole , Anne Lee, Jan Jones, Jonathan Fox

### **BACKGROUND AND OBJECTIVES:**

The Scottish Medicines Consortium (SMC) issues advice to NHS Scotland on the clinical and cost-effectiveness of all new medicines. In Autumn 2013, the Scottish Government directed SMC to review its appraisal process for medicines used at the end of life and for very rare conditions, with the aim of increasing access to treatments. A new approach, termed Patient and Clinician Engagement (PACE) was introduced to give patients and clinicians a stronger voice in the decision making process for these medicines. A new decision making framework was also introduced for ultra-orphan medicines. In October 2014 SMC issued its first decisions using this new approach. The purpose of this study is to review the first year's experience in terms of the types of economic evaluation received, trends in the acceptance rates and the magnitude of QALY gains and cost-effectiveness ratios.

### **METHODS:**

Information was extracted from the SMC website and submissions on the use of wider societal perspective, the estimated cost per QALY and QALY gains for these medicines and acceptance rates. These data were compared to historical data and/

or corresponding data for other medicines assessed that were not eligible for consideration under the PACE process to investigate any trends arising from the introduction of the new approach.

**RESULTS:**

In the first year, 36 medicines have been appraised through the PACE process: 25 (70%) of these medicines were considered as an orphan, orphan equivalent or end of life medicine and 11 (30%) were considered under the ultra orphan decision making framework. Only 2 (18%) of the ultra orphan medicine submissions included analysis from a societal perspective. For medicines considered via the PACE process the median QALY gain for medicines accepted was 0.35 and for medicines not recommended the figure was 0.67. The comparative figures for other medicines (n=x) were 0.13 and 0.11 respectively. The mean cost per QALY for medicines accepted via the PACE process was £35,744 compared to £16,557 for other medicines. The acceptance rate for PACE medicines was 69%, compared to 96% for all other medicines (n=47) assessed during the same time period. As a proxy for change over time, in the 3 years prior to the introduction of the PACE process, the overall acceptance rate for orphan and cancer medicines was 48%.

**CONCLUSIONS:**

The acceptance rate for medicines used at the end of life and for very rare conditions has increased since the PACE process was introduced, despite comparatively poorer cost-effectiveness ratios. To date, adoption of alternative forms of economic evaluations and evaluations using wider perspectives for ultra-orphan medicines by companies has been limited.

.....

## OS.90 Use Of Text-Mining Tools For Systematic Reviews

**DESCRIPTION:**

A preliminary review of text-mining tools as an emerging methodology to support systematic review processes. Text-mining tools are currently being used in a wide range of applications, including support for systematic review searching, screening, appraisal, and synthesis. Additional research is needed to address the reliability, validity, and practicality of these emerging technologies in the context of the systematic literature review.

**AUTHORS:**

Robin Paynter, Lionel L. Bañez, Elise Berliner, Eileen Erinoff, Jennifer Lege-Matsuura, Shannon Potter, Stacey Uhl

**BACKGROUND AND OBJECTIVES:**

To provide a preliminary review of text-mining tools as an emerging methodology to support systematic review processes.

**METHODS:**

We conducted a literature search to identify and summarize research on the use of text-mining tools within the systematic review context. We conducted telephone interviews with Key Informants using a semi-structured instrument, and subsequent qualitative analysis to explore issues surrounding implementation and use of text-mining tools. Lastly, we compiled a list of text-mining tools to support systematic review methods and evaluated the tools using an informal descriptive appraisal tool.

**RESULTS:**

The literature review identified 670 articles, 122 of which met inclusion criteria. Support for the use of text mining was strong amongst the Key Informants overall, though most noted performance caveats or areas requiring further research. We describe

111 text-mining tools identified from the literature review and KI interviews.

## CONCLUSIONS:

Text-mining tools are currently being used in a wide range of applications, including support for systematic review searching, screening, appraisal, and synthesis. The literature-base is growing, although likely not as quickly as ongoing innovation. Additional research is needed to address the reliability, validity, and practicality of these emerging technologies in the context of the systematic literature review.

---

## OS.93 Developing An Evaluation Framework To Measure Research Impact Of PPPHealth Research Programme

### DESCRIPTION:

In 2008, the Veneto Region (Italy) started a new health research initiative called PRIHTA: a programme designed to develop projects in partnership with private actors. An evaluation of its research project impacts is essential to provide an objective measurement and to address an evidence-based public decision-making process. Using a focus group-based methodology, we define a theoretical evaluation framework applicable to regional R&D context.

### AUTHORS:

Mirko Claus, KrealD Demiraj, Massimo Castoro, Alessandra Buja

### BACKGROUND AND OBJECTIVES:

In Italy, regional authorities plan and organise health care facilities and activities through their health departments. Since 2008 the Veneto Region, Italy (4.9 mln inhabitants) has approved an

original financial model of public health research in partnership with private stakeholders (PRIHTA). (1) One of the major aims of the financed projects is to pursue the development and improvement of the quality, efficacy, effectiveness and costs of the Regional Health System. Since health research is an activity with a particularly uncertain return of investment, the scientific community interest for impact evaluation has risen, resulting in new theoretical models and multidimensional methodological approaches.(2-4) Parallel to the rising scientific interest, the increasing request for social accountability and strategic planning make the definition of meaningful criteria, to be provided to the regional policymaker and stakeholders, essential. Such criteria should be tailored to track processes of research and focused on measuring the valuable outputs and outcomes, coherently with the objectives of PRIHTA. Our study hence aims at defining a multidimensional framework in order to evaluate the PRIHTA projects approved between 2008 and 2011 (2.3 mln).

### METHODS:

We performed a review of the literature published until October 2015 with keywords such as 'research impact evaluation framework', 'health research evaluation', 'research evaluation framework'; prioritizing the research output of leading institutions in the field (5). We then discussed the collected literature in a focus group composed of representatives of Veneto Region, University of Padua researchers, principal investigators and private stakeholders to define an appropriate framework.

### RESULTS:

The framework model proposes the analysis of project results through different indicators of six macro categories i.e. processes, primary outputs, secondary outputs, short-mid-term outcomes, long-term outcomes and undesired outcomes. Processes include both the evaluation of facilitating or obstructive elements and the observance of budget and timeline schedule. Primary outputs are subdivided into scientific knowledge products,

societal knowledge dissemination products and education products. Secondary outputs encompass scientific evidence products (e.g. guidelines), the development of new projects, and the attraction or creation of resources. Short-midterm outcomes consist of patient-measured outcomes (clinical endpoints, mortality rates, influence on risk factors, and quality of life), as well as the development of human resources skills. Among long-term effects, we include the most important effects, in terms of either general public health impacts (health inequalities, epidemiological measures of disease or risk factors) or health services effects (e.g. improvement of services efficiency and therapies accessibility, new organisational models). Finally, as undesired outcomes, we consider the termination of previous research areas, the increase in health inequalities, and a rise of conflicts.

#### **CONCLUSIONS:**

Our evaluation framework provides a first systematic attempt to evaluate the impact of regional projects. It translates the achievement of the most important goals of PRIHTA into well-defined measures. These measures become the basis for an improvement of public health and health services, with specific attention to quality, efficacy, and effectiveness. We believe that our approach can improve public decision-making, and cost-benefit analysis, through innovation in health.

#### **REFERENCES:**

1. Deliberazione della Giunta Regionale n. 2187 del 08 agosto 2008. Ricerca ed Innovazione in ambito sanitario e sociale: organizzazione regionale e funzione di coordinamento. Istituzione del Programma per la Ricerca l'Innovazione e l'HTA (PRIHTA). Modifica parziale DGR n. 410 del 26/02/2008. 2187, Giunta Regionale del Veneto, 08/08/2008 Sess. (2008).
2. Penfield T, Baker MJ, Scoble R, Wykes MC. Assessment, evaluations, and definitions of research impact: A review. *Research Evaluation*. 2013:rvt021.
3. Banzi R, Moja L, Pistotti V, Facchini A, Liberati A.

Conceptual frameworks and empirical approaches used to assess the impact of health research: an overview of reviews. . 2011.

4. Donovan C, Hanney S. The 'Payback Framework' explained. *Research Evaluation*. 2011;20(3):181-3.
5. Guthrie S, Wamae W, Diepeveen S, Wooding S, Grant J, Europe R. *Measuring research: a guide to research evaluation frameworks and tools.* ; 2013."

---

## **OS.94 Integrating Drugs Budget Impact And Drugs Market Uptake Models In Horizon Scanning: The C-Tobia Mode**

#### **DESCRIPTION:**

This paper illustrates a new budget impact model (C-ToBIA) that integrates into the HS phase, budget impact analysis with an agent-based model aimed at shaping drugs uptake and data from the largest Italian administrative database. The C-ToBIA model was applied to second-line noninsulin antidiabetic drugs, with an expected 47.8 million € impact on the Italian market in 2015-2017.

#### **AUTHORS:**

Roberta Joppi, Elisa Cinconze, Luca Demattè, Renato Guseo, Claudio Jommi, Cinzia Mortarino, Daniela Pase, Alessandro Roggeri, Daniela Roggeri

#### **BACKGROUND:**

Drugs budget impact analysis (BIA) is extremely useful for payers, to estimate whether new drugs are sustainable. Horizon Scanning (HS) aims at scrutinising and collecting evidence on prioritised health technologies before their market launch. HS is focussed on unmet needs, expected place in therapy and drugs risk-benefit profile, but has usually not produced drugs BI estimates.

**OBJECTIVE:** The paper presents an original model (C-ToBIA Model) aimed at estimating the BI of emerging medicines identified, prioritized and critically assessed by the Italian Horizon Scanning Project. The model has been applied to emerging second-line noninsulin antidiabetic drugs (NIADs). The BIA was performed according to ISPOR's guidelines which stressed that (i) the expected drugs market uptake should be robustly estimated, (ii) market dynamics should be taken into account (iii) BIAs should mostly rely on real-world evidence on national/local pathways.

### **METHODS:**

The present BI analysis relied on a traditional BI model, that compares two scenarios (with and without the new drugs), integrated with (i) an agent-based model (Cellular-Automata-like - CA) aimed to shape new drugs uptake and (ii) data from the largest Italian health care administrative database (Arno-Cineca, covering 11 million inhabitants).

### **RESULTS:**

The CA model shaped future drugs market uptake (number of packs) on the basis of the 2000-2014 life-cycle of more than 200 antidiabetic drugs (ATC A10B). The model has estimated 104 antidiabetic agents launched onto the market until April 2018. Target population (i.e. 4.36% of total population currently receiving second line therapies), unit cost of avoided events (hospitalizations due to severe hypoglycaemia, 2,779 \$) and average duration of therapies (242 days) were derived from the Arno-database. Unit price per pack and expected launch date were estimated in line with the NIADs recently marketed. According to recent systematic reviews the effectiveness of the different antidiabetics was assumed comparable. Due to the less frequent severe hypoglycaemic events caused by the new drugs, their risk profile was considered better than that of other existing alternatives ( e.g. secretagogues).

The expected BI for the antidiabetics coming through in 2015-2017 is 47.8 million \$ (+3%

vs. the scenario without the new drugs). The increase in drugs expenditure (+95.4 million \$) is partially compensated by the avoided costs for hospitalisation due to severe hypoglycaemia (-47.8 million \$).

### **CONCLUSIONS:**

Predicting the BI of emerging drugs is very useful for HTA agencies and payers to timely estimate new drugs sustainability and proactively negotiate market access conditions (including price) with the pharma-companies. The C-ToBIA Model, despite its limitations (drugs uptake model should be appropriately adapted to different markets and many variables are unknown when the BI is performed), has been designed to meet this requirement.

### **REFERENCES:**

- Jommi C, Minghetti P (2015). Pharmaceutical Pricing Policies in Italy, in (ed.) Zaheer-Ud-Din Babar, *Pharmaceutical Prices in the 21st Century*, Springer, London, pp. 131-151
- Joppi R, et al. The Italian Horizon Scanning Project. *Eur J Clin Pharmacol* 2009; 65:775-781.
- Guseo R, Guidolin M. Modelling a Dynamic Market Potential: A Class of Automata Networks for Diffusion of Innovations. *Technological Forecasting and Social Change* 2009; 76:806-820.
- Bennett WL, Maruthur NM, Singh S, Comparative effectiveness and safety of medications for type 2 diabetes: an update including new drugs and 2-drug combinations, *Ann Intern Med*. 2011 May 3;154(9):602-13.
- Sullivan SD, Mausekopf J, Augustovski F et al, Budget impact analysis-principles of good practice: report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force, *Value Health*. 2014 Jan-Feb;17(1):5-14."

## OS.99 Cost Analysis Of Particle Radiotherapy In Comparison To Photon Therapy In China

### DESCRIPTION:

A cost analysis on heavy-ion and proton (particle) therapies, compared to the photon therapy was conducted based on currently established facilities in China. Results indicate that particle therapies are more costly but cost differences can be decreased when efficiency is increased and capital cost is lowered through use of domestic equipment.

### AUTHORS:

Joo Chang , Yingpeng Qiu, Xue Li, Binyan Sui , Weiwei Hou

### BACKGROUND AND OBJECTIVES:

Particle therapies are rising as a potentially more optimal treatment option compared to photon radiotherapy despite high costs. In China, there are already several particle centers in operation with several more in construction. Despite the increase in investments, the cost of particle therapy is still unclear both in China and abroad. The study aims to assess the cost of particle therapies (proton and heavy-ion) in China, compared to the most common radiotherapy using photons. The cost analysis will allow policy makers to better understand the financial components of the new technology and to establish clearer regulatory measures so that appropriate use and reasonable costs are ensured.

### METHODS:

The current capital and operational costs were estimated for the two facilities of combined therapy (heavy-ion and proton) and photon therapy, based on field surveys on two currently established particle facilities, literature review, and expert opinions. The costs per fraction for both facilities were also assessed for comparison. Sensitivity analyses adjusting efficiency and equipment cost were conducted; and different treatment costs

for patients with varying indications were also considered.

### RESULTS:

The annual costs of the combined and photon facilities were 141.4 million and 9.7 million CNY respectively. Cost per fraction was 29,938 for combined and 1,256 CNY for photon therapy, yielding a ratio of 24 to 1. If treatment room availability was increased to raise efficiency for the combined therapy, the cost per fraction will decrease from 29,938 to 6,303 CNY to maintain the annual costs. This would also equate to increase in patients that receive treatment. Utilizing domestically produced equipment will also decrease the total cost from 141.4 million to 96.4 million, leading to a 20,410 CNY per fraction.

### CONCLUSIONS:

The cost analysis indicates that particle therapy is expensive compared to the commonly used photon therapy, particularly due to high capital and operational costs. This means that the financial burden will typically fall on patients. Due to many uncertainties surrounding the proton and heavy-ion therapies, policy makers should consider the overall investment costs, epidemiological make-up of the population, and current evidence on the therapies' effectiveness and cost-effectiveness.

---

## OS.108 Updating HTA Guidelines Using HTA Methodology Research: The Dutch Experience

### DESCRIPTION:

In recent years several countries have developed HTA guidelines, mainly focused on pharmacoeconomics. Due to new methodological developments and growing experience the existing guidelines have to be updated regularly. In the Netherlands new HTA guidelines became

recently available. Information will be shared on the development of and changes in these new Dutch guidelines.

#### **AUTHORS:**

Saskia Knies, Nynke Dragt, Joost Enzing , Lotte Hermsen, Sylvia Vijgen , Maarten Ijzerman on behalf of the Expert Committee Revision Health Economic Guidelines

#### **BACKGROUND AND OBJECTIVES:**

In the last three decades countries from all over the world have developed Health Technology Assessment (HTA) guidelines. These guidelines give guidance on how health economic evaluations should be carried out in the given jurisdiction. The main advantage of guidelines is that it increases the comparability in the methods used of the studied carried out within a specific jurisdiction. However, HTA methodology is still under development. These developments may influence the outcomes of the assessments used to inform decisions regarding new health technologies. As assessments are usually led by guidelines, it is important to have up to date guidelines. Regular updates of HTA guidelines taking the latest results of HTA-research into account are therefore warranted. The Dutch pharmacoeconomic guideline was last updated in 2006 and therefore it was decided in January 2014 that the guideline should be updated and revised.

#### **METHODS:**

National guidance and reports on HTA methodology were used for information on recent developments in the field. In addition, international guidance from for example EUnetHTA and ISPOR, health economic guidelines from among others NICE and Belgium and literature on HTA methodology were used as background information. An external expert committee consisting of twelve members was established to advice the National Health Care Institute on the structure and content of the guideline. During the revision process an expert meeting and a consultation round were organized to collect feedback from stakeholders.

#### **RESULTS:**

Previously there were three separate guidelines, being the pharmacoeconomic guideline, costing guideline and the guideline for outcomes research available in the Netherlands. In the revision process these three guidelines were integrated into a single health economic guideline. In December 2015 the new Dutch health economic guideline became available. The guideline was officially launched during a specially organised symposium in February 2016. During this symposium it was also made clear how the latest developments in HTA methodology and international guidance were taken into account and/or incorporated into the new guideline.

#### **CONCLUSIONS:**

For the development of the new Dutch health economic guideline several national and international sources were used. To start with, the terminology used was adjusted to the internationally known terms, for example the classification of cost categories and uncertainty were adjusted to the terms used in international guidance. From the start of the revision process it was decided to incorporate state of the art methods, but with the requirement that the new methods should be sufficiently developed. The guideline should result in methodologically comparable assessments of sufficient quality, but with the opportunity to use other methods whenever deemed necessary.

---

## **OS.109 Providing Information On New And Emerging Health Technologies:A User Survey**

#### **DESCRIPTION:**

We will present the results of an online survey about CADTHs horizon scanning bulletins to determine Canadian decision-makers' satisfaction with their level of information, format, readability and relevance.

## **AUTHORS:**

Ken Bond, Andrew Dzuba, Jeff Mason, Leigh-Ann Topfer

## **BACKGROUND AND OBJECTIVES:**

As a national HTA agency, the audience for CADTH publications is diverse-- ranging from decision makers in the federal government and larger provinces to small health authorities and hospitals in remote and rural areas. Meeting the needs of such a broad audience can be challenging. Since 1997, CADTH has published over 140 horizon scanning bulletins in a series called Issues in Emerging Health Technologies. Feedback on these bulletins found readers liked the format and content. To coincide with a re-design of CADTH publications we sought to do a more thorough assessment of reader satisfaction with the level of information, format, readability and topic relevance of these bulletins.

## **METHODS:**

A 15-question, online survey was designed using FluidSurveys and distributed using MailChimp to over 2,400 contacts by CADTH's Liaison Officers (CADTH representatives in different jurisdictions).

## **RESULTS:**

We received 101 responses. Responses from clinical managers, government policymakers and regional health authorities were the largest groups of respondents (44%). Survey respondents wanted information on new technologies as close to the time of Canadian marketing as possible (42%) or early in clinical use (49%). The level of information in the bulletins was sufficient for 89% of respondents. Most readers preferred a summary of the evidence (60%), rather than detailed critical appraisal (40%); and a summary (70%) rather than detailed statistical information (30%). Most (86%) thought the bulletins were a good information source, but while 58% found them useful for planning only 33% thought they provided sufficient information to make decisions about introducing or funding new technologies.

## **CONCLUSIONS:**

While most respondents were satisfied with the bulletins, relevance could be increased by expanding the breadth of topics covered, for example to include technologies from community care. Readers were also more interested in technologies in a shorter time horizon (closer to Canadian marketing and diffusion). Some pieces of information decision makers need were not covered in the bulletins. The missing pieces were not identified by the survey respondents, though they probably concern the local context, competing priorities and budgets. Future one-on-one discussions with decision makers could identify the other information needed to improve the value of these bulletins for decision making.

---

## **OS.114 Lack Of HTA: An Obstacle For Development Through Drug Repurposing**

### **DESCRIPTION:**

To address inefficiencies in drug development, manufacturers often leverage known and approved chemical entities by repurposing them for approval in the same or different indication. This research aims to identify the proportion of on and off patent repurposed products from January 1995 to Dec 2015, the path used for repurposing, and the nature of benefit associated with these products.

### **AUTHORS:**

Adam Plich, Cécile Rémuzat, Francesca Tavella, Pascal Auquier, Mondher Toumi

### **BACKGROUND AND OBJECTIVES:**

To address inefficiencies in drug development, manufacturers often opt to leverage already known and approved chemical entities by repurposing them for approval through various regulatory processes in the same or different indication. This approach is referred to as value added medicine,

new therapeutic entities, or repurposing life cycle management. This process allows for a substantial reduction in the development costs and safety risk, as such entities are already known and commercialized. However, several disincentives for developing such products exist when they are off patent, even though they may bring patient benefit. First, the policies of many countries (e.g., UK, Germany, Poland, Belgium, Austria, etc.) consider them as generic, and therefore are not eligible for HTA review. Second, in these countries the target product is automatically priced as generic irrespective of the additional value they may bring to patients and society. Finally, in many countries these products are grouped in one single tender together with generics leaving no opportunities to realize the benefit. The objective of this research is to identify the proportion of on and off patent repurposed products from January 1995 to December 2015, the path used for repurposing, and the nature of benefit associated with these products.

#### **METHODS:**

We performed a systematic literature search to identify products repurposed using the following sources: Medline, Embase, Google scholar, Cochrane, GaBi, EMA website, HTA agencies websites in Europe when information is available in English or French. We used a repurposing definition and classification from Murteira et al. 2013, which categorizes repurposing activities as repositioning, reformulation and adding as fixed dose combination. We identified on or off patent status based on the availability of generics either in France, UK or Germany. Benefit was determined based on HTA reports in France (HAS) and Scotland (SMC) in the manufacturer communication.

#### **RESULTS:**

Based on the definition, we identified 197 already known and approved entities that underwent a repurposing strategy off patent. This represents 36% of all identified repurposed products. Among these, we observed the following processes: repositioning (41%) in a new indication, reformulation including

a drug device combination (67%), and fixed dose combination (19%), although some combined multiple processes. Reported patient benefit was usually considered by HTA as insufficient evidence in most cases. Each identified benefit was classified as improved (i.e., convenience of use, efficacy, safety, tolerability, equity, adherence, patient preference) leading potentially in most cases to resource use and cost reductions.

#### **CONCLUSIONS:**

There is a catch 22 when using repurposing approaches, as such products when off patent are usually treated as generic. Furthermore, the return on investment of generating robust evidence is unlikely leading manufacturers to invest conservatively in the clinical development. These products may currently represent an opportunity to provide a valuable intermediate step before switching patients to expensive new therapies, and therefore the redevelopment of off patent products may bring value for society. However current regulation prevents recognition of such product benefit, as they are not eligible for HTA assessment and are clustered in generic tenders in many countries.

---

## **OS.124 Economic Evaluation Of Transcatheter Aortic Valve Implantation Treated By Medical Management**

#### **DESCRIPTION:**

For patients with severe aortic stenosis who are ineligible for surgical aortic valve replacement, transcatheter aortic valve implantation may be an important treatment option which may prolong life and improve quality of life of these patients. However, its high costs had hindered its usage in Taiwan. To support National Health Insurances reimbursement decision on TAVI, this study aims to perform economic evaluation for transcatheter aortic valve implantation including cost-utility

analysis and budget impact analysis under the National Health Insurance's viewpoint in Taiwan.

**AUTHORS:**

Yi-Fan Li, Shu-Chen Chu, Elena Chia-Ling Chen, Chih-Chung Huang, Grace Hui-Min Wu

**BACKGROUND AND OBJECTIVES:**

For patients with severe aortic stenosis who are ineligible for surgical aortic valve replacement, transcatheter aortic valve implantation may be an important treatment option which may prolong life and improve quality of life of these patients. However, its high costs had hindered its usage in Taiwan. To support National Health Insurance's reimbursement decision on TAVI, this study aims to perform economic evaluation for transcatheter aortic valve implantation (TAVI) including cost-utility analysis and budget impact analysis under the National Health Insurance's (NHI) viewpoint in Taiwan.

**METHODS:**

Cost-utility analysis with a Markov model framework was conducted to evaluate the cost-effectiveness of TAVI compared with medical management (MM) with a 10-year time horizon. Costs and outcomes were discounted at 3% per year. Medical costs were taken from claim data of the National Health Insurance. Utilities of each health states of aortic stenosis were obtained by a survey based on 30 subjects recruited from general population using visual scale, time trade-off, and standard gambling methods. One-way sensitivity analysis and probabilistic sensitivity analysis was performed to investigate the impact of uncertainty of parameters on the cost-effectiveness results. One to three times Gross Domestic Product (GDP) per capita was used as the cost-effectiveness threshold for the incremental cost-effectiveness ratio (ICER) per quality-adjusted life-year (QALYs) gained. Budget impact analysis was performed to assess the affordability.

**RESULTS:**

The base case analysis demonstrated that the ICER of TAVI was more than three times GDP per capita. One-way sensitivity analysis showed that the cost of TAVI was the most influential parameters. However, based on the results of threshold analysis, if the cost of TAVI reduced to lower than USD \$20,000, the ICERs became lower than one time GDP per capita, which were far below the plausible value of the cost of TAVI. Moreover, if TAVI is reimbursed under the NHI (excluded the cost of Core Valve), the budget impact was estimated to be about NT\$50.8 million to NT\$52.8 million, while the budget impact is estimated to be about NT\$295 million to NT\$307 million if the cost of Core Valve was included.

**CONCLUSIONS:**

Although TAVI significantly improved the clinical outcomes and quality of life for patients with severe aortic stenosis who are ineligible for surgical aortic valve replacement, our study showed that it may not be a cost-effective treatment option due to its high cost.

.....  
**OS.125 Cost Effectiveness Of Antidepressants And Anticonvulsants For Treatment Of Chronic Low Back Pain**

**DESCRIPTION:**

Abstract presents the results of clinical and cost effectiveness antidepressants and anticonvulsants for treatment of chronic low back pain in patients with associated with neuropathic pain component in India. Present study highlighted the usefulness of pregabalin followed by amitriptyline in treatment of chronic low back pain in patients with associated with neuropathic pain component.

**AUTHORS:**

Kapil Gudala, Dipika Bansal, Babita Ghai

## **BACKGROUND AND OBJECTIVES:**

Various antidepressants and anticonvulsants are proven to be effective in various neuropathic pain conditions. However, their clinical and cost effectiveness in mixed pain condition like chronic low back pain with accompanying neuropathic pain component (CLBP-NPC) is not yet established for patients in India. So, present study assessed the clinical and cost effectiveness of antidepressants and anticonvulsants in patients with CLBP-NPC by performing meta-analysis and cost effectiveness analysis from the health care payer perspective respectively.

## **METHODS:**

A meta-analysis of randomised controlled trials and prospective cohort studies evaluating use of pregabalin, amitriptyline, duloxetine, gabapentine and naproxen in patients with CLBP-NPC was conducted. The outcomes of interest include 50% pain reduction and relative risk (RR) was calculated using random effects model. Cost-effectiveness analysis was performed from health care providers perspective using decision tree model for 3 months of time period. Transitional probabilities were obtained from meta-analysis. Quality adjusted life year (QALY) was considered as effectiveness measure. Utilities for CEA was obtained from an unpublished cross-sectional study conducted in patients with CLBP-NPC from our research group. Cost-effectiveness was expressed as incremental cost to achieve one additional QALY.

## **RESULTS:**

We didn't find any study that assessed the efficacy of gabapentine in patients with CLBP-NPC. Pregabalin was found to be most effective followed by duloxetine, amitriptyline and naproxen. The model estimated an ICER of 5070 INR for pregabalin over naproxen. Pregabalin dominated among all followed by amitriptyline, duloxetine and gabapentine in comparison to naproxen.

## **CONCLUSIONS:**

Pregabalin followed by amitriptyline were found to

be both clinical and cost effective in treatment of CLBP-NPC in Indian settings.

---

## **OS.127 Medical Devices In The Brazilian Public Health System (SUS), Technology Evaluation And Incorporation**

### **DESCRIPTION:**

This paper presents the workflow for the incorporation of medical devices into the Brazilian Health System (SUS) with particular aspects such as, learning curve; combined procedures; infrastructure needs; onboard technology and total cost of ownership; to be observed in the elaboration of a report or rapid review to the National Committee for Health Technology Incorporation (CONITEC).

### **AUTHORS:**

Murilo Contó, Clarice Alegre Petramale, Carla de Agostino Biella

### **BACKGROUND AND OBJECTIVES:**

Regarding medical devices, the Health Technology Assessment (HTA) process should consider some specific particularities. This paper presents the workflow for the incorporation of medical devices into the Brazilian Health System (SUS) with some particular aspects such as, learning curve; combined procedures; infrastructure needs; onboard technology and total cost of ownership; to be observed in the elaboration of a report or rapid review to be sent for appraisal by the National Committee for Health Technology Incorporation (CONITEC). These aspects can have a direct influence on the costs related to technologies as well as on the effectiveness of the outcomes. Conducting an HTA process related to medical devices in compliance with these aspects, makes it possible to achieve an efficient incorporation with a more accurate resource allocation into SUS,

ensuring the effectiveness of expected outcomes and the possibility to safely maintain these technologies during their entire life cycle.

## **METHODS:**

A narrative description of the evaluation process and incorporation of medical devices that permeate the National Committee for Health Technology Incorporation (CONITEC) was held from the authors' experience, and a discussion of the characteristics of these technologies to be observed in preparing the documentation to the CONITEC. It was considered the Brazilian legal framework comprising the management process and incorporation of health technologies in the Brazilian Health System (SUS).

## **RESULTS:**

The incorporation demands had a better methodological rigor that is reflected also in the quality of the final recommendation report and consequently the technology adoption into SUS. The recommendation reports include mostly clear identification of the target population and the expected outcomes. About medical devices, that information came to have a key role to establish what the ideal technical specification of the material or equipment to be incorporated. The approach to issues such learning curve, infrastructure and total cost of ownership, contribute to guide managers to have better planning for the acquisition, maintenance and replacement of these technologies.

## **CONCLUSIONS:**

There is the need to be extended to carry out studies involving medical devices, for making decision on the incorporation of new technologies, often hampered by the lack of scientific evidence demonstrating consistent data about accuracy (sensitivity and specificity). For the incorporation of medical devices can proceed from the perspective of efficiency in resource allocation, it is essential that the evaluation of these technologies be performed covering all the particulars described

in this work. A systematic approach to the specific aspects in this article are of utmost importance to make decision with the minimum possible uncertainty as to their impact.

## **REFERENCES:**

- "Brasil. Lei nº 12.401, de 28 de abril de 2011. Altera a Lei nº 8.080, de 19 de setembro de 1990, para dispor sobre a assistência terapêutica e a incorporação de tecnologia em saúde no âmbito do Sistema Único de Saúde : SUS. Diário Oficial União nº 81 seção 1:1.
- Drummond M, Griffin A, Tarricone R. Economic Evaluation for Devices and Drugs: Same or Different? *Value in Health*. 2009, v. 12: 402-406.
- Velazquez-Berumen, A. Development of Medical Device Policies. WHO Medical Device Technical Series, WHO : Organização Mundial da Saúde; 2011.
- Organização Mundial da Saúde. Clinical Evidence for Medical Devices: Regulatory Processes Focusing on Europe and the United States of America; 2010.
- Brasil. Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Departamento de Ciência e Tecnologia. Diretrizes Metodológicas: elaboração de estudos para avaliação de equipamentos médico-assistenciais. Brasília: Ministério da Saúde; 2013.
- Brasil. Portaria GM 2.888 de 30 de dezembro de 2014. Define a lista de produtos estratégicos para o SUS. Brasília: Ministério da Saúde; 2014.
- Brasil. Balanço CONITEC: 2012-2014 / Ministério da Saúde, Comissão Nacional de Incorporação de Tecnologias no SUS. Brasília: Ministério da Saúde; 2014.
- Brasil. Resolução de Diretoria Colegiada da ANVISA nº 67 de 21 de dezembro de 2009. Dispõe sobre normas de tecnovigilância aplicáveis aos detentores de registro de produtos para saúde no Brasil. Brasília: ANVISA; 2009
- Brasil. Resolução de Diretoria Colegiada da ANVISA

nº 185 de 22 de outubro de 2001. Dispõe sobre a regulamentação de registro de produtos médicos. Brasília: ANVISA; 2001.

CONITEC - Comissão Nacional de Incorporação de Tecnologias no SUS [homepage na Internet]. [acesso em julho e setembro de 2015]. Disponível em: <http://conitec.gov.br/index.php>.

Brasil. Portaria GM nº 3.134 de 17 de dezembro de 2013. Cria a Relação Nacional de Equipamentos e Materiais Permanentes financiáveis para o SUS (RENEM) no âmbito do Ministério da Saúde. Brasília: Ministério da Saúde; 2013.

Hulley SB, Cummings SR. Designing Clinical Research. 2ª Edição. Philadelphia: Lippincott Williams and Wilkins; 2001.”

---

## OS.136 The Role Of Experiential Knowledge In Research Prioritisation, Regulation And Technology Appraisal

### DESCRIPTION:

We consider the role of patients experiential knowledge in three settings: research prioritisation, regulation, and technology appraisal in the UK. We found that the contribution of experiential knowledge brings different perspectives to those of other experts or stakeholders in decision making, and conclude that more explicit guidance is needed for organisations wishing to increase patient involvement in their work.

### AUTHORS:

Nicky Britten, Kristina Staley , Ken Stein

### BACKGROUND AND OBJECTIVES:

Chalmers and Glasziou (2009) have highlighted the problem of research waste, caused in part by the lack of engagement of end users. By involving patients and carers in judgements about evidence and recommendations that directly affect their lives, researchers and decision makers can help ensure subsequent adoption of new technologies. There is growing public and patient involvement in various settings within the UK health service and associated organisations, and this allows for comparisons between different ways of working. In this paper we review the role of patients' experiential knowledge in three different settings. By experiential knowledge we mean patients' own lived experiences of particular health conditions, treatments for these conditions, or caring for people with these conditions.

### METHODS:

We draw on our own work in research prioritisation within an academic-health care collaboration, a hypothetical patient drug licensing panel, and a national health technology organisation. In each setting we describe the ways in which the lived experience of patients and carers influences (or might influence) decision making. In the collaboration, patients sit on the stakeholder panels which prioritise research questions, and have equal voting rights as other stakeholders. In the hypothetical drug licensing panel, patients provided their own interpretations of evidence from trials which underpinned the licensing of a drug. In the health technology organisation, patients' experiential knowledge was provided in the form of documents and via attendance at advisory group meetings. We compare and contrast the contribution of experiential knowledge in these three settings.

### RESULTS:

We found that the contribution of experiential knowledge brings different perspectives to those of other experts or stakeholders in decision making. These may be about the impact of the condition

or its treatment, the relevance of research carried out to test potential treatments or interventions, and wider implications relevant to the adoption of new treatments or technologies. The experiential knowledge of patients is not the same as qualitative or quantitative research evidence about health conditions and their treatments, but rather an interpretive tool. In all three settings we found that experiential knowledge influenced the interpretation of evidence presented to decision making bodies, and served to correct assumptions made by other experts and stakeholders.

### CONCLUSIONS:

Our findings suggest that decision making bodies should provide more explicit guidance about how experiential knowledge will be used in their own organisations. In particular, questions about the selection of patients, and whether or not patients participate in decision making or instead present their experiences, require further consideration. We aim to develop and pilot practical guidance for health technology and other organisations, that facilitates the use of experiential knowledge.

### REFERENCES:

I Chalmers, P Glasziou. Avoidable waste in the production and reporting of research evidence. Lancet 2009; 374: 86-89.

---

## OS.137 Budget Impact Analysis Of Using Dihydroartemisinin Piperavaquine To Treat Uncomplicated Malaria

### DESCRIPTION:

Dihydroartemisinin-piperavaquine when used as the first-line drug to treat uncomplicated Plasmodium falciparum malaria in children produces more health benefits with less costs, compared with artemether-lumefantrine, from the Tanzanian health system perspective.

### AUTHORS:

Amani Thomas Mori, Ole Frithjof Norheim, Bjarne Robberstad

### BACKGROUND AND OBJECTIVES:

Several studies have shown that dihydroartemisinin-piperavaquine (DhP) is more cost-effective than artemether-lumefantrine (AL) for the treatment of uncomplicated Plasmodium falciparum malaria in Africa. However, DhP is more expensive than AL; hence, a budget impact analysis is warranted to establish its affordability. Therefore, this study aims to predict the budget impact of using DhP as a first- or second-line drug to treat uncomplicated malaria in children in Tanzania.

### METHODS:

A dynamic Markov decision model was developed based on clinical and epidemiological data to estimate annual cases of malaria in children aged under 5 years. The model was used to predict the budget impact of introducing DhP as the first- or second-line anti-malarial drug, from the health system perspective. Cost data was collected at a district hospital and the prices of drugs and diagnostics came from the Medical Stores Department, the International Drug Price Indicator Guide and the Global Funds. Probabilistic sensitivity analysis was performed to explore overall uncertainties in input parameters.

### RESULTS:

The model predicts that the treatment policy that uses AL and DhP as the first- and second-line drugs (AL + DhP), respectively, will save about 934,200 US\$ per year, while achieving a 3% reduction in the number of malaria cases, compared with that of AL + quinine. However, the policy that uses DhP as the first-line drug (DhP + AL) will save an extra 500,342 US\$ per year, while achieving a further 5% reduction in the number of malaria cases, compared with the policy of AL + DhP.

**CONCLUSIONS:**

The policy that uses DhP as the first-line drug to treat uncomplicated malaria in children in Tanzania is the most cost saving, and it produces more health benefits as well, than when it is used as the second-line drug. Therefore, Tanzania and other African countries with similar healthcare system and malaria epidemiology should consider using DhP as the first-line drug to treat uncomplicated malaria.

.....

## OS.140 Reproductive Information Quality And The Probability Of Unplanned Pregnancies

**DESCRIPTION:**

The paper develops a framework that connects information quality to the probability of unplanned pregnancies. A data set of 15,000 Brazilian women allows for a reduced-form test of the framework. Estimates indicate that correct information about fertility is negatively associated with the probability of unplanned pregnancy. The results also suggest that having incorrect information leads to lower welfare than having no information.

**AUTHORS:**

Bruno Wichmann, Roberta Wichmann

**BACKGROUND AND OBJECTIVES:**

The paper develops a framework that connects information quality to the probability of unplanned pregnancies. Women have incentives to take actions to influence the probability of pregnancy according to their pregnancy intentions. A woman with incorrect information may choose an action that can increase the chances of a mismatch between intentions and the pregnancy outcome, leading to lower welfare.

**METHODS:**

We take advantage of a large data set of Brazilian women to estimate models of unplanned pregnancies. Our regressions include several control variables, census regions fixed effects, and account for sample selection issues. The paper investigates the relationship between information quality and unplanned pregnancies, disentangling the effects of different types of information sets (correct, incorrect, and empty) on the unplanned pregnancy probability. A data set of fifteen thousand Brazilian women between the ages of 15 and 49 allows for a reduced-form test of the framework.

**RESULTS:**

Empirical results corroborate theoretical predictions. Estimates indicate that correct information about fertility is negatively associated with the probability of unplanned pregnancy. The results also suggest that having incorrect information leads to lower welfare than having no information. We report three interesting results: i) a negative effect of correct information; ii) a positive effect of incorrect information; and iii) no effect between empty information and the probability of unplanned pregnancies.

**CONCLUSIONS:**

When interpreting these results through the lenses of our conceptual framework, we find that a woman with incorrect information about fertility will likely be worse off than a woman with no information. Our paper provides evidence of the existence of a gradient of effects streaming from information quality to unplanned pregnancies, with the detrimental effect of low quality information being greater than the beneficial effect of high quality information. This finding can help policymakers to improve the design of information programs with focus on unplanned pregnancies.

.....

## OS.141 NICE Medtech Innovation Briefings: Informing Decisions About Innovative Technologies

### DESCRIPTION:

NICE Medtech Innovation Briefings (MIBs) are designed to support NHS and social care commissioners and staff who are considering using innovative medical technologies. This presentation describes this new NICE information resource and the evidence review process, giving an overview of the programme to date. It explains how MIBs can add value for decision-makers in the UK NHS and beyond.

### AUTHORS:

Ruth Louise Poole, James Evans , Grace Carolan-Rees

### BACKGROUND AND OBJECTIVES:

The National Institute for Health and Care Excellence (NICE) provides guidance and advice to improve health and social care in the UK. NICE Medtech Innovation Briefings (MIBs) were commissioned by NHS England and introduced in 2014 in response to a need for a rapid, objective review of information about novel technologies. They are designed to support decision-making by clinicians, managers, policy developers, commissioners and procurement professionals, and may be of interest to patients and the public. MIBs are not formal NICE guidance.

A medical device or diagnostic test is eligible if CE-marked and available to the NHS, or if appropriate regulatory approval and NHS launch is expected soon. It must be new or an innovative modification of an existing technology, with potential patient or system benefits, and not covered by another guidance-producing body. Topics arise from a variety of sources, and are prioritised and chosen according to a published selection framework.

This presentation will describe the contents of a MIB and how it can be used to make informed decisions, as well as conserve resources for local organisations. The production process and the progress of the programme will also be discussed.

### METHODS:

Each briefing describes a medical technology and its place in the treatment pathway. Key points from published evidence are summarised, with a particular focus on clinical benefits and cost implications. MIBs also present a critical review of this evidence. Consideration is given to the context of the evidence base for the management of the condition, equality issues, and implications for local decision-making or changes to clinical practice.

Comments are invited from the manufacturer, specialist practitioners (with relevant experience of the technology or care pathway), and representatives of patients or carers where appropriate. The production timeline is approximately 12 weeks.

### RESULTS:

Between February 2014 and November 2015, 45 MIBs were published, and another 17 were in development. As a novel, rapid evidence summary, technical challenges have been faced by those involved in the production of MIBs, and continuous learning has informed the refinement of the development process. Feedback from companies and users of the briefings suggest that they are of value and that they are being used beyond their target audience of the NHS in England.

### CONCLUSIONS:

Early indications are that the MIBs are successfully providing useful summaries to inform decision-making about new technologies, from a fast, flexible and responsive programme. Raising awareness of this valuable resource will reduce the need for local organisations to produce their own, similar reports. Ultimately this will save staff time, effort and resources, whilst encouraging the

adoption of innovative technologies that benefit both health and social care systems and patients.

## REFERENCES:

National Institute for Health and Care Excellence (2014). Interim process and methods statement for the production of Medtech Innovation Briefings (MIBs). Version 1.1. Available from: <https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-advice/Medtech-innovation-briefings/MIB-interim-process-methods-statement.pdf> [Accessed 23/11/15]

National Institute for Health and Care Excellence (2015). Medtech innovation briefings. Available from: <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-advice/medtech-innovation-briefings> [Accessed 23/11/15]

National Institute for Health and Care Excellence (2015). Medtech innovation briefings: Frequently asked questions. Available from: <https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-advice/Medtech-innovation-briefings/MIB-faq-document.pdf> [Accessed 23/11/15]

---

## OS.142 What Impact Have Drug Replacement On Hospital Treatment? A Health Technology Assessment Discussion

### DESCRIPTION:

Drug product changes occur in hospitals for different reasons: improved efficacy or tolerance of a drug, reduced costs, new pharmaceutical innovations or drug shortage. The development of a process model for drug product changes is shown by the example of the Klinikum rechts der Isar in Munich (MRI).

### AUTHORS:

Rainer Riedel

### BACKGROUND AND OBJECTIVES:

Drug product changes occur in hospitals for different reasons: improved efficacy or tolerance of a drug, reduced costs, new pharmaceutical innovations or drug shortage. The aim of this analysis is to develop a process model for drug product changes and to determine a hospital specific threshold when product change is reasonable, provided that the efficacy and safety of the new product is economically reasonable

### METHODS:

The individual process steps at the Klinikum rechts der Isar in Munich (MRI) were recorded to develop a process model. The required expenditure of time for the different process modules was documented and a process cost calculation undertaken.

### RESULTS:

Product changes can be divided into three groups: generic changes, identical active ingredient but different brand name, and complex drug changes with different active ingredients or changed drug formulation. The latter change is associated with a higher demand for information, which is reflected in higher process costs. Relevant costs arise during the process of product purchase and on the ward. The cost per product change inclusive operating expenses at the MRI range from 2.300 to 6.420 and depend on the frequency of prescription and the complexity of the product

### CONCLUSIONS:

This Health Technology Assessment shows that main costs for a drug product change arise due to additional staff costs on the ward. Reasonable thresholds can aid in decision making when considering cost effectiveness and potential risks of the medication or patient safety.

## REFERENCES:

Drug product changes, process model, process costs, HTA,, drug shortage

---

## OS.144 Benchmark In Clinical Pathway Of Stroke Therapy On The Basis Of 534 Acute Hospitalized Patients

### DESCRIPTION:

Actually one observes increasing work loads for the hospital staff (nurses, doctors) during the last 10 years by an average increase of 30% more hospitalized stroke patients. As a part of a project a comparative process study including a process cost analysis were performed for acute hospitalized stroke patients.

### AUTHORS:

Rainer Riedel

### BACKGROUND AND OBJECTIVES:

Actually one observes increasing work loads for the hospital staff (nurses, doctors) during the last 10 years by an average increase of 30% more hospitalized stroke patients. Owing to the larger number of patients and the coincidental reduced length of stay of the stroke patients cause an increasing work load. Normally one would expect at this point an adopted risen staff but in Germany one simultaneously registered none additional staff. According to this situation one has to look for tools to assure the high level of patient safety, the patient outcome standards and the cost effectivity.

### METHODS:

During this project a comparative process study including a process cost analysis were performed for acute hospitalized stroke patients. For this analysis 534 patients (96 patients with a hemorrhagic apoplexia, 200 patients with an

ischemic apoplexy without a lysis therapy and 238 patients with an ischemic apoplexy with a lysis therapy) were enrolled into this program. The medical outcome were measured according the classic neurological tools

### RESULTS:

On the basis of the following neurological clinical tools the medical outcome was mapped: NIHSS(National Institut of Health Stroke Scale), mRS (modified Rankin Scale), FIM (Functional Independence Measure), FAM (Functional Assesment Measure),,, FRB Early Rehabilitation- Barthel Index. . On the basis of the evaluated nursing, diagnostic and therapeutic measures clinical pathways for the above mentioned three patient groups were developed in combination with a cost benefit analysis. These study results will be presented during the presentatio

### CONCLUSIONS:

During this pilot study one gains critical evidence that clinical pathway orientated 'stroke therapy' can improve the medical outcome in these samples. Additionally one gets first positive hints that clinical pathway treated stroke-patients have positive benefits during the HTA-analysis.

---

## OS.149 Real-World Evidence (RWE) And The Value For Health Care Decision-Making In Rare Diseases

### DESCRIPTION:

Research and decision-making in rare diseases is associated with a myriad of challenges. Conducting RCTs is not always possible in this context, and much valuable knowledge can be obtained from real-world evidence (RWE). We are presenting a real-world study, the methods and outcomes, demonstrating the value of RWE in rare diseases, and sharing recommendations for research and

application in future.

**AUTHORS:**

Ruzan Avetisyan, Hongwei Wang, Wei Zhang

**BACKGROUND AND OBJECTIVES:**

Rare diseases research poses many unique challenges, including but not limited to the small size of the patient population, heterogeneity of manifestations, geographic spread, and others. Conducting well designed RCTs is not easy in this context, and much valuable evidence can be obtained from observational studies and more broadly from real-world evidence (RWE). However, while there is a growing recognition of the value of RWE in the health care, there is limited use of RWE to address questions in rare diseases research, practice and policy. This can be due to various factors, including questions around the quality of data, methodological challenges of generating the evidence, generalizability and applicability of results, and others.

We are here presenting some of the findings of a recent retrospective real-world study conducted in a rare disease area, to demonstrate the value of RWE in addressing knowledge gaps and supporting health care decision-making. In addition, we aim to discuss our perspective on the key challenges, opportunities, and recommendations for successful use of RWE.

**METHODS:**

A real-world study was performed investigating a population of patients diagnosed with pulmonary alveolar proteinosis (PAP). Unique individuals with PAP were identified retrospectively within a US health care claims database. Data sources of this type represent a comprehensive, de-identified database that includes data on clinical diagnoses, comorbidities, medical procedures, prescription medication, utilization of other health care resources and corresponding expenditures, and other variables. The results on these data elements were compared between the patients

with PAP and an age and gender matched control population. Analyses were conducted to evaluate epidemiologic parameters, disease burden, early manifestations, treatment patterns and subpopulation characteristics.

**RESULTS:**

Applying study criteria, 164 patients with PAP (mean age 47 years) were included in the analyses. The study demonstrated the first ever PAP prevalence estimates in the US - 6.87/million. In comparison to the control population, predominant diagnoses included: dyspnea and respiratory abnormalities (47%), unspecified essential hypertension (34%), chest pain (32%), cough (26%), post-inflammatory pulmonary fibrosis (26%), abdominal pain (24%) among others (P<0.01). The most frequently used medications included analgesics/narcotics (44%), glucocorticoids (36%) and antibiotics (quinolones [29%], macrolides [28%]). Health care costs were significantly higher in patients with PAP than controls for inpatient (P=0.044), outpatient (P<0.001) and prescription drugs (P<0.001).

**CONCLUSIONS:**

The study provided new and important evidence about this rare condition. The original database was large (about 30 million individuals), allowing the inclusion of patient numbers that are extremely hard, and time and resource consuming to recruit via other study designs. This study has shown the feasibility and the value of generating RWE in rare diseases using health care databases, which have the potential to address many research, practice and policy questions. Investment of resources for doing the study was minimal, whereas the evidence generated was impactful, fast and efficient. Recommendations for future real-world research and applications will be discussed.

## OS.151 Assessment Of Health Technology Usage In Family Group Practices Of Ulaanbaatar City

### DESCRIPTION:

Family group practices are the primary resources of health care services for citizens of Ulaanbaatar city, Mongolia. The Minister for Health and Sports has approved a standard for services to be provided by FGP. The rapid assessment took place in 2015 to review the implementation of this standard which includes the list of health technologies to be used by the FGP.

### AUTHORS:

Amarjargal Tserendorj, Oyunaa Lkhagvasuren, Dulamsuren Samdan

### BACKGROUND AND OBJECTIVES:

Family group practices are the primary resources of health care services for citizens of Ulaanbaatar city, Mongolia. The Minister for Health and Sports has approved a standard for services to be provided by FGP. The rapid assessment took place in 2015 to review the implementation of this standard which includes the list of health technologies to be used by the FGP.

Main objective of the assessment is to identify gaps in between approved standard and practical implementation of the standard. The findings from the assessment will contribute in revision of the Family Group Practices' services provision standard and assist in evidence-based decision making regarding supply and financing of health technologies.

### METHODS:

Pre-developed questionnaire which includes questions related with the standard of health care services provided by FGP. Individual interview and actual on-site observation of existing health technologies at the FGPs and its utilization were the

main methods used in the assessment

### RESULTS:

The rapid assessment of health technologies utilization at the Family group practices has identified several key challenges in provision of health care services by these groups.

Majority of FGP do not provide all services that are highlighted in the standard. Despite the fact that the standard has the list of suggested health technologies to be used for services delivery, not all FGP are equipped with these technologies.

### CONCLUSIONS:

The rapid assessment of FGP standards of operations have identified some key challenges that are faced by health care providers in provision of services. These challenges can be addressed by revision of the standard or by an increase of financing of health technologies that need to be provided to FGP.

---

## OS.155 Evaluation Of Guidelines With Automated Educational Messages For Improving Use Of Laboratory Tests

### DESCRIPTION:

This research is part of a wider health services project aimed at changing primary care physicians laboratory testing behaviour. Laboratory testing is an integral part of healthcare delivery, however, research suggests that is currently being used ineffectively at a significant cost to healthcare budgets worldwide. This IT intervention aims to use the laboratory system as a medium to deliver a strategy for improving the effective use of tests in General Practice.

**AUTHORS:**

Sharon L Cadogan, John P Browne, Colin P Bradley, Mary R Cahill

**BACKGROUND AND OBJECTIVES:**

Laboratory testing is a major component of healthcare budgets worldwide, and demand for laboratory testing is increasing faster than medical activity. However, research suggests that up to 70% of these tests made not benefit patient care. Meanwhile, technology in laboratory medicine is advancing and could provide the ideal platform for effectively delivering an intervention to improve testing behaviours of physicians. Hence, the objectives of the current study are to a) implement a multifaceted education-based strategy among General Practitioners (GPs) in the South of Ireland and, b) to evaluate the effectiveness of this strategy.

**METHODS:**

This IT based intervention consists of two components aimed at targeting two key test requesting behaviour issues raised by GPs in our previous qualitative interviews: issues with a) interpreting the results and b) a lack of knowledge about when to request the test. The combined guidelines and educational messages intervention will be evaluated using a quasi-experimental Interrupted Time Series design. Segmented poisson regression analysis will be used to determine the impact of the intervention, both immediately (change in level) as well as over time (change in trend). Phase 1 (implementation stage) of the study involved creating and adding educational messages to the hospitals laboratory system and sending guidelines to all GPs (Oct 2015). Phase 2 will evaluate the effect on GP requesting patterns using ITS analysis (Jan 2016).

**RESULTS:**

Results for the three month follow up will be available 31st January 2016.

**CONCLUSIONS:**

This intervention study could lead to more effective use of laboratory services in the South of Ireland, and in turn could save a substantial amount of healthcare funds. The effects of this intervention could also be transferable across the health services.

.....  
**OS.165 Value In The Making In Medical Technology Introduction: An Interactive HTA**

**DESCRIPTION:**

How can we account for a value-conscious adoption and implementation of complex (in-hospital) medical innovations when value is prone to sometimes considerable uncertainty during introduction? We examine the fruitfulness of multi-stakeholder dialogue to both justify and realise value. An actionable guidance is provided to stimulate stakeholders engagement in structured deliberation on innovations value, noticeably as part of business modelling and implementation planning.

**AUTHORS:**

Payam Abrishami, Klasien Horstman

**BACKGROUND AND OBJECTIVES:**

The adoption and implementation of complex in-hospital innovations typically present highly consequential clinical, social, financial, and managerial challenges within and beyond the adopting organisation. Many contemporary health care systems have been calling for a more value-conscious introduction of (complex) emerging medical technologies to ensure that the limited resources spent will result in socially desirable outcomes and improve the health of the population. The value-conscious introduction of an innovation provokes a public justification for

choices and plans made during its introduction; why one should adopt the innovation; how one will realise the promised benefits of the innovation in the real world and at what monetary and societal costs. These questions render a participatory examination of the innovation's wider impacts in the context of use in the real world. Existing research and practice both fall short in addressing participatory approaches in the decision-making setting involving the adoption and implementation of complex (in-hospital) medical innovations. The objective of this conceptual analysis is to address how we can account for a value-conscious introduction of these innovations when value is prone to 'sometimes considerable' uncertainty during introduction.

#### **METHODS:**

Drawing on insights from Health Technology Assessment (HTA), Science, Technology, and Society (STS) studies, public policy, and Health Services Research (HSR), a conceptual synthesis of different strands of literature is presented. We also reflect on the introduction of the da Vinci® surgical robot in the Netherlands as an example of a complex emerging medical technology.

#### **RESULTS:**

We first outline a range of socio-technical processes contributing to value uncertainty of emerging medical technologies and explain how the formal evidence basis of the innovation is, by itself, inadequate to justify actual value. We, then, examine the fruitfulness of multi-disciplinary, multi-stakeholder deliberation (MSD) on medical technology introduction as a platform for 'value in the making': a participatory endeavour to appraise an innovation's impact and mitigate value uncertainties during the course of implementation. Finally, a concrete actionable guidance is provided to stimulate the uncommon practice of MSD on complex in-hospital technology, notably, as part of business modelling and implementation planning.

#### **CONCLUSIONS:**

Deliberation between technology developers, care providers (including potential adopters and rejecters), researchers (evidence producers), patients, technology assessors, payers, policy makers, and representatives of the public on the value of complex medical innovations helps support their responsible introduction and appropriate use. Our analysis sets forth two priorities for research and practice on the introduction of complex emerging medical technologies: (1) building capacity, commitment, and competence for engaging in deliberation with the aim of cumulative learning; and (2) regarding the entry of medical innovation as prudent societal experimentation, in need of ongoing value evaluation and optimisation.

---

## **OS.167 The Patient Reported Outcomes, Burdens And Experiences (PROBE) Phase 1**

#### **DESCRIPTION:**

The Patient Reported Outcomes, Burdens, and Experiences (PROBE) Study aims to develop and validate the reliability, reproducibility and responsiveness of a low cost, easily administrable inventory for collecting and interpreting patient relevant self-reported outcomes, burdens and experiences. The study addresses the growing desire within Health Technology Assessment and payer communities to enhance the direct patient voice in health care decision-making.

#### **AUTHORS:**

Mark Skinner, Randall Curtis, Neil Frick, Alfonso Iorio, Michael Nichol, Declan Noone, Brian O'Mahony, David Page, Jeffrey Stonebraker

#### **BACKGROUND AND OBJECTIVES:**

The Patient Reported Outcomes, Burdens, and Experiences (PROBE) Study aims to develop a new

global tool to respond to a growing desire within Health Technology Assessment (HTA) and payer communities to enhance the direct patient voice in health care decision-making. This emerging dimension of the healthcare environment presents a significant opportunity but also raises an urgent need to improve patient organizations' ability to move advocacy beyond emotion and anecdote to arguments grounded in systemically generated evidence directly collected from real-world patient experiences. Traditional HTA methodology may not fully capture the value patients place on health care interventions, particularly for rare diseases such as hemophilia. Patients have knowledge, perspectives and experiences that are unique and contribute to essential evidence for HTA. The PROBE study aims to develop and validate an inventory able to recode experiential data contributed directly by patients through their patient organizations to a valid foundation for evidence-based decision making suitable for submission within an HTA.

#### **METHODS:**

Phase 1 includes developing and testing a questionnaire for content, relevance, clarity and completeness, as well as assessing methodology and feasibility. The PROBE questionnaire was generated by the investigator team after a review of hemophilia-specific and generic assessment tools and survey instruments. It incorporates EQ-5D-5L and augments it with additional questions from domains identified as important by patients (e.g., pain, independence, educational attainment, employment, relationships, activities of daily living). The questionnaire was refined in cycles of small focus groups of patients and the general population, until no more comments about the meaning and scope of the questions were raised and face validity assessed. Local language versions were produced. Eighteen countries worldwide were invited to participate. Primary outcomes include: response rate, percent complete responses, time to completion, cost per completed survey.

#### **RESULTS:**

Phase 1 field work is on-going. During the first

6 months, 15 of 17 countries that agreed to participate have completed field work with 618 responses recorded (103% of study objective). Preliminary experience indicates the study methodology is feasible and time to completion has met study objectives of 0-15 minutes (70% report a completion time of 0-15 minutes, 17% 16-20 minutes, 6.6% 21-25 minutes, 3.6% 26-30 minutes and 2.8% more than 30 minutes). A full review to understand age, language, educational attainment or country variations is planned. A Phase 2 reproducibility (test:retest) study is being implemented including a web-based version with adaptive testing and item response theory to determine the next question based on previous answers.

#### **CONCLUSIONS:**

PROBE aims to provide a valid foundation for evidence-based decision making suitable for submission within an HTA. More robust and relevant patient reported data could improve advocacy efforts to introduce and sustain care as well as be useful in raising awareness within the community and the public of the impact of treatment for persons living with hemophilia and the value of effective prevention.

---

## **OS.173 IMI GetReal: Stakeholder Views On The Early Use Of Pragmatic Trials During Medicine Development**

#### **DESCRIPTION:**

We present the results from a stakeholder workshop undertaken by the pan-European IMI GetReal consortium which had the aim of eliciting comprehensive stakeholder views on the acceptability and usefulness of pragmatic clinical trials for establishing relative effectiveness of new medicines.

**AUTHORS:**

Pall Jonsson, Maciej Czachorowski, Michael Chambers, Ryan Tomlinson, Helen Birch, Sarah Garner

**BACKGROUND:**

Pragmatic clinical trials (PCTs) are randomized clinical trials that allow comparison of health interventions in diverse patient populations in routine clinical practice. To date, few PCTs trials have been implemented before marketing authorization with the explicit purpose of supporting regulatory and HTA assessments.

**OBJECTIVES:**

To elicit a comprehensive stakeholder view on the acceptability of early use (before marketing authorization) of pragmatic clinical trials for informing relative effectiveness of new medicines in regulatory and HTA assessments.

**METHODS:**

The Innovative Medicine Initiative's GetReal project ([www.imi-getreal.eu](http://www.imi-getreal.eu)) is a pan-European consortium which aims to show how robust new methods of evidence collection and synthesis could be adopted earlier in pharmaceutical R&D and the healthcare decision making process. Work package 1 of GetReal conducted a workshop attended by key European and US stakeholders to elicit views on the acceptability and usefulness of pragmatic clinical trials, conducted prior to market authorization, for establishing relative effectiveness of new drugs. The workshop combined presentations, structured breakout sessions and plenary discussions.

**RESULTS:**

Three key questions were posed: 1) which effectiveness questions would pragmatic designs best address? 2) How strongly would results from pragmatic designs be accepted as evidence? 3) How can the value of and acceptability of PCTs be maximized? The majority of views indicated

that PCTs had a strong role in situations when randomized controlled trials (RCTs) cannot answer the question of effectiveness; in particular when efficacy is not predicted to match effectiveness, for reasons such as patient characteristics, comorbidities, or real-world patient behavior. Strengths of evidence arising from PCTs generally relate to external validity of the results. Weaknesses reflect lack of internal validity, such as difficulties with analyses, for example in subgroup analyses, dealing with treatment changes and multiple comparators.

**CONCLUSIONS:**

PCTs are still very much in their infancy. Questions remain regarding the situations in which pragmatic elements could add the most value, and the timing of pragmatic trials in the clinical development. Best practice guidelines on the use of early pragmatic designs will help guide the design of future PCTs. Further collaborative efforts such as case studies and evidence synthesis will provide valuable insight in this respect.

---

## OS.180 Publically Available Patient-Oriented Research Methods Guidance Materials: A Horizon Scan

**DESCRIPTION:**

Growing evidence suggests committed engagement of patients, their caregivers and families in health research improves the applicability of research produced and increases the relevance and implementation of clinical research leading to improved patient care. While making research questions, outcomes, and mechanisms for dissemination of health research more patient focused is nothing new, there has been a recent surge in the prominence in the literature around the conduct of 'Patient-Oriented Research'.

## **AUTHORS:**

Lucy Turner, Chantelle Garritty, Joshua Montroy, Bev Shea, and Dean Fergusson for the Ontario SPOR SUPPORT Unit

## **BACKGROUND AND OBJECTIVES:**

Growing evidence suggests committed engagement of patients, their caregivers and families in health research improves the applicability of research produced and increases the relevance and implementation of clinical research leading to improved patient care. While making research questions, outcomes, and mechanisms for dissemination of health research more patient focused is nothing new, there has been a recent surge in the prominence in the literature around the conduct of 'Patient-Oriented Research'. Strategies which aim to support such a 'change in research culture' exist, however little is collectively known about where they are located, their funding, structure and scope. Moreover, optimal methods for conducting Patient-Oriented Research are relatively unexplored. To our knowledge there is currently no agreed upon definition of what Patient-Oriented Research comprises and how this impacts research teams. While organizations and scientific literature was searched and identified in 2011 (Nass, 2012, PCORI White Paper), additional methods and approaches to conducting Patient-Oriented Research have since been published.

## **METHODS:**

The objective of this horizon scan was to identify global organizations which support or conduct Patient-Oriented Research (or otherwise named) and have publically accessible methods materials on their organization website. Two researchers independently conducted a grey literature search in google.ca and google.com to identify Patient-Oriented Research organizations. A list of search terms was identified using previously published PCORI literature search terms and local and provincial content expertise. We aimed to keep inclusion criteria broad and to capture methods materials pertaining to the whole

research continuum, from priority setting to dissemination. Screening and data extraction was conducted independently and in duplicate with third party consensus when necessary. Materials were defined as, but not limited to: frameworks, toolkits, methodological standards, rubrics, guidelines, podcasts, webinars, within researcher or researcher-patient (or otherwise) networks. Resources were not restricted to a particular target audience and included materials focused towards a range of stakeholders.

## **RESULTS:**

We identified 57 organizations with available patient-engagement materials. A total of 113 identified guidance documents covering a range of high level organization or national structure plans, a series of guidance manuals for translational researchers, methods for optimal engagement in comparative effectiveness research, methods for optimal engagement in systematic reviews, details on ethics considerations for Public and Patient Engagement, guidance on the use of social media, ensuring diversity of patients, cost calculators for grant budgets, tools for evaluating success and quick grab engagement templates. The scale of organizations varied from local to national research organization levels. Organizations were predominately UK (n = 14) and US (n = 16). Over a third (20/57) of organizations received government or government agency funding. Materials were primarily focused on effective methods for patient-engagement at the project level, yet guidance does exist for organizations.

## **CONCLUSIONS:**

Materials exist providing experiential and detailed guidance on methods for priority setting, patient-engagement and conducting patient-oriented research, we identified no comparative research of identified methods. It is timely to give consideration of the development and uptake of patient-oriented research methods in HTAs and published materials and guidance produced by leading global research organizations can assist.

---

## OS.189 Optimization Of The General Surgery Service Of The University Hospital Pedro Ernesto

### DESCRIPTION:

A great cause of suffering in a population is the waiting time for treatment when elective surgical procedures are needed. The model described was used in the identification, evaluation and optimization of the surgical queuing system, proposing solutions to assist the management in order to reduce waiting time for patients in surgery queues.

### AUTHORS:

Gerson, Nunes da Cunha, Cid, Manso de Mello Vianna, Fabiano, Saldanha Gomes de Oliveira, Gabriela, Bittencourt Gonzalez Mosegui, Lia, Roque Assumpção, Marcus Paulo, da Silva Rodrigues

### BACKGROUND AND OBJECTIVES:

"The General Surgery Department in the Faculty of Medicine of the State University of Rio de Janeiro (UERJ) has about 800 patients waiting for an elective surgical procedure nowadays. Usually 12 surgeries are performed in a week where the adopted queue discipline is FIFO (First In First Out) including case mix of benign and cancer cases of a tertiary center. If there are worsening cases along the line not configuring an emergency situation, the elective queue discipline is broken. Due to the relationship between surgeries demand and services capacity, the queue grows indefinitely. This work intends to propose a computational model to simulate a queue discipline that reduces the patient waiting time.

The computational model considers local capacity in the supply of services and the demand for surgical procedures. The objectives of this study are to identify and to model the available service

queues; identify their organization methods; identify areas susceptible to changes in the service chain capable of impacting with the progress of the queue; propose scenarios and workarounds front rows optimization to contingencies and other factors that may change the pattern of demand; and develop a solution that will optimize the use of materials, budget and human resources."

### METHODS:

The queuing theory is a statistical technique to understand the dynamics of the queuing system flow. First, a survey of hospital procedures and protocols used in the intake sector was compiled. Then they have created and validated the logical model of queues and optimization algorithms. Finally a support decision system was developed with facilities like configuration interface and visualization of results. Through statistical analysis, the control parameters of the flow of patients could be adjusted by customizing solutions to the reality of the Surgery Service.

### RESULTS:

Various service bottlenecks were identified and some procedures have been changed based on the preliminary simulations. Among them, the possibility of inpatient can be operated by any medical staff and not just who made the first assignment. Another important aspect was to demonstrate that the adoption of single line respecting patient's disease and comorbidities, with the possibility of easing FIFO policy in some cases, reduces the average waiting time in the queue. Other treatment protocols are being studied and is being analyzed the adaptability of optimization algorithms.

### CONCLUSIONS:

The large number of patients waiting for medical care is one of the major ills of the Unified Health System. Waiting for a surgery one, two or more years brings an intangible suffering from the standpoint of the health system manager. With the proposed model it was possible to provide the

HUPE a management tool in the elective general surgery system. This instrument aimed to increase the efficiency of elective surgery system and decrease the waiting time for patients. In addition, this instrument should enable the HUPE a planning specific actions that can positively impact the queue of patients.

## REFERENCES:

Harper, P.R., and Shahani A.K.. 2002b. 'Modelling for the Planning and Management of Bed Capacities in Hospitals.' *Journal of the Operational Research Society*53: 11-18

Lowery, J.C. 1992. 'Simulation of a Hospital Surgical Suite and Critical Care Area.' In *Proceedings of the 1992 Winter Simulation Conference*, 1071-78. WSC -92.

Santibáñez, P., V. Chow, J. French, M. Puterman and S. Tyldesley. 2009. "Reducing patient wait times and improving resource utilization at British Columbia Cancer Agency's ambulatory care unit through simulation." *Health Care Manag Sci* 12:392-407.

Schmeiser, B. 2004. 'Simulation output analysis: a tutorial based on one research thread.' In *Proceedings of the 2004 Winter Simulation Conference*, Edited by R. G. Ingalls, M. D. Rossetti, J. S. Smith, and B. A. Peters, 162-170. Piscataway, New Jersey: Institute of Electrical and Electronics Engineers, In

Tan, K. W., C. Wang, and H. C. Lau. 2012. 'Improving Patient Flow in Emergency Department Through Dynamic Priority Queue'. In *Proceedings of the IEEE International Conference on Automation Science and Engineering (CASE)*, 125-130.

Tan, K. W., W. H. Tan, and H. C. Lau. 2013. 'Improving Patient Length-of-Stay in Emergency Department Through Dynamic Resource Allocation Policies'. In *Proceedings of the IEEE International Conference on Automation Science and Engineering (CASE)*.

Vanden-Bosch, P. M. and D. C. Dietz. 2000.

"Minimizing expected waiting in a medical appointment system" *IIE Transactions* 32: 841-848.

Walter, S. 1973. "A comparison of appointment schedules in a hospital radiology department." *British journal of preventive & social medicine* 27(3): 160-167.

---

## OS.194 Social Preferences For Rare Diseases In Spain

### DESCRIPTION:

A survey is presented analysing the social preferences and willingness to pay of citizens for rare conditions, how that WTP changes with increasing opportunity cost and the allocation principles proposed by governments.

### AUTHORS:

Oriol Solà-Morales, Noemie Knebelman

### BACKGROUND AND OBJECTIVES:

Rare Diseases are seen by policymakers as a source of controversy, given the small numbers but perceived individual cost. However very little is known about the perception of the general public about these preferences. Our study sets out to investigate whether there exists a preference for rarity among the Spanish population, and to compare Spanish societal preferences for rarity with Norwegian and Canadian ones.

### METHODS:

An online survey comprising 12 questions was completed by 224 respondents in July 2015. They were asked to give treatment priority to one of two patient groups, a rare and a common disease group. Variations of this task were reiterated with different resource allocation options and, most importantly, with increasing opportunity costs for treating a rare disease patient relative to a common disease one. Respondents were then questioned

about their favored principle and criteria for health resource allocation, and about government's responsibility regarding the financing of rare disease treatments.

### **RESULTS:**

The descriptive analysis of the results reveal a strong preference for rarity, notably contrasting with the results of the Norwegian and, to a lesser extent, the Canadian surveys. Respondents show elasticity to increases in opportunity cost of treating rare diseases, which is accompanied by decreasing preference for rarity. Yet, rare disease patients are consistently prioritized by about 25% of Spanish respondents regardless of opportunity cost. The valuation of rarity is again reflected in the vast majority of respondents believing the government should systematically reimburse rare disease treatments, regardless of their prices and, to some extent, of their effectiveness.

### **CONCLUSIONS:**

The results thus reflect a rejection of the widely used QALY framework for reimbursement decisions by favoring rare disease treatments in resource allocation tasks, despite high opportunity costs and limited effectiveness.

---

## **OS.201 Health Technology Assessment Of Medical Devices For Rare Diseases**

### **DESCRIPTION:**

Impediments to patient access to technologies for rare conditions (orphan devices) arise due to challenges in meeting typical (standard) HTA evidentiary requirements. We investigated whether agencies have explicit pathways, tailored evidentiary requirements and decision-criteria for assessment of these technologies. Fit-for-purpose' pathways including Multi Criteria Decision Analysis (MCDA) frameworks may be appropriate for HTA for the coverage of orphan technologies.

### **AUTHORS:**

Rashmi Joglekar, John Gillespie

### **BACKGROUND AND OBJECTIVES:**

Health technology assessment (HTA) plays a key role in determining access to medical technology. Impediments to patient access to 'orphan' devices (for treatment of rare conditions, with prevalence of 40-50 cases/100,000) arise due to the challenges in meeting typical (standard) HTA evidentiary requirements. Difficulties in patient recruitment for clinical trials pose hurdles in the generation of clinical and cost-effectiveness data, and thresholds applicable to mainstream technologies may be unsuitable for therapies that are the patients' only treatment option. Evidence for these therapies may not meet the requirements of a standardised 'one-size-fits-all' HTA process, and alternative approaches may be warranted.

### **METHODS:**

A literature review was carried out to determine approaches by HTA agencies around the world in evaluating orphan devices. We investigated whether agencies have explicit pathways, tailored evidentiary requirements and decision-criteria for assessment of orphan technologies.

### **RESULTS:**

Defined pathways for orphan drugs - but not orphan medical devices are available. Although not specific to orphan devices, the US Food and Drug Administration's (FDA) Humanitarian Device Exemption (HDE) program facilitates access to devices for rare diseases. However there is no similar approach in the HTA process informing reimbursement decisions. Australia has a well-defined framework for assessing medical technology for reimbursement decisions, but no specific provision for orphan medical devices. Multi Criteria Decision Analysis (MCDA) frameworks for orphan drug evaluation are available in some jurisdictions, but have yet to be routinely used in HTA of medical devices.

**CONCLUSIONS:**

While some jurisdictions recognise the need to use new approaches to consider the value of orphan drugs we found little evidence that orphan devices are considered similarly. Access to approved last-line medical devices needs to be accelerated to meet the high unmet clinical needs of very small patient populations with no effective alternative treatment options. These technologies do not meet conventional assessment requirements used to inform coverage decisions. 'Fit for purpose' pathways, with appropriate decision criteria, need to be available for the evaluation of last-line innovative 'orphan' health technologies. Budget impact may be limited due to small indicated populations.

**REFERENCES:**

Rare Disease Terminology and Definitions-A Systematic Global Review: Report of the ISPOR Rare Disease Special Interest Group Richter T., Nestler-Parr S., Babela R., Khan Z.M., Tesoro T., Molsen E., Hughes D.A. (2015) Value in Health, 18 (6) , pp. 906-914.

.....

## OS.203 Where Are We With The Challenge Of High-Cost Medicines? Global Comparison Of The Reimbursement

**DESCRIPTION:**

Since 2011, a series of breakthrough hepatitis C treatments, direct-acting-antivirals (DAAs), were brought into the market. However, their high launch prices have been extensively criticized as a barrier to equal and timely access. Case-studies were conducted for the US, the UK, and Japan to investigate their responses to this challenge by capturing effects this had on their reimbursement decision-making processes.

**AUTHORS:**

Amina Sugimoto, John Cairns

**BACKGROUND AND OBJECTIVES:**

Since 2011, a series of breakthrough hepatitis C virus (HCV) treatments, direct-acting-antivirals (DAAs), were brought into the market, which demonstrated high clinical effectiveness, shorter treatment duration and fewer side effects than existing treatments. With the discovery of HCV-DAAs, a complete cure has now become possible for the disease that affects more than 170 million people worldwide. However, their high launch prices (e.g., Sovaldi: \$84,000, and Harvoni: \$95,000) have been extensively criticized as a barrier to equal and timely access not only by the low-and-middle income countries, but also by the high-income countries. HCV-DAAs, therefore, highlighted one of the emerging consequences of health innovation worldwide: Third-party payers (TPPs) are finding increasingly difficult to cover the cost of the growing demand for and availability of effective but high-cost treatments for prevalent diseases. Therefore this study was conducted to investigate how countries are responding to this challenge by capturing the global movement of reimbursement decision-making progress for HCV-DAAs, and the effects this had on respective decision-making processes and the public debate on pricing and availability of HCV treatments.

**METHODS:**

Case studies were conducted for the United States, the United Kingdom, and Japan from August 2015 to January 2016. These countries were chosen because more accurate information was publicly available and the investigator had access to potential interviewers. Representing the three continents with different approaches with respect to drug-reimbursement decisions also made a comparative analysis possible and interesting. A media analysis was first conducted to understand the global trends of HCV-DAA adaption. Document review was then conducted simultaneously with semi-structured interviews with 30 persons

representing the TPPs, the industry, patient-groups, and academia in each country.

### RESULTS:

Although the reimbursement decision-making process is different in the three countries studied, the high prices of HCV-DAA had equally raised the awareness of the issue on access to high-cost medicines and accelerated the movement towards reviewing their current systems. For example, the discussion on introducing health technology assessment (HTA) was accelerated in Japan. Their approaches differed mainly by 1) the severity of HCV endemic; 2) the government's approach to the HCV endemic; and 3) how they captured HCV-DAA as a rare breakthrough drug or as one of the high-cost medicines that may become prevalent in near future.

### CONCLUSIONS:

While globalization continues to increase harmonization of drug development process, the differences in the reimbursement-decision making process have become one of the barriers to meet equal access worldwide. A global effort is needed to develop a system where countries can share lessons learned, as described in this study, in order to improve the future access to high-cost medicines.

---

## OS.204 At What Point In The Life Cycle Of Technologies Are HTA Reports Requested?

### DESCRIPTION:

This study describe when in the life cycle HTA is requested, based on the experience from an independent Argentinian agency (IECS). Based on 130 evaluations performed in 2014-2015, near half were evaluated at experimental stage, when there is no evidence for its routine use. Only slightly more than a third of the health technologies were finally recommended for wider use.

### AUTHORS:

Andrea Alcaraz, María Calderón, Akram Hernández-Vásquez, Federico Augustovski, Andrés Pichón-Riviere

### BACKGROUND AND OBJECTIVES:

Health technologies (HT) have a natural life cycle with five stages: research/development, experimental, innovative, general use, and obsolescence/replacement. Health Technology Assessment (HTA) can be useful in all these stages. Our objective was to describe when in the life cycle of a technology the HTA is requested, based on the experience from an independent Argentinian HTA agency (IECS) member of INAHTA.

### METHODS:

We analyzed all the reports performed by IECS for a consortium of public, social security and private health care institutions in Argentina and Uruguay during 2014 and 2015.

Two independent researchers evaluated the reports and classified the life-cycle stage of each HT. Discrepancies were solved by consensus.

We considered the HT in the experimental stage if there was no approval from a regulatory agency (FDA, EMA or National Agency), or if the quality of the evidence measured by GRADE was very low or low (except for orphan diseases) and non experimental if it was approved by a regulatory agency and the GRADE quality of evidence was moderate or high. The non-experimental HTs were then classified in three groups: innovative if the direction of the recommendation was positive or positive with restrictions and if it was not yet widely adopted by coverage policies; in the general use stage when it fulfills the criterion for innovative HT with at least five policies recommending coverage; or non-effective if the direction of the recommendation was negative. Finally, we considered that an HT was in obsolescence/ replacement when the reason for assessment request was to discontinue its use.

## RESULTS:

We evaluated 130 HTA reports: 26% related to drugs, 11% devices, 30% medical procedures and 34% diagnostic technology. We found that 72% (93/130) HTs were approved by at least one regulatory agency.

The quality of the evidence measured by GRADE was high in 34%, moderate in 30%, low in 30% and very low in 6%. Nine were HTA for orphan diseases.

None HT were requested at the research/development or obsolescence/replacement stages.

43.85% (57/130) of the HTs evaluated were in the experimental stage. This situation was more frequent in medical procedures (68%) being 44% in diagnostic technology, 29% for devices and 18% for drugs. The difference was statistically significant ( $p=0.001$ ).

73 HTs (56.15%) were in non-experimental stages. Of these, 21 (16.15% of total) were in the innovative stage and 19 (14.62%) in general use.

Considering all the HTAs, only 37.69% (49/130) had a positive or positive with restrictions coverage recommendations.

## CONCLUSIONS:

Near half of the HTs performed by the main HTA agency in Argentina were evaluated at an experimental stage, when there is no evidence for its routine use. Only slightly more than a third of the HTs were finally recommended for wider use.

---

## OS.210 Horizon Scanning Alerts In Brazil: Informing Society

### DESCRIPTION:

This study aimed to construct a Horizon Scanning alert model centered on society to be applied on Brazilian's Early awareness and alert system. The

obtained alert model will be important to promote access by the different segments of society to information based on the best scientific evidence available, and will assist in health decision-making in Brazil.

### AUTHORS:

Gomes Pollyanna, Souza Andrea, Souza Ávila

### BACKGROUND AND OBJECTIVES:

In the context of Health Technologies Assessment, Early awareness and alert (EAA) systems or horizon scanning systems aim to identify, filter, prioritise and disseminate information about new and emerging health technologies to assess or predict their impact on health, health services and (or) society. Brazil's EAA system is being structured in recent years and one of the steps to achieve this goal is RADAR, a virtual space that provides information about new and emerging health technologies. The RADAR can be accessed by CONITEC's (National Committee for Health Technology Incorporation ([www.conitec.gov.br](http://www.conitec.gov.br)) website and offers two kinds of documents: alerts and reports. The objective of this study was to construct a Horizon Scanning alert model centered on society into its broad meaning, including patients, health managers and professionals, legal professionals and decision makers.

### METHODS:

The websites of all agencies that are part of EuroScan (European Information Network on New and Emerging Health Technologies) were searched in order to collect reports and alerts regarding new and emerging technologies. Based on this search, there were selected six documents to a deeper analysis about its structure, contents and the categories of information approached. The themes addressed in those six selected documents were categorized in the following topics: Technology related information; Patient and setting related information; Evidence and policy; and Impact predictions. These categories of information are recommended by EuroScan Methods Toolkit, a

document developed by members of EuroScan.

### RESULTS:

The analysis of the international material allowed us to know how different kinds of technologies are assessed. Considering the relevance of the information for Brazil's alerts costumers, the speed of obtaining data and the availability for the elaborating team, there were elected the topics that would be included in the Brazil's Horizon Scanning alert model according to the four categories that were mentioned before. The elected topics to compose the alert's model were: Target population; Disease characteristics; Assessed technology; Reported benefits; Manufactory; Published Clinical Guideline in Brazil; Efficacy and safety; Weaknesses and strengths.

### CONCLUSIONS:

Brazil's template obtained from this study is an important tool for the elaboration of Horizon Scanning alerts. The alerts could play a key role in the dissemination of information based on the best scientific evidence to diverse society segments. The reading of alerts by legal professionals can assist them in the proceedings of legalization of access to health care. In patients' and health professionals' sphere the alerts can be an important source of information free of conflicts of interest. So, this whole process could improve the process of incorporation of technologies in Brazilian Public Health System.

### REFERENCES:

BRASIL. Comissão Nacional de Incorporação de Tecnologias no SUS - CONITEC. Ministério da Saúde. 2015. Available from: <http://www.conitec.gov.br/>

Simpson S, et al. A toolkit for the identification and assessment of new and emerging health technologies. Birmingham: EuroScan. 2014;31

## OS.211 Options For Formulary Development In Middle-Income Countries

### DESCRIPTION:

The purpose of this study is to explore options to bridge the organisation of the health system and its priorities, and the translation of those into a framework for developing drug formularies. In addition, we discussed possibilities for considering or combining macro-level decision making factors and micro-level factors to determine the overall value of medicines.

### AUTHORS:

Karla Hernandez-Villafuerte, Martina Garau, Adrian Towse, Louis Garrison, Simrun Grewal

### BACKGROUND AND OBJECTIVES:

A number of middle-income countries (MICs) are evolving their health systems toward universal health coverage for patient populations. Such countries often have limited drug formularies and some form of essential drugs list. The purpose of this study is to explore options to bridge the organisation of the health system and its priorities, and the translation of those into a framework for developing drug formularies. In addition, we discussed possibilities for considering or combining macro-level decision making factors (focusing on the health system organisation and its priority setting) and micro-level factors (looking at intervention-specific effects) to determine the overall value of medicines.

### METHODS:

We explored published literature, conducted semi-structured interviews with experts, run a structured workshop with a sub-set of the interviewees, and administered an survey before and during the workshop. In addition, we applied our framework to the health systems of Mexico and Indonesia.

We break down the decision-making process into:

(1) nomination and prioritisation; (2) assessment of selected interventions; (3) appraisal of selected interventions; and (4) financial assessment.

## RESULTS:

The macro-level factors will be an important particularly during the prioritisation stage. This because, the selection of treatments based on a macro-factor analysis will allow to target the scarce resources only to assess in depth those interventions that have the highest health system intervention value, meaning interventions that are feasible (considering the WHO six building blocks) and match the national priorities. The second element of the decision-making process is the assessment of selected interventions. In this case, the focus should be on the analysis of the micro-level factors, particularly the estimation of an aggregate measure of value of the intervention. Depending on the country's resources, this can consist of a cost-effectiveness analysis but should also include other attributes, such as the characteristics of the target population (e.g. socioeconomic status, age and gender). Once the intervention has been assessed, the appraisal committee responsible for the final formulary decision should consider the macro-level analysis from the prioritisation stage and the micro-level analysis from the assessment stage to make formulary decisions. Finally, financial measures to make an intervention affordable should be considered.

## CONCLUSIONS:

The need for incorporating macro-level factors in the formulary decision making process was detected in the literature review as well as in the interviews with the international and national experts. This was reinforced by the analysis of the Mexican health system which shows a highly fragmented formulary decision making process which hinder the incorporation of national and states priorities in the decision of incorporate new treatments in the national and institutional positive lists. Additionally, equity was identified as an important micro-level factor for the Mexican health

system that is not formally considered during the process.

---

## OS.212 Economic Evaluations: Tendencies In Southern Africa

### DESCRIPTION:

Collaboration between African researchers is essential in the generation of evidence to support the decision making process. Based on the collaboration pattern between Southern African countries, this study aims at analysing whether it is possible to take advantage of the transferability of results and methodologies of the available HTA analysis to generate positive external benefits in other African countries.

### AUTHORS:

Karla Hernandez-Villafuerte, Ryan Li

### BACKGROUND AND OBJECTIVES:

The need for an efficient and effective allocation of the scarce resources has stimulated the search for evidence based tools that inform health sector policy makers during the decision process. One tool that has received the support of an important part of the scientific community is HTA. In Southern Africa the production of these analysis has been characterised by the lack of resources and human capital. Given the fact that collaboration between researchers has been an important element in the diffusion of knowledge in an uncountable number of fields, it could be also a key factor to overcoming the problems that generation and transferability of evidence to support the decision making process in Southern Africa is facing. Based on the collaboration pattern, the study aims at having an indication of the potential of transferring information between the countries to generate positive external benefits between the Southern African countries.

## **METHODS:**

We conducted a rapid evidence assessment that includes economic evaluations carried out in 20 countries (Angola, Botswana, Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia, Zimbabwe, Ghana, Kenya, Nigeria, Ethiopia and Uganda). Based on the articles identified, we explored the relationship between the Southern African authors and their respective co-authors. Additionally, with the aim of having an indication of the advancement and the areas in which the evidence is growing, the article second objective is to analyse the main tendencies of the HTA literature in Southern Africa.

## **RESULTS:**

The main result suggests that the collaboration between the African researchers is weaker than that between the African researchers and the researchers from USA and Europe. Moreover, the findings indicate that the economic evaluations are performed by authors with strong connections with researchers inside their own countries. Additionally, results also indicate that there exists a tendency in the economic evaluations conducted in Southern Africa towards the analysis of health treatments related to communicable diseases, in particular HIV and malaria. Moreover, the assessment of drugs and non-imaging diagnostic tools are the two most common types of technologies assessed in Southern Africa.

## **CONCLUSIONS:**

Analysis suggests that the transfer of information between the Africans faces important challenges. This because the collaboration between the researchers is weak and the assessment is more influenced by the collaboration with the occidental countries than the collaboration with other African countries. In view of this, it is recommended the application of methods that stimulate networking among researchers from different African countries. Organizations and institutions from high income countries interested in supporting the resource

allocation process in Southern African could include the promotion of collaboration as part of their agendas.

---

## **OS.214 How Long Does HTA Take?**

### **DESCRIPTION:**

Access to health care starts when drugs are reimbursed, so the time between regulatory approval and reimbursement is key in gaining access to treatment. This abstract explores the amount of time that process takes across Europe, with the intention to relate the analysis to Asia.

### **AUTHORS:**

Judith Rubinstein, Yin Ho, Ashley Jaksa, Emily Rubinstein

### **BACKGROUND:**

Data on the amount of time it takes for a drug to be reimbursed is largely from 10 to 15 years ago, and significant changes have been made to the reimbursement process since then. Europe has the most mature body of health technology assessment (HTA) agencies, so it is hopeful that there are lessons to be learned from them that can be applied to other world areas, in particular, Asia.

### **OBJECTIVES:**

To determine the amount of time it takes for reimbursement agencies to evaluate drugs after regulatory approval and whether the length of time to reimbursement decisions differs or changes over time or by disease condition.

### **METHODS:**

Using Context Matters large database, we matched European Medicines Agency (EMA) drug approvals with reimbursement decisions by indication from HTA agencies across Europe (G-BA, HAS, NICE, and SMC). We calculated the time it took from

EMA approval of the label to the time of the first reimbursement decision. The overall sample size was 1,293 HTAs from 2005 to 2015.

## RESULTS:

In Europe, the average time to make a decision was 292 days. On average, SMC took 244 days to make a decision for a first review and was significantly faster than other European agencies. G-BA averaged 314 days to make a decision, HAS averaged 310 days, and NICE averaged 363 days, but the differences were not significant. There were no significant differences between positive and negative decisions.

Oncology drugs had a significantly shorter time to decision (247 days, n=422) than non-oncology drugs (314 days, n=871), and positive decisions took significantly less time than negative ones (209 vs. 321 days). The trends over other therapeutic areas were less pronounced, but among individual disease conditions, the time to reimbursement decisions widely varied.

Labels approved after 2012 had an average time to a decision of 185 days, but all drugs reviewed after 2012 had a significantly longer average of 328 days.

## CONCLUSIONS:

On average, it takes HTA agencies 9.6 months to issue a reimbursement decision after the drug has been approved by the EMA. Depending on the role of the HTA agency within the health care system, this disparity can significantly delay patient access to therapies. Oncology drugs have a shorter time differential (8.1 months) from EMA approval to a reimbursement decision than non-oncology drugs (10.3 months); this may be due to the severity of illness or political pressure placed on HTA agencies to reimburse oncology drugs. SMC, on average, took the shortest amount of time to make a reimbursement decision.

Policy makers need to be aware of the trade offs inherent to the HTA process. A thorough assessment of the efficacy and cost-effectiveness

of a drug takes time and this could delay access to medicines. In addition, it takes several years before an HTA agency is able to catch up with the backlog of pre-existing labels, as evidenced by the significant disparity between the time to make HTA decisions for more current labels and that same differential for all current reviews.

---

## OS.217 Public Consultation Of Guidelines In Brazil: Patient Involvement, Transparency, Implementation Tool

### DESCRIPTION:

Presenting the new content-targeted form for mandatory public consultation of guidelines developed by the Brazilian Ministry of Health, prior to its official and final publication. This new form is intended to be a tool to include the users from the Brazilian public health system in the guideline development process. The new form was already used in three guideline public consultations, summing 341 contributions, with a great number of them from patients and people related to patients (37%).

### AUTHORS:

Ana Carolina de Freitas Lopes, Tacila Pires Mega, José Baulosa Alonso Neto, Jorgiany Souza Emerick Ebeidalla, Edison Vieira de Melo Júnior, Vania Cristina Canuto Santos, Clarice Alegre Petramale

### BACKGROUND AND OBJECTIVES:

"Patient participation in health care decisions has clear benefits. It increases the adherence to the treatment and it is a sign of respect to patient's individuality and needs. Evidence-based health care guidelines are being developed by the Brazilian Ministry of Health since 2000, but still face challenges concerning patient participation. The country continental length, with more than 200

million inhabitants, the important discrepancies in social, socioeconomic and health care services place patient involvement, transparency and implementation as the main challenges in guidelines development process. The Brazilian online form for guidelines' public consultation is constantly evolving. Here, we describe his latest version.

To present the new content-targeted form for mandatory public consultation of guidelines developed by the Brazilian Ministry of Health."

### **RESULTS:**

It was developed a new consultation form, to be applied to all guidelines produced by the Brazilian Ministry of Health, prior to its official and final publication. The new form, released in August-2015, is content-targeted. Along with the identification questions, the participant is asked to give an overall valuation of the guideline in a 5-point Likert scale. The participant may also name any information not addressed in the guideline or suggest altering the ones that are included. It were added two questions about implementation, where the participant, taking into account his or her local setting, may identify the possible barriers and facilitators one can face at implementing the proposal guideline. There is also a field addressed to any general comments the participant may have, as well as another one to upload any paper or document the participant judges important. The new form was already used in three guideline public consultations, summing 341 contributions, with a great number of them from patients and people related to patients (37%). Contributions from healthcare professionals accounted for 49% of total, and contributions from people who has interest in the field accounted for 14% of the total.

### **CONCLUSIONS:**

The new content-targeted form for public consultation of guidelines in Brazil is intended to be a tool to include the users from the Brazilian public health system in the guideline development process. Comprehensive societal participation

is known to increase the transparency about the decision-making process, and serves as another implementation tool to put the recommendations into practice. Time is still required to ascertain whether this new instrument model draws representative and valid information on the opinion of the Brazilian population.

---

## **OS.225 Horizon Scanning Alerts With Sofosbuvir And Ledipasvir (Harvoni®) For The Treatment Of Hepatitis C**

### **DESCRIPTION:**

Horizon Scanning within the Brazilian Ministry of Health (MoH) seeks to predict which technologies have potential to impact health care in Brazilian Public Health System. The objective of this project was to draw up the first Alert with Harvoni® drug (Sofosbuvir and Ledipasvir) for the treatment of Hepatitis C and assess the applicability of the model prepared by the MoH.

### **AUTHORS:**

Andrea Brígida de Souza, Ávila Teixeira Vidal, Pollyanna Teresa Cirilo Gomes, Vânia Cristina Canuto Santos, Clarice Alegre Petramale

### **BACKGROUND AND OBJECTIVES:**

Horizon Scanning within the Brazilian Ministry of Health (MoH) is a structuring process and seeks to predict which technologies have potential to impact health care in the Brazilian Public Health System (SUS). Reports and alerts produced about Horizon Scanning are available in the RADAR virtual space, accessed by CONITEC's (National Committee for Health Technology Incorporation [www.conitec.gov.br](http://www.conitec.gov.br)) website. The Horizon Scanning Alerts are shorter publications, with concise and objective information, focusing on a new or emerging health technology. Therefore, the MoH drew up an Alert model centered on society,

health managers and health professionals, to guide the construction of these reports and to be utilized within the SUS. In order to assess the applicability of this model, viability of the proposed topics and level of difficulty in finding the suggested information, the first Alert with Harvoni® (Sofosbuvir and Ledipasvir) for the treatment of Hepatitis C was drawn up.

#### **METHODS:**

An Alert model prepared by the MoH was used. The databases used to search the content of the alert were ClinicalTrials.gov, PubMed® and Cortellis®. In order to analyze the applicability of the Alert model elaborated, a paired evaluation was made in a follow-up sheet.

#### **RESULTS:**

Some topics were included or adapted as a result of information found and needs observed. The 'Drug Registration in the world' topic was included to display the registration and commercialization status of the technology in other countries. The 'Clinical research' and 'Completed and in progress studies' items were included in a separate topic to highlight this information. The 'Reported benefits' topic was excluded because the data on the technology effectiveness was already covered in another topic on scientific evidence. It was decided not to include economic evaluation, because despite it being relevant, information on the topic is limited within Brazil.

#### **CONCLUSIONS:**

In preparing the Alert with Harvoni®, it was found that the topics chosen for the construction of the documents are feasible to be obtained in a timely manner. Horizon Scanning Alerts will be able to promote access by different segments of society to information based on the best scientific evidence available and can assist in health decision making processes. It is noteworthy that the alert is not a clinical guideline and does not represent a favorable or unfavorable position of the MoH in regards to the use of the technology.

---

## **OS.230 The Road Map For HTA Development In Kazakhstan: For Well Informed Health-Care Decisions**

#### **DESCRIPTION:**

The Republican Center for Health Development is devising The Road Map of HTA Development in the Republic of Kazakhstan in 2016-2020.

#### **AUTHORS:**

Temirkhan Kulkhan, Ainur Sassykova

#### **BACKGROUND AND OBJECTIVES:**

Despite significant investments during last years in clinico- and pharmacoeconomic evaluation, as part of a formulary listing or reimbursement submission, too much research is wasted and too many decisions are still not well informed. The objective was to invent the long-term strategy for the HTA development in the Republic of Kazakhstan.

#### **METHODS:**

We conducted a survey of HTA terms in 6 countries (Kazakhstan, Turkey, Tajikistan, Kyrgyzstan, Uzbekistan, and Montenegro). Informal stakeholder interviews within the framework of first Eurasian Forum of HTA were used to supplement lacking information.

#### **RESULTS:**

Rising affordability and accessibility of the healthcare services have been considered as the most important policy issues in Kazakhstan. In light of this fact The Republican Center for Health Development is devising The Road Map of HTA Development in the Republic of Kazakhstan in 2016-2020. Healthcare professionals and managers who are responsible for seeking reliable information and learning sufficient skills to use evidence-based resources to provide optimum patient care should

promote hospital based HTA on the regional level and support HTA research and CPG development in clinics. There is growing recognition of the need for local efforts that go beyond sharing the evidence. Hospital based HTA should be accountable to their patients, governments, and third party payers.

### **CONCLUSIONS:**

Regional HTA Agencies and National CPG developers in Kazakhstan in post carriage period would produce relevant, reliable, transparent, and up-to-date evidence synthesis and recommendations, avoiding unnecessary duplication on regional and national levels, making their Works accessible to decision makers, and engaging stakeholders.

---

## **OS.240 What Is The Value Of Low-Level Research Evidence For Decision-Making?**

### **DESCRIPTION:**

This presentation aims to introduce a newly developed quality appraisal tool for case series studies, present the most appropriate ways of using and adapting it to specific HTA topics, provide an opportunity to discuss the value of low-level research evidence used to inform decision-making, and explore the possibility of involving other HTA agencies in further validation of the tool.

### **AUTHORS:**

Carmen Moga, Bing Guo

### **BACKGROUND:**

Case series studies, characterized by a lack of a control group, are sometimes the only research evidence available to inform policy decisions on the safety and effectiveness of healthcare technologies such as medical devices and interventional surgery procedures. Assessing the robustness of these studies is challenging; in contrast to the

availability of well-developed quality appraisal tools for randomized controlled trials or studies with comparative groups, no widely accepted, validated tool exists for the quality appraisal of case series studies.

### **OBJECTIVES:**

To introduce a newly developed quality appraisal tool for case series studies and present the most appropriate ways of using and adapting it to specific health technology assessment (HTA) topics; to explore opportunities for involvement of other HTA agencies in further validation of the tool.”

### **METHODS:**

A collaborative effort by HTA researchers from Canada, Australia, and Spain resulted in a 20-criterion quality appraisal checklist with a clearly defined guidance developed specifically for case series studies. The face and content validity of the checklist were evaluated via a modified Delphi process, and the relationships between the items were evaluated by a principal component analysis.

### **RESULTS:**

A modified Delphi process culled an initial list of 30 criteria to a more ‘user-friendly’ 18-criterion checklist. Two new criteria were added later to the checklist based on a literature review of other case series studies checklists. The resulting checklist examines the quality of reporting and risk of bias in case series studies. First-hand experience with the tool and its guidance indicated a general level of satisfaction by the researchers. Feedback helped to improve the clarity and feasibility of the checklist and its guidance. The checklist was used by multiple researchers to appraise a random sample of 105 case series studies, and the principal component analysis revealed two components. The first component (10 criteria) indicated the extent to which a case series presented traditional features of a statistical hypothesis-testing paradigm. The second component (seven criteria) indicated whether detailed descriptions of the subjects’ characteristics that might feature in the

experimental design were present, particularly in judgments about the likelihood of confounding.

### CONCLUSIONS:

This collaborative effort attempted to address the issue associated with the usefulness and validity of including low-level research evidence in answering healthcare technology policy questions. While including case series studies in an HTA may be appropriate, applying a quality assessment tool to scrutinize such studies' conduct and reporting will help increase HTA researchers' confidence in their conclusions and reduce the uncertainty of the decision-making process. Potential users of this tool should determine which of the 20 criteria are essential in accordance with the specific condition and technology under review. The guidance may also need to be customized for each review. Further validation of the tool for a larger scale is required.

### REFERENCES:

Moga C, Guo B, Schopflocher D, Harstall C. Development of a quality appraisal tool for case series studies using a modified Delphi technique. Edmonton: Institute of Health Economics; 2012. Available at <http://www.ihe.ca/advanced-search/development-of-a-quality-appraisal-tool-for-case-series-studies-using-a-modified-delphi-technique>. Accessed September 22, 2015.

Guo B, Moga C, Harstall C, Schopflocher D. A principal component analysis is conducted for a case series quality appraisal checklist. *J Clin Epidemiol*. 2015 Aug 22 [Epub ahead of print].

.....

## OS.241 Efficacy, Safety And Cost-Effectiveness Of Aripiprazole For Schizophrenia: A Systematic Review

### DESCRIPTION:

This study consists of a systematic review of the efficacy, safety and cost-effectiveness of aripiprazole in comparison with the antipsychotic drugs provided by the Brazilian public health system. Aripiprazole was not considered a possible therapeutic option only for patients with failure to the alternative for the treatment of patients that did not achieve an adequate response with the available drugs.

### AUTHORS:

André Santos, Isabella Godói, Cristina Brandão, Juliana Alvares, Helian Nunes, Francisco Acurcio, Augusto Guerra

### BACKGROUND AND OBJECTIVES:

Schizophrenia is a chronic debilitating condition characterized by disturbances in thought, behavior and affect. It occurs, approximately, in 0.3 to 1% of the world's population (1-7). Aripiprazole is a dopamine-serotonine system stabilizer that has partial agonist activity in D2 and 5-HT1A receptors and antagonist activity in 5-HT2A receptors (7-9). This study proposes a systematic review of the efficacy, safety and cost-effectiveness of aripiprazole in comparison with the antipsychotic drugs already provided by the public health system of Brazil (Unified Health System, SUS) as a first step for assessment for inclusion of this technology as a standard treatment in the country.

### METHODS:

The Cochrane Library (via Bireme), Medline (via Pubmed), LILACS and Centre for Reviews and Dissemination (CRD) databases were searched for Randomized Controlled Trials (RCTs) and for pharmacoeconomic studies that evaluated the efficacy, safety and cost-effectiveness of

aripiprazole in the treatment of patients with schizophrenia. We also searched for Health Technology Assessment (HTA) reports in websites of HTA agencies of countries with public health systems. The quality of RCTs was assessed by modified GRADE (10-12).

## RESULTS:

Eleven RCTs and eleven pharmacoeconomic studies were included. The quality of the RCTs varied from poor to moderate. In most studies aripiprazole did not present advantages in reduction of PANSS and CGI scores and with respect of treatment discontinuation when compared to haloperidol, risperidone, quetiapine, ziprasidone and olanzapine, all provided by SUS. We observed better metabolic profile for aripiprazole in comparison with olanzapine, but not with ziprasidone. In the four HTA reports recovered aripiprazole was recommended as an alternative therapy for patients not responsive to first-line treatments. Cost-effectiveness studies from Greece, USA, Sweden and Spain favored olanzapine and risperidone over aripiprazole.

## CONCLUSIONS:

Considering the use, the quality of evidence and the results of the studies available to date, as well as the high cost-effectiveness ratio, aripiprazole cannot be considered a better therapeutic alternative for the treatment of patients with schizophrenia than the already available drugs in SUS at the moment. It can, nevertheless, be useful for the treatment of patients that did not achieve an adequate response with the available drugs. The technology should be reassessed with the emergence of new data and after price reduction.

## REFERENCES:

1. Weinberger DR, Harrison PJ. Schizophrenia. 3 ed. Chichester: Wiley-Blackwell; 2011. 721 p.
2. National Institute for Health and Care Excellence (NICE). Psychosis and schizophrenia in adults: treatment and management. 2014.

3. Brasil. Portaria nº. 364, de 9 de abril de 2013. In: Saúde Md, editor. Brasília: Imprensa Nacional; 2013. p. 62.

4. American Psychiatric Association (APA). Diagnostic and Statistical Manual of Mental Disorders fifth edition (DSM-5). 5 ed. Washington: American Psychiatric Association; 2013.

5. American Psychiatric Association (APA). Diagnostic and Statistical Manual of Mental Disorders fourth edition (DSM-IV). 4 ed. Washington: American Psychiatric Association; 1994.

6. Messias EL, Chen CY, Eaton WW. Epidemiology of schizophrenia: review of findings and myths. The Psychiatric clinics of North America. 2007;30(3):323-38.

7. Brunton LL, Chabner BA, Knollmann BC. Goodman & Gilman's The Pharmacological Basis of Therapeutics. 12 ed: McGraw-Hill Education; 2011. 1808 p.

8. El-Sayeh HG, Morganti C, Adams CE. Aripiprazole for schizophrenia. Systematic review. The British journal of psychiatry : the journal of mental science. 2006;189:102-8. Epub 2006/08/02.

9. Argyriou E, Petroggona M, Charitaki S, Belivanaki M, Giannakopoulos G, Kolaitis G. Aripiprazole in children and adolescents with schizophrenia (Provisional abstract). Current Psychopharmacology [Internet]. 2012; 1(2):[117-21 pp.]. Available from: <http://onlinelibrary.wiley.com/o/cochrane/cldare/articles/DARE-12013000943/frame.html>.

10. Higgins J, Green S. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0: The Cochrane Collaboration; 2011. Available from: [www.cochrane-handbook.org](http://www.cochrane-handbook.org).

11. Guyatt G, Oxman A, Kunz R, Falck-Ytter Y, Vist G, Liberati A, et al. GRADE: going from evidence to recommendations. British Medical Journal. 2008;336:1049-51.

12. Guyatt G, Oxman A, Vist G, Kunz R, Falck-Ytter

Y, Alonso-Coello P, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *British Medical Journal*. 2008;336:924-6.

---

## OS.243 Exploring Unwarranted Variations In Clinical Healthcare Practice: Implications For De-Implementation

### DESCRIPTION:

The research aimed to determine the magnitude of variation in the implementation of NICE disinvestment initiatives in the English NHS, through geographical analysis of the rates of use of low-value interventions.

### AUTHORS:

Hannah Flynn, Ken Stein, Bridie Kent, Helen Lloyd

### BACKGROUND AND OBJECTIVES:

With most health services, including the English NHS, grappling with significantly constrained resources, the need to produce more value from existing service is crucial. Since 2009, The National Institute of Health and Clinical Excellence (NICE) has been supporting the NHS by identifying 'low-value' activities for disinvestment. These technologies are identified through the various workstreams that make up NICE's work programme of guidance for the NHS. Technologies may be of limited value because the balance between benefit and harm that they offer is not favourable, or because the evidence supporting their use is insufficient. These 'low-value' procedures have been brought together to form an online constrained resource of 'Do not Do' (DND) technologies. Yet despite such efforts, there is mixed and limited evidence on the value of this approach. Patient preference, diagnostic thresholds used by clinicians, and patients' and clinicians'

beliefs about the value and efficacy of procedures may influence how these DND recommendations are being implemented. There is likely, therefore to be some variation in how much influence DND recommendations will have in the health system.

### METHODS:

The research was based on the hypothesis that there is a degree of variability in the uptake and implementation of NICE DND recommendations and therefore high geographic variation in clinical procedure rates. The research therefore aimed to determine the magnitude of this variation through geographical analysis of the rates of use of DND technologies in England.

30 NICE 'DND' recommendations were identified by a panel of clinicians and managers in one region of England as having high impact potential if de-implemented. Using Hospital Episodes Statistics data, volumes of prioritised 'DNDs' were collated, with standardised admission rates calculated for each intervention to demonstrate the extent of geographical variation in use. Heat based maps (graphical representation of data where the individual values contained in a matrix are represented as colours) were then generated using the boundaries of Clinical Commissioning Groups, the populations used for the purposes of commissioning health care. Each heat map highlights variations in clinical practice, allowing us to examine the patterns of de-implementation for technologies considered to be of limited value.

### RESULTS:

The production of heat based maps highlighted a significant magnitude of variation for all prioritised DNDs, with some procedures (e.g. arthroscopic knee washout for the treatment of osteoarthritis) having a 9-fold variation in admission rates across CCGs. This suggests that NICE DND recommendations are not being implemented effectively and further research is required to determine how de-implementation strategies can be improved.

## CONCLUSIONS:

De-implementation strategies, in this case publication of a list of procedures for which support from national evidence-based guidance is lacking have not had a uniform or pronounced effect on the extent of use of low value procedures. The factors which influence this, including data quality and reporting systems, remains unclear.

.....

## OS.244 Realist Exploration Of Unwarranted Variation In Clinical Healthcare Practice

### DESCRIPTION:

The aim of the research is to identify key factors underpinning de-implementation strategies in the English NHS. This will provide a contextual framework for future de-implementation practices; taking explicit account of barriers/facilitators for change in practice. In order to meet this aim, a theory-driven realist evaluation in being undertaken which focuses on exploring the context-mechanism-outcome relationship in patterns of change, addressing guiding question: what works in de-implementation, for whom, and under what circumstances?"

### AUTHORS:

Hannah Flynn, Ken Stein, Bridie Kent, Helen Lloyd

### BACKGROUND AND OBJECTIVES:

De-implementation of ineffective, inefficient, harmful or inappropriate clinical practices is a growing priority for health systems. However, various challenges from political, clinical and patient perspectives have been identified for de-implementation processes. In England, the National Institute for Health and Clinical Excellence (NICE) provides the health service with evidence-based guidance on a wide range of topics. In developing this guidance, technologies are identified which are regarded as 'low-value'.

These have been brought together into an online database of 'Do not Do' recommendations which is available as the basis for de-implementation within the health service. These DND technologies may not be clinically effective (and therefore not good value for money), have a close risk/benefit ratio, or they are not supported by adequate evidence. Our initial research suggests that there is wide variation in the extent of de-implementation of these technologies, with much acti

### METHODS:

The research is based on the principles of realist evaluation, a largely qualitative approach that is centrally concerned with testing and refining program theories which account for the complex and dynamic interaction among context, mechanism, and outcomes in social systems. A relatively unstructured initial exploratory literature search was undertaken, guided by a limited number of search terms centred on the topic of investigation (disinvestment, de-implementation, withdrawal, etc.). These searches were designed to locate a broad range of sources, including policy documents, to identify and map, in realist terms, 'programme theories' (explanations of how de-implementation initiatives are supposed to work in order to produce their desired outcomes, i.e. reduction of clinical intervention use) which will facilitate the creation of an evaluation framework.

### RESULTS:

Using focus groups and semi-structured interviews with leading stakeholders, combined with the distribution of a national 'de-implementation' survey to those involved in de-implementation initiatives, we are testing these programme theories and exploring their credibility. This will be done in a pragmatic and reflexive manner to build iteratively on our initial programme theories. These will be endorsed, refuted and then refined to inform the production of an evaluation framework which will aid future de-implementation practices.

## CONCLUSIONS:

The final realist programme theory will be summarised through narrative synthesis, using text, summary tables, a logic model and where appropriate graphics to summarise individual papers/reports and draw insight from the analysis of primary research undertaken. The results of the synthesis will be written up according to the 'Realist and Meta-Review Evidence Synthesis: Evolving Standards' (RAMESES) standard for reporting realist reviews.

---

## OS.247 Use Of Bayesian Multi-Parameter Evidence Synthesis To Inform Health Care Decision Making

### DESCRIPTION:

Bayesian multivariate meta-analysis methods will be introduced with a number of examples illustrating how this flexible methodology can help to synthesise data from heterogeneous sources to inform health care decision-making. Examples of application will include combining treatment effects measured on alternative scales, inclusion of observational data and making predictions about treatment effect on long term endpoints including quality of life.

### AUTHORS:

Sylwia Bujkiewicz, John Thompson, Sze Huey Tan, Richard Riley, Keith Abrams

### BACKGROUND AND OBJECTIVES:

Evidence-based decision-making requires careful synthesis of available evidence. When assessing new health technologies to make reimbursement decisions, the health technology assessment (HTA) process relies heavily on meta-analysis of effectiveness of new interventions. The evidence base is typically obtained from the systematic literature review of randomised controlled trials

(RCTs) and sometimes real world evidence (RWE) such as from observational studies. There is often a lot of heterogeneity in reporting of clinical outcomes due to, for example, variety of scales on which effectiveness can be measured, different time points at which different studies report their outcomes or different control arms. Bayesian statistics provides flexible framework for modelling complex data structures by allowing multiple parameters to be modelled simultaneously. Network meta-analysis (NMA) facilitates simultaneous comparison of multiple treatment options whereas multivariate meta-analysis (MVMA) allows to model jointly treatment effects on multiple correlated outcomes. While NMA is becoming a standard tool for synthesising evidence in HTA, MVMA has not been widely used despite of substantial methodological developments in this area [1,2] and many advantages of this approach to evidence synthesis. This talk aims to introduce the concepts of Bayesian methods for efficient synthesis of evidence in HTA.

### METHODS:

MVMA methodology will be briefly introduced and its application illustrated in scenarios for its use for purpose of (i) combining all available evidence on correlated outcomes from RCTs and also RWE [3] and the implications for estimating the health-related quality of life (HRQoL) values [4,5], (ii) predicting treatment effect on a target clinical endpoint from treatment effects on surrogate endpoints [6,7], and (iii) exploiting such prediction framework to inform decision modelling, based on examples in rheumatoid arthritis, multiple sclerosis and cancer [3-7].

### RESULTS:

Applying MVMA to an example in rheumatoid arthritis allowed inclusion of larger number of RCTs, by including data on effectiveness reported on alternative scales, and of RWE in the form of informative prior distributions. This led to more precise estimates of clinical effectiveness which in turn gave estimates of HRQoL predicted with reduced uncertainty. In multiple sclerosis, MVMA

facilitated use of data on multiple surrogate endpoints which were modelled jointly as predictors of treatment effect on the final outcome and in another scenario was used to combine all available evidence to inform mapping disease-specific HRQoL measure onto EQ-5D scale. In prostate cancer, use of MVMA led to prediction of unreported progression-free survival which enabled to populate otherwise much simplified economic model.

### CONCLUSIONS:

Joint analysis of multiple outcomes has an advantage of taking into account the correlations between the outcomes. This can give benefits of reducing uncertainty by borrowing of strength across studies and outcomes, and also can reduce outcome reporting bias [8]. Taking into account of correlations between outcomes when summarising evidence to inform an economic evaluation may help to fill the gaps in a set of parameters needed to populate economic model and have implication for estimating the net benefit associated with treatment.

### REFERENCES:

1. Jackson D, Riley R and White IR. Multivariate meta-analysis: Potential and promise. *Statistics in Medicine* 2012;30:2481-2498.
2. Riley RD, Abrams KR, Lambert PC, Sutton AJ and Thompson JR. An evaluation of bivariate random-effects meta-analysis for the joint synthesis of two correlated outcomes. *Statistics in Medicine* 2007;26:78-97.
3. Bujkiewicz S, Thompson JR, Sutton AJ, Cooper NJ, Harrison MJ, Symmons DPM, Abrams KR., Multivariate meta-analysis of mixed outcomes: a Bayesian approach. *Statistics in Medicine*, 2013; 32: 3926 - 3943.
4. Bujkiewicz S, Thompson JR, Sutton AJ, Cooper NJ, Harrison MJ, Symmons DPM, Abrams KR., Use of Bayesian multivariate meta-analysis to estimate HAQ for mapping onto EQ-5D in rheumatoid

arthritis, *Value in Health*, 2014; 17: 109-115.

5. SH Tan, Graphical and statistical methods in health technology assessment, PhD thesis supervised by S Bujkiewicz and KR Abrams, University of Leicester, submitted 30 Sept 2015.
6. S Bujkiewicz, JR Thompson, E Spata, KR Abrams, Uncertainty in the Bayesian meta-analysis of normally distributed surrogate endpoints, *Statistical Methods in Medical Research*, August 2015, e-pub ahead of print.
7. Bujkiewicz S, Thompson JR, Riley RD, Abrams KR, Bayesian meta-analytical methods to incorporate multiple surrogate endpoints in drug development process, *Statistics in Medicine*, e-pub ahead of print, 3 November 2015.
8. Kirkham JJ, Riley RD and Williamson PR. A multivariate meta-analysis approach for reducing the impact of outcome reporting bias in systematic reviews. *Statistics in Medicine* 2012;31:2179-2195."

---

## OS.248 Use Of Multivariate Network Meta-Analysis To Combine All Available Evidence For Predicting Outcome

### DESCRIPTION:

In early decision-making, evidence on effectiveness of new interventions may be limited to short term surrogate endpoints and predictions of the effect on final outcome need to be made. Treatment effects on surrogate endpoints may be heterogeneously reported. Multivariate network meta-analysis can be used to combine all available evidence on surrogate endpoints for predicting treatment effect on final outcome effectively.

### AUTHORS:

Sylwia Bujkiewicz, John Thompson, Keith Abrams

## BACKGROUND AND OBJECTIVES:

In early regulatory and health technology assessment (HTA) decision-making, evidence on effectiveness of new interventions may be limited, especially in disease areas where measuring the effectiveness on final clinical outcome requires long follow-up time. To accelerate the delivery of new interventions to patients, early decisions may have to be made based on effectiveness measured on short term surrogate endpoints. Conditional licensing can take place based on evidence on surrogate endpoint later confirmed by accumulated data on the final outcome [1]. At an early stage it is useful to predict what will be the treatment effect on the final outcome from the estimate of the treatment effect on surrogate endpoints. Prediction can be made using multivariate meta-analytic methods [2,3] which can include predictions from multiple surrogate endpoints. Models for predicting treatment effect on the final outcome from treatment effect measured on surrogate endpoints are constructed based on data

## METHODS:

While multivariate meta-analysis (MVMA) can be used to model surrogate endpoints, network meta-analysis (NMA) combines data from trials investigating different treatment contrasts and has the advantage of estimating effects for all contrasts individually. We exploit this framework to model surrogate endpoints by the use of multivariate NMA (mvNMA) [4,5]. By modelling treatment effects on multiple surrogate endpoints jointly using mvNMA, unreported effects for each treatment contrast are predicted by both the inherent structure of the network meta-analysis, where treatment effects on all contrasts can be obtained through indirect comparisons, and by taking into account of the correlation between the effects on multiple outcomes. The effect on the final outcome can then be predicted from the effect on one or more surrogate endpoints using joint mvNMA and MVMA model.

## RESULTS:

The modelling techniques were investigated using an example from multiple sclerosis, where the disability progression is the final outcome, while relapse rate and number of MRI lesions are the candidate surrogate endpoints. Data from 20 randomised controlled trials were collected which included nine 3-arm trials. A third of the trials did not report the treatment effect on MRI. The mvNMA was used to predict the unreported effects which were then used to predict the effect on the disability progression from the effect on MRI or jointly both MRI and relapse rate.

## CONCLUSIONS:

Use of mvNMA allows for inclusion of larger evidence base in modelling of surrogate endpoints. This method helps to avoid large amount of valuable evidence from being discarded due to incomplete reporting, potentially increasing precision of predictions [6] and avoiding outcome reporting bias [7].

## REFERENCES:

1. H-G Eichler et al, From Adaptive Licensing to Adaptive Pathways: Delivering a Flexible Life-Span Approach to Bring New Drugs to Patients, *Clinical Pharmacology & Therapeutics* 2015, 97 (3): 234-246.
2. S Bujkiewicz, JR Thompson, E Spata, KR Abrams, Uncertainty in the Bayesian meta-analysis of normally distributed surrogate endpoints, *Statistical Methods in Medical Research*, August 2015, e-pub ahead of print.
3. Bujkiewicz S, Thompson JR, Riley RD, Abrams KR, Bayesian meta-analytical methods to incorporate multiple surrogate endpoints in drug development process, *Statistics in Medicine*, e-pub ahead of print, 3 November 2015.
4. Achana FA, Cooper NJ, Bujkiewicz S, Hubbard SJ, Kendrick D, Jones DR and Sutton AJ, Network meta-analysis of multiple outcome measures

accounting for borrowing of information across outcomes, *BMC Medical Research Methodology*, 2014, 14:92.

5. Efthimiou O, Mavridis D, Cipriani A, Leucht S, Bagos P, Salanti G: An approach for modelling multiple correlated outcomes in a network of interventions using odds ratios. *Statistics in Medicine* 2014, 33(13):2275-2287.

6. Bujkiewicz S, Thompson JR, Sutton AJ, Cooper NJ, Harrison MJ, Symmons DPM, Abrams KR., Multivariate meta-analysis of mixed outcomes: a Bayesian approach.

*Statistics in Medicine*, 2013; 32: 3926 - 3943.

7. Kirkham JJ, Riley RD and Williamson PR. A multivariate meta-analysis approach for reducing the impact of outcome reporting bias in systematic reviews. *Statistics in Medicine* 2012;31:2179-2195.

---

## OS.251 Immunosuppressive Therapy For Renal Transplantation In Adults: A Systematic Review

### DESCRIPTION:

The clinical effectiveness of basiliximab and rabbit anti-human thymocyte immunoglobulin as induction therapy, and immediate-release and prolonged-release tacrolimus, belatacept, mycophenolate mofetil, mycophenolate sodium, sirolimus, and everolimus as maintenance therapy in adult renal transplantation was systematically reviewed. Eighty-six RCTs were identified and network meta-analyses were conducted. Despite the high number of included studies limited clinical effectiveness evidence was found.

### AUTHORS:

Marcela Haasova, Tracey Jones-Hughes, Jaime Peters, Tristan Snowsill, Helen Coelho, Louise Crathorne, Chris Cooper, Ruben Mujica-Mota, Jo

Varley-Campbell, Nicola Huxley, Jason Moore, Matt Allwood, Jenny Lowe, Chris Hyde Hyde, Mary Bond, Rob Anderson

### BACKGROUND AND OBJECTIVES:

Renal transplantation accompanied with induction and maintenance immunosuppressive therapy is the preferred option in end stage kidney disease due to improved duration and quality of life when compared to dialysis. The National Institute for Health and Care Excellence conducted a technology appraisal to update a previous guidance for the NHS in England on the use of immunosuppressive agents in adult kidney transplantation (TA85). We present the results of the systematic review conducted as part of the appraisal.

### METHODS:

The evidence for the clinical effectiveness of basiliximab (BAS) and rabbit anti-human thymocyte immunoglobulin (rATG) as induction therapy, and immediate-release tacrolimus (TAC), prolonged-release tacrolimus (TAC PR), belatacept (BEL), mycophenolate mofetil (MMF), mycophenolate sodium (MPS), sirolimus (SRL), and everolimus (EVL) as maintenance therapy in adult renal transplantation was reviewed. Searches were conducted in Medline (OVID), Embase (OVID), CENTRAL (Wiley) and Web of Science (ISI), CDSR, DARE and HTA (The Cochrane Library via Wiley) and HMIC (OVID). Included studies were selected according to predefined methods and criteria. Outcomes evaluated were mortality, biopsy-proven acute rejection (BPAR), graft function and graft loss. Included studies were extracted and quality appraised. Data were tabulated, discussed narratively and, where appropriate, network meta-analyses (NMAs) were undertaken within a Bayesian framework. For NMAs assessing the effectiveness of induction therapy, the reference treatment was no induction/placebo. For NMAs evaluating the effectiveness of maintenance therapy, the reference treatment was ciclosporin (CSA) + azathioprine (AZA).

**RESULTS:**

Eighty-six RCTs of variable quality were included. Compared with placebo/no induction, rATG and BAS appeared more effective in reducing BPAR, but the evidence does not suggest a statistically significant difference between the two treatments. None of the maintenance regimens performed consistently well on all outcomes. BEL+MMF appeared more effective than TAC+MMF and SRL+MMF at reducing mortality. MMF+CSA, TAC+MMF, SRL+TAC, TAC+AZA and EVL+CSA appeared more effective than CSA+AZA and EVL+MPS at reducing BPAR. SRL+AZA, TAC+AZA, TAC+MMF and BEL+MMF appeared more effective in improving graft function than CSA+AZA and MMF+CSA.

**CONCLUSIONS:**

Despite the high number of included studies there is limited conclusive evidence on the clinical effectiveness of induction or maintenance therapies. Compared with placebo/no induction, we found evidence that rATG and BAS were more effective in reducing BPAR. With regard to maintenance therapy, the NMAs showed none of the maintenance regimens performed consistently well on all four outcomes and a great deal of heterogeneity was noted. High quality, better reported, longer-term RCTs sufficiently powered for subgroup analysis are needed.

.....

## OS.254 Are HTAs Biased When Evaluating High-Cost Drug Combinations?

**DESCRIPTION:**

Drug manufacturers are increasingly releasing innovative combination therapies. This raises the question of whether payers will evaluate a combination of two high-cost, branded drugs differently than a high-cost drug reviewed alone or in combination with other non-high-cost, or non-branded therapies. Though we know that cost is

always a factor, is the fact that two high-cost drugs are being reviewed instead of just one creating a bias in HTA evaluations?

**AUTHORS:**

Rachel Jao, Craig J. Gibson, Daniel Liden

**BACKGROUND AND OBJECTIVES:**

Drug manufacturers are increasingly releasing innovative combination therapies. This raises the question of whether payers will evaluate a combination of two high-cost, branded drugs differently than a high-cost drug reviewed alone or in combination with other non-high-cost, or non-branded therapies. Though we know that cost is always a factor, is the fact that two high-cost drugs are being reviewed instead of just one creating a bias in HTA evaluations?

**METHODS:**

Data from 2005-2015 were included in this analysis for the following HTA agencies: SMC, NICE, pCODR, CCO, CADTH, G-BA, HAS, and PBAC. Four high-cost, branded combinations were reviewed by at least one of the above agencies: idelalisib + rituximab; lapatinib + trastuzumab; pertuzumab + trastuzumab; and trametinib + dabrafenib. The reimbursement decision rates for each high-cost combination were calculated (for each agency and across all agencies) and compared to the decision rates of the same drugs reviewed alone or in combination with non-high-cost therapies. Any discussions in the HTA reviews around the overall cost of the combination and around lower cost alternatives (specifically, whether regimens/ combinations with a single high-cost agent were highlighted because they were lower cost) were noted.

**RESULTS:**

The results show that high cost drugs reviewed alone or with non-high-cost therapies receive positive decisions at a slightly higher rate than high-cost combinations. However, this association was not statistically significant (p=.457). The

overall negative decision rate for the four high-cost combinations was 29% (6/21) compared to 18% (20/112) for drugs reviewed alone or with non-high-cost therapies. The negative decision rate for each combination are as follows: idelalisib + rituximab: 13% (1/8); lapatinib + trastuzumab: 100% (1/1); pertuzumab + trastuzumab: 33% (3/9); and trametinib + dabrafenib: 33% (1/3). There were only two instances (PBAC for pertuzumab + trastuzumab and pCODR for trametinib + dabrafenib) in which there was a discussion around the cost of the combination. For PBAC, recommendation of the combination was dependent on the improved cost-effectiveness of trastuzumab alone. For pCODR, it was explicitly mentioned that the price of the combination was a key driver of cost-effectiveness estimates and that a reduction in price would be required to improve this.

**CONCLUSIONS:**

As more high-cost combinations are introduced, it will be crucial for manufacturers to understand the factors behind payer decisions in order to gain patient access successfully and faster. Our results suggest that despite the additional budget burden of using two high cost agents in combination, there is no difference in the rate of positive decisions. This is interesting given the stated emphasis placed on cost by many of the selected HTA agencies, and may reflect a recognition of the additional benefits offered to patients by these combination therapies. Further data is required to accurately measure the impact of high-price combinations on HTA decision-making. As more high-cost combinations are reviewed by HTA agencies, further research will focus on the influence of other variables such as appropriate comparator, survival benefit, and patient populations.

.....

## OS.255 Does HTA Share Their Clinical Evidence Sources?

**DESCRIPTION:**

This research focuses on the clinical trials cited by the HTA documents. The goal is to assess how often agencies used a nonspecific study name, and to see if this more common in certain disease areas or agencies. This should highlight where there is room for improvement in scientific waste.

**AUTHORS:**

Emily Rubinstein, Judith Rubinstein, Rachel Sliman, Lorraine Versoza, Mitchell Smith

**BACKGROUND:**

Increasingly there is an emphasis for more transparency in health technology assessments (HTAs); this is seen in initiatives such as EUnetHTA and conferences such as this one. This focus is particularly important when it comes to transparency within the assessments themselves. Since there are only a few pivotal trials used across the regulatory bodies and HTA bodies, the same evidence is used several times over. Knowing which specific trial is used helps removes waste in the HTA system and allows for clearer decision-making across all HTA bodies. This is particularly important to countries that are setting up HTAs, knowing the data used to reach a decision can help them to understand how decisions were reached.

**OBJECTIVES:**

This research focuses on the clinical trials cited by the HTA documents. The goal is to assess how often agencies used a nonspecific study name, and to see if this more common in certain disease areas or agencies. This should highlight where there is room for improvement in scientific waste.

**METHODS:**

One thousand, six hundred and twenty-five indication specific HTA reviews, from 2009-2015 for 50 disease conditions, were used for this

analysis. The agencies included were NICE, SMC, HAS, IQWiG, G-BA. For HAS and IQWiG the English translations provided by the agency were used. For G-BA an abbreviated Context Matters' translation was used. Studies were considered unnamed if they were referred to by the review by names such as: Study 1, Phase III Trial, Dual therapy trial, Active control trial, Observational study. Pooled analysis was removed from the sample, as it was assumed it was specific to the agency's population.

**RESULTS:**

A total of 8418 unique clinical trial outcomes match the 1625 HTA review items; of this 1271 or 15% have unnamed trials. Pooled analysis made up 1324 (15.7%) clinical trial outcomes. These were removed from the denominator (now 7094) for the rest of the analysis, making the percentage of unnamed studies 18% or almost one in five trials. Only 11 of the 50 disease conditions do not have unnamed trials. SMC has the most disease conditions (32), and the highest percentage of unnamed reviews (29). This in stark contrast to IQWiG, where only Breast Cancer has unnamed studies, for less than 1% of the reviews in total.

**CONCLUSIONS:**

Clinical trials serve as the backbone in the lifecycle of the drug; this remains true for a drug during HTA. HTA documents rely on the studies submitted by the manufacturer to make a decision. It is important that they are clearly stated in the HTA documents. Doing this will lead to a clearer understanding of where data came from, and it can help inform the future HTA. The agencies in this analysis are considered bellwether agencies; their influence carries outside their borders. It is imperative that they lead the way in transparency.

.....

## OS.258 Assessment Of The Value Of Telemedical Monitoring Of Diabetic Foot Ulcer Patients

**DESCRIPTION:**

In 2012, a national implementation of telemedical monitoring of patients with diabetic foot ulcer was initiated in Denmark. The purpose of the implementation was to improve the quality of care and reduce the number of outpatient visits and the costs per patient. The aim of this presentation is to describe the results from this HTA of a new innovative health technology based on MAST (Model for Assessment of Telemedicine).

**AUTHORS:**

Mette Bøg Hørup, Kristian Kidholm, Lise Kvistgaard Jensen, Benjamin S. Rasmussen, Knud Bonnet Yderstræde

**BACKGROUND AND OBJECTIVES:**

In 2012 a national implementation of telemedical monitoring of patients with diabetic foot ulcer was initiated in Denmark. The intervention included improving the skills of the municipality wound nurses and improving the possibilities of the nurses to communicate with hospitals physicians regarding the treatment of the specific patient. This was made possible by use of an IT-system called plejenet.dk in which municipality nurses could register the treatment of patients with diabetic foot ulcers and submit questions and pictures of the ulcers to hospital physicians.

The purpose of the implementation was to improve the quality of care and reduce the number of outpatient visits and the costs per patient.

In relation with this national implementation a health technology assessment of the value of the telemedicine intervention was also planned. The aim of this presentation is to describe the results from this HTA of a new innovative health

technology based on MAST (Model for Assessment of Telemedicine).

## **METHODS:**

MAST - Model for Assessment of Telemedicine - was used as a framework for the HTA. This includes assessment of safety, clinical effectiveness, patient perception and economic and organisational aspects, Kidholm et al. (2012).

The assessment is based on a randomised controlled trial (RCT) with 374 patients, data from public registers, a number of studies patient perception and interview and survey studies with a sample of 418 health professionals of the perception of clinical staff in hospitals and municipalities in the five regions in Denmark.

The clinical study is published in Rasmussen et al. (2015a) and one the organisational studies are described in Rasmussen et al. (2015b).

## **RESULTS:**

The assessment has demonstrated the following outcomes of the telemedicine intervention:

**Safety:** The IT system plejenet.dk has been used in treatment of more than 1000 patients and has a high degree of technical reliability.

**Clinical impact:** The RCT showed that the telemedicine patients have a reduced number of outpatient visits and the same clinical outcomes with regards to wound healing and amputation rate.

**Patient perception:** Studies of patient perception shows that the patients have a high degree of satisfaction because of the improved collaboration between municipalities and hospitals and the time saved for transportation.

**Economics:** Based on the RCT the reduction in the costs per patients by use of telemedicine was estimated to between \$400 and \$3000.

**Organization:** Results from interviews and surveys indicate that the project has led to increased skills of the municipality nurses. Communication

between primary and secondary health care is also improved.

## **CONCLUSIONS:**

The assessment of the of the national implementation of telemedical monitoring of patients with diabetic foot ulcer demonstrates a number of benefits for patients, the clinical staff and the economy of the health care sector.

Even though the intervention is implemented in all regions, the assessment has also demonstrated a number of differences in the degree of implementation of the telemedicine intervention in the five regions in Denmark and not all regions are using all facilities of the intervention. Therefore improved benefits are still possible by a more consistent implementation in all regions.

## **REFERENCES:**

KIDHOLM, K., EKELAND, A. G., JENSEN, L. K., RASMUSSEN, J., PEDERSEN, C. D., BOWES, A., FLOTTORP, S. A. & BECH, M. 2012. A model for assessment of telemedicine applications: MAST. *Int J Technol Assess Health Care*, 28 (1), 44-51.

RASMUSSEN, B. S., FROEKJAER, J. & BJERREGAARD, M. R. 2015a. A Randomized Controlled Trial Comparing Telemedical and Standard Outpatient Monitoring of Diabetic Foot Ulcers. *Diabetes Care*.

RASMUSSEN, B. S., JENSEN, L. K., FROEKJAER, J., KIDHOLM, K., KENSING, F. & YDERSTRAEDE, K. B. 2015b. A qualitative study of the key factors in implementing telemedical monitoring of diabetic foot ulcer patients. *Int J Med Inform*, 84 (10), 799-807.

## OS.261 Priority Setting In HIV/ AIDS Control In Indonesia

### DESCRIPTION:

An integration of the Multi Criteria Decision Analysis (MCDA) and Accountability for Reasonableness (AFR) frameworks may have potential to improve priority setting processes in health through the use of multiple criteria and engagement of all relevant stakeholders. This study describes the first time implementation of the MCDA-AFR approach to develop the five-years (2014-2018) HIV/AIDS strategic plan for West Java province in Indonesia.

### AUTHORS:

Noor Tromp, Rozar Prawiranegara, Adiatma Siregar, Rudi Wisaksana, Lucas Pinxten, Juul Pinxten, Arry Lesmana, Scott Maurits, Deni Sunjaya, Gert Jan van der Wilt, Rob Baltussen

### BACKGROUND AND OBJECTIVES:

Various methods have been used to guide priority setting in health but have been criticized for being rather technocratic, not sufficiently pragmatic and not process orientated. Recently, an integrated approach was proposed that combines the Multi Criteria Decision Analysis (MCDA) and Accountability for Reasonableness (AFR) frameworks. We describe the first time implementation of the MCDA-AFR approach to develop the five-years (2014-2018) HIV strategic plan for West Java province in Indonesia.

### METHODS:

A project team (n=5) was formed that implemented the following steps between January and October 2013: 1) formation of a stakeholders' consultation panel, 2) definition of criteria for priority setting, 3) assessment of performance of interventions, 4) arrangement of a deliberative process on priorities, 5) implementation of rationing decisions and evaluation. The approach was evaluated using indepth interviews with the members of the consultation panel.

### RESULTS:

First, a consultation panel (n=23) was formed of policy-makers, West Java AIDS commission's program managers, community organizations' staff, health care workers and researchers. Second, the panel selected four criteria for priority setting: an intervention's 1) impact on the epidemic, 2) impact on reducing stigma in society, 3) cost-effectiveness, and 4) contribution to universal access. Third, the panel proposed 50 interventions and data was collected on their performance on the four criteria. Fourth, after a deliberative process the panel agreed that HIV testing and treatment packages were the most attractive intervention to scale while mitigation activities were least attractive. Fifth, funding and implementation agencies were identified for the most attractive interventions.

### CONCLUSIONS:

Compared to previous processes, this approach improved the transparency, the use of evidence and stakeholder engagement in priority setting in HIV control. Main challenges were the availability of data and existing structures like the influence of donors and a missing direct link to funding of the prioritized interventions. To further improve the combined MCDA-AFR approach we propose to incorporate an situational analysis and to develop better methodological guidelines for its application.

---

## OS.268 Priority Setting For Universal Health Coverage In Thailand

### DESCRIPTION:

Civil society organizations, patients associations and lay citizens are engaged in coverage policy-making processes of the largest health scheme in Thailand. This study suggests that although these civic groups had limited technical capacity and most of their proposed interventions were not adopted, they made significant contributions as their proposals raised policy awareness on health

service delivery problems which affect health of the entire population.

#### **AUTHORS:**

Sripen Tantivess, Suradech Duangtipsirikul, Kumaree Pachanee

#### **BACKGROUND AND OBJECTIVES:**

Established in 2002, Thailand's Universal Coverage Scheme (UCS) offers health services to 50 million people (75% of the population). From 2009 the Scheme has introduced a program to ensure that its benefit package development is transparent, participatory and based on evidence. As such, academics, health professionals, industry, policymakers, civil society organizations, patients associations and lay citizens are engaged in topics submission and selection, assessment and appraisals. This study examines the role of civic participation in the policy-making processes.

#### **METHODS:**

This research was conducted in September and October 2015. We reviewed relevant documents such as research reports and meeting minutes. Respective information was also retrieved from the program's database. Quantitative and qualitative approaches were employed in the data analysis.

#### **RESULTS:**

During 2009-2015 the three civic groups submitted 42 topics, most of which involved interventions for screening/diagnosis (31%) and treatment (29%). Sixteen topics (38%) were selected, by a working group comprising representatives of key stakeholders, for further assessments. By October 2015, assessment results, mainly cost effectiveness and budget impact, of 6 interventions had been appraised by the UCS Benefit Package Committee, and only device for self-monitoring of blood glucose and ambulance service to transfer in-patients to receive home-based palliative care were adopted as new benefits. It was also found that the civic groups had limited technical capacity. However, their proposals were unique in two

aspects: many interventions aimed for addressing health needs of the poor and other vulnerable, while other proposals drew attentions of policymakers to the issues of inequity, low quality and inadequate coordination in the service delivery system. Apparently, the UCS manager was assigned to take proper actions.

#### **CONCLUSIONS:**

Civic participation significantly contributed to Thailand's universal health coverage policy, as the non-expert actors raised policy awareness not only on the demand of their networks, but also on existing problems which affect health of the entire population.

---

## **OS.269 Future Elderly Care In China, How Should It Be? Aspects From The Chinese Youngsters In Guangzhou**

#### **DESCRIPTION:**

The Chinese healthcare system is at a crossroads of the history. Multiple challenges are encountered due to the demographic changes. The aim of this study was to investigate the aspects of the Chinese youngsters on the future elderly care system. A significant social-cultural consciousness difference of youngsters on elderly care was found between China and other parts of the world.

#### **AUTHORS:**

Hao Cai, Yanguang Cai, Yingshan Tao, Hongxia Chen, Ruihuan Pan, Leying Zhu, Ole Hejlesen

#### **BACKGROUND AND OBJECTIVES:**

The Chinese healthcare system is at a crossroads of the history (1,2). On one hand, the traditional way of delivering healthcare service by family members is crumbling due to the 'one child policy' (3-5). On the other hand, the aging population in China is rising rapidly (6-8). It is estimated that by the year

2020, citizens over 60 in China will be over 15% (9). It is thereby urgent to identify new healthcare delivery model with economical sustainability. In this scenario, aspects from the Chinese youngsters are becoming critical to be known (10). This particular age group is expected to afford most of healthcare expenses in the coming years. Hereby, the aim of this study was to investigate the aspects of the Chinese youngsters on the future elderly care system.

## **METHODS:**

500 questionnaires were distributed to the undergraduate student from a university in Guangzhou. The age variance is between 18 and 25. 384 questionnaires were received with the response rate of 76.8%. 376 were recognized as valid answers. The criterion of recognition is 100% completeness of answers in all sections. The questionnaire contains topics concerning from overall perspective on the Chinese healthcare system to themes in relation to elderly care. SPSS 23.0 were used for the analysis.

## **RESULTS:**

In the situation when social security mechanism cannot provide enough financial support to parents, 82.6% of the respondents have chosen the option of 'try everything to help'. When asking about preferable eldercare delivery model, 64.4% of the respondents chose 'living and taking care by families'. 21.4% have chosen 'district nursing' and 14.2% chose 'nursing home'. At the third section, in terms of youngsters' attitudes on the new technology, 17% of the respondents are very much willing to use the new technology. 69.8% remained moderate, and the rest are holding negative attitudes. Regarding the financial support of the future Chinese healthcare system, 13.6% of the respondents voted for 'tax', and 16.6% chose 'insurance', 8.8% chose 'family support', and all the others chose 'a hybrid system combing both tax and insurance'. When asking about the most important principle of the healthcare system, 24.2% supported 'free of charge', 37.8% were leaning against 'universal', and the rest voted for 'effective

and efficiency'. In the last section, when asking about the most critical issue to be addressed in the current Chinese healthcare system, 42% of the respondents chose 'expensive', 13.4% voted on 'long waiting time', 17.2% were on 'inequality between urban and rural area', and the rest chose 'none of them above'.

## **CONCLUSIONS:**

These results indicated a significant social-cultural consciousness difference of youngsters on elderly care between China and other parts of the world. It is suggested that in the future health technology design and assessment, designers and researchers should realize these differences to better serve the need of local community. The result is also argued to be generalized in countries as Korea or Japan, which sharing same social-cultural origins as China (11,12).

## **REFERENCES:**

1. Yip W, Hsiao WC. Market watch - The Chinese health system at a crossroads. *Health affairs*. 2008;27(2):460-8.
2. Dong Z, Phillips MR. Evolution of China's health-care system. *The Lancet*. 2008;372(9651):1715-6.
3. Zhang Y, Goza FW. Who will care for the elderly in China?: A review of the problems caused by China's one-child policy and their potential solutions. *Journal of Aging Studies*. 2006;20(2):151-64.
4. Deutsch FM. Filial piety, patrilineality, and China's one-child policy. *Journal of Family Issues*. 2006;27(3):366-89.
5. Li X, Zhang W. The impacts of health insurance on health care utilization among the older people in China. *Social Science & Medicine*. 2013;85:59-65.
6. Feng ZL, Liu C, Guan XP, Mor V. China's Rapidly Aging Population Creates Policy Challenges In Shaping A Viable Long-Term Care System. *Health affairs*. 2012;31(12):2764-73.

7. Peng XZ. China's Demographic History and Future Challenges. *Science*. 2011;333(6042):581-7.
8. Cai F, Du Y. The Social Protection System in Ageing China. *Asian Economic Policy Review*. 2015;10(2):250-70.
9. The national office on elders. The prediction of aging population trend in China: Xinhuanet; 2006 [cited 2015 28 October]. Available from: [http://news.xinhuanet.com/video/2006-10/11/content\\_5467909.htm](http://news.xinhuanet.com/video/2006-10/11/content_5467909.htm). [Chinese]
10. Tsai H-H, Chen M-H, Tsai Y-F. Perceptions of filial piety among Taiwanese university students. *Journal of Advanced Nursing*. 2008;63(3):284-90.
11. Chen M. *Asian Management Systems*, 2nd ed. London: Cengage Learning EMEA; 2004.
12. Markus HR, Kitayama S. The cultural psychology of personality. *Journal of Cross-Cultural Psychology*. 1998;29(1):63-87.

---

## OS.275 Coverage With Evidence Development: Routine Activities Needed To Improve Quality Of Data Gathered

### DESCRIPTION:

This abstract proposes methodology to improve the quality of observational data through activities we call active surveillance. We demonstrate that active surveillance can enhance treatment register data and increase their value in CED decision-making. Active surveillance would support the objectives of STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) group by additionally driving quality prospectively.

### AUTHORS:

Hannah Patrick, David Glynn, Bruce Campbell, Mirella Marlow

### BACKGROUND AND OBJECTIVES:

Coverage with Evidence Development (CED) provides for funding of health technology conditional on gathering data through a clinical trial or registry designed to determine effectiveness and identify rare adverse events. CED has been used worldwide with varying success. Academic rigor of treatment registers has been criticised for their poor quality of data due to inadequate coverage and incompleteness but good quality observational data could be a powerful tool for CED because they have potential to reduce uncertainty around treatment costs, prevalence, safety, natural history and provider experience.

We report on efforts to improve the quality of observational data from treatment registers using activities which we call active surveillance (proactive monitoring of the quality and coverage of data submitted to a register and regular communication with those submitting data, with a view to improving its quality).

### METHODS:

Active surveillance has five aspects:

1. Establishing a management structure

Steering group members demonstrate their independence by declaring all possible conflicts of interest.

2. Agreeing a mandatory data subset

A 'mandatory' subset of the full data set should include only the most important items and become the focus of subsequent close monitoring and action where gaps persist.

3. Preventing and monitoring incoherent entries

The database should be user-friendly with rules inbuilt software rules to discourage nonsense entries. Clinical specialists review face validity of data and prompt enquiries to data submitters.

4. Motivating those submitting data

High quality data submission is encouraged by regular feedback to participants.

#### 5. Triangulation and data linkage of register data to external data sources

Triangulation and linkage of register data to other databases collecting information on the target population may be used to identify cases missed by the register and supplement outcomes.

#### **RESULTS:**

Case study: In 2009, the National Institute of Health and Care Excellence (NICE) published guidance on negative wound pressure in the management of the open abdomen (a technique used for complex intra-abdominal problems that make closure difficult, e.g. severe sepsis). The project Advisory Committee considered the evidence on safety inadequate, recommending that hospitals using the procedure they should make special arrangements for clinical governance and data collection. A national audit of management and outcomes of open abdomen in the UK was organised but the clinical event is rare and patients present acutely in both specialist units and general hospitals. In order to alert hospitals to the presence of patients on their wards for whom data submission was necessary, registry data were triangulated against those in a database maintained by the Intensive Care National Audit and Research Centre (ICNARC). Data validation was undertaken by academics and specialist clinicians who identified clinically questionable entries and communicated with hospital staff to verify the information.

#### **CONCLUSIONS:**

The study yielded the largest independent survey of management of the open abdomen ever reported, was published in 2013 and informed review of national guidance.

Use of active surveillance would improve the quality of observational data and thereby increase their value as an adjunct to clinical trial data when making decisions about the use of healthcare interventions.

---

## OS.279 Bronchial Thermoplasty (BT)

#### **DESCRIPTION:**

There was limited good level of evidence to suggest that treatment with BT in moderate and severe asthma was safe and effective in improving quality of life and reducing exacerbations. Bronchial thermoplasty should be considered as a complex interventional bronchoscopy and should only be utilised in selected patients by privileged pulmonologists in accredited centres. Registry of patients undergoing BT should be maintained.

#### **AUTHORS:**

Junainah Sabirin, Rugayah Bakri, Zalina Ahmad

#### **BACKGROUND AND OBJECTIVES:**

In asthmatic, chronic remodeling of the airways increased airway smooth muscle mass. It was reported that 12.0% of adult asthmatic in Malaysia has moderate persistent asthma and 8.3% had severe persistent asthma. Bronchial thermoplasty (BT), a novel device-based approach to treat severe persistent asthma was developed to reduce abnormal increase in airway smooth muscle mass. The review was requested to assess the feasibility of introducing the technology in government hospitals in Malaysia. The objective of this systematic review was to assess the safety, efficacy, economic and organizational implication of BT as a complement to existing asthma medications for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids (ICS) and long-acting  $\beta_2$ -agonists (LABA).

#### **METHODS:**

Studies were identified by searching electronic databases through the Ovid interface, and PubMed. The last search was run on 10 February 2014. Relevant literature was appraised using the Critical

Appraisal Skills Programme (CASP) and graded based on guidelines from the U.S./Canadian Preventive Services Task Force.

**RESULTS:**

A total of 303 titles were identified through Ovid interface and PubMed. Based on inclusion and exclusion criteria, seven articles were included in the review: one Horizon scanning report, one systematic review and meta-analysis, four Randomised Controlled Trials (RCTs), and a follow-up study of one RCT. There was limited good level of evidence to suggest that treatment with BT in moderate and severe asthma was safe. However, BT was associated with an increased in the frequency of adverse respiratory events and hospitalisations for adverse respiratory events during the period immediately after treatment. In the post treatment period (six to 52 weeks after the last BT procedure), there was no increase in adverse respiratory events and hospitalisations for adverse respiratory events.

There was limited good level of evidence to suggest that BT improved Asthma Quality-of-Life Questionnaire (AQLQ) scores, Asthma Control Questionnaire (ACQ) scores, symptom-free days, morning peak expiratory flow (PEF), fewer days lost from work / school or other activities due to asthma, and reduced exacerbations. The forced expiratory volume in 1 second (FEV1) values remained stable between year one and year five after BT.

There was no retrievable evidence on cost-effectiveness.

More evidence is required on the safety and effectiveness of the procedure in the long term (> than five years).

**CONCLUSIONS:**

Bronchial thermoplasty should be considered as a complex interventional bronchoscopy and should only be utilised in selected patients by privileged pulmonologists in accredited centres. Registry of patients undergoing BT should be maintained.

.....

.....

## OS.288 The Consideration Of Values In Developing Quality Standards: Emerging Issues And Challenges

**DESCRIPTION:**

A systematic, thematic review of quality standards identified explicit and implicit values used in decision making. Emerging challenges include a more formal consideration of the resource impact of quality standards. Understanding the role of value judgements can support consistently application across different health- or social care-related decision problems, and the relevance of quality standards to the care system.

**AUTHORS:**

Tony Smith, Gillian Leng

**BACKGROUND AND OBJECTIVES:**

Quality standards describe high quality health and social care where a need for quality improvement has been identified. They are aspirational yet must be achievable and measurable by health and social care commissioners and providers. Quality standards are drawn from evidence-based guidance, usually developed in the context of social values judgements that underpin the work of our guideline development programmes. The aim of this study was to understand the use of values by the committees that develop quality standards, and to inform the transparent and consistent application of values within future quality standards.

**METHODS:**

A systematic, thematic review of explicit and implicit value judgements in recent quality standards (informed by stakeholder and service user participation) was undertaken. Themes included steps on care pathways, care settings and types of commissioner from different public sector agencies. We reviewed governmental and societal expectations of our programme, including the social value judgements that inform decisions

about effectiveness and cost-effectiveness in our source guidelines. These recognise the mismatch between demands and available resources, and the need to allocate limited resources fairly.

**RESULTS:**

We identified explicit values shared with our guideline development programmes, and other types of judgements that may be classified in terms of values. We identified emerging challenges where a more explicit approach to the consideration of values alongside evidence is necessary. These include ensuring that quality standards are relevant to a sustainable health and social care system working in the context of demographic changes (such as population ageing, comorbidities and the use of multiple medicines), public health challenges (such as obesity and antimicrobial stewardship) and the need to ensure best use of scarce resources while supporting innovative and developmental practice.

**CONCLUSIONS:**

The quality standards programme should continue to evolve to deliver products that are relevant to population health and wellbeing, and which contribute to improvements in overarching national outcomes relating to premature mortality, chronic and acute care, patient experience, patient safety, healthy lifestyles and wellbeing. The programme can contribute to driving quality improvements in key policy areas, but must ensure its recommended actions are achievable locally in the context of financial pressures. The systematic, thematic review of our use of values had limitations in scope, but the understanding we gained of the value judgements that are currently used to select quality standards from the wider array of evidence-based guideline recommendations will inform our next steps. Important among these will be a more formal consideration of the resource impact of our quality standards, and the need to focus on achievability in resource terms along with identifying opportunities for disinvestment. Only by understanding the role of value judgements in our process can we ensure that these are applied consistently to different

health- or social care-related decision problems.

**OS.289 Safety And Effectiveness Of Irreversible Electroporation In Pancreatic Cancer: A Systematic Review**

**DESCRIPTION:**

Irreversible electroporation (IRE) is a novel ablation modality to non-thermally cure soft tissue tumors. This study was systematically reviewed the safety and effectiveness of IRE in pancreatic cancer. IRE seems promising technology, but more evidences are needed to justify its routine clinical use for treating pancreatic cancer.

**AUTHORS:**

Ah Ram SUL, Jin Hyeong KIM

**BACKGROUND AND OBJECTIVES:**

Irreversible electroporation (IRE) is a novel ablation modality to non-thermally cure soft tissue tumors. This technique uses short electrical fields to make irreversible nanopores in the cell membrane, to disrupt the cellular homeostasis. IRE causes apoptosis to induce cell deaths, but the other thermal ablation procedures lead to necrosis. IRE can be utilized in regions where precision and conservation of the extracellular matrix, blood flow and nerves are primarily required. Because it may selectively damage the cancerous cells, IRE is expected to provide more targeted therapy.

Because IRE is initially introduced in Korea, it is mandatory to undergo New Health Technology Assessment based on Article 55 of the Korean Medical Services Act. The purpose of this research was to evaluate the safety and effectiveness of IRE for treating pancreatic cancer.

**METHODS:**

To perform a systematic review of evidence on

the safety and effectiveness of IRE in pancreatic cancer, we conducted literature searches to identify relevant articles published until June 23rd, 2014. Ovid-MEDLINE, Ovid-EMBASE, The Cochrane Library and the international databases of health technology agencies were searched. The literatures on IRE for damaging pancreatic cancer were retrieved. Only human studies which reported appropriate outcomes were included. The SIGN (Scottish Intercollegiate Guidelines Network) methodology checklists were used for critical appraisal. After data extraction, descriptive analysis was carried out. All the review processes were developed and finalized in consultation with clinical experts and radiation oncologist, hepato-biliary-pancreatic surgeon, and vascular surgeon.

### RESULTS:

The search yielded 662 articles, 6 studies (1 cohort study, 4 case series, and 1 case report) of which met our inclusion criteria. Concerning safety issues, there were no reported treatment-related deaths or serious complications. Effectiveness outcomes were reported in 6 articles. Using IRE, complete ablation rates of locally advanced pancreatic cancer in two relatively large-scale studies were 94.4% (51/54) and 96.3% (26/27), respectively. Recurrence rates after IRE ranged between 0 and 27.8% in pancreatic cancer. In one study, when IRE was applied in combination with standard therapy (chemotherapy and radiotherapy), survival of locally advanced pancreatic cancer was significantly improved.

### CONCLUSIONS:

Based on the current findings, we concluded that IRE seems promising treatment options. It is potentially beneficial method because it can be employed to the region adjacent to critical structures.

However, there was insufficient evidence, both quantitatively and qualitatively, to clarify the safety and effectiveness of IRE in the management of pancreatic cancer. It was concluded that this procedure was in an experimental stage for the

specified indication. More evidences are required to consider this technique in the routine clinical use.

### REFERENCES:

1. Bagla S, Papadouris D. Percutaneous irreversible electroporation of surgically unresectable pancreatic cancer: a case report. *Journal of Vascular Interventional Radiology* 2012; 23: 142-145.
2. Dunki-Jacobs EM, Philips P, Martin RC 2nd. Evaluation of resistance as a measure of successful tumor ablation during irreversible electroporation of the pancreas. *Journal of the American College of Surgeons* 2014; 218: 179-187.
3. Månsson C, Bergenfeldt M, Brahmstaedt R, Karlson BM, Nygren P, Nilsson A. Safety and preliminary efficacy of ultrasound-guided percutaneous irreversible electroporation for treatment of localized pancreatic cancer. *Anticancer Research* 2014; 34: 289-293.
4. Martin RC 2nd, McFarland K, Ellis S, Velanovich V. Irreversible electroporation in locally advanced pancreatic cancer: potential improved overall survival. *Annals of Surgical Oncology* 2013; 20: S443-S449.
5. Martin RC 2nd, McFarland K, Ellis S, Velanovich V. Irreversible electroporation therapy in the management of locally advanced pancreatic adenocarcinoma. *Journal of American College of Surgeons* 2012; 215: 361-369.
6. Narayanan G, Hosein PJ, Arora G, Barbery KJ, Froud T, Livingstone As, Franceschi D, Rocha Lima CM, Yrizarry J. Percutaneous irreversible electroporation for downstaging and control of unresectable pancreatic adenocarcinoma. *Journal of Vascular and Interventional Radiology* 2012; 23: 1613-1621.

## OS.294 Drivers Of Value In Medical Device Evaluation. What Makes For A Positive Recommendation?

### DESCRIPTION:

A qualitative study of positive medical device guidance from UK NICE identifying the primary factors that influenced the decision to recommend. We created a framework to capture these drivers for each individual technology to provide a summary of that devices value to patients and the NHS.

### AUTHORS:

Susan Peirce, Alisatair Ray, Grace Carolan-Rees

### BACKGROUND AND OBJECTIVES:

The UK National Institute for Health and Care Excellence (NICE) publishes Medical Technologies Guidance (MTG) which are evaluations of single medical technologies (devices or diagnostics). A scope document defines the boundaries of the evaluation and the claims for the product. The manufacturer produces a review of published evidence and cost-consequence economic model, which are scrutinised by experts in medical device evaluation. These submissions are then reviewed by an independent committee (Medical Technologies Advisory Committee, MTAC). To achieve a positive recommendation in the published guidance a device must be both clinically effective and cost-neutral or cost-saving in comparison to current 'standard care'. A wide variety of device types have been through this process since its inception in 2010. The purpose of this project was to determine whether the factors that drive a positive recommendation could be identified and generalised, and to provide an easy-to-use overview of the value of the technology to the NHS. In this context traditional HTA measures of value, such as QALYs and ICERs, are not appropriate. Drivers of value were defined as outcomes from device use that are beneficial to payer, user, patient

or society and that the committee relied on most in making its adoption recommendation.

### METHODS:

Ten MTGs with a positive recommendation (December 2010 to January 2013) were subjected to inductive thematic analysis. Drivers of value were extracted, grouped and categorised. The categories were used to create a framework: a generic table that could be used to summarise the clinical and economic outcomes of device use. Iterations of framework development involved populating the table for each technology, discussion of differences and ambiguities, regrouping items, and refining the table. Validation of the framework (and instructions) was conducted by other analysts, and we sought feedback on the completed outputs from potential end-users: industry stakeholders and guidance users.

### RESULTS:

The categorisation of drivers of value was inevitably influenced by the MTG evaluation process and overall the factors were divided into 'clinical' and 'system' outcomes. Clinical drivers were: clinical effectiveness, performance characteristics of the technology, complications/adverse events and other patient benefits. The system drivers were: additional interventions, length of stay, medication, sustainability, key cost savings and 'other'. Two levels of support for the drivers were identified; published evidence, and an acceptance by MTAC of expert or patient opinion. The final framework was deemed to be a useful summary of the potential value of a device technology.

### CONCLUSIONS:

We conducted a review of positive guidance to identify the drivers of value that resulted in a recommendation by NICE, and created a framework by which such evaluations could be summarised. The categories used in the framework are influenced by the conditions defined by NICE for a positive recommendation, the devices used to develop the framework and the documentation

of committee discussions in the MTG documents. However, we present this framework as a useful summary with which to quickly identify potential benefits from the adoption of a medical device, to be used as an adjunct to the MTG documents.

#### REFERENCES:

National Institute for Health and Care Excellence (2011) Medical Technologies Evaluation Programme Methods Guide

Campbell, B., & Campbell, M. M. (2012). NICE Medical Technologies Guidance. Applied health economics and health policy, 10(5), 295-297.

---

## OS.299 Strategic Reorganization Of A 10 Year Old Hospital-Based HTA Unit

#### DESCRIPTION:

This work aimed to adapt the hospital-based (HB) HTA unit located in Sherbrooke (Québec, Canada) to rapid changes in the field of HTA and to become more focused on the needs of policy makers.

#### AUTHORS:

Jean-Francois Fiset, Christian Bellemare, Thomas G. Poder, Suzanne K. Bédard, Sylvain Bernier

#### BACKGROUND AND OBJECTIVES:

In order to evaluate the impact of our recommendations, we conducted a descriptive and qualitative study in 2013. Generally speaking, beside a high level of satisfaction, results of this study and local consultation with managers pointed to improve our working methods. Moreover, members of the team realised also the need to change our philosophical approach as to be more inclusive in the scientific process. As a result, we decided to perform a review of all processes that led to the adoption of a revised strategic plan. This work aimed to adapt the hospital-based (HB) HTA unit

located in Sherbrooke (Québec, Canada) to rapid changes in the field of HTA and to become more focused on the needs of policy makers.

#### METHODS:

Several focus groups with all members of the HTA unit were conducted. Data from local consultation and results from the study assessing the impact of our recommendations allowed us to perform a SWOT analysis which enabled us to evaluate our Strengths, Weaknesses, Opportunities and Threats. These outcomes were then regrouped into strategic issues and subsequently strategic vision. In order to implement these actions, three major priorities were generated. Performance indicators were created for each priority. Measures will be taken annually over a 5 years period.

#### RESULTS:

The main weaknesses and threats were negative perception of the time required to perform an HB-HTA evaluation, lack of standardized processes and products and unawareness of the HTA unit among managers and physicians. Principal strengths and opportunities were good perceived credibility among clients, presence of a multidisciplinary team and high level of financial constraint in the hospital. Three strategic priorities resulted from this SWOT analysis: increase credibility (among non-users of HB-HTA), utility and visibility. We produced a standardized document for scoping meetings, two short products, a service agreement and a standardized review process of manuscripts to enhance our credibility. Work completed on utility has resulted in a new approach that involves participation of key stakeholders in the HTA process, specifically during the drafting of recommendations. In addition, our service offering now includes high technologies acquisition support. In order to increase the HTA unit's visibility, up to 20% of time is allocated for activities related to topics, such as scientific publications with peer reviews and local presentations. More work on credibility, utility and visibility is expected in the following months. Preliminary results suggest an improvement in our processes: satisfaction related

to the delay of production increased from 62% to 93%. Moreover, the return rate of clients rose from 37% to 72% and we noted an 18% increase in the number of evaluations.

### **CONCLUSIONS:**

Preliminary results suggest that our strategic reorganization strengthened our capacity to meet policy makers' needs and reinforce our abilities to performed HB-HTA. In times of high financial restraint, key decisions has to be taken towards actions that will improve the way we support policy makers' decisions in the allocation of quality care and services to patients.

---

## **OS.302 State Of Rare Disease Management In Southeast Asia**

### **DESCRIPTION:**

This study aims to examine the status of rare disease management in Southeast Asian countries. It will serve as the basis for a more active discussion on how countries in the region can address an under-recognised rare disease burden. This will improve the overall healthcare landscape of Southeast Asia.

### **AUTHORS:**

Asrul Akmal Shafie, Nathorn Chaiyakunapruk, Azuwana Supian, Jeremy Lim, Matt Zafra

### **BACKGROUND AND OBJECTIVES:**

Rare diseases, also referred to as orphan diseases, are characterised by their low prevalence with majority of them are chronically debilitating and life threatening. Given the low prevalence and the widely dispersed but very small patient base for each disease, there may often be a disproportion availability of treatments and resources to manage patients, spur research and train experts. This is especially true in Southeast Asian countries that are currently in the process of implementing or

revising their universal health coverage schemes. This study aims to examine the status of rare disease management in Southeast Asian countries. It will serve as the basis for a more active discussion on how countries in the region can address an under-recognised rare disease burden and enhance national and regional capacities.

### **METHODS:**

The study consists of literature reviews and key stakeholders interviews in six focus countries, including the Philippines, Singapore, Malaysia, Indonesia, Vietnam, and Thailand and five countries as best practice, comprising of France, Canada, Australia, Taiwan, and South Korea. Rare disease management initiatives across each country were examined based on the World Health Organization's framework for action in strengthening healthcare systems.

### **RESULTS:**

The results suggest rare disease management remains challenging across Southeast Asia, as many of the focus countries face fundamental issues of basic healthcare systems, governance, patient advocacy and awareness, clinical expertise and patient management, funding and newborn screening of rare disease. There are only a limited number of genetic specialists where Thailand has only 22 geneticists available to serve the whole population of 67 million people, with most of them located in major cities. Due to limited funding, large majority of rare disease financing is through industry subsidisation, employer benefits, charitable work or out-of-pocket payment. However, treatment for Type 1 Gaucher disease received positive economic choice in Thailand despite 50 times greater than the cost-effectiveness threshold. The recently passed The Rare Disease Act of the Philippines 2015 has classified rare diseases patients as 'persons with disability', thus allowing patients to benefit from the statutory benefits provided for in the Republic Act 9442. Nonetheless, there are substantial improvement opportunities, including leveraging best practices from around the world

and organising a multi-stakeholder and regional approach and strategy.

## CONCLUSIONS:

Generally, Southeast Asian countries have made significant progress in the management of rare disease, but there remain key areas for substantial development opportunities. Ultimately, if the focus countries work together to manage rare diseases, the region will see an improvement of patient outcomes through better funding and community support, leading to a better understanding of rare disease patient needs and how to improve their daily experiences. This in turn will also improve the overall healthcare landscape of Southeast Asia.

## REFERENCES:

1. Institute of Medicine (US) Committee on Accelerating Rare Diseases Research and Orphan Product Development, Accelerating research and development, in Rare diseases and orphan products, M.J. Field and T.F. Boat, Editors. 2010, National Academies Press (US): Washington (DC).
2. Kaplan, W., et al., Priority medicines for Europe and the world - 2013 update. 2013, WHO Library.
3. Health Grades. Statistics by country for rare diseases. Right diagnosis 2015 [cited 2015 21 September]; Available from: [http://www.rightdiagnosis.com/r/rare\\_diseases/stats-country.htm](http://www.rightdiagnosis.com/r/rare_diseases/stats-country.htm).
4. Cho, B.-K. and T. Tominaga, Moyamoya disease update. 1 ed. 2010, Japan: Springer. 387.
5. The Economist Intelligence Unit, The shifting landscape of healthcare in Asia-Pacific, in The Economist insights. 2015.
6. World Health Organization Regional Office for South-East Asia, Health situation in the South-East Asia Region 2001-2007, W.H. Organization, Editor. 2008, World Health Organization.
7. European Organisation for Rare Disease Rare diseases: understanding this public health priority. 2005.
8. America, S.a.H.o.R.o.t.U.S.o., Orphan Drug Act. 1983: USA.
9. Thorat, C., et al., What the Orphan Drug Act has done lately for children with rare diseases: a 10-year analysis. *Pediatrics*, 2012. 129(3): p. 516-21.
10. Administration, D.o.H.a.H.S.F.a.D., Improving the Prevention, Diagnosis, and Treatment of Rare and Neglected Diseases. 2011.
11. World Health Organization, Strengthening health system to improve health outcomes: WHO's framework for action. 2007.
12. An act promulgating a comprehensive policy on needs of persons afflicted with rare disorders. 2015.
13. The magna carta for disabled persons, and for other proposes, in 9442. 2006.
14. Ministry of Health Malaysia, Malaysian National Medicines Policy 2012. 2012.
15. Attorney-General's Chambers Singapore, Medicines (Orphan Drugs) (Exemption) Order 1991, in GN No. S 470/1991, Attorney-General's Chambers Singapore, Editor. 2005 (Revised Edition): Singapore.
16. Pacific Bridge Medical, Orphan Drugs in Asia 2014. 2014. p. 151.
17. Ho Chan, W.S., Taiwan's healthcare report 2010. *Epma j*, 2010. 1(4): p. 563-85.
18. Angara, E.J., Rare diseases act of The Philippines. 2009.
19. Rare Disorders Society Singapore. Rare disorders. 2011 [cited 2015 6th July]; Available from: <http://www.rdss.org.sg/about-us/>.
20. Malaysian Rare Disorders Society. Rare diseases. 2013 [cited 2015 6th July]; Available from: <http://www.mrds.org.my/>.
21. Philippine Society for Orphan Disorders. Rare Diseases. 2012 [cited 2015 6th July]; Available

from: <http://www.psod.org.ph/contact-us/>.

22. Rainbow Across Borders. About Rainbow Across Borders. 2015 [cited 2015 21 August ]; Available from: <http://rabasia.org/about.php>.

23. Rare Voices Australia. Rare Voices Australia. 2015 [cited 2015 28 November]; Available from: <https://www.rarevoices.org.au/page/7/our-purpose>.

24. Buske, O.J., et al., PhenomeCentral: A Portal for Phenotypic and Genotypic Matchmaking of Patients with Rare Genetic Diseases. *Hum Mutat*, 2015. 36(10): p. 931-40.

25. Malaysia, M.o.H., Guidelines for treatment of lysosomal storage diseases by enzyme replacement therapy in Malaysia. 2012.

26. Excellence, N.I.f.H.a.C., The guidelines manual. 012, National Institute for Health and Clinical Excellence: London.

27. Kanters, T.A., et al., Cost-effectiveness of enzyme replacement therapy with alglucosidase alfa in classic-infantile patients with Pompe disease. *Orphanet J Rare Dis*, 2014. 9: p. 75.

28. Teerawattananon, Y., et al., The use of economic evaluation for guiding the pharmaceutical reimbursement list in Thailand. *Z Evid Fortbild Qual Gesundhwes*, 2014. 108(7): p. 397-404.

29. Schey, C., T. Milanova, and A. Hutchings, Estimating the budget impact of orphan medicines in Europe: 2010 - 2020. *Orphanet J Rare Dis*, 2011. 6: p. 62.

30. Divino, V., et al., The budget impact of orphan drugs in the US: A 2007-2013 MIDAS sales data analysis, in 56th ASH Annual Meeting and Exposition. 2014.

31. Institute of Human Genetics. Newborn screening. 2012 [cited 2015 6th of July]; Available from: <http://ihg.upm.edu.ph/>.

32. Congress of the Philippines, Republic Act

No. 9288: An act promulgating a comprehensive policy and a national system for ensuring newborn screening, in 9288, R.o.t. Philippines, Editor. 2004: Metro Manila.

33. The World Bank, 2012 world development indicators. 2012, The World Bank: United States of America.

34. Leong, Y.H., et al., Expanded newborn screening in Malaysia. *Malaysian Journal of Medical Sciences* 2014. 21(2): p. 63-67.

35. Biochemical Genetics and National Expanded Newborn Screening Laboratory Newborn screening for IEMs. 2014 [cited 2015 6th July]; Available from: <http://www.kkh.com.sg/services/children/newbornscreeningiems/Pages/Home.aspx>.

36. Therrell, B.L., et al., Current status of newborn screening worldwide: 2015. *Semin Perinatol*, 2015. 39(3): p. 171-87.

37. Tangcharoensathien, V., et al., Health-financing reforms in southeast Asia: challenges in achieving universal coverage. *Lancet*, 2011. 377(9768): p. 863-73.

38. Medicines (Orphan Drugs) (Exemption) Order. 1991: Singapore.

39. Chan, W.S.H., Taiwan's healthcare report 2010. *European Association for Predictive, Preventive and Personalised Medicine (EPMA Journal)* 2010. 1: p. 563-585.

40. Taiwan Foundation for Rare Disorders. Rare disease control and orphan drug act. 2004 [cited 2015 6th July]; Available from: [http://www.tfrd.org.tw/english/laws/cont.php?kind\\_id=25&top1=What we do&top2=Public Policy Issues&top3=Rare Disease and Orphan Drug Act](http://www.tfrd.org.tw/english/laws/cont.php?kind_id=25&top1=What we do&top2=Public Policy Issues&top3=Rare Disease and Orphan Drug Act).

41. Population Reference Bureau. World population data sheet 2013. 2013 [cited 2015 8 October]; Available from: [http://www.prb.org/pdf13/2013-population-data-sheet\\_eng.pdf](http://www.prb.org/pdf13/2013-population-data-sheet_eng.pdf).

# OS.312 Comparative Efficacy Of Antimicrobial Central Venous Catheter In Reducing Bloodstream Infections

## DESCRIPTION:

Although the use of antimicrobial central venous catheter (CVC) is recommended, there remains a need of an up-to-date synthesis of evidence relating to its use. This network meta-analysis aimed to evaluate the comparative efficacy of antimicrobial CVCs in clinical outcomes. Rifampicin-based impregnated CVC was the most effective in preventing catheter-related bloodstream infection and other related clinical outcomes.

## AUTHORS:

Huey Yi, Chong Nai Ming, Lai Nathorn, Chaiyakunapruk

## BACKGROUND AND OBJECTIVES:

The central venous catheter (CVC) is an essential device in the short and long-term management of hospitalized patients. Catheter-related bloodstream infection (CRBSI) is the major complication associated with CVC. Although many established guidelines recommend the use of antimicrobial CVC, an increasing body of research evidence on various types of antimicrobial impregnations warrants an up-to-date synthesis of evidence relating to their use. Therefore, this network meta-analysis aimed to evaluate the comparative efficacy of antimicrobial CVCs in reducing CRBSI and other important clinical outcomes.

## METHODS:

We systematically searched five electronic databases - MEDLINE, the Cochrane Central Register of Controlled Trials (CENTRAL), EMBASE, CINAHL, and other internet sources for randomized controlled trials, on-going clinical trials, and unpublished studies up to March 2015. The standard search strategy of the Cochrane Anaesthesia Review Group

(CARG) was used. Studies that assessed CVCs with antimicrobial impregnation, coating or bonding with non-impregnated catheters or catheters with another impregnation were included. Risk of bias was used. We performed a network meta-analysis using the Frequentist random-effects model to estimate pooled risk ratio (RR) with 95% confidence intervals (CIs) for all outcomes. The ranking probability based on the surface under the cumulative ranking curve (SUCRA) was estimated based on a Bayesian approach.

## RESULTS:

Fifty-nine randomized controlled trials with a total of 15,145 catheters were included. A total of 14 interventions were investigated, including 13 types of antimicrobial impregnated catheters. Of these 59 studies, there were low or unclear risks of bias for most criteria, except blinding. For the prevention of CRBSI, minocycline-rifampicin impregnated catheter was associated with a significantly lower rate of CRBSI than non-impregnated catheter (RR 0.29; 95%CI 0.16-0.52), chlorhexidine-silver sulphadiazine (0.38; 0.21-0.71), chlorhexidine (0.12; 0.03-0.55), and 5-fluorouracil (0.42; 0.19-0.93) impregnations. Similarly, miconazole-rifampicin impregnation significantly reduced catheter colonization in all comparisons except against cefazolin coating and 5-fluorouracil impregnation. In addition, the network meta-analyses revealed that rifampicin-based impregnated catheter, either minocycline-rifampicin or miconazole-rifampicin, appears to be associated with the largest benefit in the reduction of sepsis, CRBSI per 1,000 days, catheter colonization per 1,000 days, catheter-related local infection, catheter failure, mortality attributed to CRBSI, and adverse effects. No evidence of inconsistency was found.

## CONCLUSIONS:

In this network meta-analysis, rifampicin-based impregnated CVC was the most effective in the prevention of CRBSI and other related clinical outcomes. This analysis is relevant for clinical decision making to improve the management of patients who require a CVC use.

## OS.315 Challenges To Undertaking A Systematic Review Of Rapid Diagnostic Tests In Sepsis

### DESCRIPTION:

Rapid identification and treatment of sepsis are associated with the best outcomes. Current microbiological techniques take several days. Rapid new tests have been developed and were evaluated in a systematic review of diagnostic accuracy. Despite a large number of diagnostic accuracy studies, the evidence on likely effect of the rapid molecular tests on clinical outcomes is lacking

### AUTHORS:

Marrissa Martyn-St James, Abdullah Pandor, Rachid Rafia, Lesley Uttley, John Stevens, Jean Sanderson, Ruth Wong, Gavin Perkins, Ronan McMullan, Paul Dark, Matt Stevenson

### BACKGROUND AND OBJECTIVES:

Sepsis is a condition characterised by the body's inflammatory response to a bacterial, viral or fungal infection which can lead to multiple organ failure and death. Rapid identification and treatment of sepsis are associated with the best outcomes; however, current microbiological techniques for detecting pathogens in those with suspected blood stream infection or sepsis takes several days. Rapid new tests have been developed which can detect pathogen Deoxyribonucleic acid of bacteria and fungi in whole blood samples with results available within approximately six hours under optimal conditions. The aim of this study was to identify the methodological issues affecting the evaluation three polymerase chain reaction tests (SeptiFast, Sepsitest and IRIDICA) for the rapid identification of pathogens in patients with suspected sepsis compared with blood culture with or without MALDI-TOF mass spectrometry.

### METHODS:

A review of the literature (published and

unpublished) to May 2015 was undertaken in accordance with established guidelines for undertaking systematic reviews and meta-analysis of diagnostic tests. The strengths and limitations of the evidence-base were examined and recommendations were made for future research.

### RESULTS:

A total of 66 studies (single index studies: SeptiFast, n=57; Sepsitest, n=3; IRIDICA, n=4; two index test studies, n=2) were included. Sixty-two reported data on the performance of diagnostic accuracy; however, reporting of clinical endpoints such as mortality, hospitalisation and length of stay; change in initial treatment, time to change in treatment was limited. Several issues were identified across the studies that affected the strength and generalisability of the results. These included variations related to the population (e.g., how sepsis was defined and diagnosed), intervention (e.g., sample volumes, test timing), reference standard (lack of details) and outcomes.

### CONCLUSIONS:

Despite a large number of diagnostic accuracy studies, the generalisability and robustness of the results is limited and the evidence on likely effect of the rapid molecular tests on clinical outcomes is lacking. Whilst further diagnostic accuracy studies are likely to add little, additional studies that quantify the clinical utility of the tests in clinical practice are urgently needed.

---

## OS.318 Updated NICE technology appraisals patient submission template; informing health care decisions

### DESCRIPTION:

Patient evidence is submitted to NICE by patient organisations and their nominated individual patient experts. Following the update of the NICE

Technology Appraisals Methods Guide, feedback from patient experts, and the development of the international patient group submission templates, NICE developed and piloted two new submissions templates (for patient organisations and for individuals) and is presenting the findings.

**AUTHORS:**

Heidi Livingstone, Gill Leng, Laura Norburn, Chloe Kastoryano

**BACKGROUND AND OBJECTIVES:**

Patient evidence is submitted to NICE by patient organisations and their nominated individual patient experts. Following the update of the NICE Technology Appraisals Methods Guide in 2013, and feedback from patient experts in a survey in 2012, and the development of the international patient group submission templates, NICE developed two new submissions templates (for patient organisations and for individuals) and has piloted the new templates.

**METHODS:**

The templates were drafted using the new Methods Guide and feedback from the patient survey. Comments were sought from a sample of: 1) Patient experts 2) Lay members of the technology appraisal committee 3) NICE staff who work with patient organisations and individuals on technology appraisals Based on feedback, the drafts were updated and then compared against the international HTAi patient submission template for medicines, and further changes made. The new template was implemented in July 2014 and piloted.

**RESULTS:**

Key changes to drafts included: 1) reflecting the updated patient evidence section of the 2013 Methods Guide, 2) differentiating the content between the organisations' and the individuals' templates, 3) clearer formatting and layout, 4) making the questions easier to understand and providing clearer information about how to

complete each question 5) introducing a 'key messages' section, using the bullet point model from the international template. Result from the pilot show that the new templates are easier to use both for organisations and individuals.

**CONCLUSIONS:**

Although the submission template is easier to complete than its predecessor, patient groups and individuals would like more guidance on: 1) what patient evidence the decision making committee most values 2) a supplementary guide or more help and support in writing their submissions Patient organisations have also stated that they would like feedback on the impact and value of their submissions to help them improve future evidence submissions.

.....

## OS.321 New Methods For Early Diagnostic Of Cancer

**DESCRIPTION:**

Electron paramagnetic resonance (EPR) is an innovative non-invasive method which is demonstrating the high information content in the diagnosis and monitoring of treatment of malignant neoplasms. The EPR methodology demonstrates certain advantages over the currently used methods for early diagnosis of active malignant neoplasms and in the monitoring and control of cancer recurrence. EPR spectroscopy is not opposed to other methods of cancer diagnostics, but it can add significantly to efforts on the preclinical and early diagnostic.

**AUTHORS:**

Ainura Sassykova, Temirkhan Kulkhan, Gulnara Gurtuskaya

**BACKGROUND AND OBJECTIVES:**

In oncology, the factor in successful treatment of any type of cancer is early diagnostic. Electron paramagnetic resonance (EPR) is an innovative

non-invasive method which is demonstrating the high information content in the diagnosis and monitoring of treatment of malignant neoplasms. The method of EPR based on measurement and interpretation of the resonant response of spin labels for diagnosis of structural and functional disorders of albumin. There is the project on approbation of innovative technology in cancer detection were performed in Kazakhstan. The purpose of project is the study of effectiveness of EPR technique for the early diagnosis of cancer and determining the applicability of the method in screening studies of population.

**METHODS:**

The study was double-blind, 150 serum samples were measured. Differences between samples taken from apparently healthy individuals and patients with confirmed malignancy were identified in the analysis of EPR spectra obtained using laboratory EPR-analyzer.

**RESULTS:**

In group A (cancer patients) in 68 cases was detected of active malignancy from 75 samples. In 7 cases the method detected lack of activity malignant proliferation. The sensitivity of the method in this group was 90.6%. In group B (healthy group) in 11 cases the method showed the likelihood of malignancy in patients, and there is no possible cancer in 64 cases from 75 samples. Thus, the specificity of the methodology in healthy group was 85.3%. Many of these false-positive cases are due to the presence of inflammation in the acute form, or accepting drugs in high concentrations.

**CONCLUSIONS:**

The EPR methodology demonstrates certain advantages over the currently used methods for early diagnosis of active malignant neoplasms and in the monitoring and control of cancer recurrence. EPR spectroscopy is not opposed to other methods of cancer diagnostics, but it can add significantly to efforts on the preclinical and early diagnostic.

.....

.....

## OS.332 Broadening The Perspective In Economic Evaluation—A Case Study Of Dementia Interventions

**DESCRIPTION:**

In certain disease areas such as dementia, it is necessary to broaden the perspective of economic evaluation for healthcare resource allocation decision making. The extended cost-per-QALY analysis and the Cost Consequence Analysis (CCA) with Multi-Criteria Decision Analysis (MCDA) are the two frameworks which can be used routinely in HTA with a wider perspective.

**AUTHORS:**

Thaison Tong, Praveen Thokala, John Brazier

**BACKGROUND AND OBJECTIVES:**

The practice of health technology assessment (HTA) in the UK has traditionally been dominated by cost-per-QALY analysis with a restricted perspective (the healthcare perspective). However, a wider perspective is often considered to be more appropriate, especially when an intervention has substantial wider impact on society. This has been confirmed in the area of dementia interventions where our review found that the adoption of a societal perspective is the most common among studies.

Nonetheless, it is not clear how a wider perspective could be implemented consistently in routine HTA. Two methodological frameworks appear to be useful for economic evaluation taking a wider perspective: the extended cost-per-QALY analysis and the cost consequence analysis (CCA) with Multi-Criteria Decision Analysis (MCDA) approach. The former is more prescriptive and scientific evidence-based, whereas the latter is more pragmatic decision making. How can they help broaden the perspective in economic evaluation? What are the strengths and limitations of each approach?

## **METHODS:**

We explored the operationalisation of the two methodological frameworks using dementia interventions as a case study.

A patient-level cost-effectiveness model was developed which can assess a wide range of interventions in dementia from pre-diagnostic to post-diagnostic stage. The cost outcomes include NHS cost, local authority cost, private payment for social care, and informal care. The benefit outcomes include patient QALY and carer QALY.

The model's estimates were fed into the extended cost-per-QALY analysis and the CCA with MCDA. A decision making workshop was conducted for the implementation of the CCA with MCDA. The participants included the NHS decision makers, the local authority decision makers, clinicians and nurses in dementia care.

## **RESULTS:**

Both frameworks were feasible to be operationalised in this case study. They suggest two different results for the final decision. However, the results are sensitive to the values of the thresholds in different sectors in the extended cost-per-QALY analysis and the criteria weights in the CCA with MCDA.

The extended cost-per-QALY analysis is more prescriptive and scientific evidence-based. It requires more rigorous research for the estimates of the cost-effectiveness thresholds in other sectors (e.g. local authority, private sector). Once we have a strong evidence base for the thresholds in other sectors, the extended cost-per-QALY analysis can be applied consistently in routine HTA. This framework is more appropriate for decisions at national level.

The CCA with MCDA is more pragmatic and can overcome the lack of evidence regarding the thresholds in other sectors. This framework can be appropriate for decisions at local or regional level.

## **CONCLUSIONS:**

In certain disease areas, it is necessary to broaden the perspective of economic evaluation for healthcare resource allocation decision making. The extended cost-per-QALY analysis and the CCA with MCDA are the two frameworks which can be used routinely in HTA under a wider perspective.

---

## **OS.333 Hospital HTA: A Tool For Improving Nursing Practice**

### **DESCRIPTION:**

This presentation will describe examples of HTA reports relating to nursing practice and nursing administration. Applying HTA to nursing can improve the quality and safety of care while promoting the professional development of nurses.

### **AUTHORS:**

Matthew D. Mitchell, Julia G. Lavenberg, Sara Holland, Stephanie Maillie, Rebecca Trotta, Craig A.

### **BACKGROUND AND OBJECTIVES:**

To date, most health technology assessment (HTA) reports have addressed topics relating to new and/or costly drugs, devices, and procedures. However, there are many other questions relating to the quality and safety of care that are equally amenable to evidence-based decision-making. Many of these topics involve nursing practice.

### **METHODS:**

Our center employs rapid review methods to produce evidence reports for physicians, nurses, and administrators in our hospital system. The core staff of the center includes a research analyst who is also a registered nurse, and liaisons to the nursing staff at each of the system hospitals. Nurses and nurse administrators are encouraged to submit topics for review, participate in the internal review of draft reports, and help disseminate review findings.

**RESULTS:**

Seventeen percent (52/303) of the reports completed from the founding of our center in July 2006 through December 2015 are on topics primarily relating to nursing, and 47 nurses or nurse practitioners have been co-authors of our reports. Examples of report topics relating to nursing include process of care topics like maintenance of central venous catheters, devices such as disinfecting caps for central lines, and topics relating to nursing administration and policy such as debriefing programs to reduce stress from critical incidents. Review findings have been used in the development of policy statements and other guidelines for nursing care, implemented in clinical decision support systems, and published in the peer-reviewed literature.

The proportion of reports relating to nursing has increased during the history of our center: from about 10 percent of reports in our first three academic years 2007-09 (7 of 73 reports) to over 30 percent in our three most recent academic years 2013-15 (30 of 98 reports). The increase cannot be attributed to any single cause. Factors that could have contributed to that growth include the addition of a nurse to our analyst staff, increasing the number of nurse liaisons, and a general trend away from drug and device topics to process of care and policy/management topics. Of the 53 nursing-related reports, 37 were on topics relating to process of care, 8 were on devices, 5 were on policy issues, 2 were on diagnostic tests, and one was on a drug. The median time for completion of these reports was 8 weeks.

Nurse participation in the commissioning, review, and dissemination of HTA reports helps fulfill all four key areas of the Magnet accreditation process for nursing excellence: 1) engaging nurses in evidence-based practice, 2) professional development and recognition, 3) improved quality of care and patient outcomes, and 4) research to advance nursing practice.

**CONCLUSIONS:**

A hospital-based HTA center can collaborate with nurses to create timely evidence reports on nursing topics. Applying HTA practices to nursing care can reduce variations in care, strengthen nursing practice, and provide nurses with opportunities for professional development.

.....

## **OS.341 Rapid Health Technology Assessment For Proton And Heavy Ion Therapy In China**

**DESCRIPTION:**

This project used rapid HTA to evaluate if the Chinese government should expand the use of the proton and heavy ion therapy in China. Rapid HTA method, literature review, field investigation, expert consultation and key informant interview were conducted. These facilities are very costly and only suitable for a few indications. We do not recommend expanding these facilities on a large scale in China.

**AUTHORS:**

Xue Li, Yanzhu, Chen, Liwei, Shi, Yuzhao

**BACKGROUND AND OBJECTIVES:**

The use of particles (notably protons and heavy ions) for medical purposes was first proposed by Robert Wilson in 1946. Since then, 137,000 patients have been treated by particle therapy around the world. There are 50 proton and 8 heavy ion treatment centers so far, with 36 additional treatment centers under construction. China treated their first patients in 2004 using proton therapy in Shandong Wanjie Hospital, followed by two other centers in Lanzhou and Shanghai. Thus far, more than 1,400 patients have been treated in these facilities. With growing interest and access to such expensive and sophisticated technology, the China National Health Development Research

Center (CNHDRC) was commissioned by the Chinese National Health and Family Planning Committee (NHFPC, Chinese Ministry of Health) to conduct a rapid technology assessment to support national planning and decision making on proton and heavy ion therapy.

Objectives:

- (1) To analyze proton and heavy ion therapy's attributes and efficacy;
- (2) To analyze the development and application of this technology, with related policies, allocated infrastructure and human resources;
- (3) To analyze safety and effectiveness of this technology;
- (4) To assess cost, cost-effectiveness and budget scenario analysis of this technology;"

#### **METHODS:**

"Rapid health technology assessment (HTA) developed by Ottawa Hospital Research Institute was the main method used. Literature review, field investigation, expert consultation and key informant interview were conducted.

8 steps of rapid HTA are as follows:

- (1) Needs assessment (week 1);
- (2) Definition of the evaluation questions (week 1);
- (3) Proposal writing (week 1);
- (4) Literature research; expert consultation (week 1 & 2);
- (5) Literature screening (week 2);
- (6) Evidence assembling; field investigation and scenario analysis (week 2 & 3);
- (7) Report writing (week 4);
- (8) Feedback and revision of the report (week 5)."

#### **RESULTS:**

Protons or heavy ions enable irradiation of small areas in high doses while sparing surrounding structures, allowing advantage over traditional radiotherapy. However, only a few indications such as ocular cancers, brain/spinal and pediatric cancers have been proofed to be effective. Additionally, proton and heavy ion facilities are very costly. Treatment for each fraction is around 278,000 Yuan in China.

#### **CONCLUSIONS:**

We do not recommend expanding proton or heavy ion therapy in China. The government should control the number of facilities for medical use. We recommend that the government use this technology as research project to support the development of the domestic industry.

#### **REFERENCES:**

- Goodman, C. (2012). Rapid Reviews at the HTAi Meeting. HTAi Annual Conference. Bilbao, Spain.
- Watt et al. (2008). Rapid reviews versus fullsystematic reviews: An inventoryof current methods and practicein health technology assessment. International Journal of Technology Assessment in Health Care, 24:2 (2008), 133-139.
- Hailey, D. (2009). A preliminary survey on the influence of rapid health technology assessments. International Journal of Technology Assessment in Health Care, 25:3 (2009), 415-418.

# OS.350 Prioritisation Of Emerging Medical Devices In Health Technology Assessment

## DESCRIPTION:

The research explored feasibilities and challenges of using non-traditional information sources with pragmatic internet searches from manufactures, professional organisations, grey literatures and social media, in identification and prioritisation of emerging medical technologies when clinical data is not yet available.

## AUTHORS:

Ning Ma, Wendy Babidge, Guy Maddern

## BACKGROUND AND OBJECTIVES:

With a large number of new medical devices emerging every year, ever more sophisticated healthcare options are increasingly available to patients and clinicians. However, it can be difficult to prioritise the latest and most effective technologies especially when clinical data is not yet available. The objective of this research was to investigate a large range of information sources to identify new and emerging health technologies in the field of medical imaging using a range of traditional and novel search strategies. A time horizon of up to 20 years was used. This information was used to inform deliberations and priority setting at a policy level in the Australian healthcare system. The limitations and benefits of these sources will be discussed.

## METHODS:

While peer-reviewed publications were traditionally searched, more pragmatic search methods through a wide range of online sources were used, but were standardised where possible. Online sources included manufactures and professional associations, grey literature, technology websites, and social media. Empirical development of keywords during the searching process continued until all project questions were answered. In

addition, an extraction template which focused on innovation, manufacturers, costs and likelihood of impact was used on every emerging technology to systematically organise and present information to prioritise policy settings.

## RESULTS:

Many examples of novel technologies were identified through informal sources. Useful information was organised and analysed in a systematic way to form the evidence-base. However, there were limitations and challenges. The template was frequently revised to be more practical in collecting and presenting available information. Certain sources were better than others. For example, information from professional bodies tended to be reliable but non-comprehensive whereas manufactures were good at showcasing innovations but with a lack of transparency and verifiability. The lack of regulatory information also hindered our efforts to the prioritisation of emerging technologies.

## CONCLUSIONS:

Our findings provide a useful guidance in prioritising medical imaging technologies over a broad time horizon. In the absence of clinical data, it is feasible to identify and prioritise newly emerged medical technologies through non-traditional resources. However, more research in methodologies should be done to pragmatically overcome efficiency and reliability issues of using non-traditional information sources. Moreover, information transparency and accuracy should be provided by manufactures.

## OS.351 Cost-Effectiveness Of Sequential Use Of ELF Test/ARFI And ELF Test Alone Versus Biopsy

### DESCRIPTION:

New non-invasive methods to diagnose liver fibrosis are being considered as an alternative to liver biopsy. We estimated the cost-effectiveness of sequential use of ELF test/ARFI and ELF test alone compared to biopsy to assess liver fibrosis in HCV patients from the perspective of a hospital in Spain. The incremental cost-effectiveness ratios (ICERs) were respectively 13,400€ and 11,500€ per quality-adjusted life year.

### AUTHORS:

Marcelo Soto, Laura Sampietro-Colom, Luis Lasalvia, Aurea Mira, Wladimiro Jiménez, Miquel Navasa

### BACKGROUND AND OBJECTIVES:

Non-invasive diagnosis of liver fibrosis (LF) has rapidly evolved in recent years. Though biopsy is used to stage most cases of liver disease, it is well known that this procedure has several limitations. First, sampling errors can occur, especially when smaller sized biopsies are analysed. In addition, histological examination is prone to intra- and inter-observer variation, which may occur even when widely validated systems are used to score liver damage. Finally, liver biopsy is an invasive procedure with associated morbidity and mortality.

Most non-invasive methods have shown good diagnostic accuracy to detect LF. In addition, non-invasive tests can be repeated over time, and in cases of indeterminate results two or more methods can be combined. The sequential use of ELF test (as a blood test for patients with suspected liver disease), and ARFI (as a specific tool to confirm the presence and severity of liver disease) has been proposed. However, health and economic implications of this approach have not been

reported. Therefore, the aim of the current study was to assess the accuracy of the sequential use of ELF test/ARFI in the diagnosis of LF, as well as its cost-effectiveness compared with the use of biopsy in patients with ALD.

### METHODS:

A Markov model simulating LF progression in HCV was developed to estimate health outcomes and costs during lifetime for a cohort of 40-year-old men with abnormal levels of transaminases. The analysis was performed from the perspective of a University Hospital in Barcelona. Clinical data were obtained from published literature. Costs were sourced from administrative databases of the Hospital. Three different testing alternatives were studied: a single liver biopsy; annual ELF test followed by ARFI if ELF test is positive; annual ELF test without ARFI as a confirmation test. Deterministic and probabilistic sensitivity analyses were carried out to examine the robustness of the results.

### RESULTS:

Annual sequential ELF test/ARFI and annual ELF test alone increased the number of quality-adjusted life years (QALYs) relative to biopsy by 1.06 and 1.48, respectively. Incremental costs were 14,244 and 16,996, respectively. The corresponding cost-effectiveness ratios (ICERs) for sequential ELF test/ARFI and annual ELF test alone were respectively 13,400\$ and 11,500\$ per QALY.

The sensitivity analysis showed that results were robust: the lowest ICER (5,800\$ per QALY) was obtained when the discount rate was 0, whereas the highest ICER (21,400\$ per QALY) occurred when the assumed cost of antivirals was high (72,000\$ for a 12-week treatment). The remaining parameters of the model had a minor impact.

### CONCLUSIONS:

Testing for liver fibrosis annually with non-invasive methods resulted in a substantial reduction in the number of events (cirrhosis, hepatocellular

carcinoma and fibrosis-related death) and a significant increase in QALYs for HCV patients, compared with a single liver biopsy. ELF test alone had the best health outcomes, but it was also the most costly of the strategies. In light of these results sequential ELF test/ARFI can be considered as an option providing a balance between proper care and costs. (NOTE: The ELF test is not available for sale in the U.S.)

---

## OS.355 Study On Benefit Of New Medical Reform In Primary Health Institutions?

### DESCRIPTION:

In order to analyze the benefit of new medical reform in primary health institutions from primary healthcare workers perspective, this study used stratified, multistage, random methods to extract 1889 primary healthcare workers from 6 cities in Shandong province. The conclusion is compared to the earning capacity and other benefits, working load increased more significantly, that effort and reward imbalance.

### AUTHORS:

Xiaoqiang Qin, Wenqiang Yin, Dongmei Huang, Hui Tan, Haihong Cao, Muye MA, Mengqi Tang, Yan Wei

### BACKGROUND AND OBJECTIVES:

In 2009, the CPC Central Committee and the State Council issued "Opinions on Deepening the Health Care Reform" around the basic requirements of the basic, strong base, build mechanism?proposed to change the operation mechanism and government investment mechanism of primary health care institutions, and actively promote the development of the medical and health system. Since then, the government had adopted policies and measures to strengthen the reform and development of primary health care institutions from the aspects of infrastructure construction, health service team construction, investment and compensation

mechanism. What changes of primary health care institutions to happen in the reform process? How well do primary health care institutions benefits?

Objective: This study analyzes the benefit of new medical reform in primary health institutions from primary healthcare workers' perspective, and provides reference for the improvement of primary health care reform.

### METHODS:

Drainage method: According to the level of economic development (good, medium and poor), using multi-stage stratified sampling method to extract 1889 primary healthcare workers from 6 cities in Shandong province. A questionnaire survey was carried out by the scale of "the benefit of new medical reform in primary health institutions", which was developed by the research group, and according to the principle of information saturation, we selected 10 medical personnel and some management personnel to conduct in-depth interviews.

Statistical analysis method: Using SPSS21.0 software package for data collection and analysis, factor analysis was used to simplify the scale, and the composition ratio was used for statistically described.

### RESULTS:

52.3% of the primary healthcare workers think that the primary health institutions to benefit in the service level,31.1% think that the benefit in terms of social environment, the primary healthcare workers who think earning capacity benefit account for 15.6%,80.7% consider that the work load is impaired ;the highest degree of benefit in service level , a score of 4.15 points, followed by social environment (3.84), earning capacity (3.41),working load(1.78);

### CONCLUSIONS:

After the new medical reform, primary health care institutions had improved in service level, social environment and earning capacity, the working

load is increased significantly. In the perspective of healthcare workers, there are differences in the extent of benefit, the benefit of primary health care institutions in terms of service level is the highest, followed by the social environment, earning capacity, the benefit in working load had damaged. Compared to the earning capacity and other benefits, working load increased more significantly, that effort and reward imbalance.

---

## OS.375 Is Partial Knowledge Adequately Considered In Uncertainty Analysis For Economic Evaluation

### DESCRIPTION:

HTA experts and decision makers should wonder how to handle the weakness of the current framework of uncertainty analysis which has a tendency to ignore ubiquity of unquantifiable uncertainty. A case study of manufacturer submissions to the French National Authority for Health showed that partial knowledge is not adequately considered in uncertainty analysis of economic evaluation of innovative drugs.

### AUTHORS:

Salah Ghabri

### BACKGROUND AND OBJECTIVES:

In the process of reimbursement decision and price negotiation of innovative drugs the challenge for decision makers is to determine the extent to which we can be confident that these drugs are cost-effective relative to other therapeutic alternatives. Since October 2013, the French National Authority for Health (HAS) is required to provide the inter-ministerial pricing committee (CEPS) with an efficiency opinion on innovative drugs likely to have a significant impact on national insurance expenditures. The aim of this study is to identify and discuss issues related to uncertainty

encountered by HTA experts in their appraisals of cost-effectiveness models submitted to HAS by manufacturers.

### METHODS:

We reviewed all manufacturer submission files that comprised a cost-effectiveness analysis (CEA) and were assessed by HAS at the end of July 2015. Three sources of uncertainty were identified: methodological, parameter and structural uncertainty. Methods to explore methodological and parameter uncertainty included overall compliance with the reference case as well as deterministic and probabilistic sensitivity analyses. Methods for handling structural uncertainty included scenario analyses.

### RESULTS:

Methodological and parameter uncertainty were the sources of uncertainty that were most frequently explored by manufacturers. The analysis of methodological and parameter uncertainty was generally considered to be acceptable. Performing sensitivity analysis of model input parameters with probabilistic sensitivity analysis was fairly compliant with HAS guideline (57 % of the submissions). In contrast, the analysis of structural uncertainty was frequently lacking (46% of the submission). Either the approach to model the history of the disease under study was unsatisfactory or the medium or long term drug effectiveness in real life setting was not adequately explored.

### CONCLUSIONS:

The lack of analysis of structural uncertainty raises the following questions. Is there a risk for HTA agencies to make sub-optimal appraisals because of incomplete uncertainty information? Do HTA appraisals of cost-effectiveness models intrinsically underestimate uncertainty because parameters estimates do not arise from real life settings? HTA experts and decision makers should wonder how to handle the weakness of the current framework of uncertainty analysis which has a tendency to ignore ubiquity of unquantifiable uncertainty. Therefore

additional sources of uncertainty (i.e. non statistical uncertainty) should be included or at the very least acknowledged in the economic evaluation of innovative drugs.

---

## OS.378 Force Field Analysis Of HTA Introduction At National Level In China

### DESCRIPTION:

The use of HTA to inform priority setting in health at a national level requires high-level commitment and support. This work aims to identify the Marco-level forces that affect the introduction of HTA into policy-making process at a national level in China.

### AUTHORS:

Lanting, LU, lanting, Kalipso Chalkidou

### BACKGROUND AND OBJECTIVES:

Since 2009, the current health reform has made numerous progresses, mostly in the improvement of the provision of health services, including the coverage and extension of health benefit packages. Almost achieving universal coverage, China is facing the challenges encountered by most health systems across the globe: scarce health-care resources versus unlimited demand. There is a clear need of HTA in health decision-making in China, but why is the extremely low level of utilisation of HTA in the national prioritization process? This paper intends to reveal the forces influencing the introduction of HTA into policy-making process at a national level in China based on force field analysis and interviews with relevant decision-makers.

### METHODS:

This paper applied force field analysis to reveal the forces influencing the introduction of HTA into policy-making process at a national level in China. Information gathered from interviews with relevant decision-makers at national level has been used to

validation the elected forces.

### RESULTS:

Based on a clear understanding of relevant decision-making bodies at the national level and current progress of health reform in China, It has been found that the top resisting forces include direct ones like low HTA analysis capacity, established work patterns and lack of incentives and indirect ones like existing efforts made to improve health system. It has also been found that there is a gap in the recognition of HTA between different departments at the national level.

### CONCLUSIONS:

Based on our analysis, it is recommended that working to reduce the top resisting forces may be the most effective in introducing HTA into health policy-making. Recommendations of clear paths on how to reduce the resisting forces have been identified and discussed.

---

## OS.379 Publication Bias And Selective Reporting: Are Summary Online Trial Reports Sufficient?

### DESCRIPTION:

Despite improvements in registration of clinical trials, the problem of selective reporting and publication bias persists. As a consequence, the true harms of many treatments remain hidden, while their benefits are exaggerated. Healthcare decisions based on such biased evidence expose patients to unnecessary harms. Our study compares the newly available sources of trial data and their reporting of harms data.

### AUTHORS:

Tarang Sharma, Louise Schow Jensen, Nanna Freund, Peter C. Gøtzsche

## BACKGROUND AND OBJECTIVES:

“Less than half of all studies are subsequently published,(1) and unfortunately it is usually the trials in which the new drug does not show added benefit, shows a negative effect or where there are considerable adverse events, where this occurs most frequently. (2,3) Trials that are primarily sponsored by industry are also less likely to be published when compared to non-industry sponsored trials ( $p < 0.001$ ). (4) Therefore only partial information reaches the public and informs decision-making and the extent of this bias is exceptionally high in anti-depressant trials. (5)

We wanted to test whether the summary online trial reports posted on Eli Lilly’s website(6) capture serious harms of antidepressants reliably when compared to the full clinical study reports (CSRs). CSRs of duloxetine and fluoxetine were obtained from the European Medicines Agency (EMA) and UK’s Medicines & Healthcare products Regulatory Agency (MHRA) and the matching summary reports were taken from Eli Lilly’s website and compared for their reporting of serious harms.”

## METHODS:

We included 26 CSRs that we received from EMA and MHRA on the two drugs. All were on double-blind placebo controlled trials and contained patient narratives or individual patient listings of harms. The CSRs were converted into a searchable format. Two researchers extracted data independently on primary outcomes of mortality and suicidality (suicide, suicide attempt or preparatory behaviour, intentional self-harm and suicidal ideation) and secondary outcomes of aggressive behaviour and akathisia. A third researcher extracted data for all four outcomes from the matching summary reports and the results from the two sources were compared.

## RESULTS:

Four duloxetine trials had no summaries on the website. All 8 deaths (6 on duloxetine and two on placebo) post-randomisation in the other 22 trials

were noted in the summary reports (but 1 suicide on duloxetine prior to randomisation was missing). Of the 20 suicide attempts (14 on duloxetine, 3 on fluoxetine and 3 on placebo), only 2 were documented in the summary reports, and none of the 14 suicidal ideation events were mentioned. Only 10 of the aggressive behaviour events from a total of 25 were found online, and only 3 out of the 17 akathisia events were found.

## CONCLUSIONS:

In the summary reports, almost all deaths were noted, but all suicidal ideation events were missing, and the information on the remaining outcomes was incomplete. Summary reports are insufficient as source documents for conducting reliable assessments of harms. To elucidate them reliably, access to anonymised individual patient data is needed.

More data from CSRs will become available in the future with the EMA’s new policy to make new submissions public.(7) Data from previously conducted trials has started to become available through the clinical study data request forum.(8) Both these initiatives will reduce research waste and will improve decision-making.

## REFERENCES:

- 1 Scherer RW, Langenberg P, von EE. Full publication of results initially presented in abstracts. Cochrane Database of Syst Rev 2007. Issue 2. Art. No.: MR000005.
- 2 Dickersin K, Chan S, Chalmers TC, Sacks HS, Smith J. Publication bias and clinical trials. Controlled Clinical Trials 1987; 8(4):343-353.
- 3 Jones CWH. Non-publication of large randomized clinical trials: cross sectional analysis. BMJ 2013; 347.
- 4 Ross JS, Mulvey GK, Hines EM, Nissen SE, Krumholz HM. Trial Publication after Registration in ClinicalTrials.Gov: A Cross-Sectional Analysis. PLoS Med 2009; 6(9):e1000144.

5 Turner EH, Matthews AM, Linardatos E, Tell RA, Rosenthal R. Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy. *N Engl J Med* 2008; 358(3):252-260.

6 Eli Lilly and Company. Clinical Trial Report (CTR) Summaries. 2014. Available from: [http://www.lillytrials.com/results/ctr\\_toc.pdf](http://www.lillytrials.com/results/ctr_toc.pdf) [Accessed 01 February 2014]

7 European Medicines Agency. Publication and access to clinical-trial data. 2014 Available from: [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2013/06/WC500144730.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/06/WC500144730.pdf) [Accessed 15 September 2014].

8 Clinical study data request site. Available from: <https://www.clinicalstudydatarequest.com/> [Accessed 1 October 2015].

---

## OS.382 Beyond EQ-5D: What Patients Say Is Important

### DESCRIPTION:

This web-based study, part of an EU funded project to advance HTA methodology, explored patients views on whether EQ-5D-5L adequately captured the aspects of health which had a significant impact on their wellbeing. Patients completed an online version of EQ-5D-5L and identified aspects of their illness which have had a big health impact that were not captured by the EQ-5D-5L.

### AUTHORS:

Jean Mossman, Panos Kanavos, Olina Efthymiadou

### BACKGROUND AND OBJECTIVES:

The background to the study was the view expressed by people living with serious illnesses that EQ-5D did not capture all the aspects of their illness and treatment which had a significant impact on their health. A literature review had concluded that the EQ-5D index does not adequately reflect patient health status across a range of conditions,

and it is likely that a significant proportion of the subjective patient experience is not accounted for by the index.

This study, part of a large, EU funded project to advance HTA methodology, aimed at creating new data on Health Related Quality of Life (HRQoL) based on patients rather than the general population. It was intended to clarify whether the preferences derived from the general population differed from those of defined groups of patients. If coverage decisions are to reflect the things that matter to the users of a specific technology, their views should be embedded in the decision making and capturing their perspective in a utility measure can help achieve this. We set out to determine whether EQ-5D-5L successfully captured key aspects of health and to identify the policy implications of using of the value sets drawn from specific patient populations.

### METHODS:

We conducted a retrospective, web-based survey of patients using sample comprised of adult individuals with a diagnosed disease. Participants were identified through a network of patients and patient associations held by the LSE Medical Technology Research Group.

European contacts included 44 individual patients and 337 patient organizations, covering all 30 EEA countries representing 278 national organisations and 30 Pan-European organisations. In addition, 12 international organisations were approached in Australia, Brazil, China, Japan, Malaysia and Singapore.

A multidimensional, self-completed questionnaire was developed using the EQ-5D-5L instrument comprising three sections: demographics; health state utility; and additional dimensions related to QoL outcomes.

### RESULTS:

767 patient surveys were completed from 37 countries and 123 diseases. Countries comprising

the largest part of the patient sample included UK (52% of all sample), Greece (7%), France (5%), Denmark (5%), and Romania (5%). The average patient age was 50 years, the majority were female (77%), married/cohabiting (67%) and employed (40.7%). 51% (n=359) of respondents consider this instrument insufficient in capturing all of the disease aspects which added a significant burden on their HRQoL. The most commonly reported issues included fatigue (19.5%) and medication side effects (9%); less commonly reported were sleep deprivation, loss of confidence and sexual problems.

**CONCLUSIONS:**

We have demonstrated that in a self-selected population, EQ-5D-5L does not capture all aspects of health state that matter to patients. While the study has limitations (for example, respondents are involved with patient organisations and come largely from the UK and other EU countries), it indicates that using EQ-5D-5L raises inconsistencies in QoL preferences between country and disease specific patient populations and might not represent the dimensions of QoL that really matter for chronically ill individuals. Further research is needed to clarify how patients' disease-specific utilities map against a generic tool such as EQ-5D to better reflect patients' experiences.

Based on the present analysis, it seems that utilization of EQ-5D-5L in HRQoL measurement raises potentially serious inconsistencies in capturing QoL preferences between country and disease specific patient populations and might not be representative of the dimensions of QoL that really matter for chronically ill individuals and their caregivers.

**REFERENCES:**

Tordrup D, Kanavos P & Mossman J.  
Responsiveness of the EQ-5D to clinical change: is the patient experience adequately represented?

.....

.....

## OS.394 The Scottish Health Technologies Group's Innovative Medical Technology Overview (IMTO) Process

**DESCRIPTION:**

The Scottish Health Technologies Group's Innovative Medical Technology Overview (IMTO) process has demonstrated that evidence-based HTA decisions are possible when seeking to unlock value in new technologies. However, in doing so, it is important to recognise that evidence thresholds may vary across technologies, and that HTA agencies may require collaboration with other stakeholders to maximise the potential of new technologies.

**AUTHORS:**

Edward Clifton, Susan Myles

**BACKGROUND AND OBJECTIVES:**

The Scottish Health Technologies Group (SHTG) provides advice to NHS Scotland on the clinical and cost effectiveness of existing and new technologies. Up until 2014, this advice was based only upon peer-reviewed published literature. However, evaluating non-medicine technologies poses different challenges to those encountered when assessing medicines, for example; medical devices are often developed incrementally, and many of the manufacturers are small companies with limited resources for, and experience of, undertaking controlled trials. With this in mind, SHTG introduced the IMTO process, a 'health technology assessment (HTA)-light' approach which shifts the balance of assessment away from scientific evidence towards more pragmatic decision making. The IMTO process goes beyond the traditional SHTG evidence assessment framework, with a key focus on collaboration with innovation stakeholders across NHS Scotland.

**METHODS:**

The IMTO process provides manufacturers of

non-medicine technologies the opportunity to submit their clinical and cost effectiveness evidence for independent assessment within NHS Scotland. The aim of this assessment, following a critical review of the relevant strengths and weaknesses of the submitted evidence, is to provide objective information that will contribute to the local decision-making of NHS professionals. Underpinning the IMTO process is the theory that evidence thresholds vary according to the decision problem; so although the evidence base may not always be equal, evidence-based decisions are possible.

Outcomes planning evaluation methodology has been used to evaluate the impact of the IMTO process to date, whilst important collaborations between Scottish innovation stakeholders have taken place since the inception of the IMTO process. Both such activities serve to maximise the potential for IMTOs to unlock the value of new technologies.

## RESULTS:

The evaluation of the IMTO pilot demonstrated that the IMTO process has been successful in the short time the process has been implemented. For example, the published IMTOs for two of the six technologies assessed during the IMTO pilot have already affected clinical decision making. The value of these new technologies may have gone unrecognised within the traditional HTA approaches.

To further ensure that the value of new technologies is captured, SHTG is collaborating with NHS Procurement, a new hospital-based Innovation Centre within NHSScotland, and NHS innovation 'test beds'. The Innovation Centre provides manufacturers with access to panels of clinicians for early feedback, while the 'test beds' offer the opportunity for further in situ testing. Such collaboration has led to a three-stage process of technology registration and early clinical feedback, followed by a cyclical association between evidence assessment and further evidence generation.

## CONCLUSIONS:

The IMTO process has indicated that it is possible to undertake early evidence-based decisions potentially unlocking the value of new technologies, although it should be recognised that evidence thresholds will vary according to the technology under assessment. Importantly, the process has highlighted the importance for HTA agencies to work alongside other stakeholders if the potential of new technologies is to be fully realised in a timely fashion.

---

## OS.396 Measuring The Value Of HTA Cooperation In Europe: The Example Of EUnetHTA

### DESCRIPTION:

EUnetHTA was established to create a sustainable HTA network across Europe that brings added value. Working time/costs of the project's staff were documented. Aggregated results were integrated into a model, which calculates the average costs per hour and person days needed to produce joint assessments. Added value can be achieved from the network through the national re-use of joint assessments.

### AUTHORS:

Gottfried Endel, Ingrid Wilbacher, Sonja Scheffel, Vera Szeker, Bertalan Nemeth, Eleanor Guegan, Andrew Cook, Christoph Künzli

### BACKGROUND AND OBJECTIVES:

EUnetHTA was established to create an effective and sustainable network for HTA across Europe and to support cross-border collaboration between European HTA organisations that brings added value at the European, national and regional level.

The task of workpackage 3 on 'evaluation and data collection on costs and efficiency' within EUnetHTA JA2 was to evaluate the value and efficiency gains

generated by the reduction of redundant work, defined as the re-use and adaptation of EUnetHTA joint assessments at national or organisational level. The aim is to achieve an added value at the European level where the output of national adaptations is higher than the input (costs and working hours) of joint assessments.

## **METHODS:**

The working time and costs of the staff on this project were documented in timesheets and submitted as part of an annual financial statement. An extraction database was developed for importing timesheets. The output from this database is one table summarizing all hours and costs by expert level and workpackage-identifier per country in an anonymized and aggregated format.

This table was put into an automated Excel cost-benefit calculation tool which summarizes the information by country, workpackage, staff function and according to the European Cooperation on Health Technology Assessment study (dividing the information into three scenarios: administrative, operative, content-related workpackages).

## **RESULTS:**

“The results of the data were integrated into a model, which calculates the average costs per hour, the average person days needed to produce a joint assessment and the added value (depending on the national re-use).

The costs per joint assessment are known at an average level in person days (hours) and costs (\$) for one project year. The model can be used for calculating the added value of the network by re-using the joint assessments at national level, which was defined as the success of the network. The model is generic and can be used under different assumptions.”

## **CONCLUSIONS:**

Our model shows that added value can be achieved from the network through the national re-use of

EUnetHTA joint assessments, even though other benefits (which are not taken into consideration here) are of higher value. An informed consent is possible now, in terms of planning and estimating further resources needed for this network.

Limits: Data were available for only one project year.

Lessons learned:

- This documentation is sensitive for providing evidence on the effectiveness of the involved scientist.
- Organisations can use this tool to calculate the numbers of person days saved by reducing redundant work.

## **REFERENCES:**

ECORYS (2013): European Cooperation on Health Technology Assessment. Economic and governance analysis of the establishment of a permanent secretariat. ECORYS Netherland BV: Rotterdam.

<http://www.eunetha.eu/>

---

## **OS.398 Cost-Utility And Decision-Making At A National, Regional And Local Level: A Matter Of Perspective**

### **DESCRIPTION:**

In New Zealand we compared recommendations based on HTA and cost-utility analysis across three levels of health care organisation; nationally, regionally and locally at a single centre. Differences in perspective were not based on clinical evidence or on the interpretation of study data, but rather on consideration of how implementation costs would impact budgets perceived affordability and willingness to pay.

**AUTHORS:**

Anita Fitzgerald, Stephen Munn

**BACKGROUND AND OBJECTIVES:**

In the Northern Region of New Zealand, hospital-based Health Technology Assessment (HTA) is used to make decisions regarding both the implementation of new technologies and the configuration of existing services across four District Health Boards (DHBs). Recently however, we have discovered that the application of HTA to clinical practice can differ markedly between national, regional and local services, particularly in terms of cost-utility, perceived affordability and willingness to pay. Transcatheter aortic valve implantation (TAVI) is an alternative to open heart surgery for inoperable patients or for whom surgery carries high risk. In 2015, an HTA was carried out as part of a part of a National decision-making process in New Zealand. At the same time, an independent hospital-based HTA was also conducted investigating whether expanding eligibility criteria to intermediate risk patients would be beneficial regionally, and also for patients from the single provider centre. A detailed cost analysis was undertaken at both a regional and local level. The objectives of this study were to evaluate the decision making-process for consideration of TAVI at a national level, a regional level and within a single centre and to investigate reasons for the differences in perspectives between agencies at each level.

**METHODS:**

We collected cost data for patients who received TAVI or surgical aortic valve replacement (SAVR) between June 2012 and July 2015 including costs prior to and following the intervention where available. We were able to access detailed cost data for patients who received cardiothoracic services at both a regional level and for Auckland DHB alone. Analysis of the cost data, together with the perceived affordability and practicality of implementing TAVI were considered and recommendations made at a regional and local

level. These recommendations were compared with those published by a National HTA agency.

**RESULTS:**

Access to detailed cost data was a key driver of differences in perspectives between agencies. The National level agency considered the average intervention costs, likelihood of various outcomes and the need for equity across the country; the regional agency considered value for money and the access to services; while the single provider centre considered reimbursement for services, budget impact and potential cost-savings of freeing surgical space (bed-days and operating time). Apparent differences in perspective were not based on clinical evidence or on the interpretation of study data, but rather on consideration of how the costs would impact budgets and affordability.

**CONCLUSIONS:**

This example highlights the practical application of HTA at different levels of the health care system in New Zealand. Despite the availability of good quality HTA including cost-effectiveness studies, there were other influences acting upon decision-making processes that caused different levels of health care organisation to respond differently and challenged evidence-based approaches. Access to detailed data and its application to perceived affordability was the starkest difference between the different levels of decision making.

**OS.400 High Satisfaction And Implementation Rates For HTA Performed By Clinicians With Support And Quality**

**DESCRIPTION:**

Since 2006, a HTA process is used where clinicians or managers nominate technologies for HTA performed by the clinicians who are involved in use of the technology and including an organisation

for support to the clinicians and quality control. Satisfaction with the HTA process and the implementation rate are high.

**AUTHORS:**

Lennart Jivegård, Christina Bergh, Jenny Kindblom, Ola Samuelsson, Petteri Sjögren, Henrik Sjövall, Annika Strandell, Therese Svanberg

**BACKGROUND AND OBJECTIVES:**

The implementation of Health Technology Assessment (HTA) results in evidence-based care. Evidence-based care improves patient benefits. Implementation of the results of HTA reports is, however, often slow due to factors such as non-availability of a relevant high quality HTA, when needed, and poor knowledge of and engagement in HTA by clinicians. Mini-HTAs performed by clinicians may address some of these problems, but often lack systematic literature review, and adequate quality. In our needs-led activity-based HTA process, HTA questions can be nominated by clinicians and managers. The departments that will be involved in the use of the technology are responsible for the conduct of a HTA. Clinicians are assigned to the HTA project and given time for the HTA work by the head of their department, and receive thorough methodological support by HTA experts and information specialists from our HTA-centrum. Quality assurance is done by HTA-centrum experts, external reviewers and a regional HTA quality assurance board. For promising technologies with low/very low certainty of evidence according to GRADE, research grants for evidence development can be applied for after completion of the HTA.

Objectives. To study clinicians' appreciation of the HTA process as well as HTA production times and implementation rate.

**METHODS:**

Annual HTA production and production times were studied. Questionnaires were sent to the managers for the first 30 produced HTA reports regarding

their validation of the HTA and whether the results had been implemented or not. Questionnaires regarding work load during the HTA and satisfaction with the HTA process were sent to the clinicians who participated in HTA projects during 2015.

**RESULTS:**

HTA production (n= 85, 385 clinicians) increased from three in 2008 to 11 per year 2014-15. The number of participating clinicians per project increased by 33%. Clinicians reported 37 work hours during 5.1 months (median values) for the HTA project. Ninety per cent of the first 30 HTAs were used for decisions by managers, and 82% were entirely or mainly implemented in clinical practice. More than 95% of the managers rated quality and timeliness as high. The participating clinicians rated the HTA process with a median of 10, mean 8.8 (scale 0 - 10) and 96% would recommend it to colleagues.

**CONCLUSIONS:**

Our needs-led activity-based HTA process in which clinicians produce HTA reports with thorough support and quality control attracts high interest and appreciation by clinicians. The main products of our HTA process include timely delivered high quality HTA and significantly improved HTA competence among clinicians. Both are equally important to increase evidence -based care. Since the HTA reports were used by managers, and usually implemented in clinical practice, our HTA process addresses many of the problems related to poor implementation of HTA. We believe the current HTA principles can be adopted in most hospitals and significantly increase evidence-based care.

## OS.401 Managing Uncertainty In Reimbursement Decisions Through Risk Share Agreements

### DESCRIPTION:

This study examined the use of risk share agreements by the Australian government and drug sponsors in relation to listing drugs on the Australian Pharmaceutical Benefits Scheme.

### AUTHORS:

Danny Liew, Hansoo Kim

### BACKGROUND AND OBJECTIVES:

Data submitted in reimbursement dossiers are often insufficient for decision-making due to uncertainty regarding key factors such as effectiveness beyond clinical trial durations, incremental gain due to lack of head-to-head evidence, appropriate comparators, and place of the new health technologies within management algorithms. All these flow on to financial uncertainty. The problem of clinical and/or financial uncertainty is highlighted by a stagnating world economy, ever-growing demand from patients and clinicians for timely access to the latest health technologies, and fierce market competition.

In Australia, to prevent delay in the listing of a drug on the Pharmaceutical Benefits Schedule (PBS) despite clinical and/or financial uncertainty, risk share agreements (RSA) were recently introduced. RSAs involve drug sponsors taking on some of the financial risks associated with PBS listing, and comprise various schemes that essentially involve sponsors offering rebates when usage exceeds an agreed threshold and/or agreed outcomes are not met.

This study sought to describe the use of RSAs in recent reimbursement decisions made by the Australian Pharmaceutical Benefits Advisory Committee (PBAC).

### METHODS:

Public summary documents from the PBAC meetings in March 2015 and July 2015 (the latest available) were reviewed. Note was made of whether or not RSAs were proposed by the sponsor and/or the PBAC, how these differed by the type of submission (major [new listing] versus minor) and whether there was an association with the outcome of the submission (recommendation versus rejection or deferment).

### RESULTS:

At the two PBAC meetings in March and July 2015, a total of 108 submissions were considered, of which 66 (61.1%) were major submissions for listing on the PBS. Of these, 28 (42.4%) involved RSA proposals and 38 (57.6%) did not. Of the 28 major submissions that involved RSAs, 19 (67.9%) were positively recommended by the PBAC, compared to 19 of the 38 (50%) major submissions that did not involve RSAs.

### CONCLUSIONS:

RSAs are becoming more common in relation to Australian reimbursement decisions. They allow for payers and industry sponsors to find common ground in dealing with clinical and/or financial uncertainty and ensure that patients are granted timely access to new health technologies.

---

## OS.404 Applying Multi-Criteria Decision Analysis (MCDA) Simple Scoring As An Evidence-Based HTA Methodology

### DESCRIPTION:

This presentation will summarize a workshop constructed to develop MCDA criteria for the evaluation of off-patent products in emerging markets. Twenty-two criteria were identified and categorized into four categories: product, manufacturer, service and economics. Drug safety,

manufacturing site quality certification and quality assurance of active pharmaceutical ingredient and the production process were the top three criteria across all categories.

#### **AUTHORS:**

Diana Brixner, Nikos Maniadakis, Zoltan Kalo, Shanlian Hu, Atholl Johnson, Jie Shen, Kalman Wijaya

#### **BACKGROUND AND OBJECTIVES:**

Delivering effective, universal, and efficient health care is an important policy goal across countries worldwide. HTA has been established to evaluate patented pharmaceuticals in many health care systems, however, this HTA methodology has not been applied to off-patent pharmaceuticals. Given its critical role in reaching and retaining universal coverage, a group of academia and industry experts have undertaken an initiative to develop a HTA methodology for off-patent products and conducted significant work in this area both at the theoretical and practical implementation levels.

MCDA simple scoring has been emerging as a useful approach, which can be applied for pharmaceutical pricing, reimbursement, and formulary listing assessment. This method can be easily adapted to suit particular characteristics of individual health care systems, of particular interest to healthcare systems in search of a sound methodology to evaluate off-patent pharmaceuticals. These markets use off-patent products to treat a majority of their patient populations, which plays a vital role in achieving universal coverage.

This presentation will summarize a workshop constructed to develop MCDA criteria for the evaluation of off-patent products.

#### **METHODS:**

Twenty-two criteria were identified through a review of the literature and WHO, FDA, and EU procurement directives and categorized into four categories: product, manufacturer, service

and economics. These criteria were presented, discussed, and ranked from five (significantly important) to zero (not important) with fifty-seven healthcare experts and decision makers across emerging markets at the International Society of Pharmacoeconomics and Outcome Research (ISPOR) Annual Meeting in Milan, 9th November 2015. An audience response system was used to collect the data for each category.

#### **RESULTS:**

Drug safety, manufacturing site quality certification and quality assurance of API & production process were the top three criteria across all categories. In the product category level, Bio-Equivalence (BE), level of interchangeability, and Pharmaceutical Equivalence (PE) were the top three criteria. In the manufacturer category, manufacturing site quality certification, quality assurances of API & production process and supply track record were the top three criteria. In the service category pharmacovigilance, local investment and distribution practices were the top three criteria. Finally, in the economic category, drug safety, clinical efficacy & efficacy and direct cost were the top three criteria.

#### **CONCLUSIONS:**

MCDA simple scoring can be deployed as a HTA methodology to evaluate off-patent pharmaceuticals. There is a three-fold benefit to this approach: 1) Evidence based criteria for MCDA including (BE, PE, and drug safety) 2) Proper stakeholder involvement from emerging markets to create transparent and decision across healthcare stakeholders for MCDA and 3) Easily adaptable methods to suit healthcare priorities and development stages. The presented criteria for MCDA are flexible and can be tailored based on healthcare priorities and stages.

#### **REFERENCES:**

"Vakaramoko Diaby, Kaitryn Campbell, Ron Goeree & Multi-Criteria Decision Analysis (MCDA) in healthcare: A bibliometric analysis, operations research for healthcare vol.2, issues 2013: 20-24.

World Health Organization. Annex 7. Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. 2006. Report No.: 937

Hattacharyya, Lokesh; Schuber, Stefan; Sheehan, Catherine; William, Roger (2006). "Excipients: Background/Introduction"

World Health Organization. Quality Assurance Pharmaceuticals, volume 2, second updated edition

WHO Technical Report Series, No. 957, 2010

<http://www.accme.org/requirements/accreditation-requirements-cme-providers/policies-and-definitions/cme-content-definition-and-examples> accessed 3 Nov 2015

World Health Organization. [http://www.who.int/medicines/areas/quality\\_safety/safety\\_efficacy/pharmvigi/en/](http://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/) accessed 3 Nov 2015

EU High Level Pharmaceutical Forum (Oct 2008)

EU Directive 2010/84/EU, Article 101" (PDF). <http://ec.europa.eu>. Retrieved 2015-10-26.

FDA Guidance for Industry: Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims

WHO: Drug and therapeutics committees: A Practical Guide. 2003"

---

## OS.414 Assessing Value-For-Money For Orphan Drugs; Mismatch Of Applied Methods, Economic Theory And Data

### DESCRIPTION:

Concerns regarding the inadequacy of conventional cost-utility analysis to capture societal values and preferences are explored, with particular attention to orphan drugs. How economic theory might be employed to adjust CUA

is detailed. Potential problems of using different methodologies are considered; generally and with specific examples, and the lack of necessary primary data is highlighted

### AUTHORS:

Camille Schubert, Skye Newton, Tracy Merlin

### BACKGROUND AND OBJECTIVES:

Many public healthcare providers are familiar with considering 'value-for-money' when making the decision of whether or not to fund a new technology. Acknowledging that numbers of adverse health events avoided, or even years of life gained, don't capture all outcomes society values, cost-effectiveness analysis (CEA) has routinely evolved to cost-utility analysis (CUA); incorporating consideration of benefits in the broader sense of quality-of life. However when it comes to orphan drugs and rare diseases this method of analysis is considered by many, at best & impractical; or at worst - still inadequate; to quantify societal values and make access and funding decisions. We sought to identify the concerns that existed around the use of CUA - particularly in the orphan drug setting and examine what alternative approaches could be utilised either to improve the \$/QALY metric, or define an alternative metric for decision-makers.

### METHODS:

Both peer-reviewed and 'grey' literature was searched to identify characteristics of value potentially associated with new health technologies which are not captured in conventional CUA. Literature on economic theory and methodology was reviewed to identify whether adjustments to conventional CUA methodology or alternative approaches could be applied that would more convincingly capture societal value. Consideration as to the practicality of implementing analysis of alternative metrics was considered in the context of (i)decision-making bodies broadly, and (ii)some specific examples of orphan drugs currently in use in Australia which do not meet conventional cost-

effectiveness criteria for funding.

**RESULTS:**

There is strong theoretical support for using adjusted approaches to CUA; methods such as broadening the capture of costs and outcomes beyond the treated patient to more genuinely reflect a societal perspective, weighting quality-adjusted life-years gained to incorporate equity values and societal preferences and adjusting funding ICER thresholds are well-described. There are empirical studies and data on societal preferences for various equity concerns which could be utilised (or replicated). Additionally, Multi-Criteria Decision Analysis was identified as another approach. However when considering how alternative value-metrics might be applied in practice, issues of consistency and inadequate data were problematic.

**CONCLUSIONS:**

While it is apparent that conventional CUA as currently undertaken, do not always adequately capture societal values with respect to equity preferences for funding healthcare technologies, theoretically there is the ability to add to the capability of this methodology such that equity considerations are included. However, no matter how conceptually complete the adjusted QALY metric becomes, unless there is adequate evidence generated in primary research, particularly with respect to what benefits new technologies can offer, but also with respect to how society does value equity, then adjusted metrics can only remain a concept.

.....

## OS.420 Implementation Status And Governmental Regulation Of Non-Invasive Prenatal Testing In China

**DESCRIPTION:**

With a view from the perspective of values and evidence, this qualitative study interviewed 114 person relevant to non-invasive prenatal testing by focus groups discussion, and presented the clinical practice and governmental regulation of NIPT in China.

**AUTHORS:**

Jian Ming

**BACKGROUND AND OBJECTIVES:**

Non-invasive prenatal testing (NIPT) appears to be a promising health technology as it has been shown to be effective in detecting trisomy 21, 18 and 13. But NIPT was 'called off' in China in 2014 due to ethical concerns and its controversial direct-to-clients model of providing NIPT. Subsequently, the National Health and Family Planning Commission initiated a pilot project in early 2015 to strengthen the regulation of NIPT practice.

This study aims to examine some initial outcomes of the pilot project, with a view to providing information for policy-makers to guide decision-making regarding governmental regulation of NIPT in China.

**METHODS:**

Three focus groups (FGs) were conducted with relevant government officials (n=22) from three provinces (Zhejiang, Shandong and Hunan) which represent regions of different levels of socioeconomic development in China. Sixteen FGs were conducted with health workers (n=92) from 16 hospitals in the same three provinces and Shanghai. FGs were conducted with a semi-structured question guide to explore how the FG participants view the current situation of and

challenges facing NIPT. The interviews were transcribed and analyzed using narrative and thematic approaches.

**RESULTS:**

The hospitals differed in the extent of their involvement in NIPT. Two different models were adopted: Hospitals conducting the entire process of NIPT by themselves (7 hospitals) and hospitals collecting blood samples and having them tested by a third party, mostly companies specializing in genetic testing or other hospitals (6 hospitals). With regard to governmental regulation, the government faces multiple challenges such as establishing a reasonable price structure for NIPT services; dealing with for-profit genetic testing companies' direct-to-clients service model with its considerable ethical, privacy-protection and quality ramifications; and achieving a balance between management and over-regulation.

**CONCLUSIONS:**

NIPT has demonstrated sensitivity and specificity in detecting trisomy 21, 18 and 13 and should have a useful role to play in China's healthcare system. However, in addition to assessing the efficacy of NIPT, there is a need to establish supporting systems of pricing, insurance coverage, market regulation, and quality assurance. It is also necessary for government to achieve a balance between governance and over-regulation.

.....

## OS.424 Robotic Surgery: Meteor Or Supernova? Results From A Web-Based Survey

**DESCRIPTION:**

The paper summarizes the results of a web based survey aimed at describing the pattern of diffusion of robotic surgery in Italy over time over time. After an experimental phase, in which centres owing surgical systems tested them in several types of procedures, hospitals started to optimize the use of

this technology and to use it in smaller subgroups of patients.

**AUTHORS:**

Cicchetti A, Fiore A, Coretti S, Ghirardini A

**BACKGROUND AND OBJECTIVES:**

"Since its market access, robotic surgery has been becoming integral part of patient surgical management, but its adoption at a hospital level has often been driven by strategic view rather than clinical evidence.

The aim of this study is to provide an overview of the current use of robotic surgery a few years after its first experiences of implementation in Italy, in order to identify trends of utilization."

**METHODS:**

A web-based survey addressed to hospital managers of Italian hospitals owning a surgical robotic system was designed. Hospital managers were given 6 months to participate in the survey. Once the survey was closed, data was cleaned and analyzed using Gini coefficient and Lorenz curves to investigate the distribution of robotic interventions among the centers involved in the survey from 2011 to 2014. These results were compared with scientific literature on robotic surgery to see whether the increase/reduction in the utilization rate of surgical robot for specific types of interventions was or not accompanied by the availability of new compelling evidence.

**RESULTS:**

Seven hospitals eventually took part in the survey. Data referred to applications of robotic surgery in urology, gynecology and abdominal surgery. So far, robust clinical evidence supports the use of robotic surgery in a few applications, such as radical prostatectomy, partial nephrectomy and radical hysterectomy. For a few types of interventions (such as radical prostatectomy), both the number of operations performed with robotic support and the number of centres performing robotic

surgery has been increasing over time. For partial nephrectomy, the number of centres performing robotic surgery has been increasing over time, but the overall number of robotic interventions has been decreasing meaning that centres are now trying to target robotic surgery on specific subgroup of patients.

### **CONCLUSIONS:**

Our evidence suggests that after an 'experimental' phase, in which centres owing surgical systems tested them in several types of procedures, hospitals started to optimize the use of this technology and to use it in smaller subgroups of patients. Scientific literature and cost containment considerations might have affected these decisions.

---

## **OS.425 Providing Value: Patients Experiences, Perceptions Of Professional Care, Support**

### **DESCRIPTION:**

This session will present the SBU report on Self-harm: patients experiences and perceptions of professional care and support published in 2015. There is little research into treatment received by people who self-harm, nor their experiences of the healthcare and school systems. Why, how and what the results of the report were will be presented and discussed.

### **AUTHORS:**

Sophie Söderholm Werkö

### **BACKGROUND AND OBJECTIVES:**

Self-harm can take different forms and have different functions, i.e. people self-harm for many different reasons. Self-harming behaviour is more common among teenagers and young adults than in other adults. It usually begins between the ages of 12 and 14 and is more common in girls

than boys. In Swedish school-based studies from 2011, 34-42% of the participants reported having harmed themselves at least once, while 15-20% reported repeated acts of self-harm (on at least five occasions).

There is little research into treatment received by people who self-harm, nor their experiences of the healthcare and school systems. This applies to children and adolescents as well as adults. This session will present how people who self-harm experience their interactions with the healthcare and educational services. Because of the close relationships and the dependence of young people on relatives and friends, these perspectives are also included when they have been reported in the included studies.

The term non-suicidal self-injury (NSSI) refers to behavior which is not intended to result in suicide. This distinguishes NSSI from suicidal behavior, where death is the intention.

### **METHODS:**

Scientific literature databases relevant to the research questions were searched. The project group used predetermined inclusion criteria to select relevant studies. The methodological quality of the included studies was assessed, the majority conducted with qualitative methods of analysis. Strength of evidence was rated and ethical and social aspects were considered.

### **RESULTS:**

The scientific evidence supports the perceptions of people who self-harm that it is important that healthcare professionals have a supportive approach and listen to them. They also feel that healthcare personnel do not understand them and have a judgmental approach.

People who self-harm consider it important that healthcare personnel should be well-versed in psychiatry and self-harming behaviour. Their perception is that the healthcare services fail to ensure continuity of contact with the same

healthcare professional, and that interventions are planned without their participation. Negative experiences and perceptions of healthcare services have discouraged them from subsequently seeking help.

### **CONCLUSIONS:**

There is a need for significant improvement in the attitudes of healthcare personnel to treating people who self-harm. Good communication between healthcare professionals and adults with self-harming behaviour includes participation and continuity and can be crucial in motivating continued treatment. At present, many adults feel that healthcare professionals are judgmental, do not listen to them and lack sufficient knowledge, both of psychiatry and self-harm. They say that they are rarely offered the opportunity to participate in planning their care, that there is a lack of continuity in terms of treatment plans and staff, and that the care lacks meaningful content.

### **REFERENCES:**

SBU. Self-harm: patients' experiences and perceptions of professional care and support. Stockholm: Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU); 2015. SBU Alert-report no 2015-04. <http://www.sbu.se/201504E>

---

## **OS.426 HTA In Practice: An Australian Example**

### **DESCRIPTION:**

Focus lies on the Australian reimbursement process for an implantable medical device (iMD). Assessed evidence included safety, effectiveness- and patient-reported outcomes. The clinical evidence demonstrated that compared to No Treatment the medical device is superior in terms of effectiveness and non-inferior in terms of safety. Using a Markov model the iMD was cost-effective compared to No Treatment and a comparative iMD.

### **AUTHORS:**

Ruth Zoehrer, Melodi Kosaner-Kliess, Bettina Schlick, Manuela Mariacher, Michael Urban, Vibrant MED-EL Hearing Technology GmbH, Innsbruck, Austria-Europe

### **BACKGROUND AND OBJECTIVES:**

The here presented work focuses on the evaluation of an implantable medical device (iMD) in order to obtain reimbursement for the Australian market. This decision depends on value arguments, informed by evidence of safety, effectiveness and patient-reported outcomes compared to standards of care or other comparative services.

**INTRODUCTION:** Health care in Australia, namely Medicare, is funded out of general tax revenue and covers hospital and medical services. For reimbursement/public funding the Medical Services Advisory Committee (MSAC) provides advice to the Minister of Health on whether medical services should be listed on the Medicare Benefits Schedule (MBS) based on HTA applications, such as the here presented one.

### **METHODS:**

After submission of several application forms to undergo MSAC review a value dossier was created in accordance with guidelines. Data requirements for the systematic review, the PICO's (Population-Indication-Comparator-Outcome(s)), were defined in agreement with MSAC. Several databases were searched using a comprehensive search strategy to identify publications assessing safety, effectiveness, patient-reported outcomes and economical outcomes. MSAC agreed comparators to include no treatment and other iMD's (from now on referred to as comparator).

### **RESULTS:**

The submission process involved a well-defined stepwise process on clarification of eligibility, PICO's, and clinical claims. Out of a total of 670 citations, the data from 47 studies reporting on functional gain, speech recognition score in

quiet and noise, subjective outcomes using self-assessment questionnaires and safety outcomes were presented in the submission. Only 6 studies or systematic reviews dealing with economic analyses could be identified. Level III to Level IV evidence from non-randomised cohort studies and case series were used to support the clinical claim and data was summarized narratively and supported with tabulated results. For cost-effectiveness analyses a state-transition (Markov states) model was developed. The clinical events in the model were defined as events that can affect the costs and course of treatment in the short or long-term and included 'successful', 'successful with complications' and 'device failure' as main health states. The estimated costs of iMD's were taken from different sources: MBS, Australian Refined Diagnostic Related Group, and manufacturers' homepages. The time horizon for the economic model was 10 years with a cycle length of 6 months. Both deterministic and probabilistic sensitivity analysis was carried out to reduce uncertainty.

### CONCLUSIONS:

The clinical evidence demonstrated that compared to No Treatment, the iMD is superior in terms of effectiveness and non-inferior in terms of safety. iMD seems to be highly cost effective based on the cost/QALY when compared to No Treatment and when based on patient benefit for comparing against the comparator. The incremental cost-effectiveness ratios were calculated over the estimated iMD lifetime of 20 years and results demonstrated consistent outcomes, particularly increased incremental effectiveness in the long-term. We are awaiting MSAC's decision whether or not they support the reimbursement (advice to the Minister of Health) of an iMD for the Australian market.

.....

## OS.433 The Relationship Between Surgeon And Hospital Volume And Outcomes In Lower Limb Vascular Surgery

### DESCRIPTION:

This study investigated the association between hospital/surgeon volume and outcomes in lower limb vascular surgery in Europe. Seven studies were included. There might be an association between increase in hospital/surgeon volume and decrease in amputations, and a co-variation between amputation/mortality rate by hospital volume but not by surgeon volume. Larger review studies are needed to confirm the association.

### AUTHORS:

Edward A. Goka, Patrick Phillips, Edith Poku, Munira Essat, Helen Buckley Woods, Eva C Kaltenthaler, James B Chilcott, Steven Walters, Phil Shackley, Jonathan Michaels

### BACKGROUND AND OBJECTIVES:

Peripheral vascular disease is a major cause of death and disability. An unpublished review of reviews gave inconclusive results about importance of volume in lower limb (LL) vascular surgery. An understanding of the relationship between volume and outcome would aid in planning and delivery of healthcare. This review investigated:

1. The relationship between the volume of LL vascular surgery undertaken by individual surgeons and pre-specified outcomes.
2. The relationship between the volume of LL vascular surgery undertaken in individual hospitals and pre-specified outcomes.

### METHODS:

The review was undertaken according to a registered protocol on PROSPERO. Comprehensive literature searches were conducted on Medline and Medline in Process, Embase, the Cochrane Library

Databases Science Citation Index and CINAHL. Proceedings from five key conferences (2010-2015), and citations and references of included studies were also searched.

Studies from Europe, of adults undergoing elective/emergency LL vascular surgery reporting effect of hospital/surgeon volume on risk of mortality, amputation, repeat surgery, length of hospitalisation, and other adverse events (AEs) were included. Data was extracted and cross-checked by two reviewers. In the initial search titles and abstracts were screened. Full text papers were retrieved for studies that appeared to meet inclusion criteria. A third reviewer was consulted in event of disagreements. Study quality was assessed using a modified ACROBAT-NRSI tool. Odds ratios of outcomes by hospital or surgeon volume were summarized using tables."

## RESULTS:

Seven studies conducted in UK (n=3); Sweden (n=2); Finland (n=1); UK and Ireland (n=1) were included. A total of 62,649 patients who had received diverse lower limb revascularization procedures provided data for this review.

The data sources included routine data UK (N=2), and prospective data from vascular projects in Europe (n=5). Outcome reporting was presented by hospital volume (n=5), surgeon volume (n=1), or by a combination of both (n=1); with volume defined as quartiles in some studies and continuous in others.

The evidence suggests association between increase in hospital<sup>1-3</sup>/surgeon<sup>3,4</sup> volume and decrease in amputations, and a co-variation between amputation/mortality rate by hospital volume but not by surgeon volume. Two studies<sup>1,2</sup> found amputation/mortality co-varied by hospital volume, while two studies<sup>3,4</sup>, with amputation/mortality data by surgeon volume, found discordant results. There were insufficient number of studies reporting on the other variables; but their results suggest high volume hospitals might undertake more repeated surgeries<sup>1</sup>/revascularisations

and limb salvage<sup>4</sup> procedures, but there was no association between hospital volume and length of hospitalization<sup>5,6</sup>. The impact of volume on other adverse events (AEs) was unclear; one study<sup>1</sup> found an association between low hospital volume and increased number of AEs, the other two studies found no association between hospital<sup>5</sup>/surgeon<sup>7</sup> volume and AEs.

## CONCLUSIONS:

High volume hospitals/surgeons might undertake fewer amputations. In addition, mortality and amputations may co-vary by hospital volume. However, the small number and poor quality of some of the included studies, makes it difficult to draw firm conclusions. A larger review, including studies from all over the world, is recommended.

## REFERENCES:

1. Moxey PW, Hofman D, Hinchliffe RJ, Poloniecki J, Loftus IM, Thompson MM, et al. Volume-outcome relationships in lower extremity arterial bypass surgery. *Annals of Surgery*. 2012;256:1102-1107.
2. Elfstrom J, Troeng T, Stubberod A, Elfstrom J, Troeng T, Stubberod A. Adjusting outcome measurements for case-mix in a vascular surgical register--is it possible and desirable? *European Journal of Vascular & Endovascular Surgery*. 1996;12:459-463.
3. Kantonen I, Lepantalo M, Luther M, Salenius P, Ylonen K, Kantonen I, et al. Factors affecting the results of surgery for chronic critical leg ischemia--a nationwide survey. *Finnvasc Study Group. Journal of Vascular Surgery*. 1998;27:940-947.
4. The Vascular Surgical Society of Great Britain and Ireland. Critical limb ischaemia: management and outcome. Report of a national survey. The Vascular Surgical Society of Great Britain and Ireland. *European Journal of Vascular & Endovascular Surgery*. 1995;10:108-113.
5. Goode SD, Keltie K, Burn J, Patrick H, Cleveland TJ, Campbell B, et al. Effect of procedure volume

on outcomes after iliac artery angioplasty and stenting. *British Journal of Surgery*. 2013;100:1189-1196.

6. Berridge DC, Scott DJ, Beard JD, Hands L, Berridge DC, Scott DJ, et al. Trials and tribulations of vascular surgical benchmarking. *British Journal of Surgery*. 1998;85:508-510.

7. Troeng T, Janzon L, Bergqvist D, Troeng T, Janzon L, Bergqvist D. Adverse outcome in surgery for chronic leg ischaemia--risk factors and risk prediction when using different statistical methods. *European Journal of Vascular Surgery*. 1992;6:628-635.

.....

## OS.439 Divergent Views Of Healthcare Professionals And The Adoption Of Home Based Dialysis Therapies

### DESCRIPTION:

Using institutional logics as a theoretical lens, we focus on how healthcare professionals deal with evidence while adopting home based dialysis (HBD). The adoption and diffusion of HBD grew in the 1980s and then declined in most countries, before attempts to re-introduce it. The dynamics and tensions arising from the logics of different stakeholders are important for understanding innovation trajectories.

### AUTHORS:

Paola Roberta Boscolo, James Barlow

### BACKGROUND AND OBJECTIVES:

Several aspects of evidence-based medicine have been criticized (Greenhalgh et al., 2014; Fernandez et al., 2015), nevertheless it shapes the adoption and diffusion of healthcare innovations (Denis et al., 2002). It is important to understand how available evidence is interpreted and by whom (Ferlie et al., 2000, 2005; Fitzgerald et al., 2003). We focus on

healthcare professionals and how they deal with evidence while adopting and assimilating home based dialysis (HBD).

Renal failure poses a global public health challenge (Lancet, 2014). Different therapies are available, but dialysis remains the most widely used. HBD became available in the 1970s, increasingly adopted in the 1980s and then declined in most countries, before more recent attempts to re-adopt it.

Despite positive evidence (Vanholder et al., 2014), HBD diffusion is globally low and uneven. Financial incentives have been introduced in different countries to stimulate its adoption, but this has been problematic due to inadequate cost information locally (Abma et al., 2014).

We provide a holistic perspective, acknowledging field, organizational and individual level factors that potentially impact on adoption and diffusion. We adopt 'institutional logics' as a theoretical lens and aim to contribute to a deeper qualitative research methodology in health care.

### METHODS:

A multiple-case study aimed at contrasting different hospitals within the Italian NHS with regard to their choices about dialysis. Since 2001 responsibility for healthcare has been delegated to the regional level. This allowed us to consider the potential impact of different contexts, while focusing on a single country. Four hospitals were purposively selected to illustrate a diversity of cases. Data sources included archival materials and semi-structured interviews with all physicians and nurses working in each renal unit. Qualitative analysis allowed a deep investigation of the values and beliefs that contribute to healthcare professionals' choices.

### RESULTS:

The choice of providing HBD is partially related to its evidence base. When discussing scientific evidence in the abstract, physicians agree about its direction, but when considering the same evidence for local decisions, other considerations

.....

prevail. The reasons why physicians decide to adopt or refute HBD are similar, and related to a mix of emotional and scientific factors. Others have identified a 'professional logic' in healthcare (Dunn, 2010; Kellogg, 2009, 2011). We found both physicians and nurses hold a professional logic, but the way it shapes their behaviour is different, due to different logics blending in these professional categories.

## CONCLUSIONS:

Advocating a shift from hospital to HBD without considering the wide spectrum of therapies available and local contextual factors is insufficient. The research makes a contribution to the healthcare innovation adoption and diffusion literature, which mainly focuses on well-defined technological innovations. Using the theoretical lens of institutional logics provides deeper insight into the factors impacting on innovation assimilation, which play out simultaneously at organizational and field levels. Objective evidence contributes to adoption choices, but the dynamics and tensions arising from the logics of different stakeholders enrich our understanding of innovation trajectories.

## REFERENCES:

AA.VV - The Lancet (2014), Editorial, 24th May 2014, 'Seizing the opportunity to rethink renal research', Vol. 383.

Abma, I., Jayanti, A., Bayer, S., Mitra, S., Barlow, J. (2014). 'Perceptions and experiences of financial incentives: a qualitative study of dialysis care in England', *BMJ Open*, no. 4.

Denis, J.L., Hebert, Y., Langley, A., Lozeau, D., Trottier, L.H. (2002). 'Explaining diffusion patterns for complex health care innovations', *Health Care Manage Rev*, 27(3):60-73.

Dunn, M.B., & Jones, C. (2010). 'Institutional logics and institutional pluralism: The contestation of care and science logics in medical education, 1967-2005'. *Administrative Science Quarterly*, 55(1):

114-149.

Ferlie, E., Fitzgerald, L, Wood, M. (2000). 'Getting evidence into clinical practice: an organizational behaviour perspective'. *Journal of Health Services Research & Policy*; 5: 96 - 102.

Ferlie, E., L. Fitzgerald, Wood, M. and Hawkins, C. (2005). 'The (non) spread of innovations: The mediating role of professionals'. *Academy of Management Journal* , 48(1), 117-134.

Fernandez, A., Sturmberg, J., Lukersmith S., Madden, R., Torkfar G., Colagiuri R., Carulla, L.S., 'Evidence-based medicine: is it a bridge too far?', *Health Research Policy and Systems* 2015

Fitzgerald, L, Ferlie E, Hawkins C. (2003). 'Innovation in healthcare: how does credible evidence influence professionals'. *Health and Social Care in the Community*, 11:219 - 28.

Greenhalgh, T., Howick, J., Maskrey, N. (2014). 'Evidence based medicine: a movement in crisis?' *Evidence Based Medicine Renaissance Group, BMJ*, 348: g3725.

Kellogg, K. (2009). 'Operating room: Relational spaces and micro-institutional change in surgery'. *American Journal of Sociology*, 115(3): pp. 657-711

Kellogg, K.C. (2011). 'Hot lights and cold steel: Cultural and political toolkits for practice change in surgery'. *Organization Science*, 22, 482-502.

Vanholder R., Biesen W.V, Lameire N. (2014). 'Renal replacement therapy: how can we contain the costs?' [www.thelancet.com](http://www.thelancet.com), May, 383."

# OS.440 Estimating The Size Of Advanced Gastroenteropancreatic Neuroendocrine Tumour Sub-Populations To Support

## DESCRIPTION:

In the context of reimbursement frequently recommended for restricted sub-populations, identifying relevant epidemiologic data in the literature to support target population sizing is challenging. Therefore, model-based approaches represent a valuable and novel option. This study aimed at developing a population growth model to estimate the number of patients with specific types of gastroenteropancreatic neuroendocrine tumors (GEP-NETs) over a five-year horizon.

## AUTHORS:

Aurore Bergamasco, Gabrielle Nayroles, Anne-Marie Castilloux, Jérôme Dinet, Anthony Berthon, Sylvie Gabriel, Yola Moride

## BACKGROUND AND OBJECTIVES:

Gastroenteropancreatic neuroendocrine tumours (GEP-NETs) are rare neoplasms. For innovative treatments, recommendations by payers or health technology agencies frequently involve sub-populations of patients that are more restricted than the approved indications. Because epidemiologic data published in the literature are not specific to GEP-NETs restricted sub-populations, generating relevant data to support pricing and reimbursement strategies, and providing robust estimates of their budget impact represent a major challenge for a successful market access. This study aimed at developing a model to estimate the number of patients with specific site and type of GEP-NETs over a 5-year horizon for two GEP-NET sub-populations: i) patients with stable/slow progressing well-differentiated, functioning and non-functioning GEP-NETs and unresectable locally advanced/metastatic disease; and ii) patients with stable/slow progressing well-differentiated, non-functioning GEP-NETs and

unresectable locally advanced/metastatic disease. For both sub-populations, tumors originating from the hindgut (colon and rectum) were excluded.

## METHODS:

A literature review was conducted to obtain data on incidence, prevalence and survival estimates of GEP-NETs across different regions (EU, US and Australia). Following the identification of the crude prevalence and incidence rates for a broader GEP-NET population, estimates were obtained for each sub-population of interest using proportions of GEP-NETs by site and type derived from clinical studies. Then, these figures were further refined using clinical expert opinions. A target population growth model that maps the population journey through the 5-year period was developed.

## RESULTS:

Prevalence of well-differentiated GEP-NETs was 13.22/100,000, proportion of NETs with unresectable locally advanced/metastatic disease was 50 %, and proportion of patients with stable/slow progressing disease was 50%. The 22.4% tumors originating from the hindgut were excluded. For the second sub-population, proportion of non-functioning tumors was 70%. In the 5-year span, respectively for the first and second sub-population of interest, the predicted number of patients is expected to increase, from 8,079 to 10,154 and 5,655 to 7,108 in EU; from 8,051 to 10,119 and 5,636 to 7,083 in the US; and from 593 to 746 and 415 to 522 in Australia.

## CONCLUSIONS:

Because the second sub-population of interest is a subgroup of the first, lower estimates were obtained. In the absence of published epidemiologic data on specific sub-populations, modeling techniques can be used to estimate trends in target populations in order to meet expectations of pricing and reimbursement authorities.

# OS.456 Systematic Review Of The Economic Burden In Patients With Pulmonary Arterial Hypertension

## DESCRIPTION:

This study systematically reviews and evaluates evidence on costs of PAH and cost-effectiveness of PAH treatments, and summarizes corresponding cost-drivers. It is found that economic burden of PAH is substantial; sildenafil is a cost-effective treatment compared with other medications; medical costs are cost-drivers. Paucity of large-national evidence and estimates of indirect costs of PAH requires concern, especially in China.

## AUTHORS:

Shuyan Gu Huimei Hu, Hengjin Dong

## BACKGROUND AND OBJECTIVES:

Pulmonary arterial hypertension (PAH) is a relatively rare but life-threatening disease with no efficient cure, which may impose a tremendous economic burden on patients and healthcare systems. However, most existing studies mainly emphasize epidemiology, clinical characteristics and medications of PAH, as well as efficacy and cost-effectiveness of specific PAH treatments. Large observational studies reporting economic burden are lacking; and those economic evaluation studies available merely concentrated on certain PAH treatments, lacking of head-to-head comparison studies covering all comparable medications. Therefore, this study is to systematically review and evaluate current evidence on costs of PAH and cost-effectiveness of PAH treatments, and summarize the corresponding cost drivers.

## METHODS:

Systematic literature searches were conducted in English (PubMed, Web of Science, ScienceDirect) and Chinese (China National Knowledge Infrastructure, Wanfang Data, Chongqing VIP) databases to identify studies (2000-2014) assessing

costs of PAH or cost-effectiveness of PAH treatments. Search results were independently reviewed and extracted by two reviewers. Only studies (1) examined real-world economic burden of PAH; (2) on economic evaluations of specific PAH treatments; (3) on adult patients with PAH; and (4) wrote in English or Chinese were included. Costs were converted into 2014US dollars.

## RESULTS:

Of 1959-citations identified in initial-search, 19-papers were finally included: 8 on economic burden of PAH, 11 on economic evaluations of PAH treatments. The economic burden of PAH was considerable large, with direct healthcare costs per patient-month varied from \$2476 to \$11,875 across studies, while none reported indirect cost. Healthcare costs may change over time following the disease progression and medications use, mainly with an increase in pharmacy costs but a decrease in medical costs. Sildenafil was reported to be a cost-effective treatment with lower cost and better efficacy compared with other medications. Medical costs were reported to be the cost-drivers.

## CONCLUSIONS:

The economic burden in patients with PAH is substantial. Sildenafil is a cost-effective treatment option for clinicians and patients to choose. Opportunities for savings exist from advanced new treatments and improved disease management which may play a role in reducing patients' medical costs. Implement of shared decision making and integration of palliative care into PAH treatment may make a difference in improving disease management. While paucity of large national evidence in this area and absence of estimates in indirect costs of PAH requires researchers' concern, especially in China. Potential language bias may be the main limitation of this study.

# OS.458 Cost-Effectiveness Of Saxagliptin Versus Glimepiride As Second-Line Therapy Added To Metformin

## DESCRIPTION:

This study estimates long-term cost-effectiveness of saxagliptin (SAXA)+metformin (MET) vs glimepiride (GLI)+MET in patients with T2DM inadequately controlled with MET in China. It is found that SAXA+MET was more cost-effective and well-tolerated with fewer adverse-effects (AEs) compared with GLI+MET. As a second-line therapy, SAXA may address some of the unmet medical needs attributable to AEs in T2DM treatment.

## AUTHORS:

Shuyan Gu, Jing Deng, Lizheng Shi, Yiming Mu, Hengjin Dong

## BACKGROUND AND OBJECTIVES:

Increasing prevalence and poor management of type 2 diabetes mellitus (T2DM) impose heavy disease burden on patients and healthcare system in China. Glimepiride (GLI) is a third-generation sulfonylureas anti-diabetic drug. It is widely used as second-line therapy in China with proved efficacy, while its non-negligible adverse effects (AEs) (e.g. weight gain, increased risk of hypoglycemia) may impede treatment effect. Saxagliptin (SAXA) as a new agent with recognized efficacy and beneficial hypoglycemia and weight profiles looks promising to solve this problem and consolidate second-line therapy. However, there are no direct head-to-head studies comparing both the long-term benefits and costs of SAXA with GLI as second-line treatment added to metformin (MET) in a Chinese population. Thus this study aims to estimate the long-term cost-effectiveness of SAXA+MET vs GLI+MET in patients with T2DM inadequately controlled with MET in China.

## METHODS:

The Cardiff Diabetes Model was used to simulate disease progression and estimate the long-term effect of treatments on patients. Systematic literature reviews (English and Chinese databases) and hospital surveys (one secondary hospital and one tertiary hospital) were conducted to obtain model-needed China-specific patients profiles, clinical data, and costs. From payers' perspective, health insurance costs (2014¥) were considered for drug acquisition and diabetes-related events, and estimated over a 40-year period. One-way and probabilistic sensitivity analyses were performed.

## RESULTS:

SAXA+MET had lower predicted incidences of cardiovascular and hypoglycemia events and a decreased total cost compared with GLI+MET (¥241,072,807 vs ¥285,455,177). There were increased numbers of quality-adjusted life-years (QALYs; 1.01/patient) and life-years (LYs; 0.03/patient) gained with SAXA+MET compared with GLI+MET, and the incremental cost of SAXA+MET vs GLI+MET (¥44,382) resulted in ¥43,883/QALY and ¥1,710,926/LY gained with SAXA+MET. Sensitivity analyses confirmed that the results were robust.

## CONCLUSIONS:

In patients with T2DM in China, SAXA+MET is a preferred option demonstrating greater benefits and lower costs compared with GLI+MET. SAXA is likely to represent a durable, well-tolerated and cost-effective treatment option for physicians and decision-makers as second-line therapy in combination with MET for T2DM inadequately controlled with MET alone in China. It may address some of the unmet medical needs in T2DM treatments attributable to AEs and reduce the economic burden of diabetes.

# OS.459 Cost-Effectiveness Of HLA-DQB1 And HLA-B Alleles Testing For Clozapine-Induced Agranulocytosis

## DESCRIPTION:

Clozapine has superior therapeutic efficacy in the treatment of schizophrenia to other antipsychotic drugs, however underutilized because of its agranulocytosis liability. Clozapine-Induced Agranulocytosis was associated with single amino acid changes in HLA-DQB1 (126Q) and HLA-B (158T). We found that the HLA-DQB1 and HLA-B allele testing guided strategy was more cost-effective than the mandatory systematic long-term absolute neutrophil count monitoring.

## AUTHORS:

François R. Girardin, Antoine Poncet, Arnaud Perrier, Nathalie Vernaz, Mark Pletscher, Marie Besson, Jean Villard, Jeffrey A. Lieberman

## BACKGROUND AND OBJECTIVES:

Clozapine has superior therapeutic efficacy in the treatment of schizophrenia to other antipsychotic drugs. However, it is underutilized because of its agranulocytosis liability and the burden of mandatory absolute neutrophil count monitoring (ANCM). Clozapine-Induced Agranulocytosis (CIA) was associated with single amino acid changes in HLA-DQB1 (126Q) and HLA-B (158T), but the utility for clinical practice remains unknown.

To assess the cost-effectiveness of HLA-DQB1 and HLA-B allele testing compared to current US ANCM in schizophrenic patients taking clozapine, we defined two strategies: 1) Clozapine prescription for all patients with targeted ANCM only in patients tested positive for one or both of the alleles of susceptibility (genetic guided strategy-GGS); 2) No ANCM in any patient and alternative antipsychotic prescription to clozapine in patients tested positive for one or both of the alleles of susceptibility (clozapine substitution strategy-CSS).

## METHODS:

We performed the cost-effectiveness analysis from a third-party payer perspective with a 3-year time-horizon, assuming a CIA cumulative rate of 0.7%. The HLA-DQB1 and HLA-B alleles prevalence CIA among positive patients treated with clozapine were based on genome-wide genotyping and whole-exome sequencing (n=385; sensitivity=0.41; specificity=0.85). We set a mean cost of genetic testing of \$200 per patient. Model and parameter uncertainty were assessed with one-way and probabilistic sensitivity analyses. Costs, Quality-Adjusted Life-Year (QALY), ICER, and probability for each strategy of being cost-effective given a willingness-to-pay (WTP) threshold per QALY.

## RESULTS:

In the base-case scenario, the GGS was the most cost-effective strategy up to a WTP threshold of \$3.9 million per QALY: long-term ANCM became cost-effective if the WTP exceeded this value. Cost-effectiveness results were sensitive to changes in the cost of genetic testing, CIA prevalence, and infection-related death rate. Given a WTP threshold of \$50,000 per QALY, there was a higher than 99% probability that the HLA alleles testing remains cost-effective if the genetic testing cost stays under \$700.

## CONCLUSIONS:

In patients with schizophrenia taking clozapine, pharmacogenetic testing associated with CIA is cost-effective by limiting systematic and long-term ANCM to patients having alleles of susceptibility.

## OS.466 The Impact Of Magnitude Of Clinical Benefit On HTA Recommendations For New Anticancer Drugs

### DESCRIPTION:

European HTA agencies face difficulties when assessing the clinical relevance of anticancer medicines. HTA guidelines and reports do not show a clearly defined threshold for what is considered a clinically relevant improvement of OS/PFS. Defining a minimum standard for what could be considered a clinically relevant OS/PFS gain would be a relevant step towards consistent, transparent and informed decision-making

### AUTHORS:

Iga Lipska, Sarah Kleijnen, Teresa Alves, Neil McAuslane, Lawrence Liberti, Hubertus Leufkens, Anke Hövels, Wim Goettsch

### BACKGROUND:

The burden of cancer is increasing (1). Patients' needs and expectations for new and potentially valuable cancer medicines are rising and intensify pressure on decision makers to grant timely access to new cancer drugs. However, clinicians and policy-makers struggle to determine the clinical benefit of anticancer drugs (2) (3) (4) and to ensure that the patient receives the best possible therapy available. There is evidence that European health technology assessment (HTA) agencies consider overall survival (OS) and quality of life (QoL) to be patient-relevant endpoints although (conclusive) data on these endpoints are not always available. HTA guidelines suggest that progression free survival (PFS) is regarded as a surrogate endpoint. Yet, most agencies seem reluctant to discard PFS data despite weak evidence on surrogacy of PFS for OS.

### OBJECTIVES:

To investigate how the magnitude of the effect size of OS and PFS impacts on European HTA

recommendations for new anticancer drugs.

### METHODS:

HTA guidelines and reports for pricing and/or reimbursement decisions in six European jurisdictions were compared: England, France, Germany, The Netherlands, Poland and Scotland. Anticancer drugs were selected that received market authorization in Europe between 2011-2013, and for which at least four HTA reports from different jurisdictions were available. To enable the comparison of HTA recommendations across jurisdictions we developed and implemented a dichotomous (positive/negative) classification of HTA recommendations. Data for OS and PFS effect magnitude were analysed for all jurisdictions.

### RESULTS:

Fourteen anticancer drugs fitted the inclusion criteria giving a total of 72 HTA recommendations, of which 52 (72%) were positive. OS gains reported in the HTAs varied from no improvement/OS data not yet mature (crizotinib) to 10,4 months (afatinib). PFS gains ranged from 1,4 months (cabazitaxel) to 6,1 months (pertuzumab). Drugs with similar magnitude of OS and/or PFS effect were found to have different HTA recommendations across the jurisdictions. Both OS/PFS gain and Hazard Ratio (HR) for OS/PFS are considered relevant for HTA recommendations.

### CONCLUSIONS:

Based on the preliminary results we conclude that European HTA agencies face difficulties when assessing the clinical relevance of anticancer medicines. HTA guidelines and reports do not show a clearly defined threshold for what is considered a clinically relevant improvement of OS/PFS. Defining a minimum standard for what could be considered a clinically relevant OS/PFS gain would be a relevant step towards consistent, transparent and informed decision-making in a rapidly evolving field such as oncology.

## REFERENCES:

1. Jemal A, Bray F, Center MM, Ferlay J, Ward E, Forman D. Global cancer statistics. *CA Cancer J Clin.* 2011;61(2):69-90.
2. Cherny NI, Sullivan R, Dafni U, Kerst JM, Sobrero A, Zielinski C, et al. A standardised, generic, validated approach to stratify the magnitude of clinical benefit that can be anticipated from anti-cancer therapies: the European Society for Medical Oncology Magnitude of Clinical Benefit Scale (ESMO-MCBS). *Ann Oncol.* 2015;26(8):1547-73.
3. Schnipper LE, Davidson NE, Wollins DS, Tyne C, Blayney DW, Blum D, et al. American Society of Clinical Oncology Statement: A Conceptual Framework to Assess the Value of Cancer Treatment Options. *J Clin Oncol.* 2015;33(23):2563-77.
4. Kleijnen S, Lipska I, Alves T et al. The assessment of oncology medicines for pricing & reimbursement decision in European countries. In submission

---

## OS.469 Determinants Of Health Technology Assessment Knowledge Translation: Triangulation Of Data in China

### DESCRIPTION:

In order to measure the determinants and explain the mechanism of HTA knowledge translation in China, qualitative and quantitative data were collected from HTA researchers and policy makers. In this study, grounded theory and structural equation model demonstrate that sufficient communication, strengthening training, improving the importance of HTA, and enhancing collaboration can facilitate the knowledge translation of HTA in China.

### AUTHORS:

Yan Wei, Yingyao Chen, Lizheng Shi

## BACKGROUND AND OBJECTIVES:

Since the introduction of health technology assessment (HTA) to China in the 1980s, there are numerous HTA studies. Despite the efforts, the integration of HTA and policy-making processes is still in its infancy in China. Knowledge translation is playing an important role in formulating evidence-based policymaking and facilitating HTA's policy impact. Regarding to knowledge translation, there are direct and indirect facilitators and barriers in the translation from HTA to policy making. Scientific evidence is just one of many factors in the successful implementation of knowledge translation. This study aims at measuring the determinants and explaining the mechanism of HTA knowledge translation in China.

## METHODS:

A mixed-methods study was conducted based on a concurrent design. Qualitative and quantitative data were collected from HTA researchers and policy makers in China. A triangulation was used to integrate data and to interpret determinants of the knowledge translation. Based on triangulation, hypothesis were formulated from a grounded theory analysis. And quantitative data was analyzed using structural equation model to develop the mechanism underlying knowledge translation from researchers to policy makers.

## RESULTS:

A sample of 382 HTA researchers and 112 policy makers were surveyed using structured questionnaires, and 21 HTA researchers and 17 policy makers completed a 1 to 1.5 hour in-depth interview individually. The structural equation model had 4 latent variables, including organizational factors, the perception of stakeholders, demand factors and communication between researchers and policy-makers. The structural equation model identified organizational factors and perception of stakeholders affected the HTA knowledge translation through the communication between researchers and policy-makers. The demand factors influence the

knowledge translation directly. The communication between researchers and policy-makers had an extremely high direct effect value (0.78).

### **CONCLUSIONS:**

Sufficient communication, strengthening related training in HTA knowledge translation, improving the importance of HTA in evidence-based policy, and enhancing collaboration between HTA researchers and policy makers can facilitate the knowledge translation of HTA evidence in China.

---

## **OS.474 Using International HTAs In Local Settings - Have We Reached Our Goal?**

### **DESCRIPTION:**

The aim of adopting international HTAs for local purposes is to ensure high quality evidential basis for decision-making and avoid duplication and thus wasting of resources. In Norway we have so far used three HTAs produced by the European Network for HTA (EUnetHTA) to answer national commissions from our health services. After briefly presenting these examples and outcomes, the ways the HTA information was adapted, and challenges encountered, the presentation will further elaborate on learnings from these "adaptation experiences", and how these processes may have influenced decision making. Finally will be discussed what we can take on board from our experience so far to possibly improve reuse of international assessments in the future.

### **AUTHORS:**

Katrine Frønsdal

### **BACKGROUND AND OBJECTIVES:**

The very first step when conducting an HTA is to look for already existing HTAs on the same subject. In cases where others have performed an updated systematic literature search for studies relevant to

our own research question, done a proper quality assessment, graded and summarized the evidence appropriately using validated tools, we can – and should– reuse the assessment. We are so-called "adopting" and/or "adapting" the HTA in question into our "local setting", this to ultimately ensure a solid evidential ground for decision-making, and importantly, not to waste resources on repeating the whole assessment ourselves.

EUnetHTA aims at facilitating the sharing of information and efficient use of resources available for HTA in Europe, such as the reuse of European HTAs, including those produced by the EUnetHTA itself. For that purpose, EUnetHTA has developed various tools and methods to promote the collaboration between European countries in producing HTAs, such as the HTA Core Model as assessment framework and a database for planned and ongoing projects. Several organizations from EU Member States, EEA and EFTA countries, including Norway, regional agencies and non-for-profit organizations have already tried the tools and actual collaboration in HTA productions. However, less is known about the reuse of HTAs, and how they initially were chosen to be adopted locally, how they actually were adapted, and what the outcomes were, and if this "adaptation-process" possibly may have played a role in terms of decision-making and implementation.

During early stages of the EUnetHTA collaboration, an adapting toolkit was developed with the intention of ensuring better use of existing HTA reports, and adapting the HTA Core Model within assessments made for one country into "advice appropriate to other contexts". Although the purpose of this tool remains highly relevant (e.g. avoid waste of resources by minimizing duplication of work), it is uncertain to which extent the tool actually has been used in local settings. It could even be questioned to which degree such a tool can be helpful at all, or if it is possible to provide sensible advices with any tool, beyond overarching guidance, as for instance questions related to relevance, applicability and transferability.

## METHODS:

To date, the Norwegian Knowledge Centre for the Health Services (NOKC) has fruitfully taken advantage of three EUnetHTA-produced HTAs for carrying out own assessments. Two of these were commissioned directly by Norwegian Health Authorities, and one was carried out based on specific interest by Norwegian clinicians within the field of cardiology. These included two so-called rapid assessments: "Renal denervation for resistant hypertension" and "Mechanical thrombectomy for acute ischemic stroke", and one so-called "core HTA": "Effect of abdominal aortic aneurysm (AAA) screening". The decision of adopting these HTAs was primarily based on a good knowledge of EUnetHTA's activities (NOKC being an active HTA-producing member) and knowing that other European countries were about to adapt them. Another important factor was the particular time period that the assessments were done, which was compatible with deadlines set by our commissioners in delivering the local HTA. In addition, the HTAs had been using methods for quality assessments, grading and reporting that were similar to criteria as set by NOKC. Nevertheless, HTA information from the European HTAs could not necessarily just be transferred. Whereas numericals and calculations could be used directly as such, there were differences in reporting and formats, and in interpreting results, and challenges in English wording. Hence, interpretations and sometimes even conclusions, had to be reformulated for some effectiveness outcomes, and especially for outcomes related to safety. Minor challenges were related to using information on description of the technology, its use and the health problem, as these mainly were associated with the lack of information on how common the disease was in our country, what specific products were in use in Norway, etc. When it came to organizational aspects (relevant for the AAA-screening HTA), although general issues were often relevant, we could not use much of the more detailed information from the HTA, since we needed detailed context-specific information. On the other hand, ethical issues discussed were highly

relevant to our own ethical assessment.

## CONCLUSIONS:

Despite technical and sometimes unexpected challenges, adapting these three HTAs was worthwhile, in terms of both sparing time and resources. When it comes to the actual decisions made in Norway, renal denervation has been put "on hold" until additional evidence is generated. Mechanical thrombectomy will most likely be recommended in updated guidelines, whereas AAA-screening has not been part of any decision-making process yet. One can only speculate to which extent having used collaborative European HTAs for our assessments may have influenced policy-making and further implementation, but is likely that a very early decision to adapt these EUnetHTA reports for our assessments, and NOKC's own involvement in these has played a role. So have we reached our goal? – Our experience with these three HTAs have been very positive, but it remains to fully assess the impact adaptation ultimately may have in improving well-informed decision-making. This is one of the central issues for the upcoming EUnetHTA-JA3 where national implementation, evaluation and metrics instruments and tools to help, monitoring adoption of joint HTA and national outputs are central topics.

# Posters

## Poster 1A Comparison Between Reimbursement Decisions On Oncology Drugs: CONITEC, NICE, CADTH And PBS

### DESCRIPTION:

Nowadays it is important to evaluate different contexts decision-making for new oncology technologies. Thus, the different look of agencies is important to assess the behavior of technology incorporation.

### PRESENTING AUTHOR:

Dr. Erika Camargo, Ministry of Health, Brazil

### AUTHORS:

Erika Barbosa Camargo, Fernanda De Oliveira

### BACKGROUND AND OBJECTIVES:

The National Commission for Technologies Incorporation (CONITEC) aims to recommend the inclusion or removal of health products in the Brazilian Public Health (SUS) procedures list. The CONITEC has been sedimenting, in recent years, a solid work based on evidence with economic evaluation. Objectives: To compare CONITEC's reimbursement decisions on oncology drugs with other three agencies: National Institute for Health and Clinical Excellence (NICE), Canadian Agency for Drugs and Technologies (CADTH) and Pharmaceutical Benefits Scheme (PBS).

### METHODS:

All HTA appraisals on oncology from 2012 to 2015 were analyzed from CONITEC, NICE, CADTH and PBS. The inclusion criteria were at least 2 agencies having assessed the same technology and indications as CONITEC.

### RESULTS:

Drugs assessed were: trastuzumab for advanced breast cancer; trastuzumab for early breast cancer; rituximab for non-Hodgkin's lymphoma B-cell follicular

CD20 positive; rituximab for non-Hodgkin lymphoma B-cell follicular, CD20 positive in the 1st and 2nd line; erlotinib for advanced or metastatic lung cancer, non-small cell EGFR mutation; gefitinib for advanced or metastatic lung cancer non-small cell EGFR mutation; cetuximab in combination with FOLFIRI or FOLFOX in metastatic colorectal cancer KRAS wild with exclusive unresectable liver metastases; cetuximab for squamous cell head and neck locally advanced and everolimus for advanced breast cancer in postmenopausal women. Of 9 technologies assessed PBS had 88,88% of agreement (OU decision matching) with CONITEC. CADTH and NICE had 66,66% of agreement with CONITEC. The three agencies recommended trastuzumab for both indications, erlotinibe and gefitinib. However 100% of the agencies did not recommend cetuximab in combination.

### CONCLUSIONS:

Conclusion: Although there wasn't a full match between the agencies, those who recommend technologies that CONITEC didn't include had a restricted scope of use. The recommendation of health technologies must be based in high quality evidence with an economic evaluation. CONITEC has now reached a mature, transparent and scientifically rigorous. CONITECs challenge now is to deal more transparently with multiple criteria involved in the decision, which are not reliably reported in their reports.

### REFERENCES:

Berntgen M, et a. Improving the Contribution of Regulatory Assessment Reports to Health Technology Assessments - A Collaboration between the European Medicines Agency and the European network for Health Technology Assessment. Value in Health (2014)634 - 641. Hong Ju, Kaye Hewson. Health technology assessment and Evidence-based policy making Queensland department of health Experience. International Journal of Technology Assessment in Health Care, 30:6 (2014), 595-600. web sites: <http://www.pbs.gov.au/pbs/home> <https://www.cadth.ca/> <http://conitec.gov.br/>

.....

## Poster 2A Factors Influencing Reimbursement Decisions On Medical Devices

### DESCRIPTION:

A retrospective analysis of 53 medical device appraisals for the Austrian hospital benefit catalogue 2008-2014 reveals that different factors influence reimbursement decisions of high- and medium-risk devices and in the presence or absence of RCTs supporting the submission.

### PRESENTING AUTHOR:

Tamara Rader, CADTH, Canada

### AUTHORS:

Tamara Rader, Ken Bond

### BACKGROUND AND OBJECTIVES:

CADTH's Patient Engagement Program develops and supports processes to engage with patient groups. Our purpose is to integrate patient perspectives on what matters most into the assessment of drugs, devices, diagnostics, and surgical procedures in a formal and meaningful way. CADTH uses proactive communication strategies, ensures adequate time is given for patient groups to provide input and dedicates staff members' time to support patients' contributions. Patients' perspectives and experiences are documented and reported, and feedback is given to patient organizations who have contributed patient input to assessments by the CADTH Common Drug Review. Since 2014, CADTH has provided feedback on patient group submissions in the form of a feedback letter. In addition to supporting the values of patient engagement, the letter expressed thanks and gives recognition of the group's effort. The letter highlights positive aspects of the submission and suggestions for improvement. Our objective is to determine the usefulness of the letters to patient groups in improving future submissions and other aspects of this patient engagement activity.

### METHODS:

A retrospective audit of feedback letters provided to patient groups for their submissions was undertaken. Letters were selected sequentially until a broad sample of patient groups from a range of disease areas was formed. For each patient group, one letter from the submissions processed between August 2013-July 2014 and a second letter from August 2014-June 2015 were compared. Patient groups provided unsolicited comments on the patient input process and sometimes specific responses to the letters and the suggestions contained in them. All available data (from written correspondence and verbal discussion) were summarized. Free-text responses were summarized by grouping similar answers. The purpose of the analysis is to understand the value of feedback letters, not to provide a critique of patient input received.

### RESULTS:

20 pairs of feedback letters to 17 patient groups were examined. The 40 letters represent the range of drugs assessed in a 2 year time period. The 17 groups represented a range of disease areas and geographical regions across Canada. We describe how the patient input submission changed as a result of the feedback given. Patient groups provided unsolicited comments on the process and sometimes specific responses to the letters and the suggestions. All available data (from written correspondence and verbal discussion) were summarized. Feedback letters ensure that patients' perspectives and experiences are documented and reported, and feedback is given to patient organizations who have contributed to a health technology assessment. Some feedback given to patient groups is difficult to implement, and may impact the value of the letters to patient groups.

### CONCLUSIONS:

Feedback letters document and report back how the patient input was used. They are a formal recognition of the effort of the patient group to provide input and they support patient engagement

values of fairness, equity, legitimacy and increased capacity building.

---

## Poster 4A Trends In Between-Country Health Equity In Sub-Saharan Africa From 1990 To 2011: Improvement, Convergence and Reversal

### DESCRIPTION:

The research tested both  $\sigma$  and  $\rho$  convergence of two health indicators, under five mortality rate and life expectancy, in 46 Sub-Saharan countries using the convergence model to explore the trends in between-country health equity in Sub-Saharan Africa from 1990 to 2011.

### PRESENTING AUTHOR:

Jiajie Jin, Fudan University, China

### AUTHORS:

Jiajie Jin, Lu Shi, Jiayan Huang

### BACKGROUND AND OBJECTIVES:

With substantial amounts of foreign aid invested in sub-Saharan Africa, it remains unclear whether health inequity in this region decreased over time.

### METHODS:

We use the World Health Organization's data about of 46 nations in sub-Saharan Africa to run a convergence model to track the variation of health indicators (under-5 mortality, U5MR and life expectancy, LE) from 1990 to 2011. We use both  $\sigma$  convergence to track whether the standard deviation of the study variable decreased over time and the  $\rho$  convergence to track whether the less developed entities moved toward the average level in the group. Our control variables include the natural logarithm of gross domestic product per capita, the natural logarithm of health care

expenditure per capita, the natural logarithm of development assistance for health per capita, and the share of urban residents in the population.

### RESULTS:

The variation of U5MR between countries became smaller for the first decade of the study period. Yet this  $\sigma$  convergence trend is not sustainable as after 2002 this variation of U5MR became larger. Life expectancy in Africa from 1990-2011 demonstrates a consistent convergence trend, even after controlling for the initial difference of country-level control variables.

### CONCLUSIONS:

The lack of consistent convergence in U5MR partially result from the fact that countries with higher U5MR in 1990 eventually performed better than those countries with lower U5MRs in 1990, constituting a reversal in between-country health inequity. While domestic investment in population health remains important, international aid agencies might need to reassess the priority and focus about which countries to invest health care resources, especially in the field of early childhood health.

### REFERENCES:

- [1] Marmot M, Friel S, Bell R, Houweling T, Taylor S. Closing the gap in a generation: health equity through action on the social determinants of health. *Lancet*. 2008; 372: 1661-1669;
- [2] Braveman P. Health disparities and health equity: Concepts and Measurement. *Annu.Rev.Public Health*. 2006; 27:167-194;
- [3] Sambo LG, Kirigia JM, Orem JN. Health financing in the African Region: 2000-2009 data analysis. *Int Arch Med*. 2013; 6(1):10. doi: 10.1186/1755-7682-6-10;
- [4] Olasfdottir AE, Reidpath DD, Pokhrel S, Allotey P. Health systems performance in sub-Saharan Africa: governance, outcome and equity. *BMC Public and Health*. 2011; 11: 237. doi: 10.1186/1471-2458-11-237;

- [5] Boutayeb A, Helmert U. Social inequalities, regional disparities and health inequity in North African countries. *Int. J of Equity in Health*. 2011; 10: 23-31;
- [6] Schellenberg JA, Victora CG, Mushi A, Savigny D, Schellenberg D, Mshinda H, Bryce J. Inequities among the very poor: health care for children in rural southern Tanzania. *Lancet*. 2003;361(9357):561-566;
- [7] World Health Organization. Report on WHO technical consultation on the measurement of health inequities. Geneva, Switzerland; 2001;
- [8] Boutayeb A. Evaluation of rural-urban health gaps in Morocco: 1992-2011. *BMC Res Notes*. 2012; 5: 381-386;
- [9] Ewelukwa O, Onaka C, Onwujekwe O. Viewing health expenditures, payment and coping mechanisms with an equity lens in Nigeria. *BMC Health Serv Res*. 2013; 13: 87-95;
- [10] Mtei G, Makawia S, Ally M, Kuwawenaruwa A, Meheus F, Borghi J. Who pays and who benefits from health care? An assessment of equity in health care financing and benefit distribution in Tanzania. *Health Policy and Plan*. 2012; 27 Suppl 1: i23-i34;
- [11] Ataguba J, McIntyre D. Paying for and receiving benefits from health services in South Africa: is the health system equitable? *Health Policy and Plan*. 2012; 27 Suppl 1: i35-i45;
- [12] Wabiri N, Cherisch M, Zuma K, Blaauw D, Goudge J, Dwane N. Equity in Maternal Health in South Africa: Analysis of health Service Access and Health Status in a National Household Survey. *PLoS One*. 2013; 8(9): e73864-73875;
- [13] Odeyemi I, Nixon J. Assessing equity in health care through national health insurance schemes of Nigeria and Ghana: a review-based comparative analysis. *Int J Equity Health*. 2013; 12: 9-26;
- [14] Hofman K, Blomstedt Y, Addei S, Kalage R, Maredza M, Sankoh O, Bangha M, Kahn K, Becher H, Haafkens J, Kinsman J. Addressing research capacity for health equity and the social determinants of health in three African countries: the INTREC programme. *Glob Health Action*. 2013; 6: doi: 10.3402/gha/v6i0.19668;
- [15] Hyder A, Maman S, Nyoni J, Khasiani S, Teoh N, Premji Z, Sohani S. The pervasive triad of food security gender inequity and women's health: exploratory research from sub-Saharan Africa. *Afr Health Sci*. 2005, 5(4): 328-334;
- [16] Zere E, Kirigia J, Duale S, Akazili J. Inequities in maternal and child health outcomes and interventions in Ghana. *BMC Public Health*. 2012; 12: 252-261;
- [17] Barro R, Sala-i-Martin X. Convergence. *J Polit Econ*. 1992; 100(2): 223-251;
- [18] Sala-i-Martin X. The Classical Approach to Convergence Analysis. *The Economic Journal* 1996; 106(437): 1019-1036;
- [19] Wang D, Yu T. A cluster analysis and time series approach to examine the healthcare expenditure convergence among Taiwan and the OECD countries. *Int J Behav Healthc Res*. 2008;1(1): 61-69;
- [20] Hitiris T, Nixon J. Convergence of Health Care Expenditure in the EU countries. *Appl Econ Lett*. 2001; 8(4):223-228;
- [21] Wang Z. The Convergence of health care expenditure in the US states. *Health Econ*. 2009;18(1): 55-70;
- [22] Grepin K. HIV donor funding has both boosted and curbed the delivery of different non-HIV health services in Sub-Saharan Africa. *Health Aff*. 2012; 31(7): 1406-1414;
- [23] Ravishankar N, Gubbins P, Cooley RJ, Leach-Kemon K, Michaud CM, Jamison DT, Murray CJ. Financing of global health: tracking development assistance for health from 1990 to 2007. *Lancet*. 2009; 373:2113-2124;
- [24] Edwards R. Changes in World Inequality in

Length of Life: 1970–2000. *Popul Dev Rev.* 2011; 37(3): 499–528;

[25] Clark R. World health inequality: convergence, divergence, and development. *Soc Sci Med.* 2011; 72(4): 617–624;

[26] Ngom P, Binka F, Phillips J, Pence B, Macleod B. Demographic surveillance and health equity in sub-Saharan Africa. *Health Policy Plan.* 2001;16(4): 337–344;

[27] Murray CJ, Lopez AD. Mortality by cause for eight regions of the world: Global Burden of Disease Study. *Lancet.* 1997; 349: 1269–76;

[28] UNAIDS, WHO. Report on the global AIDS epidemic. New York: US UNAIDS (2008);

[29] Lu C, Michaud CM, Khan K, Murray CJ. Absorptive capacity and disbursements by the Global Fund to Fight AIDS, Tuberculosis and Malaria: analysis of grant implementation. *Lancet.* 2006; 368(9534): 483–488;

[30] Marum E, Taegtmeyle M, Parekh B, Mugo N, Lembariti S, Phiri M, Cheng AS. 'What took you so long?' The impact of PEPFAR on the expansion of HIV testing and counseling services in Africa. *J Acquir Immune Defic Syndr.* 2012; 60: S63–S69;

[31] Vickers, B. Towards a new aid paradigm: South Africa as African development partner. *Cam Rev Int Aff.* 2012; 25(4): 535–556.

---

## Poster 5A Budget Impact Analysis Of Insulin Aspart In The Treatment Of Type 2 Diabetes Mellitus In Patients Treated With Insulin In Malaysia

### DESCRIPTION:

This study is an Excel-based budget impact analysis of insulin aspart in the treatment of type 2 diabetes in the context of Malaysia

### PRESENTING AUTHOR:

Dr. Noor Lita Adam, Tuanku Ja'afar Hospital, Malaysia

### AUTHORS:

Noor Lita Adam, Alexander, Tan, Sirinthip, Petcharapiruch, Seng Chuen, Tan

### BACKGROUND AND OBJECTIVES:

Budget impact analysis (BIA) is an essential part of comprehensive economic assessment of health care interventions. The purpose of this study is to assess the financial impact of the introduction of insulin aspart for the treatment of type 2 diabetes mellitus (T2DM) in Malaysia, from the perspective of the Ministry of Health (MoH). The clinically relevant comparator to insulin aspart (NovoRapid®) is regular human insulin (RHI).

### METHODS:

An Excel-based 5-year budget impact model, using published local epidemiological data, was built to estimate the proportion of T2DM patients treated with insulin in the public sector. Baseline characteristics and effectiveness inputs were obtained from ASEAN subgroup analysis of the A1chieve trial data. In addition to treatment costs, the cost of major hypoglycaemic events was searched and included in the analysis. All the costs were expressed in 2015 value. IMS Sales Audit Data in 2015 was analysed to provide the basis of projected adoption rates of insulin aspart and regular human insulin. Sensitivity analyses were conducted to assess the robustness of the result.

### RESULTS:

Compared to a scenario without insulin aspart, additional drug acquisition costs per year incurred by MOH were estimated to be MYR 1.05 million in 2016, increasing to MYR 1.32 million in 2020, for a cumulative total of MYR 5.96 million in 2020. Introduction of insulin aspart was expected to reduce the number of major hypoglycaemic events by 367 in 2016 to 458 in 2020, generating

a cumulative avoided expenditure of MYR 8.88 million attributed to prevent major hypoglycaemic events from 2016 to 2020. As a result, wider adoption of insulin aspart results in a cumulative budget saving of MYR 2.91 million over the 5-year time horizon.

### **CONCLUSIONS:**

A wider adoption of insulin aspart was projected to result in net cost savings in the local context of public health system in Malaysia. Additional cost savings were estimated from lower risk and therefore cost of inclusion of insulin aspart to the Ministry of Health Drug Formulary can save overall budget by the reduction of downstream cost from major hypoglycaemic events for patients treated with insulin aspart than those with regular human insulin.

---

## **Poster 6A Factors Influencing Reimbursement Decisions On Medical Devices**

### **DESCRIPTION:**

A retrospective analysis of 53 medical device appraisals for the Austrian hospital benefit catalogue 2008-2014 reveals that different factors influence reimbursement decisions of high- and medium-risk devices and in the presence or absence of RCTs supporting the submission.

### **PRESENTING AUTHOR:**

Agnes Kisser, LBI for Health Technology Assessment, Austria

### **AUTHORS:**

Agnes Kisser, Heinz Tüchler, Judit Erdös, Claudia Wild

### **OBJECTIVES:**

To analyse which factors impact medical device reimbursement decisions within the Austrian

appraisal programme on "extra medical services" for inpatient care over the past eight years.

### **BACKGROUND:**

Health technology assessments of medical devices present a well-recognized challenge to evaluators: the evidence on safety and clinical effectiveness is often of lower quality than for pharmaceuticals making a reliable assessment of the risk-benefit ratio difficult. Other factors then might gain importance in decision making.

### **METHODS:**

We collected variables on evidence base and device characteristics from all medical device appraisals and assessed their impact on the reimbursement decision by means of odds ratios (OR). Separate analyses were carried out for subgroups based on the risk class of the medical device subject of the assessment or the number of Randomised Controlled Trials (RCTs) available for the assessment.

### **RESULTS:**

Of 53 devices, 19 (36%) were accepted for reimbursement (15 with restrictions) and 34 (64%) were rejected. Variables addressing the quality of the evidence base were positive predictors for risk class II devices only, whereas no significant association could be determined in devices of risk class III. Inversely, high risk device characteristics were positive predictors in the subgroup not supported by RCTs only.

### **CONCLUSIONS:**

Our data indicate that the combination of high risk characteristics and a low evidence base are factors favoring a positive reimbursement decision of medical devices. Further analyses will be required to determine, whether this differential response is related to indication-specific characteristics, to informal notions of medical need and/or an informal early access strategy.

## Poster 7A Experimenting A Process To Involve Patients Associations And Gathering Context-Specific Patients' Views To Be Added To The Review Of Literature In An HTA Report On Dialysis Modalities

### DESCRIPTION:

This project aimed at experimenting a process to involve patients associations and gathering context-specific patients' views to be added to review of literature in HTA. We used the Patient Group Submission Template provided by HTAi subgroup on Patients and Citizens to help patient groups submit information. Besides this we tested a procedure to get patients associations into the HTA process.

### PRESENTING AUTHOR:

Alessandra Lo Scalzo, Agenzia Per I Servizi Sanitari Regionali -ASSR, Italy

### AUTHORS:

Alessandra Lo Scalzo, Anna Maria Vincenza Amicosante, Roberto Costanzi, Marina Cerbo, Tom Jefferson

### BACKGROUND AND OBJECTIVES:

Patients related outcomes and views have been recognized as important in HTA. There are two distinct but complementary ways to do this in a HTA: collect and synthesize available and relevant studies about patients' perspectives and ensuring effective engagement of patients in the HTA process so that new and context-specific evidence can be gathered. As regard to the second step, the HTAi subgroup on Patients and Citizens involvement has provided the Patient Group Submission Template for HTA of Health Interventions, intended to help patient groups submit structured, valuable information for an

assessment of a specific health technology. Besides this a HTA agency needs to adopt a transparent procedure to get patients associations into the HTA process, so that the whole range of potentially interested associations can be informed of the chance of making their voice heard. Within an HTA report on a report on Dialysis modalities we aimed at developing an ad hoc chapter on patients' views using the CM, and add to the traditional review of literature on patients' views, information collected by testing a patients associations' involvement procedure and the HTAiTemplate.

### METHODS:

We performed a review of the literature and constructed and experimented a procedure to identify and involve patients' associations by using the HTAi Template to collect context-specific evidence from patients.

### RESULTS:

For the involvement procedure, we took advantage of an existing agreement between our agency and the Italian section of Active citizenship association, and formally asked to them to point out a facilitator to find the patients associations to involve. The president and secretary of an umbrella association for dialytic persons helped us to list a number of associations at regional level to be involved. For each dialysis modalities we identified 3-5 persons as responders and views of the associations were also collected on the ways healthcare services for dialytic persons are organized in Italy. Evidence have been than analyzed and synthesized to feed the assessment part of the HTA report. Another important national association was involved as external reviewer

### CONCLUSIONS:

The procedure we tested was transparent and explicit and allowed us to obtain a sufficient feedback. We obtained information that were consistent with the information gathered from the review of the literature, but not all the responders answered providing extensive views. This may be

due to the fact that open questions to be answered in a written form could not be the best way to collect qualitative information. In future the tested procedure could be enhanced by including a broader number of associations via proactive proposals

#### REFERENCES:

Karen Facey et al. Patients' perspectives in health technology assessment: A route to robust evidence and fair deliberation *International Journal of Technology Assessment in Health Care* / Volume 26 / Issue 03 / July 2010, pp 334-340.

---

## Poster 8A Decision Criteria Used In Multi-Criteria Decision Analysis For Health Insurance Reimbursement: A Systematic Review And Development Of Decision Criteria Framework

#### DESCRIPTION:

An exhaustive literature search was performed, a conceptual framework of reimbursement decision criteria will be developed based on results of the review, and revised using Delphi method and focus groups.

#### PRESENTING AUTHOR:

Wang Dongze, Fudan University, China

#### AUTHORS:

Dongze wang, shiyi tu, yingyao chen

#### BACKGROUND AND OBJECTIVES:

Reimbursement decisions are often complex and challenging, involving uncertainty, stakeholders' disparate preference, and implicit multiple-values. A fair and legitimate process of reimbursement decision-making needs to be transparent and be equipped with an explicit consideration

of comprehensive value elements held by a wide range of stakeholders. Compared with conventional deliberative processes, Multi-criteria Decision Analysis (MCDA) has been proved to have the potential to make healthcare decision process more explicit, rational, and efficient. A lack of stringently developed decision criteria frameworks has hindered the use of the versatile decision support tool for health insurance reimbursement decision-making. The objective of this study is to identify decision criteria from studies used MCDA in health insurance reimbursement decision-making, and to develop a novel decision criteria framework for health insurance reimbursement decision-making.

#### METHODS:

An exhaustive literature search was performed using Pubmed, EMBASE, Web of Science and Cochrane to identify articles reporting decision criteria for health insurance reimbursement decision-making. Conceptual or empirical studies, which proposed or implemented MCDA, and reported descriptions of MCDA methods, or elicited stakeholders' preferences and/or values, will be included. Data on MCDA methods and decision criteria will be extracted, using a pre-designed spreadsheet. Decision criteria and their frequency of occurrence will be analyzed and reported. A conceptual framework of reimbursement decision criteria will be developed based on results of the review, and revised using Delphi method and focus groups.

#### RESULTS:

2153 potential citations were identified through electronic literature search. 1918 citations were included, after duplicates removed, for primary selection based on title and abstract. Two reviewers independently selected studies, using detailed eligibility criteria. Disagreements will be resolved through third-party adjudication when necessary. We will carry out further investigation to summarize reimbursement decision criteria and their occurrence, as well as develop a novel decision criteria framework.

## CONCLUSIONS:

We will carry out further investigation to summarize reimbursement decision criteria and their occurrence, as well as develop a novel decision criteria framework. The ultimate objective is to develop sound multi-criteria approaches to promote reimbursement decisionmaking and priority-setting.

---

## Poster 9A Review Of HTA Submissions In The UK: Are There Lessons To Be Learnt?

### DESCRIPTION:

Evidence synthesis is used in health policy decisions via the clinical effectiveness evidence in health technology assessment (HTA) submissions. Technology appraisals have been reviewed in order to identify potential learning opportunities for the statistical approaches to evidence synthesis in order to assist in the preparation for future HTAs.

### PRESENTING AUTHOR:

Sarah Batson, DRG Abacus, United Kingdom

### AUTHORS:

Sarah Batson, Gemma Greenall, Neil Webb

### BACKGROUND AND OBJECTIVES:

The quality of evidence used in manufacturers' submissions to health technology assessment (HTA) bodies is an important factor for the success of technology appraisals (TAs). Evidence synthesis is used in health policy decisions via the clinical effectiveness evidence in HTA submissions to the National Institute for Health and Care Excellence (NICE). The objective of this study was to: (i) identify criticisms of the evidence synthesis component in TAs generated by NICE and the Evidence Review Group (ERG) and (ii) provide key learnings and recommendations to minimise criticism of evidence synthesis for future HTA submissions.

---

## METHODS:

The NICE website was reviewed to identify both TAs and the associated ERG/final appraisal document reports published from January 2013 to June 2015 in any therapeutic setting.

## RESULTS:

A large proportion of the TAs included components of evidence synthesis (indirect comparisons and network meta-analyses). The main criticisms were related to the identification of studies and study selection, identification of and the use of appropriate measures to address study heterogeneity, as well as the inadequate reporting of methods and analyses.

## CONCLUSIONS:

The key learnings around the evidence synthesis submitted to NICE are related to issues around the primary evidence included in the analyses rather than the statistical methods used for evidence synthesis. To avoid many of the generic criticisms identified in this study a transparent approach to the reporting of evidence synthesis is recommended. In terms of the methods used for statistical analyses, there were limited learning opportunities. To assist in the preparation for HTA we recommend a strategic assessment of the methods of evidence synthesis used in previous HTAs in the relevant therapeutic setting.

---

## Poster 10A NMA In HTA: Novel Approaches For Searching For Indirect Evidence

### DESCRIPTION:

Network meta-analysis combines both direct and indirect evidence, providing more statistical power than simple indirect comparisons. A systematic literature search based on the PICO framework will not identify all trials which could potentially be used in an NMA network. The different types of

---

geometry of indirect comparisons are introduced and alternative strategies for searching for evidence are presented.

**PRESENTING AUTHOR:**

Sarah Batson, DRG Abacus, United Kingdom

**AUTHORS:**

Sarah Batson

**BACKGROUND AND OBJECTIVES:**

Network meta-analysis (NMA) allows the combination of information from a network of RCTs in order to compare different treatments simultaneously. NMA combines both direct and indirect evidence, providing more statistical power than simple indirect comparisons. Even where direct evidence is available, an NMA, including additional indirect evidence, can further improve the precision of treatment effect estimates. A systematic literature search, based upon the PICO framework, will identify all direct comparisons and simple first and second order indirect comparisons. However, such a 'traditional' search will not identify all trials which could be used in an NMA network. Evidence network size remains an unsolved issue in NMA and there are no formal guidelines to ensure transparency on when to extend a network or how far it should be extended for health technology assessment (HTA). The objectives of this study are to: i) present a summary of the types of indirect comparisons within evidence

**METHODS:**

Electronic searches for publications reporting research around the issues of searching for indirect evidence for the purposes of NMA/IC were performed using Embase (1980 onwards; accessed via Ovid). Reference lists of eligible publications were hand searched. Only articles published in English were included.

**RESULTS:**

Three publications were identified which reported

research relating to the issues around searching for indirect evidence for NMA (1-3). An alternative iterative approach to searching for indirect evidence has been proposed in a single publication (1) and applied to a case study in a further publication (2). The third publication assessed the benefits of extending evidence networks in terms of the precision of estimates and examined the impact of heterogeneity (3). We present two additional pragmatic approaches to literature searching for informing NMA for HTA.

**CONCLUSIONS:**

There is limited research into when to extend an evidence network or how far it should be extended for NMA in HTA. The iterative search approach identified is labour intensive and may not be feasible in practice (1, 2). In the absence of formal guidelines, an approach which optimises precision whilst keeping networks manageable is required. We propose two alternative pragmatic strategies for searching for evidence.

**REFERENCES:**

- 1.Hawkins N, Scott DA, Woods B. How far do you go? Efficient searching for indirect evidence. Medical decision making : an international journal of the Society for Medical Decision Making. 2009 May-Jun;29(3):273-81. PubMed PMID: 19470721.
- 2.Dequen P, Sutton AJ, Scott DA, Abrams KR. Searching for indirect evidence and extending the network of studies for network meta-analysis: case study in venous thromboembolic events prevention following elective total knee replacement surgery. Value in health

## Poster 11A Can “Open Data” Help The Drug Policy?

### DESCRIPTION:

Open prescribing datasets are analyzed by researchers, media, patient or consumer organizations, or companies. These studies can contribute to the evolution of drug policy, under pressure or via collaborations between decision-makers and external users, as shown by examples in the United-Kingdom, the United-States, and France. HTA feeds this kind of studies about prescribing.

### PRESENTING AUTHOR:

Dr. Hervé Nabarette, HAS, France

### AUTHORS:

Hervé Nabarette, Brian B Godman

### BACKGROUND AND OBJECTIVES:

“Open data” consists in publishing anonymous data produced by public bodies, which are downloadable at no charge. Publication of these data is supposed to strengthen accountability and efficiency of public policies. Conceptual frameworks stress the context, the nature of open datasets, their use, and impact. Open drug datasets concern drug description, pharmacovigilance or prescribing. The potential users are internal (those who work within the health system) or external (academic researchers, patient or citizen organizations, media, companies). We analyze uses of prescribing data by external users to understand how they can influence future drug policies.

### METHODS:

Through the web, we searched for mediatized studies in the United Kingdom, the United States, and France. We also focused on studies which had been carried out before releasing open data, i.e. data being obtained via legal procedures. We describe these studies, the context, the data, and their impact.

### RESULTS:

United-Kingdom. Starts ups analyzed the prescribing data of general practitioners released by the NHS Information Center in 2012. They calculated the extent of possible savings if general practitioners had more systematically followed a guideline recommending the prescription of generic statins instead of patented ones, building on previous publications. NHS managers have further identified practices which don't fully prescribe generic statins and monitored them. United-States. Journalists obtained in 2013 the prescribing data from the Medicare program via a legal procedure. They have put the spotlight on atypical practices of physicians, conflicts of interest regarding prescription practices, and financial incentives fueling prescriptions of expensive medicines. In 2015, Medicare officials decided to better monitor prescription practices, what had been rejected so far. France. In 2014, patient associations and a company obtained via a legal procedure the consumption data of a drug which caused a scandal in France in 2010 (benfluorex). Data showed that an appreciable proportion of patients were prescribed the drug off label. The publications reactivated the debate about the weakness of prescribing monitoring and on the share-out of remits between the different public bodies.

### CONCLUSIONS:

Analyses compare the practices with norms produced by the very authorities (indication from marketing authorization, equivalence of effect between drugs), or question the incentives of practitioners. The UK study was realized with the support of the NHS. It was very close to previous analyses about potential savings and its consequences were quite similar to national or local programs aiming at improving prescribing efficiency (for instance the Better Care Better Value Indicators). The 2 other studies were undertaken following legal procedures in the United States and in France before 2015, a year when the public insurances released detailed prescription data. Open data exploitation can contribute to

the evolution of drug policy, under pressure or via collaborations between decision-makers and external users. HTA contributes to these studies in defining good practices and ways of assessment (equivalence of effect between drugs, place in the therapeutic strategy).

#### REFERENCES:

The Independent. Oliver Wright. Prescribe cheaper drugs, GPs told, 'Inefficient' doctors targeted as NHS looks to save billions. December 2012.  
Weber T, Ornstein C, LaFleur J. ProPublica and Whashington Post. Medicare Drug Program Fails to Monitor Prescribers, Putting Seniors and Disabled at Risk. May 2013.  
Dab W, Le Monde, mars 2014.  
Pouvait-on détecter la dérive du Mediator ?

---

## Poster 12A Clinical Outcomes With Bioresorbable Vascular Scaffold Versus Zotarolimus And Everolimus Drug Eluting Stent : Evidence From A Bayesian Approach Network Meta-Analysis

#### DESCRIPTION:

Bioresorbable vascular scaffold (BVS) has theoretical advantages as the stent body disappears after vascular constrictive remodeling. Recent studies have suggested the clinical superiority of BVS. However, relative efficacy of BVS versus metallic drug-eluting stent (DES) has not been investigated. The objective of the study is to evaluate the clinical outcomes between BVS versus DES using a Bayesian network meta-analysis.

#### PRESENTING AUTHOR:

Hyung-Deuk Park, Medtronic Korea, Ltd., Korea

#### AUTHORS:

Hyung-Deuk, Park, Jeong-Woo (Aiden) Yi, So-Jeong, You

#### BACKGROUND AND OBJECTIVES:

Bioresorbable vascular scaffold (BVS) has theoretical advantages as the stent body disappears after vascular constrictive remodeling. Recent studies have suggested that the clinical outcomes of BVS may comparable with the everolimus-coated metallic drug-eluting stent (DES). However, relative safety and efficacy of BVS versus DES coated with zotarolimus drugs have not been investigated in depth. The objective of the present study is to evaluate the clinical safety and efficacy between BVS versus DES coated with zotarolimus using a Bayesian network meta-analysis.

#### METHODS:

A network meta-analysis of BVS versus zotarolimus-coated and everolimus-coated DES was performed. Randomized controlled trials of BVS, zotarolimus-coated and everolimus-coated DES in cardiovascular artery disease patients were identified from MEDLINE, EMBASE and COCHRANE database. Abstracts were reviewed, and studies containing information on clinical outcomes were obtained for further review. Results were pooled and analyzed by a Bayesian random-effect model. The safety outcomes were cardiac death, myocardial infarction (MI) and stent thrombosis; efficacy outcomes were target lesion revascularization (TLR), target vessel failure (TVF) and target lesion failure (TLF).

#### RESULTS:

8 studies were identified with a total of 3,865 patients. At 1-year follow-up, BVS was not associated with significant reduction of cardiac death [odds ratio (95% credible interval)=1.13 (0.88, 1.47)], MI [1.05 (0.81, 1.37)], stent thrombosis [0.89 (0.64, 1.25)], TLR [1.02 (0.85, 1.23)], TVF [1.35 (0.91, 2.00)] and TLF [0.59 (0.14, 2.53)] compared with zotarolimus-coated DES. BVS also had similar rate of cardiac death [0.48 (0.11, 1.99)], MI [0.33 (0.01, 8.20)], stent thrombosis [1.92 (0.44, 8.31)], and TLR [0.41 (0.10, 1.63)] compared with everolimus-coated DES. Zotarolimus-coated DES had similar rate of cardiac death [2.19 (0.52, 9.14)], MI [2.70 (0.09,

78.53]), stent thrombosis [2.49 (0.61, 10.20)], and TLR [1.58 (0.67, 2.33)] compared with everolimus-coated DES.

**CONCLUSIONS:**

In patients with symptomatic coronary artery disease treatment, BVS and zotarolimus-coated and everolimus-coated DES have comparable efficacy and safety.

.....

## Poster 13A Methods And Processes To Update Patient Decision Aids Supporting Patient Values And Preferences In Health Care Decision Making

**DESCRIPTION:**

Shared decision making promotes a culture where clinicians and patients work together to decide on the treatment that delivers the best outcomes for the patient, based on their personal values and preferences. This project describes the development of methods and process to update and quality assure patient decision aids to support shared decision making.

**PRESENTING AUTHOR:**

Laura Norburn, NICE, United Kingdom

**AUTHORS:**

Laura Norburn, Victoria Thomas, Gillian Leng

**BACKGROUND:**

Shared decision making promotes a culture where clinicians and patients work together to decide on the treatment that delivers the best outcomes for the patient, based on their personal values and preferences. This process can be supported by decision support tools such as patient decision aids which present information on the risks and benefits of each treatment option in a clear and

understandable way. Shared decision making and the development of patient decision aids provides an opportunity for patients to be central to decisions about the health technology or treatment that is best for them.

**OBJECTIVES:**

To develop methods and processes for updating existing patient decision aids, taking into account new health technologies, and formulate a strategy for disseminating and promoting the use of patient decision aids in the English NHS, as part of a wider culture change.

**METHODS:**

We undertook a review of existing methodologies for identifying and analysing new evidence, and tested their feasibility for updating patient decision aids. We also explored quality assurance mechanisms and their applicability to currently available patient decision aids, and patient decision aids in development.

**RESULTS:**

As a consequence of the review we developed a draft process and methodology for updating existing patient decision aids, split into 3 options: o As part of the development of upcoming NICE guidance o As an activity where NICE guidance already exists o As an activity where there is no related NICE guidance We also produced a proposal for applying NICE (and other) quality assurance mechanisms to current patient decision aids and outlined a number of options for endorsing, accrediting and collating patient decision aids.

**CONCLUSIONS:**

This project offers the opportunity for a systematic process and methodology to maintain the currency and accuracy of decision support tools, with appropriate quality assurance. This provides a mechanism to promote and help implement a culture of shared decision making more widely in the English NHS, embedding patients as full participants in decisions about their care.

---

## Poster 14A Modelling The Incremental Cost Of Adopting Neoadjuvant Pertuzumab In A Singaporean HER2+ Breast Cancer Population

### DESCRIPTION:

A discrete event microsimulation model was utilised to estimate the clinical outcomes, total lifetime cost per patient, and overall budget impact of adopting pertuzumab as standard of care in local inoperable HER2+ breast cancer patients

### PRESENTING AUTHOR:

Dr. Joseph Mocanu, Oliver Wyman, Singapore

### AUTHORS:

Joseph D Mocanu, Jeremy Lim Fung Yen

### BACKGROUND AND OBJECTIVES:

Over 1,500 women / year are diagnosed with breast cancer in Singapore and of these approximately 30% have a mutated HER2 receptor and are eligible for targeted therapies. Trastuzumab was the first of these therapies and was viewed as a paradigm shift in a subpopulation with a historically poor prognosis; today it is now even listed under the WHO's List of Essential Medicines. Its cost, however, created much debate around affordability and access. With escalating R&D costs and increasingly narrow patient subpopulations, the trend of premium priced targeted therapies has continued and HER2+ breast cancer is no exception. The arrival of second generation agents, ado-trastuzumab emtansine, and pertuzumab, raise further questions around value given these new regimens can cost significantly more per cycle than trastuzumab alone, albeit with the promise of superior clinical outcomes. The objective of this study is to predict whether there are scenarios where the use of second generation therapies

are cost effective, as defined by the implicit ICER thresholds upheld by most developed HTA agencies.

### METHODS:

A custom discrete event microsimulation model was constructed in Excel/VBA to simulate the treatment and progression of each HER2+ breast cancer patient from diagnosis until terminal state or stable disease, within a given population cohort. Given local clinical data limitations, global clinical trial data for disease free and progression free survival on a variety of locally used regimens, were combined with Singaporean life tables, epidemiology, and cost data obtained from SingStat, NCCS, MOH benchmarks, other public sources of information and local clinician interviews. For simplicity and data constraints, adverse events and deaths during treatment were excluded from the analysis.

### RESULTS:

In total, seven scenarios were evaluated for incremental cost effectiveness per life year gained (ICER/LY). These include 'ideal' treatment pathways in the Singaporean public system, 'real world' private centre treatment, and NCCN recommended regimens for each line of therapy in combination and in isolation. Of these, neoadjuvant pertuzumab in locally inoperable patients was most cost effective, with an average ICER of ~S\$12,800 ± \$360 / LY, and a total budget impact of S\$2.6 million per year. Patients are expected to live nearly 2 years longer on average vs. trastuzumab alone, and 5 years vs. chemotherapy due to fewer relapses.

### CONCLUSIONS:

This study, while not entirely representative of the 'real world' due the lack of local clinical data, suggests that there are indeed use cases where next generation targeted therapies can be cost effective despite increasingly vocal claims to the contrary – however, the key challenges of prioritisation still remain at the system level. In the

least, these types of studies and the models used within enable a more transparent and objective dialogue with policymakers, and to better empower them to make these often tough and politically charged decisions.

**REFERENCES:**

Perez et al. Trastuzumab Plus Adjuvant Chemotherapy for Human Epidermal Growth Factor Receptor 2 Positive Breast Cancer: Planned Joint Analysis of Overall Survival From NSABP B-31 and NCCTG N9831. *Journal of Clinical Oncology*. November 20, 2014 vol. 32 no. 33 3744-3752  
Hurvitz et al. Phase II Randomized Study of Trastuzumab Emtansine Versus Trastuzumab Plus Docetaxel in Patients With Human Epidermal Growth Factor Receptor 2 Positive Metastatic Breast Cancer. *Journal of Clinical Oncology*. March 20, 2013 vol. 31 no. 9 1157-1163  
Gianni, L. Five-year analysis of the phase II NeoSphere trial evaluating four cycles of neoadjuvant docetaxel (D) and/or trastuzumab (T) and/or pertuzumab (P). 2015 ASCO Annual Meeting. Oral Presentation. SingStat.  
Complete Life Tables 2008-2013 for Singapore Resident Population. Oncologist interviews (n=2) at National Cancer Centre Singapore Singapore Ministry of Health. Hospital Bill Sizes. [https://www.moh.gov.sg/content/moh\\_web/home/costs\\_and\\_financing/HospitalBillSize.html](https://www.moh.gov.sg/content/moh_web/home/costs_and_financing/HospitalBillSize.html). Accessed July 2015

---

## Poster 15A The Social Cost Of Major Depressive Disorder

**DESCRIPTION:**

The paper summarizes the existing literature on the overall economic burden of Major Depressive Disorder (MDD) in Europe as well as in Western Countries. The last part of the study focuses on the economic impact of cognitive impairment related to depression of patients' productivity losses and reports the results of an economic model.

**PRESENTING AUTHOR:**

Dr. Silvia Coretti, Università Cattolica del Sacro Cuore, Italy

**AUTHORS:**

Cicchetti A, Coretti S

**BACKGROUND AND OBJECTIVES:**

According to the World Health Organization, depression is one of the most disabling diseases, with at least 350 mln people suffering from major depressive disorder (MDD) worldwide. Despite this important burden, MDD is still strongly underdiagnosed and undertreated due to incomplete knowledge of the disease and social stigma. MDD is characterized by a significant economic burden. Indirect costs related to mortality and morbidity seem to represent the most important share of depression related costs. The aim of this study is twofold: 1) to provide an overview of the composition of the economic burden of depression based on international literature. 2) to provide an estimate of the impact of the cognitive impairment on the overall economic burden of disease.

**METHODS:**

A literature review has been conducted using PubMed search engine and references of included studies were also screened. Criteria for eligibility were: 1) OECD setting; 2) focus on MDD; 3) cost of illness studies 4) study performed after 2001. Data was extracted by a single reviewer under the supervision of a senior analyst. Results were described narratively. The second objective of the study is being achieved by building up a Markov chain to estimate the occurrence of cognitive impairment and its impact on patients' productivity losses. The model parameters will be estimated starting by the results of the literature review and adjusted based on evidence from a previous Italian survey.

**RESULTS:**

Both in the USA and in Europe the indirect costs represent the largest share of the overall burden of depression. Among the direct costs, the hospital admissions represent the most important cost items. Several studies demonstrated that a better management of disease could dramatically reduce inpatient costs. Results of the impact of cognitive impairment will be available by March.

**CONCLUSIONS:**

Depression is one of the most disabling diseases and induces high direct and indirect healthcare costs. A better knowledge of the disease direct and indirect costs could draw the attention of decision makers on this condition.

.....

## Poster 16A An Example Of HTA International Data Sharing Influencing National Decisions For Innovation Adoption: Consistency Of FDG-PET Accuracy And Cost-Effectiveness In Initial Staging Of Patients With Hodgkin Lymphoma Across Jurisdictions

**DESCRIPTION:**

The study data sharing across Jurisdictions provided an example of HTA International influencing national decisions for innovation adoption. The FDG-PET Accuracy and Cost-Effectiveness in Initial Staging of Patients With Hodgkin Lymphoma were compared amid one of each Brazilian and Italian centers. The CONITEC/ Brazilian Health Ministry decided to list PET/CT, lessons were learned and collaborative studies were furthered.

**PRESENTING AUTHOR:**

Dr. Evelinda Trindade, Sao Paulo State Health Secretariat, Brazil

**AUTHORS:**

Juliano J. Cerci, Evelinda Trindade, Valeria Buccheri, Stefano Fanti, Valentina Ambrosini, Lucia Zanoni, Artur M. N. Coutinho, Camila C. G. Linardi, Monica Celli, Dominique Delbeke, Luís F. Pracchia, Felipe A. José Soares Jr, Pier Luigi Zinzani, José C. Meneghetti, Clarice Petramale

**BACKGROUND AND OBJECTIVES:**

Metabolic imaging improves cancer program resolvitivity and was not available in public healthcare Brazil. Patients with newly diagnosed Hodgkin's lymphoma (HL) were consecutively enrolled in two centers, one in each Brazil and Italy, for this prospective trial to evaluate the cost-effectiveness of fluorine-18 (18F)-fluoro-2-deoxy-D-glucose-positron emission tomography (FDG-PET) scan in initial staging of patients with HL.

**METHODS:**

All 210 patients (120 Brazilian and 90 Italian) were staged with conventional clinical staging (CCS) methods, including computed tomography (CT), bone marrow biopsy (BMB), and laboratory tests. Patients were also submitted to metabolic staging (MS) with whole-body FDG-PET scan before the beginning of treatment. A standard of reference for staging was determined with all staging procedures, histologic examination, and follow-up examinations. The accuracy of the CCS was compared with the MS. Local unit costs of procedures and tests were evaluated. Incremental cost-effectiveness ratio (ICER) was calculated for both strategies.

**RESULTS:**

In the 210 patients with HL[1], two thirds of the Brazilian cases were advanced (stages III and IV were 77 (64.2%) vs. 32 (35.5%) amid the Italians). The sensitivity for initial staging of FDG-PET was higher than that of CT and BMB in initial staging

(97.9% vs. 87.3%; P

## CONCLUSIONS:

Currently, Brazilian lymphomas are detected latter than in Italy. FDG-PET is more accurate than CT and BMB in HL staging. Given observed probabilities, FDG-PET is highly cost-effective in the public healthcare program in Brazil. Although limited to one center at each country, these results were further corroborated by other studies[2]. HTA Impact: The plenary of the Public Healthcare System Technology Incorporation National Commission, CONITEC/ Brazilian Health Ministry, endorsed these results and listed the PET/CT. Barriers for early detection of lymphomas were prioritized for studies financing. Moreover, this collaboration formed basis for further studies and international data sharing[3,4].

## REFERENCES:

1: Cerci JJ, Trindade E, Buccheri V, Fanti S, Coutinho AM, Zanoni L, Linardi CC, Celli M, Delbeke D, Pracchia LF, Pitela FA, Soares J Jr, Zinzani PL, Meneghetti JC. Consistency of FDG-PET accuracy and cost-effectiveness in initial staging of patients with Hodgkin lymphoma across jurisdictions. Clin Lymphoma Myeloma Leuk. 2011 Aug;11(4):314-20. doi: 10.1016/j.clml.2011.06.006. PubMed PMID: 21816369.

2: Abou-Nassar KE, Vanderplas A, Friedberg JW, Abel GA, Niland J, Rodriguez MA, Czuczman MS, Millenson M, Crosby A, Gordon LI, Zelenetz AD, Kaminski M, Lacasce AS. Patterns of use of 18-fluoro-2-deoxy-D-glucose positron emission tomography for initial staging of grade 1-2 follicular lymphoma and its impact on initial treatment strategy in the National Comprehensive Cancer Network Non-Hodgkin Lymphoma Outcomes database. Leuk Lymphoma. 2013 Oct;54(10):2155-62. doi: 10.3109/10428194.2013.770151. Epub 2013 Feb 25. PubMed PMID: 23343180.

3: Carr R, Fanti S, Paez D, Cerci J, Györke T, Redondo F, Morris TP, Meneghetti C, Auewarakul C, Nair R, Gorospe C, Chung JK, Kuzu I, Celli M,

Gujral S, Padua RA, Dondi M; IAEA Lymphoma Study Group. Prospective international cohort study demonstrates inability of interim PET to predict treatment failure in diffuse large B-cell lymphoma. J Nucl Med. 2014 Dec;55(12):1936-44. doi: 10.2967/jnumed.114.145326. PubMed PMID: 25429159.

4: Cerci JJ, Györke T, Fanti S, Paez D, Meneghetti JC, Redondo F, Celli M, Auewarakul C, Rangarajan V, Gujral S, Gorospe C, Campo MV, Chung JK, Morris TP, Dondi M, Carr R; IAEA Lymphoma Study Group. Combined PET and biopsy evidence of marrow involvement improves prognostic prediction in diffuse large B-cell lymphoma. J Nucl Med. 2014 Oct;55(10):1591-7. doi: 10.2967/jnumed.113.134486. Epub 2014 Sep 11. PubMed PMID: 25214642.

## Poster 17A Using Mobile Phone Technology Strengthens Follow Up Of TB Patients Who Are Co-Infected With HIV Infection In TASO Mulago

### DESCRIPTION:

This abstract is about using mobile phone technology to strengthen follow up of TB patients who are co-infected with HIV infection in TASO Mulago. In partnership with the TB track project, we used landline phone to track TB treatment outcomes among patients on treatment in TASO Mulago. We noted high mobile phone possession and usage among the TB patients and this helped the TB nurses to counsel and clarify patients' doubts, thus strengthening adherence and sputum follow.

### PRESENTING AUTHOR:

Stephen Okoboi, The AIDS Support Organization (TASO), Uganda

**AUTHORS:**

Stephen Okoboi, Mirembe Joyce

**BACKGROUND AND OBJECTIVES:**

The expansion of mobile and wireless technologies around the world has set up an unprecedented opportunity for global health delivery. Mobile phones technology have become increasingly accessible and affordable in Uganda, total subscriptions has significantly improved among the general population. TASO Mulago is using a landline phone donated by TB track project as a central tool to follow up all the TB patients with the aim of monitoring drug adherence, sputum follow test and improving treatment success rate.

**METHODS:**

TASO Mulago with support from TB Track project bought a fixed landline which is loaded with monthly airtime from Track TB project. The phone was installed in the TB nurse’s office and fully under nurse’s control. All patients who have been diagnosed with TB disease are registered in the national TB register and their particulars recorded including phone numbers of the patients and the care givers (drug companions). The TB nurse uses the phone to counsel patients on adherence, remind the patients of the next appointments and assesses patient adherence using 3 day recall and emphasizes the need for follow up sputum sample as per national TB standards. The nurse also call the drug companion to confirm the adherence of the patient.

**RESULTS:**

We have noted a significant number of TB patients calling back to clarify their doubts on side effects, food, and symptoms of the disease, also all patients are on track with their medications and medical appointments. Sputum sample follow up at 2 months, 5 months and 8 months stands at 82% which is higher than the national at 80. Through phone conversion, we have noted patients self-manage themselves and that has enabled TB nurses to more efficiently and effectively monitor their treatment progress. Patients see mobile phones

as a useful communication tool in TB treatment because they directly interact with their service provider.

**CONCLUSIONS:**

We noted high mobile phone possession and usage among the TB patients and this helped the TB nurses to counsel and clarify patient’s doubts thus strengthening adherence and sputum follow.

**REFERENCES:**

TB Register and patients feedback

**Poster 18A Role Of Pictorial Warning On Cigarette Packets In Tobacco Cessation - A Questionnaire Survey Among Cigarette Smokers In Chennai, India**

**DESCRIPTION:**

Pictorial warning is an effective method to improve the awareness among smokers on the ill effects of smoking. The size, area covered, and position of the picture on cigarette packets needs to be reviewed to improve the quit rate.

**PRESENTING AUTHOR:**

Dr. Delfin Lovelina Francis, Tamil nadu Dr MGR medical University, India

**AUTHORS:**

Delfin Lovelina, Francis

**BACKGROUND AND OBJECTIVES:**

Warning labels on cigarette packages are meant to communicate such smoking-associated risks. The study is designed to find out the effectiveness of pictorial warnings present on cigarette packets in India for tobacco cessation among cigarette

smokers.

### **METHODS:**

A questionnaire was distributed to 800 current smokers attending an outpatient department of a college. Statistical analysis was done to find association between socioeconomic status and effectiveness of pictures to quit cigarette smoking.

### **RESULTS:**

48% smokers perceive text warning is an efficient method to create awareness. 56% emphasized the importance of pictorial warning and greater area to be covered. 43% felt that warning on cigarette packets helped them to quit smoking.

### **CONCLUSIONS:**

Though pictorial warning is an effective method to improve the awareness among smokers on the ill effects of smoking, the size, area covered and the position of the picture on cigarette packets needs to be reviewed to improve the quit rate.

---

## **Poster 19A Patient Participation In Health Decision Making: An Overview Of Current State In Indonesia**

### **DESCRIPTION:**

There is a need for patient involvement in order to increase the quality of health care. Government policy, culture, and other factors can be related to patient participation. This article is aimed to review a current state of government policy and practices of patient participation in health decision-making in Indonesia.

### **PRESENTING AUTHOR:**

Mochamad Iqbal Nurmansyah, Dokuz Eylul University, Turkey

### **AUTHORS:**

Mochamad Iqbal Nurmansyah

### **BACKGROUND AND OBJECTIVES:**

Globalization era allows information to be spread out in the fast and easy way, which causes an increasing knowledge of people. Consequently, people becomes more critical upon the services or goods that they received. In the health sector, beside the globalization issue, accountability and transparency of services also became an issue that striving healthcare to getting closer to the patient in order to obtain patient perception of quality and satisfaction. Therefore, there is a need of patient involvement in order to increase the quality of healthcare. Government policy, culture and other factors can be related to the patient participation. This article is aimed to review a current state of government policy and practices of patient participation in health decision-making in Indonesia.

### **METHODS:**

A review of the Indonesian government regulations has been conducted to gather information about patient and public involvement on each level of health decision-making. The resources of government regulation are the acts, regulations and guidelines. This article also reviews the current implementation of patient and public participation in health decision-making. Those results were categorized to the M-APR Model that provides a dimension of patient involvement in quality improvement. In this model, patient involvement would be categorized into level of involvement which are micro, meso and macro and a characters of involvement which are active, passive, reactive and proactive.

### **RESULTS:**

In the micro level, patient participation has been regulated in medical action agreement and physicians practice regulation which mentioned a perquisite of patient agreement before physicians give a treatment. In the meso level, community

healthcare planning guideline made by ministry of health mentioned that a manager should consider public opinion while makes an action plan of community healthcare. In a passive dimension, patient satisfaction survey has been required by hospital accreditation committee within hospital accreditation standard so that to enforce a hospital to conduct that survey in order to get a good accreditation. A regulation or guideline regarding patient involvement in macro level has not been found. Nevertheless, there are some practices conducted in macro level. For instance, The Ministry of Health has involved the TB patient community while establishing TB countermeasures plan that indicates an active dimension of patient involvement practice in macro level.

#### **CONCLUSIONS:**

There are some government policies regulating patient involvement in the micro level. Otherwise, less regulations has been found in meso and macro level. Government should provide a regulation and guideline in order to increase patient involvement in health decision making so that the quality of decision-making can be increased. Lack of research regarding patient involvement in health decision-making indicated that this field has not been an important issue in Indonesia. Therefore, there is a necessity to conduct a research such as a readiness of every stakeholders and possible barriers to patient involvement in health decision-making in Indonesia.

#### **REFERENCES:**

Laura Williamson (2014) Patient and Citizen Participation in Health: The Need for Improved Ethical Support, *The American Journal of Bioethics*, 14:6, 4-16, DOI: 10.1080/15265161.2014.900139  
Glyn Elwyn et al (2012) Shared decision making; patient centered care. *J Gen Intern Med* 27(10):1361-7 DOI: 10.1007/s11606-012-2077-6  
Sollecito WA, Johnson WJ (2013). McLaughlin and Kaluzny's Continuous Quality Improvement in Health Care. Fourth edition. Burlington, MA, USA: Jones & Barlett Learning.  
Ratih KW (2009) Tinjauan Yuridis Persetujuan Tindakan Medis (Informed

Consent) di RSUP DR. Kariadi Semarang. Tesis. Universitas Diponegoro Semarang. Direktorat Jenderal Bina Kesehatan Masyarakat. Pedoman Perencanaan Tingkat Puskesmas. 2006. Jakarta. Kementerian Kesehatan. Komite Akreditasi Rumah Sakit (2012) INSTRUMEN AKREDITASI RUMAH SAKIT STANDAR AKREDITASI VERSI 2012. Article has been downloaded from [http://mmr.gamel.fk.ugm.ac.id/file.php/1/moddata/forum/1/722/INSTRUMEN\\_AKREDITASI\\_RS\\_-\\_FINAL\\_Des\\_2012.pdf](http://mmr.gamel.fk.ugm.ac.id/file.php/1/moddata/forum/1/722/INSTRUMEN_AKREDITASI_RS_-_FINAL_Des_2012.pdf)

---

## **Poster 20A Pregnant Women's Willingness-To-Pay For Noninvasive Prenatal Screening For Fetal Down Syndrome In China**

#### **DESCRIPTION:**

The aim of this study is to measure pregnant women's willingness to pay (WTP) for noninvasive prenatal screening for fetal Down syndrome. A face to face survey was performed on 2,285 pregnant women. Older pregnant women showed significantly higher WTP than other pregnant women ( $p=0.002$ ). General WTP and the amount of WTP were associated with the insurance of the pregnant women ( $p=0.036$ ) and household income ( $p=0.003$ ). Additionally, general WTP was associated with their abortion history.

#### **PRESENTING AUTHOR:**

Na Li, Fudan University; Shanghai Jiaotong University, China

#### **AUTHORS:**

Na Li, Yan Xu, Jian Ming, Yingyao Chen

#### **BACKGROUND AND OBJECTIVES:**

The aim of this study is to measure pregnant women's willingness to pay for noninvasive prenatal screening for fetal Down syndrome and to identify

those factors associated with this willingness to pay.

**METHODS:**

A face to face survey was performed on 2,285 pregnant women (aged 30 years or over) for one month in four provinces or across Central and East China, including: Zhejiang, Hunan, Shandong, and Shanghai (July, August, September, October, 2015 respectively). Data about socio-demographic characteristics, health behaviors, the intention of the Down's syndrome screening and willingness to pay for NIPT screening were collected. The pregnant women's willingness to pay for NIPT screening and the factors associated with this willingness to pay were evaluated.

**RESULTS:**

From 2275 pregnant women, Median WTP was ¥1600 (quartile range[1500; 2000]) per NIPT. Median age was 31 years old [27, 35] and median gestational weeks was 18 weeks [17, 21]. About 57.2% of all pregnant women's education level were university and above, 55.3% of those job were being employed, 38.9% 19.5% 18.6% of all pregnant women were covered respectively by urban employee basic medical insurance, urban residents basic medical insurance and new rural cooperative medical insurance. The annual family income was higher than 15 million among 24.6% pregnant women. Older pregnant women showed significantly higher WTP than other pregnant women (p=0.002). General WTP and the amount of WTP were associated with the insurance of the pregnant women (p=0.036) and household income (p=0.003). Additionally, general WTP was associated with their abortion history.

**CONCLUSIONS:**

Most of the women were willing to invest in NPIT screening of DS. The general WTP significantly occurs more often and with higher amount in affected women.

.....

.....

## Poster 22A Study On Patient-reported Outcomes In Ulcerative Colitis Treatment: A Systematic Review Of The Literature

**DESCRIPTION:**

Patient-reported outcomes (PROs) play an increasingly important role in ulcerative colitis (UC) that significantly influences the quality of life (QoL) of patients. A literature search was performed on PRO studies in UC to develop and measure PROs in Japan in the future. There were many variations for PROs, but ePROs were not frequently used in UC in contrast to other therapeutic areas.

**PRESENTING AUTHOR:**

Akihito Uda, Takeda Pharmaceutical Company Limited, Japan

**AUTHORS:**

Akihito Uda, Shinzo Hiroi, Hiroyo Kuwabara, Kaoru Yamabe

**BACKGROUND AND OBJECTIVES:**

Ulcerative colitis (UC) is an inflammatory bowel disease (IBD) with recurring cycles of exacerbation and remission. Specific symptoms include mucoid and bloody stools, as well as diarrhea, abdominal pain, fever, anorexia, and anemia. Frequent diarrhea causes inconveniences with outings, thereby leading to a significant worsening of quality of life (QoL). Patient-Reported Outcomes (PROs) are useful measures to directly understand the patient's health condition. PROs play an increasingly important role in UC that significantly influences the QoL of patients. Since 2010, the number of published papers related to PROs has increased and is attracting greater attention. Nowadays, the number of electronic PROs (ePROs) has also gradually increased. Accordingly, in this study, a literature search was performed on PRO studies in UC to evaluate the types of questionnaires and

data collection methods in order to develop and measure PROs in Japanese UC patients in the future.

**METHODS:**

The literature search was conducted using MEDLINE. The inclusion criteria for studies were 1) treatment for UC, 2) use of PROs, in particular the Inflammatory Bowel Disease Questionnaire (IBDQ), 3) publish date on or after 2010. Studies were assessed for the following: country, questionnaire type, study population, study size, analysis method, paper or electronic.

**RESULTS:**

For disease-specific PROs, IBDQ was the most frequently used method among the papers searched. There were variations in IBDQ utilized, for instance SIBDQ and IBDQ-36. Mayo Clinic Sub-scores were also used frequently to evaluate symptoms such as rectal bleeding. For generic health status instruments, EQ-5D and SF-36 were the major methods. Other adopted disease-specific methods or general instruments included UC-PRO, UK-IBD-QoL, and WHOQOL-BREF, etc. Comparatively, ePROs were not frequently used in UC in contrast to other therapeutic areas. For analysis methods, there was a tendency to use Cronbach's alpha and ICC to evaluate the validity and reliability of questionnaires.

**CONCLUSIONS:**

In general, the use of ePROs has gradually increased in some therapeutic areas; however, this trend is not observed in UC. The validation between conventional PROs using paper and ePROs has also not been clarified yet in UC. Therefore, further studies are needed to perform the validation between these methods.

## Poster 23A A Systematic Review Of Economic Evaluations Of Pneumococcal Vaccination In Children In Low And Middle Income Countries

**DESCRIPTION:**

While pneumococcal conjugate vaccines (PCVs) have been available for the prevention of invasive pneumococcal disease over a decade, vaccine adoption in low and middle income countries (LMIC) is still limited. Economics evaluations (EE) play a crucial role in support of evidence-informed decisions. This review showed that PCV were reported to be cost-effective in most LMIC, which were primarily driven by several parameters.

**PRESENTING AUTHOR:**

Dr. Surasak Saokaew, University of Phayao, Thailand

**AUTHORS:**

Surasak Saokaew, Ajaree Rayanakorn, David Bin-Chia Wu, Nathorn Chaiyakunapruk

**BACKGROUND AND OBJECTIVES:**

Even though pneumococcal conjugate vaccines (PCVs) have been available for the prevention of invasive pneumococcal disease caused by *Streptococcus pneumoniae* (*S. pneumoniae*) over a decade, its adoption into national immunization program in Low and middle income countries (LMIC) is still limited. Economics evaluations (EE) play a crucial role in support of evidence-informed decisions. Objective: To provide critical summary of economics evaluations and identify key drivers of economic evaluation findings in LMIC

**METHODS:**

We searched Scopus, ISI Web of Science, PubMed, EMBASE, Cochrane CENTRAL from their inception to 30th September 2015 and limited to only LMIC. There was no language restriction. The search was undertaken using the broad combined terms

pneumococc\* AND conjugat\* AND (vaccin\* OR immun\*) AND economic OR cost-effectiveness OR cost-benefit OR cost-utility OR cost-effectiveness OR cost-benefit OR cost-utility. To be included, study must be a full EE of PCV and conducted for LMIC. Studies were extracted by two reviewers (SS, AR). The review involved standard extraction of study overview or characteristics of the study, key drivers or parameters of economics evaluation, assumptions behind the analyses, and major area of uncertainty.

**RESULTS:**

Results: Out of 134 records identified, 23 articles were included. Seven studies used Markov model, while 16 studies used decision analytic model for analysis. Nineteen studies performed a cost utility analysis (CUA) having disability-adjusted life years (DALYs) or quality-adjusted life years (QALY) as a measure of health outcome, while 4 studies only focused on cost-effectiveness analysis (CEA). Both CEA and CUA findings were provided by 6 studies. Herd effect and serotype replacement were considered in 11 and 14 studies, respectively. Current evidence showed that both PCV10 and PCV13 were likely cost-effective compared with PCV7 or no-vaccination. The most influential parameters were vaccine efficacy and coverage (17 of 23 studies), vaccine price (14/23), disease incidence (12/23), and mortality of IPD & pneumonia (8/23).

**CONCLUSIONS:**

Our review demonstrated that PCV were reported to be a cost-effective intervention in most LMIC. The findings were primarily driven by several parameters. Decision makers should consider EE findings and affordability before the adoption of PCV.

.....

## Poster 24A Developing Integrated Care Pathways For Stroke And Chronic Obstructive Pulmonary Disease Linked With Payment Reform In Rural China

**DESCRIPTION:**

In order to improve quality of services in China’s rural health institutions and control patients’ financial burdens, the CNHDRC (China National Health Development Research Center) and UK NICE introduced integrated care pathways for stroke and COPD, and partially combined with case-based payment reforms in four pilot areas with various socio-economic and demographic characteristics. This presentation discusses how pathways and payments were developed and implemented, and shares preliminary results of impact evaluation.

**PRESENTING AUTHOR:**

Wudong Guo, National Health Development Research Center, China

**AUTHORS:**

Wudong Guo

**BACKGROUND AND OBJECTIVES:**

Ongoing reforms to China’s county-level hospitals include interest in developing evidence-based integrated care pathways with the ability to control costs, while simultaneously raising the overall quality of services. Since 2013, the China National Health Development and Research Centre (CNHDRC) in collaboration with the UK NICE have developed and implemented evidence-informed ‘integrated care pathways’ linked with payment reform, for two high priority disease areas (chronic obstructive pulmonary disease-COPD and stroke). These pathways cover prevention, treatment and rehabilitation across rural health institutions, and aim to explore the solution against excessive and fast-growing medical expenditure facing by rural

population, standardize and regulate the behavior of service providers, improve the service quality, and increase the awareness of evidence-based decision making among national and local decision makers within China health system.

#### **METHODS:**

Based on existing treatment strategies, and with iterative input from China- and UK-based experts, integrated pathways were developed that were further refined by and adapted to local contexts through iterative discussion. These pathways were used as a basis to derive appropriate case payment rates following negotiations between local payers and providers. The pathways were incorporated into each hospital's electronic information system. The quantitative impact of the intervention on selected outcomes was assessed using interrupted time series (ITS) analysis with segmented regression, using data collected for 24 monthly time points before intervention and 12 monthly time points after the intervention. The focus groups and semi-structured interviews with key participants of the pilot study were employed to qualitatively assess participants' experiences and understand the perceived utility of the clinical pathways, given the possible confounding factors.

#### **RESULTS:**

By May 2015, 5,490 patients were managed by the pathways across four pilot areas, accounting for 54.04% of the total number of 10,158 patients admitted with COPD and stroke within the same time period. The billing data analysis revealed that, after a year since the implementation of the project, the intervention has overall strengthened the utilization and quality of services recommended by the clinical pathway such as statins and brain imaging (within 24 hours of hospitalization) for stroke treatment. On the other hand, there was no significant change in the use of oxygen and 'dehydrating agents' which were not recommended by the pathways. Following analysis of medical records, it appeared that growth in resource use and associated costs was reduced in the pilot diseases, and the proportion of expenses

made out-of-pocket (OOP) also decreased. In general, the implementation of pilot project led to reductions in length of stay on selected conditions, and did not negatively affect health-related quality of life based on the analysis of EQ-5D.

#### **CONCLUSIONS:**

The intervention and corresponding preliminary results suggest the pathways have led to important and positive changes in the management of stroke and COPD patients in the pilot sites. These results should be regarded as provisional, requiring further verification over a longer time period, and with additional data. It is also clear and significant that at both local and national levels the perceived importance of using evidence to inform practice has changed, the need for broader improvements in hospital performance has been reinforced, and the importance of integrated care across different tiers in the China rural health system has been highlighted. Additionally, more robust consideration of the evidence with which clinical pathways are developed is needed, calling for strengthening the use of health technology assessments.

---

## **Poster 25A** Characterization Of Patient's Perceptions On The Treatment Of Ankylosing Spondylitis And Rheumatoid Arthritis: A Patient-Centric Approach

#### **DESCRIPTION:**

Patients' perception on treatment of ankylosing spondylitis and rheumatoid arthritis are examined by using the patient-centric approach to understand what patients value during their treatment journey. A literature review and focus group interview were done.

**PRESENTING AUTHOR:**

Dr. Jittrakul Leartsakulpanitch, Janssen Asia Pacific, Singapore

**AUTHORS:**

Donatas Grabliauskas, Jittrakul Leartsakulpanitch

**BACKGROUND AND OBJECTIVES:**

Background: Both ankylosing spondylitis (AS) and rheumatoid arthritis (RA) are diseases greatly affecting patients’ productivity and quality of life. Long-term treatment, disease manifestation nature and patients’ expectation are notable to be a basis of treatment unmet need in light of previous research. Still the information on patients’ perception to treat and stay on treatment in different time points of treatment journey is limited. Objective: This study is aimed to examine the patients’ perceptions on the treatment benefits in AS and RA by using the patient-centric behavioral journey.

**METHODS:**

We reviewed literature to identify patients’ perceptions and expectations on their treatments in AS and RA. The behavioral patient journey using patient as centric point along different decision stages was developed and applied to characterizing and mapping patients’ perceptions with key decision phase in the treatment journey. Focus group and in-depth interview with RA and AS patients was done subsequently for confirmation and validation. Results showed that the patients with AS and RA perceived functional, social and emotional benefits as vital treatment outcomes to drive their decisions to initiate and continue treatment. Specifically, we found that those tangible outcomes, either directly or indirectly tangibles are well perceived and expected by patients to get changed or improved.

**RESULTS:**

In AS patients, during the treatment initiation and continuation phase, most functional benefits -

both directly and indirectly tangible, including the joint stiffness, pain reduction, ability to exercise and perform daily activities, time to see treatment effect, and persistent disease control are valued as important treatment benefits. Other benefits such as emotional stress, social relationship are reported in relation to functional benefits. While the ease of administration and safety play role more in only treatment initiation phase. Similarly, the functional improvements i.e. pain, fatigue, ability to do daily activities, sleep) as well as social and emotional benefits i.e. worriedness, mood, family/work relationship in RA are viewed as critical expectations in patient’s decision on treatment initiation and continuation. Patients’ experiences in previous treatment are key factors to drive the change of perception along the treatment journey.

**CONCLUSIONS:**

Patients with AS and RA perceived functional, social and emotional benefits as vital treatment outcomes to drive their decisions to initiate and continue treatment. Specifically, we found that those tangible outcomes, either directly or indirectly tangibles are well perceived and expected by patients to get changed or improved. These insights are essential in developing and improving the communication with patients in order to ensure the optimal treatment outcomes.

.....  
**Poster 26A Development Of A Conceptual Disease Model For Use In Economic Modelling Of An Orphan Disease Sporadic Inclusion Body Myositis (sIBM)**

**DESCRIPTION:**

A conceptual disease model should be developed to inform the structure of an economic model and, in absence of existing references, seeking multiple stakeholder feedback is critical to ensure the validity of both disease and economic models. We

describe an iterative process that was undertaken to develop a conceptually relevant model of sporadic inclusion body myositis.

#### **PRESENTING AUTHOR:**

Gorana Capkun, Novartis, Switzerland

#### **AUTHORS:**

Gorana Capkun, Aoife Callan, Ronan Mahon, Subrata Bhattacharyya, Phoebe Balkin, Ana de Vera, Parul Houston

#### **BACKGROUND AND OBJECTIVES:**

Developing an economic model to assess the cost-effectiveness of treatment therapies within a disease area is a complex process, particularly in absence of an existing disease model. It is critical to ensure that disease and economic models are conceptually credible and sufficiently capture the multiple dimensions of the disease 1. Often, the model developer requires multiple stakeholder input to make choices about what should be included and how different aspects of the disease relate to each other 2. This is particularly important for Sporadic Inclusion Body Myositis (sIBM), a rare disease that affects approximately 50.5 people per million 3. The objective of this study is to present an iterative process that was undertaken to develop a conceptually relevant model of sIBM in absence of existing references.

#### **METHODS:**

A literature search of sIBM symptom progression was completed in multiple databases using the OVID platform. Of the 450 citations screened, 21 were included for final assessment and the results informed the initial disease dimensions and relevant outcome measures of importance in sIBM. The initial conceptual model was supplemented with qualitative data on disease dimensions and progression from patient interviews. In addition, patient-reported survey data were collected directly from patients on their self-perceptions of their disease stage and how their disability was impacting them. In parallel, expert opinion was sought from leading experts in sIBM to

define disease dimensions and confirm outcome measures that may be used to monitor disease progression as well as create preliminary definitions of stages of disease.

#### **RESULTS:**

Patients and leading experts agreed that disease progression across three key dimensions of sIBM require monitoring: upper body, lower body and swallowing. Outcome measures that can measure disease progression across dimensions and reflecting patient-relevant functional impairment were suggested by leading experts. In the upper body dimension, handgrip was suggested as a potential outcome measure to capture functional decline in the upper body. In the lower body dimension, progression in ability to walk with/without assistive devices was considered important as well as measures of physical function such as six minutes walking distance and quadriceps strength. Decline in swallowing ability can be measured by varying levels of diet adaptations and progression to a feeding tube or through clinical or patient-reported outcomes.

#### **CONCLUSIONS:**

A conceptual disease model should be developed to inform the structure of an economic model and in absence of existing references, seeking multiple stakeholder feedback is critical to ensure model validity. We suggest an iterative and collaborative approach in developing a disease model that we applied to sIBM, where key disease dimensions, their corresponding outcome measures and level of impairment were defined. This work informs further analysis of relationships between disease dimensions and both Health Related Quality of Life and resource use in order to estimate overall disease progression within an economic model.

#### **REFERENCES:**

1 Chilcott, J., Tappenden, P., Rawdin, A., Johnson, M., Kaltenthaler, E., Paisley, S., Papaioannou, D. and Shippam, A. (2010) Avoiding and identifying errors in health technology assessment models:

qualitative study and methodological review, NIHR Health Technology Assessment programme: Executive Summaries.

2 Roberts, M., Russell, L.B., Paltiel, D.A., Chambers, M., McEwan, P. and Krahn, M. (2012) Conceptualizing a Model: A report of the ISPOR-SMDM Modeling Good Research Practices Task Force 2, *Value in Health*, 15; 804-811.

3 Tan, J.A., Roberts-Thomson, P., Blumbergs, P., Hakendorf, P., Cox S. and Limaye, V. (2013) Incidence and prevalence of idiopathic inflammatory myopathies in South Australia: a 30 year epidemiologic study of histology-proven cases. *International Journal of Rheumatic Diseases*, 16: 331 - 338.

---

## Poster 27A Development And Validation Of A System Of Identification Of Fever Cases

### DESCRIPTION:

The presence of fever is closely linked to viral, mainly endemic dengue and chikungunya diseases that commonly affect a large part of the population of Latin American countries. The use of infrared as a complementary diagnostic tool to help identify people with potential fever may stop or limit the spread of viral diseases such as influenza or bacterial infections; besides presenting a low cost.

### PRESENTING AUTHOR:

Ronald Rivas, Institute in Health Sciences of the National University of Asunción, Argentina

### AUTHORS:

Ronald Rivas, Pedro Galván, José Nuñez, Benicio Grossling, David Andino

### BACKGROUND AND OBJECTIVES:

The presence of fever is closely linked to viral, mainly endemic dengue and chikungunya diseases

that commonly affect a large part of the population of Latin American countries. In Paraguay as the Directorate General of Health Surveillance, Ministry of Public Health; 110 cases in 2008, with a rate of 1.8 per 100,000 inhabitants. In 2009, 6,000 cases, with an incidence of 96.1 per 100,000 inhabitants. In 2010, 20,000 cases, with an overall incidence of 310 per 100,000 inhabitants. In 2011, incidence of 728 per 100,000 inhabitants, with 47,000 cases reported. In 2012, 528 per 100,000 inhabitants. In 2013, and incidence of 2,142 until June (Asuncion, Central and Alto Parana Department). With circulation of serotypes 1, 2 and 4, with the large circulation of serotype 2 virus. That is why the need for filter stopper form procedures regarding persons experiencing this warning sign and thus avoid the spread of epidemics. Numerous studies have demonstrated that infrared thermography can help identify high body temperatures indicate a possible febrile case. As such, the use of infrared as a complementary diagnostic tool to help identify people with potential fever may stop or limit the spread of viral diseases such as influenza or bacterial infections; besides presenting a low cost. The objective of this work is to develop a system for identifying potential fever cases by means of infrared sensors.

### METHODS:

The study is an observational design; it aim sto develop a system to detect possible cases of fever and body temperature record in a data base for the follow-up. The system will be developed by the Department of Biomedical Engineering and Imaging Research Institute in Health Sciences (IICS) and TECNALIA Technological Corporation Foundation

### RESULTS:

The purpose of this study was presented and awarded in the framework of the National Council of Science and Technology (CONACYT) of Paraguay PROCIENCIA Program

## CONCLUSIONS:

The pilot study will be conducted at the Institute for Research in Health Sciences (IICS) of the National University of Asuncion (UNA) during the period 2016-2018

## REFERENCES:

1 Guevara Couto VM, Espinosa del Risco E. Comportamiento del síndrome febril prolongado en niños de la sala Maceo. Archivo Médico de Camagüey 2009;13 Disponible en: <http://www.redalyc.org/articulo.oa?id=211116124004>. Fecha de consulta: 20 de junio de 2013.

2 Patricia C. Priest, Alasdair R. Duncan, Lance C. Jennings, Michael G. Baker Thermal Image Scanning for Influenza Border Screening: Results of an Airport Screening Study. Health Canada (2004) Thermal image scanners to detect fever in airline passengers, Vancouver and Toronto, 2003. Canada Communicable Disease Report 30: 165-167

3 D Bitar, A Goubar, JC Desenclos. International travels and fever screening during epidemics: a literature review on the effectiveness and potential use of noncontact infrared thermometers.

4 MF Chang, PW Lin, LF Lin, HY Chiou, CW Chie, SF Chu, WT Chiu. Mass screening of suspected febrile patients with remote-sensing infrared thermography: alarm temperature and optimal distance. J Formos Med Assoc. 2008. Dec; 107 (12): 937-44.

5 A Nguyen, N Cohen, H Lipman. Comparison of 3 infrared thermal detection systems and self-report for mass fever screening. Emerging Infectious Diseases. 2010. 16(11):1710-17.

6 BB Lahiri, S Bagavathiappan, T Jayakumar, John Philip. Medical applications of infrared thermography: A review. Physics & Technology. 2012; 55:221-235.

7 M van Wissen, T Keller, B Ronkes, V Gerdes, H Zaaijer. Influenza infection and risk of acute pulmonary embolism. Trombosis Journal. 2007;

5:20.

8 World Health Assembly. Revision of the International Health Regulations. World Health Organisation; 2005

9 X. Basogain et al. Epidemiological Surveillance Using Information Technologies in Paraguay. Biomedical Instrumentation & Technology Journal, 2010; 2:159-165

10 5ª Conferencia Ibérica de Sistemas y Tecnologías de Información, CISTI'2010, Junio 2010. España. Epidemiological Proactive Surveillance based on Asterisk and Php. X. Basogain, V. Cane, P. Galván, M.A. Olabe, K. Espinosa, M.A. Gómez, J.L. Larrabe, M. Cabral.

11 12 Congreso Paraguayo de Pediatría. 27-30 de octubre, 2010. Asunción- Py. Sistema BONIS de notificación comunitaria de síndromes febriles basado en llamadas telefónicas. Galván P, Cane V, Basogain X, Cabral M, Samudio M, Cabello A, Páez M, Ascurra M, Allende I. Pediatría. Órgano Oficial de la Sociedad Paraguaya de Pediatría, vol 37, suplemento, Pag.85.

12 Congreso Paraguayo de Medicina Interna. Simposio Sociedad Latinoamericana de Medicina Interna. Abril. Asunción-Py. Morbilidad Percibida en Pobladores de CAMSAT previa a la implementación de la vigilancia comunitaria de síndromes febriles utilizando las TICs. MCabral, MSamudio, MAscurra, Acabello, M Paez, VCane, PGalván, IAllende, XBasogain.

13 Congreso Paraguayo de Medicina Interna. 2010 Simposio Sociedad Latinoamericana de Medicina Interna. Abril. Asunción-Py. Producción y desarrollo de un sistema de notificación de síndrome febril basado en la telefonía móvil a ser implementado en un área de influencia del hospital de Bo Obrero. PGalván, VCane, XBasogain, MCabral, MSamudio, Acabello, M Paez, MAscurra, IAllende, Congreso Paraguayo de Medicina Interna. Simposio Sociedad Latinoamericana de Medicina Interna.

14 AECID, Agencia Española de Cooperación

Internacional para el Desarrollo;(2009), A/023084/09, Proyecto TIC-Vigilancia Epidemiológica: Sistema de Información y Gestión para la inclusión social de una ciudadanía más saludable mediante las tecnologías de la información y comunicación aplicadas a las poblaciones vulnerables de síndromes febriles. BASOGAIN, Xabier et. al; (2009). Sistema BONIS: Tele Vigilancia Epidemiológica en Paraguay. XIX Jornadas TELECOM I+D " innovando, creciendo, avanzando". ISBN: 978.84.613.5636.2 Reg. 09/102407

15 e-Salud en Paraguay: Caso de Estudio Vigilancia Epidemiológica. Gaceta Sanitaria. XXVIII Reunión Científica de la Sociedad Española de Epidemiología." Epidemiología: el reto de la información, la oportunidad de la investigación". ISSN: 0213-9111, vol 24-Especial Congreso 2 - Octubre 2010 pp. 83 X. Basogain, V. Cane, M. A. Olabe, K. Espinosa, M.A. Gómez, J.L. Larrabe, M. Cabral, P. Galván, I. Allende.

---

## Poster 28A Translation Of Patient-Reported Outcomes In East Asia

### DESCRIPTION:

Patient-reported outcomes (PROs) are increasingly encouraged in clinical trials. The ISPOR PROs Translation and Linguistic Validation Task Force has developed guidelines for the translation of PROs. There is an increasing number of multi-national clinical trials which involve countries in East Asia. This study aimed to review the methods and quality of quality of life (QOL) PROs translated into Chinese, Japanese, and Korean.

### PRESENTING AUTHOR:

Schezn Lim, Costello Medical Singapore Pte Ltd., Singapore

### AUTHORS:

Schezn Lim, Gengshi Chen, Jenni Evans, Craig Brooks-Rooney

### BACKGROUND AND OBJECTIVES:

The use of patient-reported outcome measures (PROs) in clinical trials is encouraged for better understanding of diseases and treatments from the patient's perspective. Recognising the challenges for multi-national clinical trials with diverse language needs, the ISPOR PROs Translation and Linguistic Validation Good Research Practice Task Force has developed guidelines to standardise methods used in the translation and trans-cultural adaptation of PROs. There is an increasing number of multi-national clinical trials which involve countries in East Asia. This study aimed to review the methods and quality of QOL PROs translated into Chinese, Japanese and Korean.

### METHODS:

A targeted literature search was conducted in PubMed using search terms including 'translation', 'trans-cultural adaptation', 'quality of life', 'questionnaire' and 'survey'. Primary studies that translated or trans-culturally adapted existing disease-related quality of life (QoL) questionnaires into Chinese, Japanese or Korean were included. Studies of questionnaires translated into non-East Asian languages or that assessed non-disease specific QoL were excluded.

### RESULTS:

A total of 109 Chinese, 48 Japanese and 36 Korean translations were included for analysis. Translation of QoL PROs was most commonly performed in oncology (21.1% of Chinese, 39.6% of Korean, and 44.4% of Japanese studies), neurology (18.3% of Chinese and 8.3% of Korean studies) and rheumatology, allergy and immunology (12.5% of Japanese and 8.3% of Korean studies). At least one translation step recommended by ISPOR was reported in 26.6%, 27.9% and 33.3% of Chinese, Japanese and Korean translations respectively. Forward and backward translation was used in

22.3% and cognitive debriefing in 7.77% of all studies. Validation was performed in 89.0%, 60.4% and 97.2%, and reliability testing in 87.2%, 72.9% and 83.3% of Chinese, Japanese and Korean translations respectively.

#### **CONCLUSIONS:**

The use of translated PROs in disease areas such as oncology, neurology and RAI reflects the emphasis placed on patient-centred healthcare for these patient populations in East Asia. The majority of translations have been validated and tested for reliability; however, there is a low rate of reference to international translation guidelines such as those provided by the ISPOR Task Force.

.....

## **Poster 30A Assessment Of The Clinical Efficacy Of Pure Intradiscal Technique For Treatment Of Spinal Disc Herniation**

#### **DESCRIPTION:**

The authors evaluated the clinical efficacy of pure intradiscal technique for treatment of spinal disc herniation compared with open surgery, microsurgical discectomy, and various options with the use of endoscopic techniques according to research available in the database of evidence-based medicine.

#### **PRESENTING AUTHOR:**

Ainura Sassykova, Republican Center for Health Development, Ministry of Health and Social Development, Kazakhstan

#### **AUTHORS:**

Ainura Sassykova, Temirkhan Kulkhan, Gulnara Gurtuskaya, Lyazat Saduakassova, Gulmira Yermakhanova, Dana Mauyenova

#### **BACKGROUND AND OBJECTIVES:**

Spinal disc herniation (SDH) is the most common and most severe presentation of degenerate rachionopathy. According to statistics, 50% of neurosurgical patients receive treatment for a spinal disc herniation. In a majority patients with SDH are people of working age - 25-55 years, and often their disease is associated with the professional activity, which leads 70% of patients to temporary disability and brings significant economic losses to society. At the large hernia that causes neurological symptoms and is at an advanced stage, only the surgical treatment can help. Existing alongside with open surgery, microsurgical discectomy and various options with the use of endoscopic technics, the pure intradiscal technique (PIDT) has the main advantage & is minimally-invasive procedures, performing surgical manipulations without cutting the skin, through a tiny puncture of soft tissues, thereby reducing the risk of complications and shortening the time of postoperative recovery period up to 3-5 days. Objective of research conducted: The authors evaluated the clinical efficacy of PIDT compared with open surgery, microsurgical discectomy and various options with the use of endoscopic technics according to research available in the database of evidence-based medicine.

#### **METHODS:**

Review of the literature was conducted on the safety and efficacy of PIDT in databases PubMed, Cochrane Library, NICE, Clinical Trials, TripDatabase etc. according to research issues (PICOs) and key words.

#### **RESULTS:**

After literature review of 2987 sources, the relevant for criteria PICOS reports were selected for the study, 17 of which were taken for the final analysis. The remaining publications were excluded due to noncompliance with criteria of research questions.

#### **CONCLUSIONS:**

PIDT in its efficacy would not disgrace the other

methods of surgical treatment of SDH, achieving clinical benefits, associated with reducing iatrogenic injury and the early recovery of the patients. However, the strength of conclusions is limited by several factors, including: the risk of complications, lack of adequate data confirming or denying the effectiveness of PIDT due to the technical complexity of this surgery and the necessity of applying special equipment. All these factors give rise to carry out large, well-designed multicenter studies and to research it for draw maximally objective conclusions about the effectiveness of this method.

---

## Poster 31A Hyper Immunoglobulin D Syndrome (HIDS): Patients' Views Of Their Disease Journey

### DESCRIPTION:

This patient-focused study examined the impact of Hyper-IgD syndrome (HIDS) on patients and what role patients want to play and what information patients need so they can help guide their treatment.

### PRESENTING AUTHOR:

Jill Gregson, Novartis Pharma AG, Switzerland

### AUTHORS:

Karen Durrant, Kathleen Lomax, Jill Gregson

### BACKGROUND AND OBJECTIVES:

Hyper Immunoglobulin D syndrome (HIDS) is a genetic disorder characterized by recurrent attacks of fever and inflammatory symptoms and is most common in those of French or Dutch descent, but has been seen in all ethnic groups.<sup>1-2</sup> HIDS is also known as mevalonate kinase deficiency.<sup>3</sup> Objectives: To understand the impact of HIDS on the lives of patients/caregivers, to describe patient's journey from first symptoms and to learn what

patients hope to emerge in terms of future therapy, support and information.

### METHODS:

Patients with HIDS were recruited by disease experts and patient support groups. They completed a 20 page pre-interview questionnaire and a 90 minute in home interview. Patient responses were recorded and summarized. The topics covered in the interview were symptoms, patient journey, and unmet needs.

### RESULTS:

HIDS patients (n=15) were recruited between Nov 2013 - Feb 2014. Patients experienced diagnostic delay (range, 1-15 yr) during which time they underwent diagnostic tests for other conditions. HIDS was characterized by symptomatic flares and periods of wellness. Duration of attacks ranged from 2-21 days with most between 3-7 days; characterized by high fever, nausea (especially in pediatrics), and severe pain. Severity of symptoms, duration and frequency of flares decreased with age and treatment. Caregivers and adult patients reported loss of work during attacks and due to attending frequent medical appointments, limiting career choices and leading to financial dependency. HIDS also had an impact on patients' relationships and social lives by limiting their activities either through being unwell or unable to plan ahead due to fear of an attack. Most patients reported initial treatment with NSAIDs, colchicine, or steroids; however, when these were ineffective, patients switched to biologics. Responses to biologics were variable; although many reported shorter attack duration and frequency, all respondents continued to experience attacks. Around 50% have switched biologics due to lack of efficacy. Patients/caregivers reported little information was provided at diagnosis regarding causes of disease, symptoms and treatment. Patients identified improved treatment efficacy and reduced treatment side effects as areas of improvement in their care.

## CONCLUSIONS:

HIDS significantly impacts the physical, social, emotional and practical/financial aspects of patients' and caregivers lives. Greater awareness of HIDS among health care professionals may improve diagnostic delays. There is an unmet need for therapy that prevents/reduces attacks and which has patient-friendly administration. Many patients also wanted to gain a greater understanding of their disease and treatment options.

## REFERENCES:

[1] Van der Hilst JC et al. *Curr Rheumatol Rep*. 2010;12(2):101-107 [2] Lainka E, et al. *Rheumatol Int*. 2012;32(10):3253-3260 [3] Stoffels M, et al. *Curr Opin Rheumatol*. 2011;23:419-23.

---

## Poster 32A How To Develop Patient Perspective In Our Rapid HTA Process At The French National Authority For Health?

### DESCRIPTION:

Patient involvement exists at the French National Authority for Health (HAS) for the longest assessments integrating a scoping phase and a final consultation, but not as yet for the shorter 'rapid HTA' process. We are setting up a working group composed of patient representatives from our three HTA committees and HAS staff to build tools and procedures, in order to effectively take patient perspective into account.

### PRESENTING AUTHOR:

Dr. Hervé Nabarette, HAS, France

### AUTHORS:

Hervé Nabarette, Marc Guerrier

### BACKGROUND AND OBJECTIVES:

Patient involvement exists at French National

Authority for Health (HAS) for the longest assessments integrating a scoping phase and a final consultation, but not as yet for the shorter 'rapid HTA' process which lasts only three months. Patient representatives were first integrated in the Economic and Public Health Appraisal Committee in 2008. They recently joined two additional HTA appraisal committees (for drugs and medical devices), in November 2015. We are currently studying ways to foster their involvement, and more generally to effectively take their perspective into account. We try to find ways to widen the presence of patient representatives in our committees, including patient organizations (POs). POs are legally categorized as 'stakeholders' (and not as 'experts'). Due to our current regulation for rapid HTAs, their input must come after an 'assessment' step by HAS staff reviewers, at the 'appraisal' step realized by the committee meeting, via hearings.

### METHODS:

We are setting a working group composed of patient representatives from the three committees (7 people) and HAS staff to build tools and procedures. Patient HAS official representatives' inputs are a cornerstone in this work (they will meet each other, share experience between the three experienced and the four recent ). The working group will be focused on rapid HTAs and define: - A template for 'patient perspective'. We rely notably on Health Technology Assessment international tools. We translated into French the HTAi 'Values and quality standards for patient involvement in HTA' document, and Patient Group Submission templates, as work documents. Methods used by NICE, CADTH and SMC, among others, are also studied. - Criteria to decide when to invite a PO to a hearing. - Process with clear timelines: when to ask for a hearing and to contact POs, clear deadlines for POs, possibility for POs to send their contribution before the committee meeting to allow for preparation of the hearing - Some ways of supporting patient representatives and the POs in the process (e.g. how to fill the template, to give feedback after a hearing ) and measuring satisfaction of participants.

## RESULTS:

The results will consist in four deliverables as mentioned above. The template will take into account the distinction between drug and device. The translation in French of HTAi documents will be discussed with INESSS, the HTA agency for Quebec. Development of a submission template for rapid HTA may also prove useful for longer assessments containing a scoping and a consultation phase.

## CONCLUSIONS:

In the short run, patient perspective in HAS rapid HTA process will rely on patient representatives in committees and POs hearings. A working group is drawing the relevant procedures. After a 6 months trial period, this group will address new topics: needs for training, possible need for refining objectives and their underpinning values, feedback from all those involved, with the intent to improve processes.

## REFERENCES:

HAS. 2015. Call for applications for the new Drugs Clinical Appraisal Committee and the new Medical Devices Clinical Appraisal Committee, newly including patient representatives. [http://www.has-sante.fr/portail/jcms/c\\_2046154/fr/appele-a-candidatures-pour-la-commission-de-la-transparence?cid=r\\_1437955](http://www.has-sante.fr/portail/jcms/c_2046154/fr/appele-a-candidatures-pour-la-commission-de-la-transparence?cid=r_1437955) HTAi. 2015. Patient Group Submission Template for HTA of Medicines. HTAi. 2014. Values and quality standards for patient involvement in HTA.

---

## Poster 33A Adding Value To Health Research: The Dutch Experience

### DESCRIPTION:

There is a need around the globe to provide social relevant research which adheres to the principles of scientific quality, integrity, and efficiency. We present an initiative of the National Organization

for Health Research and Development (ZonMw) - based in the Netherlands - to increasing value and reducing waste by optimising programming of health research.

### PRESENTING AUTHOR:

Dr. Wija Oortwijn, Ecorys, Netherlands

### AUTHORS:

Wendy Reijmerink, Wija Oortwijn

### BACKGROUND AND OBJECTIVES:

There is a need around the globe to provide social relevant research which adheres to the principles of scientific quality, integrity and efficiency. It is known that researchers have their own responsibility for conducting their research, but also research institutions as well as funding organisations have responsibilities to implementing well-defined and robust mechanisms to reduce waste in science and add value to research. In this context, the National Organization for Health Research and Development (ZonMw) is carrying out several initiatives with regard to the effective establishment of the science system for health. ZonMw is one of the most important funding organisations of health research in the Netherlands and aims to make health research more useful for policy and practice in order to attain more societal impact. One of the initiatives focuses on optimizing research programming processes.

### METHODS:

Inspired by the work of Chalmers et al. on reducing research waste (The Lancet, 2014) we developed an analytical framework to assess research programs. The framework consists of four criteria: Social relevance, Scientific quality; Integrity; and Efficiency. For each criterion a number of indicators were developed using desk research. After pilot testing, the framework was applied to 16 representative, ongoing research programmes of ZonMw. The assessment was independently done by two researchers using desk research and interviews with programme managers.

Thereafter, the results were categorized using the payback framework of Hanney et al (2004) to provide recommendations regarding research programming.

## RESULTS:

Within ZonMw, the health research funded takes well into account indicators of social relevance (e.g. stakeholder participation and diversity in committee composition) and reasonably well scientific quality (e.g. mixed methods designs, international cooperation and knowledge sharing). Efficiency (e.g. encouraging use of existing data and systematic reviews) appears to be less well developed, while integrity (e.g. preventing publication bias) is underexposed. Tension can arise from potentially conflicting demands between the aim of creating new, innovative knowledge on the one hand and coordinated, practical knowledge building on the other.

## CONCLUSIONS:

Based on our study we can conclude that our framework works well and aligns well with international developments in the field of increasing value and reducing waste (Moher et al, 2015). The framework encompasses the categories presented by Chalmers et al and can be used for programme and project level assessments to (improve) the management and accountability of funding agencies. More focus on (societal) impact assessment, however, is essential as next step. This could be done by more transparency regarding research protocols, monitoring projects as well as by providing full reports in the public domain.

## REFERENCES:

Hanney S, Grant J, Wooding S, Buxton M. (2004). Proposed methods for reviewing the outcomes of health research: the impact of funding by the UK's 'Arthritis Research Campaign'. Health Research Policy and Systems; 2: 4. Series in the Lancet (8 January, 2014): Research: increasing value, reducing waste. Available via: <http://www.thelancet.com/series/research> Moher D, Glasziou P, Chalmers

I, Nasser M, Bossuyt PM, Korevaar DA, Graham ID, Ravaud P, Boutron I. Increasing value and reducing waste in biomedical research: who's listening? Lancet. 2015 Sep 25. pii: S0140-6736(15)00307-4. doi: 10.1016/S0140-6736(15)00307-4. Website ZonMw: <http://www.zonmw.nl/en/>

---

## Poster 34A The Setting Up Of An International Patient Panel To Guide The HTAi Patient And Citizen Involvement In HTA Interest Group In Its Work

### DESCRIPTION:

This presentation describes the steps the HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG) has taken to set up an International Patient Panel responsive to the PCIG Steering Committee. We describe the opportunities and challenges we are experiencing and how we are working to achieve a partnership with patient groups with mutually defined goals.

### PRESENTING AUTHOR:

Dr. Janet Wale, HTAi Patient and Citizen Involvement in HTA Interest Group, Australia

### AUTHORS:

Janet Wale, Melissa Sullivan, Jennifer Dickson, Kathi Apostolidis

### BACKGROUND AND OBJECTIVES:

Globally, patients are becoming empowered through increased health literacy, knowledge and skills gained through the internet and from joining patient advocacy groups. Patients are more prepared than ever to present their own experiences of diseases and treatment as part of the evidence to inform decision making. They are now recognised as important stakeholders in healthcare policy and decision making related

to access to new health interventions. Patient groups want to be valued and to make a difference by better informing health coverage and HTA processes and informing health coverage decisions. Over the last decade, the HTAi PCIG has created tools and support materials to address its objectives of developing robust methodologies to incorporate patients' perspectives in HTA and to support countries with limited experience in involving the patient and community perspective in HTA. There is now no better way to do this than to ensure a strong voice of patient groups within our internal structure. We are achieving this by setting up an international Patient Panel that responds to the PCIG Steering Committee.

**METHODS:**

In this presentation we describe the opportunities and challenges that HTAi PCIG is experiencing and how we are working to achieve our end goal of working in partnership with patient groups to achieve our mutual goals using an international 'Patient Panel' model.

**RESULTS:**

The PCIG has revised its Terms of Reference to include a Patient Panel, made up of people from patient groups who represent a range of disease areas and geographical locations. Some are familiar with HTA and have experience in providing patient submissions to their agencies. Others are new to this area and in preparing materials that can inform universal health care and HTA decision making. Our initial panel has helped in the development of an orientation package to inform new members about HTA and the work of the HTAi PCIG.

**CONCLUSIONS:**

The HTAi PCIG has initiated an international Patient Panel that works along-side its Steering Committee to inform the work of the Interest Group. By working together in partnership we aim to achieve mutual goals, show value for all concerned, and demonstrate mutual benefits and the positive impact of working with patient advocates and

patient groups.

**Poster 35A Patient Reported Outcome Measures To Assess Benefit In Patients With Symptomatic Cardiac Arrhythmia Treated With Catheter Ablation**

**DESCRIPTION:**

Cardiac arrhythmias lead to reduced quality of life for millions of patients. Symptom severity is best assessed by those affected: this can be done using patient reported outcome measures (PROMs). We developed and validated a PROM for this patient group: results suggested significant improvements in impact on life and symptom severity. Expectations were met or exceeded in 72.5% of responders.

**PRESENTING AUTHOR:**

Mirella Marlow, NICE, United Kingdom

**AUTHORS:**

Kathleen Withers, Judith White, Grace Carolan-Rees, Mauro, Lencioni, Kathryn Wood, Hannah Patrick, Michael Griffith

**BACKGROUND AND OBJECTIVES:**

Cardiac arrhythmias are estimated to affect over 2 million people in the United Kingdom every year, with 33.5 million people worldwide affected by atrial fibrillation alone. Many patients with arrhythmias develop debilitating symptoms including palpitations, breathlessness and chest pain, and may suffer reduced quality of life. Management of arrhythmias aims to reduce or abolish symptoms, and treatment options include the use of catheter ablation. Some outcomes including symptom status, physical and social function, mental health and wellbeing are best

assessed by patients themselves, using tools such as patient reported outcome measures (PROMs). PROMs measure the clinical benefit of interventions by assessing a patient's health before and after treatment using items judged important from the patient's perspective. PROMs used in other conditions help guide decision making and patient selection for treatment and to measure patient expectations of recovery and outcomes following treatment. We identified a lack of appropriate tools for UK patients with symptomatic arrhythmias, which measured an adequate range and severity of symptoms, patient expectations and patient reported complications. PROMs should be formally validated to ensure accurate and reliable measurement. Therefore we developed and tested a new tool for this patient group.

#### **METHODS:**

Using mixed methods including qualitative interviews and a longitudinal observational survey, we developed and validated a disease specific PROM for use in patients with symptomatic cardiac arrhythmias. The Cardiff Cardiac Ablation Prom (C-CAP) assesses patient expectation and procedural complications as well as measuring changes in symptom severity, frequency and duration of arrhythmia episodes and impact on life. Over 550 patients enrolled in the observational study using C-CAP together with EQ5D, 434 patients provided valid responses pre and post ablation. Study data have been analysed to measure changes in patient reported outcomes following ablation.

#### **RESULTS:**

Changes from baseline to post-ablation in the 3 disease-specific C-CAP scales showed high responsiveness (effect size >0.78). Improvements in the domains of 'impact on life', 'symptom severity' and 'frequency and duration of symptoms' were reported by 78.9%, 68.2% and 82.5% of patients, respectively. Mean improvements for these domains were 48%, 43% and 45%, respectively (p

#### **CONCLUSIONS:**

The C-CAP tool provides evidence that cardiac ablation is safe and effective, significantly improving patient symptoms and quality of life. Measuring and effectively managing patient expectations may help maintain realistic decision making about treatment, recovery and outcome. The C-CAP tool may be used at a patient or service level to measure the impact of ablation. Further analyses will measure health utility, and aim to identify differences between subgroups and changes over time. This may help further assess those patients who benefit most from ablation as well as providing cost-effectiveness data to assist decision making for patients, clinicians and funders.

#### **REFERENCES:**

Withers KL, Wood KA, Carolan-Rees G, Patrick H, Lencioni M, Griffith M. (2015) Establishing content validity in a novel patient reported outcome measure for cardiac arrhythmia ablation patients. *Health and Quality of Life* (13); 38. White J, Withers KL, Lencioni M, Carolan-Rees G, Wilkes AR, Wood KA,, Patrick H, Cunningham D, Griffith, M. Cardiff cardiac ablation patient reported outcome measure (C-CAP): validation of a new questionnaire set for patients undergoing catheter ablation for cardiac arrhythmias in the UK. Accepted for publication in *Quality of Life Research* 2015.

---

## **Poster 36A Patient Submissions To HTA: Comparing Experiences In Asia, LatIn America, And Canada**

#### **DESCRIPTION:**

A comparison of patient engagement in HTA process in Canada, Taiwan, and Colombia found that patient interest in all settings was high, but the degree of participation and the satisfaction with the process varied. These findings clearly call for collaboration to define the fundamentals:

what, when, how, and to what end should we have patients participating in HTA processes.

**PRESENTING AUTHOR:**

Dr. Durhane Wong-Rieger, Institute for Optimizing Health Outcomes, Canada

**AUTHORS:**

Durhane Wong-Rieger, Angela Chaves, Tony, Yen-Huei Tarn

**BACKGROUND AND OBJECTIVES:**

This presentation compares the evolution of HTA patient input processes and patient experiences in three countries, Canada, Taiwan, and Colombia, over the course of two to three years. While HTA Agencies worldwide express interest in patient involvement, they vary considerably in terms of what, when, how, and 'how much' patients are 'invited' to participate. Moreover, groups like HTAi Citizen and Patient Engagement Interest Group, EUPATI, IAPO, and EURORDIS have developed materials and provided training but most reflect an 'Anglo-Saxon' bias. Much less has been documented about patient engagement in Latin American or Asia. In January 2013, a patient input process was recommended in Taiwan's HTA. Among Latin American HTA agencies, only Colombia's IETS has implemented a formal patient input process.

**METHODS:**

The primary author has conducted consultations and interviews with HTA representatives and patient advocates in Asia, Latin America, and Canada over the past two to three years. In fall 2015, HTA training workshops were conducted for patient advocates in Taiwan, Colombia, and Canada. Content from meetings, observations, and training outcomes were analyzed to develop a framework for agency engagement and patient participation.

**RESULTS:**

Patient engagement varied. The options for patient

input were greatest in the most developed HTA process (Canada), providing for structured group submissions, feedback, and public members on the appraisal committee. In Taiwan, the process gives individuals only two weeks to provide input, limited to 300 words, resulting in a high level of frustration. In Colombia, selected patients are invited to participate at various stages of the assessment process with the scientific committee. Patients lack understanding of the committees' task and their role. In all settings, patients expressed concern with the lack of transparency and frustration with perceived limited influence.

**CONCLUSIONS:**

These findings confirm the lack of consensus on the value and use of patient input. In all locales, patient engagement reflects an iterative process: patients pressure HTA agencies to participate; agencies provide limited opportunities; patients provide input, often seeking training to improve their expertise; and agencies increase the scope and level of engagement. However, in order to stimulate greater HTA investment in patient engagement and greater interest among patients, these findings clearly call for collaboration to define the fundamentals: what, when, how, and to what end should we have patients participating in HTA processes.

**Poster 37A Healthcare Issues And Social Consensus In Korea: Report Of The Round Table Conference Of National Evidence-Based Collaborating Agency**

**DESCRIPTION:**

This discusses social consensus activity through Round Table Conference (RTC) which have been held by National Evidence-based Healthcare Collaborating Agency (NECA) in Korea

**PRESENTING AUTHOR:**

Dr. Ji Eun Choi, National Evidence-based Collaborating Agency, Korea

**AUTHORS:**

Ji Eun Choi, Joo Youn Kim, Seong Woo Seo, Min Jee Kim, Seihee Kim

**BACKGROUND AND OBJECTIVES:**

As healthcare techniques have developed, related issues causing social conflict have also increased. Having social consensus meetings based on social dialogue is important to resolve the conflict among interested parties. The National Evidence-based Healthcare Collaborating Agency (NECA) has held the Round Table Conference (RTC) since 2009 as one strategy for creating consensus among diverse stakeholders on specific issues and based on scientific review and social appraisal.

**METHODS:**

To select a topic for the RTC, we evaluated the appropriateness of the candidate topic in terms of the level of evidence and level of conflict. We then evaluated the priority of the topic using the checklist to capture scientific level of evidence and social value. The NECA RTC was held for the selected topic according to the process which is generally followed. This involved: organizing a steering committee, composing speakers and panels, holding preliminary and plenary meetings, preparing an agreement statement and dissemination.

**RESULTS:**

For the NECA RTC in 2014, a total of 4 topics were selected: 1) robot-assisted surgery for patients with gastric cancer, 2) robot-assisted surgery for patients with prostate cancer, 3) early diagnosis of dementia, and 4) stem cell therapy. Improvement was made in terms of 1) administrative process 2) transparent process for topic selection, 3) comprehensive participation from various parties including patients, 4) ensuring publicity for the results reports, and 5)

sufficient deliberative process.

**CONCLUSIONS:**

RTC is a useful tool to reach social consensus. However, further research is needed to establish guidelines for the process and dissemination strategies so the information can be applied to decision making in healthcare systems.

**Poster 38A A Systematic Review Of Self-Management Interventions To Improve Coping And Resilience In Common Long Term Conditions**

**DESCRIPTION:**

This systematic review attempted to establish which interventions improve coping and resilience for people living with common long-term conditions. (PROSPERO registration number CRD42014012965). Meta-analysis of coping at around 6 months (10 small studies) showed no significant improvement. No studies measured resilience.

**PRESENTING AUTHOR:**

Dr. Catherine Meads, RAND Europe, United Kingdom

**AUTHORS:**

Michelle Constable, Jim McManus, Elizabeth Jenkinson, Catherine Meads

**BACKGROUND AND OBJECTIVES:**

People with long-term conditions (LTCs) such as cardiovascular disease, diabetes mellitus, stroke, chronic kidney disease and COPD are intensive users of health services. Coping and resilience are important personal factors underpinning self-management. Objectives: This review addresses

the gap in the literature through the assessment of interventions with specific quantitative measures of coping or resilience in patients with common LTCs in line with public health priorities i.e. cardiovascular disease (CVD), diabetes mellitus, chronic obstructive pulmonary disease (COPD), stroke and chronic kidney disease (CKD).

## **METHODS:**

Databases: AMED, CINAHL, MEDLINE (Ovid), PsycINFO, EMBASE, Cochrane and Campbell Databases were searched from inception to October 2014. Included were any comparative studies in adults in any setting undergoing self-management interventions with a psychosocial component. This could include but was not limited to goal setting, problem solving, motivational interviewing, coping skills training, cognitive behavioural therapy strategies, stress management, mindfulness. Interventions were compared to inactive controls, and studies had to measure coping or resilience. Coping was defined by the use of a coping scale or a coping item or statement in a wider measure. Resilience was by a direct resilience scale such as The Connor-Davidson Resilience Scale. Results were tabulated and assessed narratively. Meta-analysis was conducted using Revman 5.3, using a random effects model due to heterogeneity of included studies. Heterogeneity was assessed using the I<sup>2</sup> statistic with standard cut-offs.

## **RESULTS:**

From the 929 identified citations 11 studies were included, 7 in diabetes mellitus, 2 in COPD, 1 in stroke, 1 in cardiovascular disease, 0 in chronic kidney disease. All studies used different interventions with programme duration and time to final assessment varying significantly, ranging from four weeks to 30 months. All studies measured coping but definitions varied, none measured resilience. There were eight randomised controlled trials and three quasi experimental studies, with considerable variation in characteristics. In general the studies were small-scale with participant numbers ranging from 18 to 411. Study quality

was generally poor. Meta-analysis of coping at around 6 months (10 studies) showed no significant improvement with the interventions (SMD 0.38 (95% confidence interval -0.04 to +0.79)).

## **CONCLUSIONS:**

To our knowledge this is the first systematic review of psychosocial interventions aimed to increase coping and resilience in common LTCs in line with public health priorities. There is insufficient evidence yet to demonstrate if self-management interventions may have a small impact on increasing coping in LTCs. More good quality, large scale RCTs are needed to investigate the impact of interventions on coping. Resilience needs to be measured in future studies. Economic factors and feasibility studies should be built into the development of interventions and reported as this will be a significant factor when commissioners are deciding which interventions to implement.

## **REFERENCES:**

- Anderson, R. M., Funnell, M. M., Butler, P. M., Arnold, M. S., Fitzgerald, J. T., & Feste, C. C. (1995). Patient empowerment. results of a randomized controlled trial. [Nurse telehealth coaching for rural diabetics: innovation in care] *Diabetes Care*, 18(7), 943-949.
- Attari, A., Sartippour, M., Amini, M., & Haghghi, S. (2006). Effect of stress management training on glycemic control in patients with type 1 diabetes. *Diabetes Research & Clinical Practice*, 73(1), 23-28.
- Ernst, G., & Hubner, P. (2012). Fractionated inpatient rehabilitation of diabetes: Results from a randomized controlled trial on rehabilitation aftercare. *Rehabilitation (Stuttg)*, 51(5), 308.
- Henry, J. L., Wilson, P. H., Bruce, D. G., Chisholm, D. J., & Rawling, P. J. (1997). Cognitive-behavioural stress management for patients with non-insulin dependent diabetes mellitus. *Psychology, Health & Medicine*, 2(2), 109-118.
- Jiang, X., & He, G. (2012). Effects of an uncertainty management intervention on uncertainty, anxiety, depression, and quality of life of chronic obstructive pulmonary disease

outpatients. *Research in Nursing & Health*, 35(4), 409-418. doi:<http://dx.doi.org/10.1002/nur.21483>

Johnson, J., & Pearson, V. (2000). The effects of a structured education course on stroke survivors living in the community, including commentary by Phipps M. *Rehabilitation Nursing*, 25(2), 59. Ko, C. H., & Gu, M. O. (2004). [The effects of a diabetic educational program for coping with problem situation on self-efficacy, self care behaviors, coping and glycemic control in type 2 diabetic patients]. *Daehan Ganho Haghoeji*, 34(7), 1205-1214.

Petty, T. L., Dempsey, E. C., Collins, T., Pluss, W., Lipkus, I., Cutter, G. R., . . . Weil, K. C. (2006). Impact of customized videotape education on quality of life in patients with chronic obstructive pulmonary disease. *Journal of Cardiopulmonary Rehabilitation*, 26(2), 112-117.

Spieß, K., Sachs, G., Pietschmann, P., & Prager, R. (1995). A program to reduce onset distress in unselected type I diabetic patients: Effects on psychological variables and metabolic control. *European Journal of Endocrinology*, 132(5), 580-586

Tacon, A. M., McComb, J., Caldera, Y., & Randolph, P. (2003). Mindfulness meditation, anxiety reduction, and heart disease: A pilot study. *Family & Community Health*, 26(1), 25-33.

Trento, M., Trinetta, A., Kucich, C., Grassi, G., Passera, P., Gennari, S., Porta, M. (2011). Carbohydrate counting improves coping ability and metabolic control in patients with type 1 diabetes managed by group care. *Journal of Endocrinological Investigation*, 34(2), 101-105. doi:<http://dx.doi.org/10.3275/7027>

.....

## Poster 39A On A "Fair" Price Of A Medical Device

### DESCRIPTION:

Concept of medical device price and value in the spotlight. Approaches to valuation, components of price, possible methods. Discussion about revenue drivers and Pay-for-Performance method applicability. Accounting for the institutional risk. A plead for revenue-oriented capital investment evaluation method.

### PRESENTING AUTHOR:

Silvie Jerabkova, University of Economics, Prague, Czech Republic

### AUTHORS:

Silvie Jerabkova

### BACKGROUND AND OBJECTIVES:

The price of a medical device, despite a clear definition of each word, is rather a tricky concept. This paper deals with disunity in approaches towards what should be considered as a "fair" price of a medical device, what are its components and above all, how should a medical device be valued. Such a valuation is crucial for designing medical care reimbursement schemes, for HTA calculations and also for innovative medical device producers' investment decisions. In the Czech Republic, the market price of a medical device does not give answers to those questions. The market price is often distorted by specific market attributes. The need for a clear methodology in determining medical device value, price and their interactions has led us to elaborate the present paper.

### METHODS:

We are using elements from Bayesian statistics to both investment decision problems and to determine the reimbursement schemes. Options valuation methods are also discussed as a possible way to assess the revenues generated by using a medical device. Revenue drivers are thus defined.

Pay-for-Performance method's applicability is examined in terms of assessing the quality of the health service rendered by the medical device in question.

**RESULTS:**

Medical devices and their use in healthcare are considered as investment (in the sense of accounting) and they are therefore valued as such. Quality of the healthcare delivered or of the health problem treated play the role of confirmation or rejection for the medical device being developed. Possible answers are offered to the question of "fairness" or "adequacy" of a medical device price given its components and market characteristics. Institutional aspect hence holds a strong importance.

**CONCLUSIONS:**

Price and value of a medical device remain complex categories. According to different situations, different techniques might be employed. Our paper provides possible suggestions in this direction and pleads for wider use of revenue-oriented methods of medical device valuation.

.....

## Poster 40A Integration Of Evidence And Values To Support Reimbursement Decision-Making On Diabetes: Experiences From HTA Agencies And Implications For Developing Countries

**DESCRIPTION:**

The purpose of our research is to analyze the experiences of integration evidence and values to support reimbursement decision-making on diabetes, and to propose suggestions for the evidence-based reimbursement in developing countries like China. Confronting limited resources

available for healthcare, evidence assessment reports which integrate values and expert opinions are the optimized forms to support evidence-based decision-making.

**PRESENTING AUTHOR:**

Dr. Jinsong Geng, Nantong University, China

**AUTHORS:**

JinSong Geng, Lili Shi, Yalan Chen, Jianwei Shi, Wenxiu Shi, Hui Wang

**BACKGROUND AND OBJECTIVES:**

Transparent and efficient systematic assessment and dissemination of the evidence and values are need for the evidence-based reimbursement decision-making. However, techniques to provide updated information to support the reimbursement was still lacking, especially for some developing countries. As a result, subjective views from experts played the most critical role in the decision-making procedure. Objectives: To analyze the experiences of integration evidence and values to support reimbursement decision-making on diabetes, and to propose suggestions for the evidence-based reimbursement in developing countries like China.

**METHODS:**

Technology assessment report from two international health technology assessment (HTA) agencies, UK's National Institute for Health and Care Excellence (NICE) and Canadian Agency for Drugs and Technologies in Health (CADTH). The inclusion criteria for reports was formal recommendations and evidence basis for reimbursement decision-making in the treatment of diabetes. Therapies which aimed at diabetes complications were excluded. Data extraction form was developed, which mainly consisted of the information of notice of recommendation, type and level of evidence, conclusions from evidence, values, relevance to clinical practice and major reasons for recommendation.

**RESULTS:**

Six reports from NICE, and twenty reports from CADTH were included in the analysis. The recommendation for not to be listed was made for 11 reports by CADTH. For the reports from NICE, recommendations were sometimes differentiate from different usage of technologies. Effectiveness, safety, economic evidence were the most common forms of evidence, and uncertainties of evidence were analyzed. Systematic review/meta-analysis and randomized-controlled trials were preferred for assessment of clinical effectiveness. Values from patients were considered, especially for their experience of disease, attitudes towards alternative treatments and clinical needs. Opinions from experts were also integrated in assessment.

**CONCLUSIONS:**

Take diabetes as an example, evidence and values are important for transparent and scientific reimbursement decision-making. Evidence should be assessed and values should be considered. Confronting limited resources available for healthcare in developing countries, evidence assessment reports which integrated values and expert opinions are the optimized forms to support evidence-based decision-making.

## Poster 41A The Review Of Price Decisions For Recently Listed Pharmaceutical Drugs In Japan

**DESCRIPTION:**

The introduction of a cost-effectiveness assessment has been discussed to consider appropriate health resource allocation. For this new scheme, the price decisions were reviewed for recently listed drugs to understand value based approaches under the current pricing system.

**PRESENTING AUTHOR:**

Hiroyo Kuwabara, Takeda Pharmaceutical Company

Limited, Japan

**AUTHORS:**

Hiroyo Kuwabara, Masaki Kasahara, Kouhei Tsujimura, Akira Tokunaga, Kaoru Yamabe

**BACKGROUND AND OBJECTIVES:**

The healthcare reform has been under big debate to maintain the sustainable health insurance system in Japan. For appropriate health resource allocation, the introduction of a cost-effectiveness analysis to evaluate economical effectiveness of existing pharmaceutical drugs has been discussed in the Central Social Insurance Medical Council (Chuikyo). To implement this new scheme, one of issues is to harmonize value based approaches with the current pricing system. We reviewed the price decisions of recently listed drugs which may be candidates for a cost-effectiveness analysis.

**METHODS:**

The information was obtained from publicly available websites of the Ministry of Health, Labour and welfare and the Pharmaceuticals and Medical Devices Agency (PMDA). The methods used for pricing decisions were reviewed and eligible drugs for premium were identified. The number of drugs receiving the premium (innovativeness, 100%; usefulness, 5-40%; pediatric or marketability, 5-10%; premium for cost calculation method (CCM), 5-100%) was summarized with rationales for premium. With respect to the drugs receiving either the premium for innovativeness or usefulness, PMDA's review reports were also examined whether pricing comparators were used in their Phase III studies.

**RESULTS:**

A total of 224 new drugs were listed on the drug price list of the Japanese National Health Insurance between 2012 and 2015. Of 224 new drugs, 182 drugs were eligible for the premium and 46 drugs (25.2%) received any of the premiums (innovativeness, 1; usefulness, 18; pediatric or marketability, 15; premium for CCM, 12). The

premium for usefulness was rewarded to four drugs based on the same drugs which were used in the Phase III studies.

### **CONCLUSIONS:**

In the past four years, there were relatively few drugs receiving the premium for innovativeness or usefulness. A clear guidance to select comparators is necessary for value based decision making when a cost-effectiveness assessment is implemented in Japan.

---

## **Poster 42A Modelling Cost-Effectiveness Of Antiretroviral Treatments In HIV: Incorporating Adherence And Non-AIDS Related Morbidities**

### **DESCRIPTION:**

Our objective was to develop a HIV model suitable for health technology assessments in treatment of naïve patients, with the ability to capture the impacts of adherence and non-AIDS related morbidities (NARMs). Information retrieved from the Data Collection on adverse events of Anti-HIV Drugs (D:A:D) cohort ( over 30,000 participants) was used to this effect.

### **PRESENTING AUTHOR:**

Rodolphe Perard, Gilead Sciences, United Kingdom

### **AUTHORS:**

Chris Kiff, Chris Parker, Neil Hawkins, Rodolphe, Perard Gillian, Scott Braithwaite, Mar, Sculpher, Elisabeth Fenwick

### **BACKGROUND AND OBJECTIVES:**

HIV continues to be a major global public health issue. Across Western Europe and North America over 2.4 million people are currently living with HIV, with over 85,000 new HIV infections diagnosed

every year. With the advent of HAART this once acute condition has been transformed into a near chronic condition. The main goal of HAART is to suppress the HIV virus in order to stop the disease progressing. In order to achieve this, patients must adhere to treatment. Single tablet regimens (STRs), which require patients to only take a single tablet, once a day, aim to improve patients' adherence to treatment and thus achieve better virologic outcomes. Information retrieved from the Data Collection on Adverse events of Anti-HIV Drugs (D:A:D) cohort (a collaboration of eleven prospective cohorts from across Europe, Australia, and the US, totalling over 30,000 participants) indicates that PLHIV suffer from immunosenescence, increasing the risk of non-AIDS related morbidities (NARMs).

### **METHODS:**

Models aiming to assess the cost-effectiveness of any new antiretroviral treatments need to account for the impact of adherence and NARMs. Our objective was to develop a HIV model with the ability to capture adherence and NARMs, suitable for health technology assessments. A literature review concluded that existing models do not adequately account for either adherence benefits associated with STRs or the impact of NARMs. A conceptual model was designed and later refined through discussions with experts with considerable experience of modelling in HIV. The refined conceptual model was developed, as an individual patient simulation model in R, to predict clinical and economic outcomes of HAART in treatment naïve patients. Increases and decreases in CD4 levels are determined through the probability of viral suppression. The absolute level of CD4, patient characteristics and current HAART are used within the model to predict NARMs, opportunistic infections and malignancies. The level of adherence impacts the long term probability of remaining virologically suppressed.

### **RESULTS:**

This HIV model predicts long-term clinical outcomes including overall survival, CD4, time

on first treatment and occurrence of NARMs. The model also predicts economic outcomes including QALYs and costs. To our knowledge this is the first HIV model to incorporate the adherence benefits that occur with STRs and the impact of NARMs (i.e. fracture, hypertension, renal, cardiovascular, and diabetes disease) on the cost-effectiveness of HAART in HIV.

### **CONCLUSIONS:**

As HIV transitions to a chronic condition, with the advent of highly efficacious treatments, this cost-effectiveness model allows HTA agencies to not only assess the impact of treatment on disease suppression but also to assess how adherence impacts disease progression and the long-term impact of NARMs.

---

## **Poster 43A** The Transition Of Patients From Curative To Palliative Care: A Systematic Review Of Ethical Issues And Applied Methods

### **DESCRIPTION:**

A systematic review of the literature revealed that there are few publications but many relevant and complex ethical issues addressed by a variety of different methods. These issues are important when planning end-of-life care for the individual in the processes of Advance Care Planning.

### **PRESENTING AUTHOR:**

Bjørn Hofmann, University of Oslo, Norway

### **AUTHORS:**

Kristin Bakke Lysdahl, Sigrid Droste, Bjorn Hofmann

### **BACKGROUND AND OBJECTIVES:**

Transitions in end-of life care are frequent and burdensome for patients, families and professionals.

This is particularly so for transitions from curative to palliative care as these pass from a treatment model to a care model. However, ethical issues, patients' preferences, values in transitions to palliative care are seldom addressed by ethicists. Objectives: To systematically review the methodological approaches applied and the relevant ethical issues concerning transitions from curative to palliative care.

### **METHODS:**

a) comprehensive systematic literature search (2013), update cluster search (2015), b) screening (predefined inclusion/exclusion criteria), c) extracting and quality assessment of relevant arguments, d) assembling to ethics domains, e) synthesis of results.

### **RESULTS:**

43 relevant publications were identified, including a few qualitative studies and review articles. The publication authors identified & partially depending on the underlying transition model (sharp-, gradual- or continuous transition) - areas influencing the transition: purpose, timing, initiating and preparing discussions, and outcome. Various ethical approaches was applied in the analyses and a number of ethical issues identified. Some examples: compassion, fidelity, honesty and courage in communication; prudence, wisdom and justice in decision making; respect patients autonomy; beneficence by balancing truth telling and nurturing hope; avoiding harm from over treatment; justice in resource allocation Most of these issues are relevant for the Advance Care Planning interventions. Some ethical issues were identified by all/most approaches, some issues not.

### **CONCLUSIONS:**

Few publications on many relevant and complex ethical issues - addressed by different methods approaches - exist. To achieve a best possible end-of-life care for people, relevant ethical issues should be integrated into communications and shared decision-making processes of Advance Care

Planning.

## Poster 44A Why Is It Difficult To Integrate Ethics In HTA? The Epistemological Reasons

### DESCRIPTION:

Ethics has been identified as a key element in HTA since its conception. However, ethical issues are still rarely part of practical HTA work. Why is this so? The basis of the contribution is the claim that ethics is often not part of HTA for 'epistemological reasons'. Therefore, the aim of the contribution will be to explore in more details and emphasize them by using the fact/value dichotomy. Our conclusion is that current HTA configuration is dominantly based on the comparison among objective and empirically testable 'facts', whilst ethics is not empirically testable. There is a sort of 'epistemological gap', which can explain why ethics is rarely part of HTA. For this reason, we suggest that the epistemological differences among the various domains of HTA should be addressed more explicitly.

### PRESENTING AUTHOR:

Pietro Refolo, Università Cattolica del Sacro Cuore, Italy

### AUTHORS:

Pietro Refolo, Dario Sacchini, Louise Brereton, Ansgar Gerhardus, Bjorn Hofmann, Kristin Bakke Lysdahl, Kati Mozygamba, Wija Oortwijn, Marcia Tummers, Gert Jan van der Wilt, Philip Wahlster, Antonio G. Spagnolo

### BACKGROUND AND OBJECTIVES:

From the conception of HTA in the 1970s, it has been argued that ethics is a constitutive part of HTA. Ethics within an HTA aims at analysing the ethical issues raised by the consequences of implementing/not implementing a health technology. Over the last 40 years, ethics has rarely been part of HTA work and ethical issues

are still not frequently addressed explicitly in HTA. Why is this so? Several reasons why ethics is not a part of HTA have been identified. The basis of the intervention is the claim that ethics is often not part of HTA for 'epistemological reasons'. Hence, the main aim of the contribution will be to explore in more details and emphasize them by using the fact/value dichotomy.

### METHODS:

Search for articles relating to ethichs and HTA and to the fact/value dichotomy

### RESULTS:

The integration of ethics in HTA can be considered as part of a certain cultural trand. It can be interpreted as an attempt to overcome the neopositivistic epistemology, which was only interested in technical and empirically testable issues.

### CONCLUSIONS:

Our conclusion is that current HTA configuration is dominantly based on the comparison among objective and empirically testable 'facts', whilst ethics is not empirically testable. In this sense, there is a sort of 'epistemological gap', which can explain why it is so difficult to integrate ethics in HTA. We suggest that the epistemological differences among the various domains of HTA are addressed more explicitly.

### REFERENCES:

- [1] Sacchini D, Virdis A, Refolo P et Al. Health technology assessment (HTA): ethical aspects. Med Health Care Philos 2009;12:453-57
- [2] Hofmann B: Toward a procedure for integrating moral issues in health technology assessment. Int J Technol Assess Health Care 2005; 21(3):312-8
- [3] Saarni SI, Hofmann B, Lampe K et Al. Ethical analysis to improve decision-making on health technologies. Bull World Health Organ 2008;86(8):617-23

- [4] Hofmann B, Oortwijn W, Lysdahl BK et Al. Integrating Ethics in Health Technology Assessment: many ways to Rome. *Int J Technol Assess Health Care* 2015;31(3):131-7
- [5] Institute of Medicine (IOM). *Assessing Medical Technologies*. Washington D.C.: National Academy Press; 1985
- [6] <http://www.eunethta.eu/about-us/faq#t287n73>
- [7] Lehoux P, Blume S. Technology assessment and the sociopolitics of health technologies. *J Health Polit Policy Law* 2000;25:1083-120
- [8] Dejean D, Giacomini M, Schwartz L et Al. Ethics in Canadian health technology assessment: A descriptive review. *Int J Technol Assess Health Care* 2009; 25 (4): 463-9 [
- 9] Droste S, Gerhardus A, Kollek R. Methods for integrating ethical aspects and social values in short HTA-reports. An international inventory. German Agency of Health Technology Assessment at German Institute for Medical Documentation and Information (DAHTA) (DIMDI);2003:9
- [10] Lavis J, Wilson M, Grimshaw J et Al. Towards optimally packaged and relevance assessed health technology assessments, Report Submitted to the Canadian Agency for Drugs and Technologies in Healthcare. Hamilton, Ontario: McMaster University Program in Policy Decision-Making;2007
- [11] Assasi N, Schwartz L, Tarride JE et Al. Methodological guidance documents for evaluation of ethical considerations in health technology assessment: a systematic review. *Expert Rev Pharmacoecon Outcomes Res* 2014;14(2):203-20
- [12] Droste S, Dintsios CM, Gerber A et Al. Integrating ethical issues in HTAs: More methods than applications?. HTAi 7th Annual Meeting: 2010 Jun 6-9; Dublin, Ireland. Maximizing the Value of HTA. Book of Abstracts; 2010:M5-02,p. 169
- [13] Hofmann B. Why ethics should be part of health technology assessment. *International Journal of Technology Assessment in Health Care* 2008; 24(4):423-9
- [14] ten Have H. Ethical perspectives on health technology assessment. *Int J Technol Assess Health Care*. 2004; 20 (1):71-6
- [15] Hofmann B. Why not integrate ethics in HTA: identification and assessment of the reasons. *GMS Health Technology Assessment* 2014;10: 1-9
- [16] Battista RN. Towards a paradigm for technology assessment in Peckham M, Smith R (eds). *The scientific basis of health services*. London: BMJ Publishing Group; 1996
- [17] Sandman L, Heintz E. Assessment vs. appraisal of ethical aspects of health technology assessment: can the distinction be upheld?. *GMS Health Technology Assessment* 2014;10: Doc05
- [18] EUnetHTA. HTA Core Model Application for Medical and Surgical Interventions (2.0). <http://mekat.hl.fi/htacore/ViewApplication.aspx?id=14248>
- [19] Hofmann B, Droste S, Oortwijn W et Al. Harmonization of ethics in health technology assessment: a revision of the Socratic approach. *Int J Technol Assess Health Care* 2014;30(1): 3-9
- [20] Hofmann B. Health Technology Assessment - science or art?. *GMS Health Technology Assessment* 2013;9:Doc08
- [21] Holm S, Ploug T. The use of empirical evidence in formulating reproductive policy advice and policy. *Monash Bioeth Rev* 2015;33(1):7-17
- [22] Irving L, Holm S; Empire Team. Using empirical data: recommendations for the use of empirical data in bioethics and the regulation of biotechnology. *Bull Med Ethics* 2003;(190):8-11
- [23] Molewijk B, Stiggelbout AM, Otten W et Al. Empirical data and moral theory. A plea for integrated empirical ethics. *Med Health Care Philos* 2004;7(1):55-69
- [24] Molewijk AC, Stiggelbout AM, Otten W et Al. Implicit normativity in evidence-based medicine: a plea for integrated empirical ethics research. *Health*

Care Anal. 2003;11(1):69-92

[25] Tondini G. I rapporti tra etica ed economia. Dalla separazione alla collaborazione. Padova: CEDAM; 2001

[26] Hume D. A Treatise of Human Nature. Book III, Part I, Section I; 1739 [

27] Putnam H. The Collapse of the Fact/Value Dichotomy and Other Essays. Cambridge, MA: Harvard University Press. 2002

[28] Schnädelbach H. Was ist Neoaristotelismus?, in Kuhlmann W. Moralität und Sittlichkeit. Das Problem Hegels und die Diskursethik. Frankfurt am Main: Suhrkamp; 1986: 38-63

[29] Marzocchi V. Ragione come discorso pubblico. La trasformazione della filosofia di K.O. Apel. Napoli: Liguori Editore; 2000

---

## Poster 45A Implementation Strategy For Evidence-Based Decision Making In HIRA

### DESCRIPTION:

The Health Insurance Review and Assessment Service (HIRA) is responsible for the review, quality assessment, and the setting and management of benefit standards of the National Health Insurance in South Korea. HIRA operates a variety of separate committees, including the Healthcare Review and Assessment Committee, five separate benefits committees, an appeals committee, the Severe Disease Deliberation Committee, and the Pharmaceutical Benefits Committee. Each committee reviews and evaluates matters regarding the decision making for the NHI coverage.

Each committee requires, contextually, the decision making for the NHI coverage. The review results should be evidence-based, reflecting the importance of a fair, specialized, objective approach. In order to achieve such objectivity, a

support system for swift, reliable, and appropriate decision-making is needed.

### PRESENTING AUTHOR:

Yoon Jung Choi, Health Insurance Review and Assessment Service, Korea

### AUTHORS:

Yoon Jung, Choi, Youn Song, Choi

### BACKGROUND AND OBJECTIVES:

The Health Insurance Review and Assessment Service (HIRA) is responsible for the review, quality assessment, and the setting and management of benefit standards of the National Health Insurance in South Korea. HIRA operates a variety of separate committees, including the Healthcare Review and Assessment Committee, five separate Benefits Committees, an Appeals Committee, the Severe Disease Deliberation Committee, and the Pharmaceutical Benefits Committee. Each committee reviews and evaluates matters regarding the decision making for the NHI coverage. Objective Each committee requires contextually the decision making for the NHI coverage. The review results should be evidence-based, reflecting the importance of a fair, specialized, objective approach. In order to achieve such objectivity, a support system for swift, reliable, and appropriate decision-making is needed.

### METHODS:

Efficient decision making has required of each committee member the ability to properly utilize evidence. The Evidence-Based Review Manual (EBRM) unique to HIRA was developed to standardize the format of official documents and the methods for the collection of evidence from literature. To improve the specialization of employees, a suitable educational framework was implemented to train employees in the use of EBRM. The EBRM Master Program was also set up to encourage continuous training within their respective departments. Masters are required to take refresher courses, and are under continuous

evaluation to ensure that they retain and improve their specialized knowledge, and in turn act as mentors to other employees.

### RESULTS:

To support establishment of an evidence-based decision making system, employees of the relevant departments underwent EBRM training. The current guideline has also formed the basis for the preparation of conference materials, ensuring that committee meetings, which are undertaken in a fair, efficient manner. As EBH specialists certified by the Human Resources Development Service of Korea (HRD), EBRM Masters are assigned at an average rate of one member per department, and serve to improve the knowledge base through cooperation and utilization of evidence.

### CONCLUSIONS:

Currently, the department overseeing each of the committees of HIRA provides decision-making support through the evidence-based materials. Additionally, the registering materials for medical treatment is an important process of policy support, as can be seen with the institutionalization and inclusion of evidence-based price evaluation as a tested topic on the Ministry of Health and Welfare Examination. However, the lack of inclusivity of evidence-based conference materials is supplemented by evidence reports such as Systematic Reviews when deemed necessary.

### REFERENCES:

2014. Evidence-Based Review Manual, HIRA

## Poster 46A Acceptability Of Health Technology Innovations: Involvement Of HIV Positive Patients In Decision Making TASO Uganda Experience

### DESCRIPTION:

This abstract shares the importance of involving patients in decision making when health technology innovations are to be introduced for use. TASO Uganda, a non-governmental organisation in Uganda, uses the strategy of patient councils who link the service providers and patients. The councils represent the views of the other patients before implementation of any new strategy or technology.

### PRESENTING AUTHOR:

Dr. Josephine Birungi, The AIDS Support Organisation, Uganda

### AUTHORS:

Josephine Birungi, Lazarus Oucul, Joyce Nankabirwa

### BACKGROUND AND OBJECTIVES:

Great Health technology Innovations to improve the quality of care for HIV positive patients have received with hesitation from patients especially in the resource limited settings and yet a huge cost and effort had been invested in the process of development. The AIDS Support Organization (TASO) Uganda, a national Non-government organization that provides care and treatment to over 80,000 HIV positive patients, has put in place a strategy to ensure that the new and relevant health technology innovations made by various stakeholders are acceptable to the patients attending the HIV clinics. The strategy is setting up of patients' councils with objectives of providing a linkage between patients and the healthcare providers so as to represent the views of the patients to TASO Senior management and the board.

### METHODS:

TASO set up patient's councils comprising of nine members all HIV positive, registered and receiving treatment at the 11 TASO HIV clinics. The patient's council is elected every 2 years by the other HIV positive patients to serve a maximum of two terms. TASO consults with the patient's council, right

from the start. Some of the innovations include; use of the mobile phone - voice calls and short text messaging to remind the patients about drug adherence, appointments, meetings and use of biometrics. One member of the management team is a person living with HIV to participate in decision making.

**RESULTS:**

There is improved utilization and uptake of the health technology innovations. Several new ideas for improvement and implementations have been raised by the patients. There is ownership of the programs using Health technology and easy scale up of the innovation. The process is time consuming as it involves a lot of forward and backward discussions.

**CONCLUSIONS:**

The involvement of the patients in decision making right from the inception of a Health technology innovative idea thru the process to the innovation in any field is critical for acceptance and uptake. It may consume time but it is worth it.

**REFERENCES:**

TASO Uganda Annual report 2015.  
www.tasouganda.org

.....

## Poster 48A Cost-Benefit Of Panoramic Radiographs Total Spine And Lower Limbs Achieved By Systems With The Use Of Films And Computed Radiology (CR) At University Center In Brazil

**DESCRIPTION:**

Cost-benefit of panoramic radiographs total spine and lower limbs achieved by systems with the use of films and computed radiology (CR) at university

center in Brazil.

**PRESENTING AUTHOR:**

Marcelo Lima, Botucatu Medical School - Unesp, Brazil

**AUTHORS:**

Marcelo, Lima, Silvana, Molina Lima, Carlos, Pilan Neto, Rodrigo, Giarolla, Ana Claudia, Molina, Raul, Ruiz Junior, Paulo, Borges, Paulo, Silvaes, Emilio, Curcelli

**BACKGROUND AND OBJECTIVES:**

The increasing technological advances, better quality and limited financial resources for investments in health care are factors that determine a need to rapid and constant changes in public and private institutions. With the evolution of Digital Radiology, technology has begun to offer new tools that improve the cost, quality and the work process in health institutions. In Clinical Hospital of Botucatu Medical School (HCFMB), x-rays are performed with the computerized radiology system, except for panoramic examinations total spine and lower limbs. This study aimed to calculate and compare the cost-benefit of panoramic radiographs total spine and lower limbs performed with the use of films and computed radiology systems.

**METHODS:**

This is a quantitative, transversal, descriptive and observational study, being carried out by analysis of documents the Radiology Sector of HCFMB. The materials used for the panoramic radiographic total column and lower limbs achieved by computerized systems and radiology system with the use of films have been identified. The costs have been allocated individually, based on the values practiced by public process, and the investment required for the institution of the new system implantation, calculated in US dollars.

**RESULTS:**

To the realization of x-rays for films system, were observed: costs with x-ray film, chemicals for revelation and maintenance processing with films; filter installation to discard of chemicals; and unavailability of network images; and repetition of exams for loss or unavailability. To the realization of radiographic procedures by computed radiology system were observed: increase the initial cost of acquisition of software and accessories for implementation of this system; however, there was a reduction in the final cost of radiography as well as related benefits for patients, professionals and institutions such as a reduced service time, improving workflow; reduce unnecessary exposure of patients and individuals occupationally exposed to X-rays by film processing error or loss of radiographs already processed, constant availability of images on the hospital system, improvement of the monitors in images quality with computer tools for analysis of radiologists and physicians who request the tests.

#### **CONCLUSIONS:**

The study identified the cost-benefit implementation of computerized radiology system in the realization of panoramic radiographs total spine and lower limbs, justifying the short-term investment by the institution.

#### **REFERENCES:**

1. Azevedo-Marques PM, Salomão SC. PACS: Sistemas de Arquivamento e Distribuição de Imagens. Revista Brasileira de Física Médica. 2009;3(1):131-9.
  2. Azevedo FMF, Koch HA. Avaliação de custos para implantação de um serviço de mamografia. Radiol Bras 2004; 37: 101-5.
  3. Goldszal AF, Bleshman MH, Bryan RN. Financing a large-scale picture archival and communication system. Acad Radiol. 2004;11(1):96-102.
- .....
- .....

## **Poster 49A** Added value of end of life and orphan medicines: a thematic analysis from the patient/carer perspective

#### **DESCRIPTION:**

The Scottish Medicines Consortium advises NHS Scotland on the clinical and cost-effectiveness of new medicines. Recent process changes have given patients and clinicians a stronger voice in decisions for end of life and orphan medicines. Thematic analysis of information provided by patients and carers has improved our understanding of the key factors that are important to patients.

#### **PRESENTING AUTHOR:**

Ailsa Brown, Healthcare Improvement Scotland, United Kingdom

#### **AUTHORS:**

Jan Jones, Eileen Harkess-Murphy, Anne Lee, Jonathan Fox, Lindsay Lockhart

#### **BACKGROUND:**

The Scottish Medicines Consortium (SMC) issues advice to NHS Scotland on the clinical and cost-effectiveness of all new medicines. Changes to our methods have recently been introduced to ensure that patients and clinicians have a stronger voice in decisions on medicines used at the end of life and for very rare conditions. This has involved the introduction of Patient and Clinician Engagement (PACE) meetings, allowing patient groups to contribute to the evidence assessment for these medicines. The meetings are intended to identify the added benefit of a medicine not already captured within conventional clinical and economic analyses. It results in the production of a consensus statement which is presented to the SMC meeting and plays an important role in the

final SMC decision.

**OBJECTIVES:**

Based on the early experience of PACE, SMC aims to gain a better understanding of what patient groups, patients and carers value and to identify key factors that are particularly important to patients.

**METHODS:**

A thematic analysis utilising a framework approach was conducted on PACE statements for all end of life, orphan and ultra-orphan medicines reviewed by SMC during a 12 month period (August 2014 to July 2015). Twenty eight patient statements were analysed to identify themes within the information provided by PACE participants.

**RESULTS:**

Quality of life, reflecting the impact of the medicine on the patient and carers' health and wellbeing was a very strong theme within PACE statements and was composed of eight sub-themes with family/carer impact, health benefits, manageable tolerability and psychological benefit found to be the strongest sub-themes within the data. Family/carer impact described the wider impact of the medicine upon families and carers of patients in terms of the opportunity to experience normal life for longer and enjoy a good quality of life. Health benefits described the perceived direct health benefits attributed to medicines. Manageable tolerability referred to the side effects of medicines and the extent to which they are tolerated and managed by both patients and clinicians. Psychological benefit described optimism on the behalf of the patient and their family/carers.

**CONCLUSIONS:**

SMC's commitment to providing robust and transparent assessment of new medicines is reflected in the introduction of the PACE process. PACE provides a strengthened patient voice in the decision-making for medicines for

the treatment of end of life, orphan and ultra-orphan conditions. Findings from this thematic analysis highlight the importance of taking a wider societal perspective in the assessment of these medicines and have improved our understanding of the key factors that are important to patients. Consideration of these factors through PACE has strengthened the assessment of new medicines in NHSScotland. Future work will be taken forward to explore how PACE consensus statements have shaped the SMC decisions.

.....  
**Poster 50A Spiritual Therapy For Mental Disorders**

**DESCRIPTION:**

Spiritual therapy is a form of counseling/ psychotherapy that involves the use of spiritual and religious beliefs for an improvement in illness. It is done either individually or people seek out the counsel of their religious leaders. This study was to assess the efficacy/effectiveness of spiritual therapy as a complementary therapy for patients with mental disorders.

**PRESENTING AUTHOR:**

Dr. Junainah Sabirin, MaHTAS, Ministry of Health, Malaysia

**AUTHORS:**

Noormah Mohd Darus, Junainah Sabirin

**BACKGROUND AND OBJECTIVES:**

Spiritual therapy is a form of counseling or psychotherapy that involves moral, spiritual, and religious influences on behavior and physical health. It is the use of spiritual and religious beliefs and values to strengthen oneself such as prayer, for an improvement in an illness. Most of the times it is done either individually or people seek out the counsel of their religious leaders. Religiosity is a term used to refer to the numerous aspects of religious activity, dedication, and belief. The

objective of this study was to do a systematic review to assess the efficacy / effectiveness, safety and economic implication of spiritual therapy as a complement therapy to standard treatment for patients with mental disorders such as anxiety, depression, schizophrenia, mental stress, insomnia or headache.

**METHODS:**

A comprehensive search strategy including electronic databases such as PubMed, Medline, OVID EBM Reviews, HTA databases, DARE, NHS website was performed. Relevant articles were critically appraised and evidence graded using US/ Canadian Preventive Services Task Force.

**RESULTS:**

Eight articles related to the effect of spiritual therapy on mental disorders were included in this review consisting of one systematic review and seven cross sectional studies. The majority of the studies were cross-sectional design. Most of the studies were limited by the nature of the population studied and short duration of study. A systematic review showed that Intercessory prayer (IP) may improve health outcomes by lowering severity scores of patients, psychotherapy and religious activities speeds recovery from anxiety as well depression in patients

**CONCLUSIONS:**

Most of the findings suggested potential benefit namely religious quality involvement was protective through personal and meditative aspects for depression anxiety and schizophrenia. However, the long term effects of spiritual therapy for mental health disorders could not be determined. Hence, there is a need for more research in this area to gauge the beneficial effect of spiritual therapy, religiosity, spiritual beliefs and practices has on health outcomes as an adjunctive treatment in patients with mental disorders such as anxiety, depression and schizophrenia.

.....

.....

## Poster 51A The Barriers Of Health Technology Assessment At Iran

**DESCRIPTION:**

This study attempts to investigate the current challenges of Iran’s health technology assessment

Result:

- 1- Lack of legal support of HTA.
- 2-Insufficient resource allocation.
- 2-Empowering the HTA experts and technical officers will improve the HTA process in the health system of Iran.

**PRESENTING AUTHOR:**

Shila Doaee, Ministry of Health, Iran

**AUTHORS:**

Shila Doaee, Alireza Olyaeemanesh

**BACKGROUND AND OBJECTIVES:**

HTA is implemented from 2008, in Iran .There are a structured organization in ministry of Health as a Health Technology Assessment office Now, more than 50 technologies has been evaluated by professors of HTA in Iranian universities and many of people is educated in HTA MSc in universities. But there are many problems in performance of the Health Technology Assessment so this study to aimed investigation of HTA challenges in HTA program at Iran.

**METHODS:**

In the first phase of method, the sources were investigated from the databases was also searched by the key term of ‘Health Technology Assessment’ up to 2011 The second phase of method included the polling of informants, managers and experts of HTA in Iran. It should be noted that a minority of the participants were some members of the scientific committee of the HTA (12 individuals) who

participated in this phase through a semi structured questionnaire designed of collected data. All challenges extracted from the phase 1 were classified in a table, and the participants were asked to state their views based on that table and they were stated reason for their views and solutions for the challenges as well as other challenges not mentioned in the questionnaire (in the form of open question). Data were analyzed by thematic analysis and then their reasons and solutions were summarized .

### RESULTS:

Twenty- two HTA challenges were specified then used for designing the questionnaire among the 22 mentioned challenges, the participants reached the highest consensus about the factors in the area of health system management (57.1%); they also strongly agreed on (42.85%) stewardship, stakeholders, infrastructures, external pressures, lack of coordination at the policy making level and lack of systematic structure for decision- making in the health system organization. The lack of legal support for HTA, insufficient resource allocation and the lack of academic courses for the involved experts were the greatest challenges expressed by Department of Health Technology Assessment at Ministry of Health.

### CONCLUSIONS:

According to comments from the players of HTA seem to the HTA challenges of Iran is related to the creation of appropriate infrastructure in the health sector in the establishment of health technology assessment so if senior managers of the Ministry of Health pay more attention to this program ,will be solved many of the problems of health technology assessment

### REFERENCES:

1. Farnoodi S. Presenting a Framework for Evaluation of Health Technologies in Health and Medical System of Iran; Case Study: Robolens Robot. STP Journal. 2009; 2 (3) :75-86.

2. Larijani B, Ameli O, Alizadeh K and Mirsharifi S.R. Prioritized list of health services in the Islamic Republic of Iran. Eastern Mediterranean Health Journal.2000; 6(2-3): 367-371.

3. Sivalal S. Health technology assessment in the Asia Pacific region. International Journal of Technology Assessment in Health Care. 2009; 25 (1): 196-201.

4. Palesh M, Tishelman C, Fredrikson S, Jamshidi, H, Tomson G & Emami A. 'We noticed that suddenly the country has become full of MRI'. Policy makers' views on diffusion and use of health technologies in Iran. Health research policy and system. 2010; 6:9.

5. Hosseini A. HTA Policy Paper 2007; Available from URL: <http://siasat.behdasht.gov.ir>

6. Chang Y. Health technology assessment in South Korea. International Journal of Technology Assessment in Health Care. 2009; 25 (1): 219-223.

7. Gulácsi L, Brodszky V, Péntek M, Kárpáti K, Varga S, Vas G, et al. History of health technology assessment in Hungary. International Journal of Technology Assessment in Health Care, 25: Supplement 1 (2009), 120-126.

8. Sampietro-Colom L, Asua J, Briones E, Gol J; AuNETS Group. History of health technology assessment: Spain. International Journal of Technology Assessment in Health Care, 25: Supplement 1 (2009), 120-126.

9. Pichon-Riviere A, Maria R, Briones E. HTA in Latin America and the Caribbean (LAC), facilitators and barriers for international collaboration: a survey. HTAi: Oral Presentation. Available from URL: [http://www.htai.org/fileadmin/HTAi\\_Files/Conferences/2008/Files/OralPresentations/Oral\\_Andres\\_Pichon-Riviere.pdf](http://www.htai.org/fileadmin/HTAi_Files/Conferences/2008/Files/OralPresentations/Oral_Andres_Pichon-Riviere.pdf)

10. Chen Y, Banta D, Tang Z. Health technology assessment development in China. International Journal of Technology Assessment in Health Care. 2009; 25 (1):202-209.

11. Akinori H. History of healthcare technology

assessment in Japan. International Journal of Technology Assessment in Health Care. 2009; 25 (1): 210-218.

12. Marzban S. A summary of HCTM report in Iran. Available from URL:[http://www.ifwkiel.de/konfer/esf-ifw/newtech\\_0507/marzban.pdf](http://www.ifwkiel.de/konfer/esf-ifw/newtech_0507/marzban.pdf)

13. HamzeKhanloo N, Bazayr M. Role and Necessity of Health Technology Assessment (HTA) in Health System. Ardabil Health Journal. 2010; 1(2).

---

## Poster 52A Comparison Of The Effect Of Treatments For Rotator Cuff Tears: Systematic Review And Meta Analysis Of Articles Analyzed By Intention-To-Treat (ITT) Method

### DESCRIPTION:

Rotator cuff tear is a leading cause of decline in the quality of life in middle-aging. The aim of this study was to compare pain, improvement of functional outcome, and range of motion (ROM) on patients with rotator cuff tear.

### PRESENTING AUTHOR:

Seihee Kim, NECA, Korea

### AUTHORS:

Seihee Kim, Jinseub Hwang, Seongwoo Seo, Min Jee Kim, Jae-Young Lim, Woo Hyung Lee, Ji Eun Choi

### BACKGROUND AND OBJECTIVES:

Due to population aging, emphasis on prolonged and healthy lives, and advancement in radiologic diagnostics, the interest in the most effective treatment and management of rotator cuff tears has been growing in recent years, leading to the development of various novel or improved treatment methods, including surgeries. However,

the clinical evidence for the proper therapeutic indications of rotator cuff tears in middle-aged and elderly patients is inadequate, and objective evidences are still lacking. Therefore, the main objective of the present study was to compare the effects of conservative versus surgical treatment in patients with rotator cuff tears by comparing the effects of surgical treatment and conservative treatment through a systematic review and meta analysis of the literature on the treatment of rotator cuff tears.

### METHODS:

We searched articles published in Ovid-Medline, Ovid-EMBASE, Cochrane library, CINAHL, Pubmed and four Korean databases until September 2014. We include only RCTs of which mean age was over 50 year old and analyzed with ITT method to avoid bias. Two reviewers extracted data independently. Outcomes were pain and shoulder function at 1 year. Indirect comparative analysis was applied for pain and Bayesian network meta analysis for the functional outcome. This study was approved by the IRB of the NECA(NECAIRB14-021-2) and Hospital of Seoul National University(B-1403/244-117).

### RESULTS:

A total of 8 studies were selected. All surgical treatment groups received the physiotherapy after the surgery. Arthroscopic repair(surgery only and with platelet-rich plasma), acromioplasty, and open repair showed the reduction in pain compared to those receiving only physiotherapy(mean difference: 0.8 to 1.4). Open repair showed significant improvements in shoulder functional scale compared to the mini-open repair and the physiotherapy(mean difference: 11.9 and 11.0).

### CONCLUSIONS:

A surgical treatment showed a comparably reduced pain than conservative treatment, and open surgery tend to be more effective than mini-open surgery and physiotherapy in shoulder functional scale in old age. Due to various factors, a well-designed

RCT is crucial in determining the most appropriate treatment method for RCR patients.

---

## Poster 53A The Role Of Observational Data Gathering In Health Technology Assessment Of New Procedures

### DESCRIPTION:

This abstract presents ongoing work to review the use of observational data gathering recommendations by the Interventional Procedures Programme of the National Institute for Health and Care Excellence UK. It presents an analysis of guidance developed since the programme was set up in 2002, assessing how far recommendations to gather further data were adhered to and how the data was used in subsequent guidance updates.

### PRESENTING AUTHOR:

Dr. Hannah Patrick, NICE, United Kingdom

### AUTHORS:

Paulo Dias, Kevin Harris, Bruce Campbell, Hannah Patrick

### BACKGROUND AND OBJECTIVES:

Unlike new drugs, for which a substantial amount of research and assessment is required before licensing, new procedures are often used in clinical practice without conclusive evidence that they are effective and safe. The UK's Interventional Procedures Programme of the National Institute for Health and Care Excellence (NICE) has encouraged good observational data collection for any guidance it produces on interventional procedures since the program's inception in 2002. Data collection was recommended via either an established register (suitably modified with new data fields if required) or by the creation of a new register, with the expectation this would better inform future guidance. The current study reviews

the effectiveness of this approach.

### METHODS:

All Interventional Procedure Guidance were reviewed sequentially from 2002 until 2015 to identify those that recommended on going data collection and an assessment will be made of whether this recommendation had been followed. Where guidance had subsequently been updated the evidence summary used to draft the updated guidance will be reviewed to ascertain whether evidence gathered had been cited and influenced subsequent decision making.

### RESULTS:

542 pieces of guidance on interventional procedures were produced from 2002-2015 of which 449 remain current (93 having been superseded). In 242 cases there were uncertainties about efficacy or safety or both and the procedure was not given a 'normal arrangements' recommendation for use in the NHS (including a recommendation that the procedure was not used in 6 cases). In 63 of the 242 cases the guidance contained recommendations for further data collection through a specific register or trial. A further 39 recommendations for further data collection were made in procedures given normal arrangements. One specific register featured 35 times in the recommendations. Of the 242 pieces of guidance where there had been uncertainties about efficacy or safety or both, 126 had been updated at some point prior to this review. Of those guidance which had been updated, an explicit recommendation for data collection had been in the initial guidance in 31 cases.

### CONCLUSIONS:

There are significant obstacles to setting up maintaining and making registers effective. A few large national registers are well accepted and used by clinicians but new registers must be supported by considerable efforts to ensure good coverage and high quality data collection(1) . Further work is necessary to assess the contribution that specified

registers have made to guidance updates. It will then be useful to review the characteristics of registers that are particularly successful in evidence development. There is an urgent need to develop methods to maximise the sustainability and effectiveness of registers in order to ensure that they deliver benefit to healthcare systems. In Europe the EUnetHTA Joint Action 3 will do further work on developing quality standards for registers to support more effective data collection (2).

#### REFERENCES:

1. Glynn D, Campbell B, Marlow M, Patrick H. How to improve the quality of evidence when new treatments are funded conditional on collecting evidence of effectiveness and safety. J Health Serv Res Policy 2015 Dec 17.
2. <http://patientregistries.eu/general-objectives>

---

## Poster 54A Development Of Web Application For Assessment Of Cognitive Functions And Detection Of Aphasias In Patients With Stroke And Traumatic Brain Injury

#### DESCRIPTION:

The objective of the project was to develop a system to facilitate the diagnosis of cognitive functions and detection of aphasia in patients post stroke and post traumatic brain injury (TBI). A web application was developed and it can be performed remotely on different operating systems (OS) (e.g., Windows, Linux, Android). A financial analysis was performed to assess the financial viability of the project.

#### PRESENTING AUTHOR:

José Núñez, Research Institute in health science UNA, Argentina

#### AUTHORS:

José Núñez, Pedro Galván, Elisa Laconich, Ronald Rivas

#### BACKGROUND AND OBJECTIVES:

Aphasia is a defect in the language due to a brain injury that disrupts production and / or understanding of words. The most common causes of aphasia in our country are the Stroke and traumatic brain injury (TBI). According to the Pan American Health Organization, in Paraguay ,strokes were the second cause of death in men and the leading cause of death in women. Also, we should note that the leading cause of TBI are the road transit accidents .According to data from the Basic Health Indicators 2013 of the Ministry of Public Health and Social Welfare. The regions with higher death rate for road traffic accident are: Misiones, Pte. Hayes, Boquerón, Alto Paraguay, Concepción and Central. Considering the above data is necessary to facilitate the post stroke patients and post TBI care service in the area of neuropsychology specially for patients who live in countryside. Objective: Develop a system based on Information and Communication Technologies (ICTs) to facilitate the diagnosis of cognitive functions and detection of aphasia in patients post Stroke and post traumatic brain injury (TBI). Therefore, the Telemedicine can facilitate access to these specialized services to patients who live in countryside

#### METHODS:

Wix was one of the Tools used for development the Web Application for tele-diagnostics of the cognitive functions. It is a program for creating web pages and has become a tool of popular web creation. Wix templates are very visual and designs optimized for mobile devices. It notes that the web developer makes exemplary use of HTML 5 technology. For tele-diagnostics we used Skype because it is an application that can be installed on the computer or mobile phone to communicate with patients through video conferencing and also it is free and easy to use

## RESULTS:

A web application based on the evaluation tests of cognitive functions was developed for the diagnosis can be performed remotely on different OS (Windows, Linux, Android). A procedures manual was prepared to use the web application developed with Skype. The design criteria of a pilot study to evaluate the efficiency of diagnosis system were defined. A financial analysis was performed to assess the financial viability of the project.

## CONCLUSIONS:

We must take advantage of the growth of ICT to provide access to specialized health services to people who are living in the countryside. Therefore, we consider relevant perform a pilot study of this tele-diagnostic system developed to allow an timely treatment and to increase the independence of patients who suffered a stroke or brain injury

---

## Poster 55A Tuak Consumption Analysis Of Tuak Drinkers In Lumban Siagian Jae Siatas Barita District Of North Tapanuli, North Sumatra 2015 (Quantitative And Qualitative Approaches)

### DESCRIPTION:

Alcohol consumption has a significant negative impact on health status and has become a common problem throughout the world. The WHO states that as many as 61.7% of the worldwide population have been drinking alcohol for more than 12 months which causes about 3.3 million deaths, or 5.9% of all deaths. Consumption behavior arises naturally due to predisposing factors, reinforcing and enabling, as the Lawrence Green theory states about the components that affect a person's behavior. This abstract will explain society's behavior on tuak consumption, as well as attitude, knowledge, and social factors

affecting tuak consumption. Made from fermented palm wine, tuak is one of the traditional alcoholic beverages in Indonesia, particularly in North Sumatra.

### PRESENTING AUTHOR:

Sukma Panggabean, Islamic State University Syarif Hidayatullah, Indonesia

### AUTHORS:

Sukma Mardiyah Panggabean

### BACKGROUND AND OBJECTIVES:

Alcohol has been known in the community and has become a common problem throughout the world. WHO states that as many as 61.7% of the worldwide population have been drinking alcohol for more than 12 months which causes about 3.3 million deaths, or 5.9% of all deaths. Lumban Siagian Jae, one of vilages in Indonesia, is the region which most of its inhabitants are tuak drinkers, whereas many health complaints are caused by tuak consumption. Recent research was to determine the patterns and the triggering factors and health complaints caused by tuak consumption in Lumban Siagian Jae, Siatas Barita District of North Tapanuli, North Sumatra.

### METHODS:

The research uses a cross-sectional study with quantitative and qualitative approaches. Samples were examined as many as 76 tuak drinkers that were obtained through a simple random sampling method. Data analysis used was univariate analysis and content analysis to describe all of variables.

### RESULTS:

Results of this research show that tuak drinkers most widely are heavy drinkers that consume tuak above 500 mL (89.5%) and had been drinking tuak for more than eight years (82.9%). The factors triggering tuak consumption are knowledge, attitude, tradition and culture, belief, family habit and roles of health worker. Drinkers' knowledge

about tuak is commonly at sufficient levels (64.5%) and the proportion of drinkers whose negative attitude toward tuak consumption was bigger (69.7%) than they whose the positive attitude. Traditions, cultural and belief become the dominant factors because it is known that tuak consumption had been made since the days of the Batak kingdom and until today most (76,2%) of tuak drinkers' families, still have the habit of tuak consuming, drinkers also believe that tuak can relieve their fatigue after working in the morning until noon. Local health authorities did not do a holistic intervention, they are more likely to do individual intervention by providing counseling when the drinkers come for treatment. Some of the health complaints that felt by many tuak drinkers are hypertension (25%), tooth loss (23.7%) and diseases of the digestive tract (19.7%).

#### **CONCLUSIONS:**

The results of recent research can be used as a reference for the government to establish the policy to solve the behavior of tuak consumption. The drinkers also should control their behavior in tuak consuming due to the tuak impacts may affect people's health status.

---

## **Poster 56A By Applying The Double Bottle Drain System To Improve The Expansive Function On The Hemo-pneumothorax**

#### **DESCRIPTION:**

The results of this study suggest that patients could be ambulated three to four hours after sheath removal following percutaneous coronary interventions, and early ambulation does not increase the risk of vascular complications. In addition to considering the dangerous conditions, agreed to remove the sheath compressor time changes for the two to four hours, and encourage

patients early activity, reducing patient discomfort caused due to bed rest. Relevance to clinical practice: the first, upgrade the sensitivity level of nursing care and evaluation system; the second, improve the quality in the field of nursing caring.

#### **PRESENTING AUTHOR:**

Tseng Hsueh-Ying

#### **AUTHORS:**

Tseng, Hsueh-Ying

#### **BACKGROUND AND OBJECTIVES:**

Four patients transfer to Intensive care unit for hemo- pneumothorax in recent 2 weeks. Before transfer to ICU, has chest tube insertion and single bottle system device. The process not improve and clinical symptoms deterioration. The doctor suggestion change to double bottle drain system. But the function is same. With failed function for fluid more than air in the bottle. Found of tube misconnection related. Therefore, I hope that the correct installation to double bottle drain systems, and improve negative pressure function.

#### **METHODS:**

Acquiring systematic review(SR) of cross-sectional studies is preferred to answer the diagnostic question according to the Oxford CEBM LOE table 2011. We formulated a PICO, and search UpToDate BMJ Clinical Evidence and Cochrane database of systematic reviews with article from 2010 to 2015. With the Keywords:( hemo-pneumothorax OR chest tube insertion) and one bottle drain system or double bottle drain system for SR ( RCT) in priority. One latest RCT(2014) was included for critical appraisal.

#### **RESULTS:**

The probability of air leak presence in time was greater for the Group 1 patients with negative suction versus the Group 2 patients ( p = 0.023).

#### **CONCLUSIONS:**

The use of negative drain system (double bottle drain system) with got well expansion of pneumothorax, hemothorax, or hemopneumothorax. It has improved the safety of patients medical environments.

---

## Poster 57A Ethical Standards In Reporting Research From Healthcare-Related Retrospective Databases

### DESCRIPTION:

Despite the progress in the healthcare-related retrospective databases using anonymous and personally unidentifiable data, the ethical rule for such database research is yet to be established. We reviewed ethical considerations required to/for such database research in journals, then found the requirement varied in each publisher. Considering its characteristics, different ethical standards from those of prospective international studies are required.

### PRESENTING AUTHOR:

Dr. Tomomi Takeshima, Milliman Inc, China

### AUTHORS:

Shinzo Hiroi, Akihito Uda, Aya Tokaji, Tomomi Takeshima, Kosuke Iwasaki

### BACKGROUND AND OBJECTIVES:

Ethical practice in healthcare research is now considered a global standard. There are many ethical guidances on the conduct and reporting of interventional clinical trials conducted in humans (eg, Declaration of Helsinki, Japan's Ethical Guidelines for Medical and Health Research Involving Human Subjects, etc). On the other hand, despite the recent progress in the healthcare-related retrospective databases using anonymous and personally unidentifiable data, the ethical rule for such database research is yet to be established.

---

This kind of database research also should be conducted with high ethical standard. Therefore, we conducted a survey of ethical considerations required to the database research for publications in peer reviewed medical journals by a review of their author/submission guidelines.

### METHODS:

We conducted a review of peer reviewed medical journal submission (authorship) guidelines to assess journal requirements regarding ethical considerations (eg, IRB/EC reviews and approvals) for the submission of retrospective database studies using anonymous and personally unidentifiable data.

### RESULTS:

A brief survey of five publishers' websites on publication policies for seven journals in general medicine with the impact factors of 10 or more revealed that four endorsed STROBE statement and one indicated the needs for IRB/EC review and approval for database studies. Two publishers left the decisions to the researchers by asking the details of ethical approval if appropriate. Another two publishers do not clearly indicate the needs for indicating IRB/EC review and approval, but one published an editorial on observational study transparency. One publisher indicated such needs for studies with patients or volunteer, but not for database study.

### CONCLUSIONS:

We found that the requirement of ethical standards for database study using anonymous and personally unidentifiable data varied in each medical journal publisher. Considering the characteristics of the database study, the ethical standards different from those of prospective international studies are called for. Further discussion is necessary to verify the research integrity of database studies.

---

## Poster 58A The Harmonization Of HTA Methods: A Way Forward?

### DESCRIPTION:

The last edition of the Italian Health Policy Forum, an initiative promoted by the Italian Society of Health Technology Assessment, concerned the harmonization of HTA methods, namely the standards to be utilized, the most appropriate decision making level to perform the assessment, and the most suitable methods for different types of technologies. The paper reports the main insights emerging from the discussion.

### PRESENTING AUTHOR:

Dr. Silvia Coretti, Università Cattolica del Sacro Cuore, Italy

### AUTHORS:

Cicchetti A, Fiore A, Coretti S, Iacopino V, Marchetti M, Mennini FS

### BACKGROUND AND OBJECTIVES:

The lack of homogeneous and transparent methods for the development of well-balanced Health Technology Assessments (HTAs) across jurisdictions carries the risk of making different decisions, which are not due to the context specific characteristics, resulting in a non-equitable allocation of healthcare resources. The aim of this study is to report the main issues emerged during the last edition of the Italian Health Policy Forum focusing on the harmonization of HTA methods.

### METHODS:

The Italian Health Policy Forum I-HPF is an initiative of the Italian Society of Health Technology Assessment (SIHTA) aimed at developing a continuative and well-structured debate around the most relevant topics concerning HTA. Delegates from industry, national and local decision makers, and representatives of scientific societies and patients' associations take part in this initiative. The

last edition of IHPF concerned the harmonization of HTA methods, and more in detail: 1) Which standards should be utilized and at what level should the assessment be performed; 2) Which methods should be used for drugs; 3) Which methods should be used for medical devices.

### RESULTS:

The extent to which health technology assessment may be considered generalizable across regional jurisdiction was discussed: economic and organizational evidence often needs to be adapted to the specific decision making context, while the other HTA domains can generally be considered generalizable across Italian regions. The role of the central government should be to define methodological guidelines for cross regional adaptation and to set priorities. The EuNetHTA Core Model has been recognized as a good starting point for the process of methods' harmonization, but some adjustments are needed to make it fit with specific national regulatory requirements and with different types of technologies.

### CONCLUSIONS:

Conclusion: The harmonization of HTA methods is an imminent challenge for Italian decision makers and HTA bodies in order to safeguard the Italian National Health Service (INHS) sustainability and the equity in healthcare access.

---

## Poster 59A Should PrEP Be Part Of The Dutch HIV Strategy: A Stakeholder Analysis.

### DESCRIPTION:

In our study we identified criteria that Dutch stakeholders find important when determining if pre-exposure prophylaxis (PrEP) should be publicly reimbursed. Our study shows that multiple (ethical) criteria play a role in national decision making, besides costs and effectiveness. Making those criteria explicit and addressing inter-stakeholder

disagreement is needed to help build bridges and push forward the decision making process worldwide.

**PRESENTING AUTHOR:**

Maarten Jansen, Radboud University Medical Center, Netherlands

**AUTHORS:**

Maarten Jansen, Noor Tromp, Rob Baltussen

**BACKGROUND AND OBJECTIVES:**

Recent results of the PROUD study of pre-exposure prophylaxis (PrEP), a pill containing antiretroviral drugs, showed an 86% risk reduction in people who took PrEP compared to those not taking PrEP (1). Even though PrEP is now strongly promoted by the WHO as a new prevention measure for HIV infections in countries worldwide, it is also considered highly controversial and PrEP is currently not made available in countries outside the United States. There has been a lot of debate about the desirability of PrEP but an overview of relevant criteria and insight into ethical considerations is lacking, leaving national policy makers in doubt about the desirability of making PrEP available. In order to support this debate and push forward Dutch decision making, we aimed to identify the (ethical) considerations, or criteria, that Dutch stakeholders find important when determining whether PrEP for at risk men having sex with men should be publicly reimbursed in the Netherlands.

**METHODS:**

A stakeholder analysis was used to identify relevant stakeholder groups from which respondents were recruited (n=21). Subsequently, in-depth, unstructured interviews were conducted. Anonymous input from completed interviews was introduced into new interviews that helped the exploration of criteria and (dis)agreement. Interviews were analyzed by creating so called interpretive frames that helped the identification of (ethical) criteria and disagreement.

**RESULTS:**

Multiple criteria were identified: effectiveness, side effects, resistance, effect on condom use and sexually transmitted infections, black market formation, cost-effectiveness, budget impact, adoption, necessity, moral obligation, own responsibility, equal access and accessibility of care. Furthermore, stakeholders sometimes disagreed about the meaning of criteria and their relevance; sometimes rejecting the use of specific criteria (particularly in the case of the own responsibility criterium).

**CONCLUSIONS:**

The results show that multiple criteria play an important role in the decision making process. Making those criteria explicit and addressing inter-stakeholder disagreement about those criteria (by the scientific community) is needed to help build bridges between stakeholders and push forward the decision making process. Focusing on just costs and effectiveness of PrEP, and ignoring 'normative-ethical' criteria, is not going to push forward the decision making process, instead, it may well delay the process.

**REFERENCES:**

(1) McCormack S, Dunn DT, Desai M, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. Published online September 10, 2015 [http://dx.doi.org/10.1016/S0140-6736\(15\)00056-2](http://dx.doi.org/10.1016/S0140-6736(15)00056-2). The Lancet.

## Poster 60A The Current Evidence On Blood Gas Analysis For Patients With Intensive Care

### DESCRIPTION:

Arterial blood gas (ABG) is routine for patients in the intensive care unit, but it is intermittent and painful, etc. The purpose is to find evidence on ABG to improve patient outcome; an electronic literature search and narrative summary was generated. The current evidence showed the possibility to better monitor blood gas and decreases patient iatrogenic blood loss without affecting patient safety.

### PRESENTING AUTHOR:

Maoling Wei, West China Hospital, Sichuan University, China

### AUTHORS:

Maoling Wei

### BACKGROUND AND OBJECTIVES:

The high technology and various clinical tests used in critical care may carry important risks to patients and contribute to the increased costs of health care system. Arterial blood gas (ABG) is the routine clinical diagnostic test for patient's respiratory failure and metabolic disturbances in the intensive care unit (ICU). But the ABG is intermittent, and the frequently blood drawn from the critical ill patients may potentially result in blood loss, increase patients pain, costs and nursing time consuming, etc. What is the current evidence on the appropriate ABG analysis? To find the evidence on blood gas test for patients with intensive care and facilitate to clinical improve for better patient's outcome.

### METHODS:

Key words and titles were searched Cochrane database of systematic reviews, Medline via Ovid, and free access guideline databases. The search terms included blood gas analysis and intensive care, etc. Search date from the first issue till 30

Dec. 2015. Included relevant research for patients required blood gas in ICU. Excluded duplication, comments, news and letters, etc. Data was extracted on blood gas monitor, patient outcome and management, etc. A narrative summary was presented as follows.

### RESULTS:

1. Fifteen full text identified mainly published from 1987 to 2015. Their designs include systematic review, comparative study & before and after study, etc.

2. The available evidence on blood gas monitor was:

a) The benefit factors to clinical and patient: a linking guideline to regular feedback, alternative monitor may help to increase appropriate requests for blood gas analysis. The alternative noninvasive, continuously oxygen saturation monitoring included bedside pulse oximetry, venous oxygen saturation measurement, goal-directed therapy and temperature correction on the ABG, etc.

b) The potential risk to patient management: unrestricted, unmonitored oxygen therapy and poor ability of correctly assess deterioration, etc.

c) No evidence available for time to mechanical ventilation and related costs.

### CONCLUSIONS:

The current evidence showed the possible approaches to better blood gas monitor and decreases patient iatrogenic blood loss without affecting patient safety. Besides the traditional goals in ICU to cure disease and restore health function, it is also necessary to assure patients to comfort, dignify, freedom from pain, humanistic technical skills and clinical tests, etc. Further prospective study should be considered appropriate blood gas monitor with well ethic, guideline for better patient management time and costs, etc.

## Poster 61A Are Drug-coated Balloons Cost-Effective For Femoropopliteal Occlusive Disease? A Comparison Of Bare Metal Stents And Uncoated Balloons With Regard To The Target Lesion Revascularization Rate

### DESCRIPTION:

The objective of this study is to perform a cost-effectiveness analysis to help hospital decision-makers with regard to the use of drug-coated balloons compared to bare metal stents and uncoated balloons for femoropopliteal occlusive disease.

### PRESENTING AUTHOR:

Jean-Francois Fiset, CIUSSS de l'Estrie - CHUS, Canada

### AUTHORS:

Jean-Francois Fiset, Thomas G. Poder

### BACKGROUND AND OBJECTIVES:

In a majority of patients requiring treatment for occlusive disease of the femoropopliteal artery, vessel revascularization by an endovascular technique is the recommended therapy. The main problem associated with this type of intervention is the restenosis of the treated lesion, which often requires a repeat of the intervention. The use of drug-coated balloons for revascularization of the femoropopliteal artery shows encouraging results with regard to this issue. The costs associated with this technology, however, are higher in comparison to commonly used medical devices, such as bare metal stents and uncoated balloons. The objective of this study is to perform a cost-effectiveness analysis to help hospital decision-makers with regard to the use of drug-coated balloons compared to bare metal stents and uncoated

balloons for femoropopliteal occlusive disease.

### METHODS:

Clinical outcomes were extracted from the results of meta-analyses already published, and cost units are those used in the Quebec healthcare network. The literature review was limited to the last three years to obtain the most recent data. The cost-effectiveness analysis was based on a two-year perspective, and risk factors of reintervention were considered. Sensitivity analyses were performed regarding the initial levels of reintervention and the effectiveness of drug-coated balloons versus bare metal stents and uncoated balloons.

### RESULTS:

The results from published meta-analyses indicated that the target lesion revascularization rate (repeated intervention) was lower for drug-coated balloons compared to uncoated balloons. When compared with bare metal stents, the results were comparable to or in favor of the drug-coated balloons. The same tendency was observed for the restenosis rate. For the mortality rate or limb amputation, no significant difference was found. The cost-effectiveness analysis indicated that drug-coated balloons were generally more efficient than bare metal stents, particularly for patients with higher risk of reintervention (TASC II C or D). The high cost of reintervention with bare-metal stents explained this result. Compared with uncoated balloons, results indicated that drug-coated balloons were more efficient if the reintervention rate associated with uncoated balloons is very high and for patients with higher risk of reintervention.

### CONCLUSIONS:

The higher a patient's risk of reintervention, the higher the savings associated with the use of a drug-coated balloon will be. For patients at lower risk, the uncoated balloon strategy is still recommended as a first choice for endovascular intervention.

## Poster 62A Comparative Effectiveness Between Long Acting Injection And Atypical Oral Antipsychotics In Schizophrenia Patients: A Systematic Review And Meta-Analysis

### DESCRIPTION:

Long-acting injectable formulations of antipsychotics are treatment alternatives to oral agents. This article intends to evaluate the safety and effectiveness of 2nd generation long acting injection (LAI). LAI may be an effective treatment for the schizophrenia patients based on existing studies. However, more studies are needed to further investigate patient safety.

### PRESENTING AUTHOR:

Miyoung Choi, National Evidence-based Healthcare Collaborating Agency, Korea

### AUTHORS:

Miyoung Choi, Chan-mi Park, Eunjung Park, Jae Kyung Suh, Ha Jin Tchoe, Jin A Choi, Jeong hoon, Ahn

### BACKGROUND AND OBJECTIVES:

Long-acting injectable formulations of antipsychotics are treatment alternatives to oral agents. This article intends to evaluate the safety and effectiveness of 2nd generation Long Acting Injection (LAI).

### METHODS:

A systematic search of electronic databases, including MEDLINE, EMBASE, PsycINFO, CINAHL and the Cochrane Library, as well as five domestic databases from 2000 to 16 April 2015, was performed. Two reviewers independently screened all references according to selection criteria. The Cochran Risk of Bias (RoB) for

randomized controlled trials and Risk of Bias for Nonrandomized studies (RoBANS) were used to assess quality of literature. Data from randomized controlled trials were combined and meta-analysis was performed.

### RESULTS:

A total 30 studies were included. The LAI group showed significantly lower relapse rate than the oral group. Time to relapse was significantly longer for LAI patients. Hospitalization duration was significantly longer for oral patients. There were no clinically significant group differences in rehospitalization rates or remission rates. PANSS total score, CGI-S score or all-cause discontinuation rate were relatively lower in the patients treated with LAI, but the difference was not statistically significant. More EPS-related and prolactin-related adverse events occurred in the LAI group. In a subgroup analysis, the remission rate was significantly higher in the LAI group approved in Korea and the remission rate was also higher as the follow-up period was longer.

### CONCLUSIONS:

LAI may be an effective treatment for the schizophrenia patients based on existing studies. However, more studies are needed to further investigate patient safety.

---

## Poster 63A Using Of Analysis Of Evidence Data In The Development Of New Combined Drugs And Study Of Their Pharmacological Activity

### DESCRIPTION:

Developing a new drug requires many years of research and a lot of costs. We conduct research on the development of new medicines based on succinic acid, ascorbic acid, and rutin. To optimize the study of pharmacological activity of our

medicines, we conducted an analysis of evidence data about the pharmacological activity of succinic acid and medicines based on it.

### **PRESENTING AUTHOR:**

Dr. Mariya Leleka, Danylo Halytsky Lviv National Medical University, Ukraine

### **AUTHORS:**

Leleka M.V., Zalis?ka O.M., Paparyha V.L.

### **BACKGROUND AND OBJECTIVES:**

Developing of new drug requires many years of research and a lot of costs. We conduct research on the development of new medicines based on succinic acid, ascorbic acid and rutin. [1] Study of pharmacological activity - one of the most important stages of development. Often combined drugs have several types of pharmacological activity and a wide range of applications. [2] For optimize the study of pharmacological activity in the development of new combined drug from a succinic acid, ascorbic acid and rutin, we conducted an analysis of evidence data about the pharmacological activity of succinic acid and famous combination therapies based on it and according to the results conducted our pharmacological research. [3]

### **METHODS:**

MEDLINE®, EMBASE®, Scopus, Cochrane Library databases and clinical trials registers between 1966 and Jun 2015 were performed. To analyze the RCT were selected and Review on the Study of the pharmacological action of drugs, which include succinic acid. Quality of evidence was assessed and each article was rated of quality. Pharmacological methods of studying the hepatoprotective (injury of rats with carbon tetrachloride) and anti-inflammatory action (exudative inflammation, model of carrageenan-induced paw edema of rats)

### **RESULTS:**

We studied 23 RCT and 6 Review. For main

pharmacological properties and by relevance RCT are grouped as follows: antigypoxic action were 7 RCT, improve iron absorption in the gastrointestinal tract - 6 RCT, hepatoprotective - 4 RCT. The study of our medication detected a hepatoprotective effect. Against the background the action of carbon tetrachloride observed a positive effect on cholesterol- and pigment forming liver function. Reducing the activity of enzymes ALT and AST in groups of animals, which treated with our medication, talks about their ability to recover morpho functional integrity of the membranes of hepatocytes and warn of changes in the liver damage with carbon tetrachloride. In the study of anti-inflammatory activity of our medicines (exudative inflammation, model of carrageenan-induced paw edema of rats) is set to ability of suppression of the inflammatory response by 19.6%

### **CONCLUSIONS:**

According to results of evidence data we confirmed hepatoprotective effect of investigational combination product based succinic acid, studied anti-inflammatory effect and conduct research on the impact of our drug on the immune system.

### **REFERENCES:**

1. Leleka M, Wronska L, Svistun N. Justification of the choice of excipients to obtain pills through amber acid, ascorbic acid and rutin. *Pharmaceutical Journal*. 2008;4:46-50. (In Ukrainian).
2. Leleka M, Zaliska O. Analysis of segment of nootropik drugs and foundation of appropriate development of new drugs based on piracetam and succinic acid. *Pharmaceutical revivev*, 2012; 1:87-91. (In Ukrainian).
3. Leleka M., Zaliska O., Paparyha V., Kozyr G., Danyluk B. Analysis of evidence data about adding succinic acid to the various medicines. *Value in Health*. 2015. 18: 685 (In Italy)

## Poster 64A From HTA To Service Provision: Example; Continuous Intrathecal Baclofen (ITB) Infusion For Severe Spasticity And Dystonia

### DESCRIPTION:

The HTA report on continuous intrathecal baclofen (ITB) infusion was used as a supporting document by rehabilitation physicians for submission of request for funding to start the service via Dasar Baru (New Policy), training of a multidisciplinary team in Froedtert and Medical College of Wisconsin, and application to bring the drug in via special permission from the Director General of Health while waiting for the registration of the drug to complete. HTA is an important tool for introducing new service in Ministry of Health, Malaysia.

### PRESENTING AUTHOR:

Dr. Junainah Sabirin, MaHTAS, Medical Development Division, Ministry of Health, Malaysia

### AUTHORS:

Junainah Sabirin, Sin Lian Thye, Nur Farhana Mohamad, Rugayah Bakri, Ooi Ai Lee, Ng Kee Hong, Yusniza Mohd Yusof

### BACKGROUND AND OBJECTIVES:

Intrathecal delivery of baclofen has been used to control spasticity in cases in which oral medications have failed to bring about the expected results. Continuous intrathecal baclofen (ITB) infusion has not been practised in any hospitals in Malaysia. Hence, Health Technology Assessment (HTA) was requested by Rehabilitation Physicians, Hospital Raja Permaisuri Bainun, Ipoh, Perak to assess the feasibility of using continuous ITB infusion for treatment of patients with severe spasticity or severe dystonia or having both conditions who were uncontrolled by conventional treatment in government hospitals in Malaysia. The aim of this

article is to highlight how HTA is use in introducing new service in Ministry of Health (MOH), Malaysia.

### METHODS:

Studies were identified by searching electronic databases through the Ovid interface, and PubMed. The last search was run on 27 June 2014. Relevant literature was appraised using the Critical Appraisal Skills Programme (CASP) and graded based on guidelines from the U.S./Canadian Preventive Services Task Force. The HTA report was prepared with involvement of multidisciplinary team and was approved by the HTA and Clinical Practice Guidelines (CPG) Council chaired by the Director General of Health (DG), Malaysia in December 2014. The utilization of the report by the requestors and the related disciplines was monitored through official meetings and emails.

### RESULTS:

A total of 63 articles for spasticity, six articles for dystonia and seven articles for dystonia and spasticity were included in the review. There was fair level of retrievable evidence to suggest that continuous ITB infusion was safe and effective in reducing spasticity, dystonia, reducing pain, improved function and quality of life in patients with severe spasticity who were unresponsive or cannot tolerate oral baclofen. The HTA report concluded that continuous ITB infusion may be utilised in patients with severe spasticity or severe dystonia or having both conditions who are unresponsive or cannot tolerate oral baclofen, by trained multidisciplinary healthcare teams. Criteria for patient selection should be developed. Hospital Raja Permaisuri Bainun, Ipoh, Perak has been identified as the centre of excellence for ITB infusion. The HTA report was used as a supporting document by rehabilitation physicians for submission of request for funding to start the service via Dasar Baru (New Policy), training of a multidisciplinary team in Froedtert and Medical College of Wisconsin, application to bring the drug in via special permission from the DG while waiting for the registration of the drug to complete. After a multidisciplinary team has been trained, several

meetings were organized to finalise the treatment strategy and starting of the programme. However, funding for the ITB pump is the most costly and challenging.

### **CONCLUSIONS:**

HTA is an important tool for introducing new service in MOH, Malaysia.

---

## **Poster 65A** The Use Of Exploratory Analyses By Evidence Review Groups In The NICE Single Technology Appraisal Process

### **DESCRIPTION:**

Evidence Review Groups undertake exploratory analyses in their critique of company submissions as part of the NICE Single Technology Appraisal Process. This research explores the possible influences of disease area, a cost-effectiveness threshold of £20,000 per QALY gained, and changes over time as the factors most likely to predict the presence and number of exploratory analyses.

### **PRESENTING AUTHOR:**

Prof. Eva Kaltenthaler, University of Sheffield, United Kingdom

### **AUTHORS:**

Eva Kaltenthaler, Christopher Carroll, Paul Tappenden, Daniel Hill-McManus, Alison Scope, Michael Holmes, Stephen Rice, Micah Rose, Nerys Woolacott

### **BACKGROUND AND OBJECTIVES:**

In the UK, the National Institute for Health and Care Excellence (NICE) commissions independent Evidence Review Groups (ERGs) to critically appraise company submissions as part of their

Single Technology Appraisal (STA) process. As part of their critique of the evidence submitted by companies, the ERGs undertake exploratory analyses to explore uncertainties. The aim of this research was to identify factors that might influence or predict the extent of ERG exploratory analyses. This study aimed to test the possible influence of disease area, a cost-effectiveness threshold of £20,000 per QALY gained, and changes over time as the factors most likely to predict the presence and number of exploratory analyses

### **METHODS:**

We undertook content analysis of over 400 documents, including ERG reports and related documentation for the 100 most recent STAs (2009-2014). Relevant data were extracted from the documents and narrative synthesis was used to summarise the data. All data were extracted and checked by two researchers.

### **RESULTS:**

Forty different companies submitted documents as part of the NICE STA process. The companies with the largest number of submissions were Roche (15), Novartis (9), Glaxo Smith Kline and Bristol Meyers Squibb (7) and Bayer (6). The principal disease areas covered by the STAs were cancer (44%), blood and the immune system conditions (11%), cardiovascular conditions (10%) and musculoskeletal conditions (8%). The vast majority of ERG reports conducted nine or fewer analyses. The incidence and frequency of ERG exploratory analyses does not appear to be related to any developments in the process between 2009 and 2014, the disease area covered by the STA, or the company's base-case ICER. However, there does appear to be a pattern in the mean number of analyses conducted by particular ERGs, but the reasons for this are unclear and potentially complex. More research is needed to understand the decision-making processes within ERGs.

### **CONCLUSIONS:**

The exploratory analyses undertaken by the ERGs

serve various functions: to plug some of the gaps in the evidence provided in company submissions; to address uncertainties; and to support NICE Appraisal Committee decision-making. More in-depth analysis is needed to understand how ERGs make decisions regarding the exploratory analyses to be undertaken. More research is also needed to fully understand which type of exploratory analyses are most useful to Appraisal Committees in their decision making.

---

## Poster 66A The Beneficial Effects Of Renin-angiotensin System Inhibitors In Chronic Liver Disease: A Systematic Review

### DESCRIPTION:

The renin-angiotensin system (RAS) has an important role in hepatic fibrosis and portal hypertension. RAS inhibitors are already accepted in the clinical field for antihypertensive management, but their effects on hepatic fibrosis are controversial. The aim of this study was to systematically review the effects of RAS inhibitors to hepatic fibrosis based on histological assessment.

### PRESENTING AUTHOR:

Gaeun Kim, Keimyung University, Korea

### AUTHORS:

Gaeun, Kim

### BACKGROUND AND OBJECTIVES:

The renin-angiotensin system (RAS) has an important role in hepatic fibrosis and portal hypertension. RAS inhibitors are already accepted in the clinical field for antihypertensive management, but their effects on hepatic fibrosis are controversial. The aim of this study was to systematically review the effects of RAS inhibitors to

hepatic fibrosis based on histological assessment.

### METHODS:

We performed a systematic review (SR) and meta-analysis (MA) of the literature using the Ovid-MEDLINE, EMBASE and Cochrane Library databases (up to January 2015) to identify clinical studies evaluating the effects of angiotensin converting enzyme inhibitors or angiotensin receptor blockers on hepatic fibrosis or cirrhosis patients based on histological assessment.

### RESULTS:

Of the 455 studies were identified, we analyzed seven studies including 1,066 patients that met our selection criteria. In the MA, patients treated with RAS inhibitors had significantly lower fibrosis scores (SMD -0.69, 95% CI -0.96, -0.42, I<sup>2</sup>=0%, p<0.00001) and less fibrosis areas (SMD -0.80, 95% CI -1.18, -0.41, I<sup>2</sup>=0%, p<0.0001) than controls. Serum fibrosis markers such as TGF- $\beta$ 1, collagen I, IV, TIMP-1 and MMP2 were significantly reduced in the intervention group. In two studies, mean arterial pressures were significantly decreased in RAS inhibitor users, but there were no reports about symptoms related to decreased blood pressure. No significant difference was found in serum creatinine levels between the intervention and control groups and significant renal dysfunction was not observed after administration of RAS inhibitors.

### CONCLUSIONS:

In conclusion, the RAS inhibitor is potential therapeutic agent for hepatic fibrosis and it can be used safely.

---

## Poster 67A Quality Evaluation Of Exclusive Medical Devices

### DESCRIPTION:

Transparency and anticorruption rules.

Relating negotiated procedures without tender

---

notice publication on exclusive products, it is requested to add a report drafted by healthcare experts (physicians, engineers) supporting motivations of exclusivity. Motivations must hold in absolute and binding need and not in opportunity and/or interest reasons.

The 'exclusivity' of manufacturer/provider must be verified in order to exclude the presence on market of manufacturers that are able to satisfy particular technical requirements'.

**PRESENTING AUTHOR:**

Ilaria Vallone, Fondazione IRCCS Policlinico San Matteo, Italy

**AUTHORS:**

Paolo Lago, Ilaria Vallone, Paolo Cassoli Paolo Cassoli, Michele Tringali

**BACKGROUND AND OBJECTIVES:**

The Hospital Based Health Technology Assessment (HB-HTA) method is applied to purchasing process of exclusive and 'irreplaceable' medical devices, to support the decision of hospital managers. Objectives: According to national rules for transparency and anticorruption, a group of regional hospitals and a welfare service adopted a common standard method for the assessment of medical devices sharing expertise and processes to evaluate exclusivity in procedure without tender for specific products. Clinical engineers collect informations and collaborates with other experts (such as physicians, economists and pharmacists) in order to write short reports about each technology for hospital decision makers.

**METHODS:**

The evaluation method, according to HB-HTA approach, is focused on the most important aspects of the clinical use of the technology such as security, reliability and organization impact. The standard procedure starts with the compilation of a form in which physicians describe the clinical needs related to a specific innovative medical device, then

a scientific literature research and a market survey are carried on. From the data collected in the Italian Medical Devices Database of the Ministry of Health, based on a specific classification and coding, technical and clinical alternatives are evaluated and compared.

**RESULTS:**

Only a little number of medical device are really irreplaceable and a MDs a real competition in a public tender with potential savings in purchasing and less bribery attempts is possible for the large part of them.

**CONCLUSIONS:**

The final aim of this project is to deliver a structured report for healthcare management and be able to identify alternative MDs on the market to limit exclusive supplies. Quality informations make decisions more robust, consistent, transparent and verifiable in order to maximize the health gains for the patients and to minimize costs and resources, through a better purchasing method.

**REFERENCES:**

International Journal of Technology Assessment in Health Care / Volume 25 / Supplement S1 / July 2009, pp 127-133 Carlo Favarettia1, Americo Cicchettia2, Giovanni Guarreraa3, Marco Marchettia4 and Walter Ricciardia5 a1 Azienda Ospedaliero-Universitaria di Udine a2 Catholic University of Sacred Heart and A. Gemelli University Hospital a3 Azienda Ospedaliero-Universitaria S.M. Misericordia a4 A. Gemelli University Hospital a5 Catholic University of the Sacred Heart

## Poster 69A The Heart Failure Caregiver Questionnaire In Caregivers Of Chronic Heart Failure Patients: Potential Of A Validation Study On The Japanese Population

### DESCRIPTION:

The objective of this study is to assess the potential to validate the Japanese Heart Failure Caregiver Questionnaire (HF-CQ) and to explore patterns of caregiver response to change in the patient's condition in the Japanese population, using evidence from the chronic heart failure (CHF) observational study.

### PRESENTING AUTHOR:

Celine Deschaseaux, Novartis Pharma AG, Switzerland

### AUTHORS:

Celine Deschaseaux, Anna Strömberg, Misook L. Chung, Tiny Jaarsma, Marie Louise Luttik, Eldrin Lewis, Raquel Lahoz, Frederico Calado

### BACKGROUND AND OBJECTIVES:

Symptoms associated with Chronic Heart Failure (CHF) are often reflected in patients becoming progressively dependent on support from family caregivers. The disease-specific Heart Failure Caregiver Questionnaire (HF-CQ) has been recently developed to assess subjective outcomes in Heart Failure (HF) caregivers demonstrating value beyond patients' health status, as increasingly requested by regulatory authorities and health-technology assessment bodies. The original American-English version of the HF-CQ includes 21 questions across three domains: physical, emotional/psychological and lifestyle. The validity and reliability of the HF-CQ has been examined in caregivers of CHF patients in America. In Japan, prevalence of CHF is relatively low, affecting about 1.2% of the population (Summary of Vital Statistics 2005) but

this figure is rapidly increasing (The Status of Aging 2007). The HF-CQ has been translated into several languages including Japanese. The aim of this study is to assess the potential of the CHF Disease Specific Program (DSP), an observational study collecting data from Japanese CHF patients and their caregivers, to demonstrate the psychometric properties of the Japanese HF-CQ and reflect the impact of CHF on psychosocial outcomes in Japanese CHF caregivers in real life.

### METHODS:

The CHF DSP observational study will collect data from patients with a physician confirmed diagnosis of CHF and their primary caregivers across different countries, including Japan. Data will be collected using a Patient Record Form (PRF) recorded by a Medical Cardiologist and self-completed forms (PSC), including measures of patients' and caregivers' psychosocial distress. The Japanese sample of patients and caregivers (n=500) will allow more robust conclusions to be drawn about the psychometric properties of the instrument and to explore patterns of caregiver response to change in the patient's condition in the Japanese population.

### RESULTS:

Following availability of the Japanese HF-CQ translated version, the DSP will be used to conduct construct and concurrent validity, reliability and responsiveness analyses of the HF-CQ and to help assess the relationship between the severity of symptoms, functioning impairment and impact on health-related quality of life experienced by CHF patients and the impact on their caregivers, in the Japanese population.

### CONCLUSIONS:

The DSP observational study has the potential to fulfil the need for a validation study of the Japanese HF-CQ and to assess country-specific impact of CHF on Japanese caregivers, thereby raising awareness of this topic.

## REFERENCES:

1. Summary of Vital Statistics. Summary of Vital Statistics. Ministry of Health, Labour and Welfare [online] 2005. Accessed on July 6, 2007. URL: <http://www.mhlw.go.jp/english/database/db-hw/populate/index.html>.
2. The Status of Aging and Implementation of Measures for Aging Society in FY 2005. Annual Report on the Aging Society 2007, Cabinet Office [online] Accessed on June 10, 2007. URL: <http://www.cao.go.jp/index-e.html>.

---

## Poster 70A Live Long Or Suffer? Willingness To Pay Among College Students

### DESCRIPTION:

Malhotra et al. (2015) is the only article that compares the trade-off between living longer and alleviating pain, to our knowledge. Also, willingness to pay studies usually focus on the elderly or sick population. This study attempts to compare the end of life values, specifically pain and life prolonging measures, of the older group to relatively healthy college students.

### PRESENTING AUTHOR:

Elisabeth Seamon, University of Hawaii at Manoa, United States

### AUTHORS:

Victoria Y. Fan, Elisabeth Seamon

### BACKGROUND AND OBJECTIVES:

Past research on the willingness to pay (WTP) typically focuses on reducing the risk of certain outcomes such as death or pain, but rarely jointly. To our knowledge, there is only one study which explicitly considered the trade-off between pain and death. Malhotra et al. (2015) calculated in Singapore the value for patients and caregivers of

increasing survival versus reducing pain, and found that patients were willing to pay more to alleviate pain than to live longer. These findings have not been explored in other settings or in a different population (e.g. young adults). In this study, we explore differences in WTP to increase survival or reduce pain by age in a population, which has generally no experience of hospitalization or significant bodily pain.

### METHODS:

100 students are recruited to participate in this study on WTP to live longer or avoid pain at younger ages. The participants use an online interface to complete the survey by choosing one of two displayed hypothetical scenarios for each of the ten questions. Additional covariates include age, gender, education, race/ethnicity, and socioeconomic and family backgrounds. Once data are collected, a panel logit regression model will be used to analyze the value of each attribute. WTP will be calculated by taking the difference between the two scenarios and dividing it by quality levels of the cost.

### RESULTS:

Data collection is nearly completed and data analysis is underway. We hypothesize that this population will be willing to pay much more to live longer and much less to avoid pain. Moreover, the near-equivalence of survival vs pain-alleviation in WTP reported by patients and by caregivers in Singapore may not be observed in this population. The results may be generalizable to college students in the United States and potentially other high-income nations.

### CONCLUSIONS:

The results of this study will expand frontier knowledge on monetary value of life to generally healthy young adults. This can show whether extending a life is more or less important than remaining pain-free at that age. We would also be able to compare these results to that of the older population to determine any differences in priorities

or values. Such conclusions can be applied to policy and resource allocation, e.g. by deciding to allocate resources to maximizing life-saving medical options vs palliative methods. Limitations of this study include small sample size with the majority being students studying public health.

#### REFERENCES:

Malhotra, C., Farooqui, M. A., Kanesvaran, R., Bilger, M., & Finkelstein, E. (2015). Comparison of preferences for end-of-life care among patients with advanced cancer and their caregivers: A discrete choice experiment. *Palliative Medicine*, 0269216315578803.

---

## Poster 71A Coming To A Common Approach In The Health Economic Modelling Of Opioid Addiction: An Open Source Reference Model Approach

#### DESCRIPTION:

Variation in perspective, approach and opaqueness of content means HTA decision makers do not receive a comprehensive, consistent and transparent picture of the economics of opioid addiction. The aim of this research was to develop an open source health economic model to help come to a common approach and achieve greater transparency in decision making.

#### PRESENTING AUTHOR:

James Kenworthy, Mundipharma International, United Kingdom

#### AUTHORS:

James Kenworthy, Will Dunlop, Jim Brown

#### BACKGROUND AND OBJECTIVES:

In order to understand the health economic

modelling work conducted to date in opioid dependence, a systematic review was conducted. It identified 18 unique models, using various modelling approaches, Markov models (n=4), decision tree with Monte Carlo simulations (n=4), decision analysis (n=3), dynamic transmission models (n=3), decision tree (n=1), cohort simulation (n=1), Bayesian (n=1), and Monte Carlo simulations for sensitivity analysis (n=1). Time horizons ranged from 6 months to lifetime. The most common evaluation was cost per quality-adjusted life-year (n=11), followed by cost-effectiveness analysis (n=4), budget impact analysis/cost comparison (n=2) and cost-benefit analysis (n=1). Countries modelled were the US (n=11), UK (n=4), Spain, Vietnam and New Zealand (one each). Finally the inclusion of societal costs was applied inconsistently across the models identified. The health economic models reviewed did not provide access to the code and calculations in the publications. This variation in perspective, approach and opaqueness of content means HTA decision makers do not receive a comprehensive, consistent and transparent picture of the economics of opioid addiction. The aim of this research was to develop an open source health economic model to help come to a common approach and achieve greater transparency in decision making.

#### METHODS:

One model was selected to be replicated from the literature. This model was developed for an HTA agency and was sufficiently detailed to allow replication. It compared the cost-effectiveness of Buprenorphine to Methadone, and acted as the starting point of the new model. The model would be co-developed in Excel and 'R' to facilitate open access. The original model was replicated and modified from decision-tree to Markov format. The model included updated healthcare and criminality costs. It also included the addition of productivity loss, HIV/HCV infection and mortality.

#### RESULTS:

When added to the base case model, HIV had the greatest individual impact on the healthcare ICER

reducing it from £14,812 to £6,000. In contrast the addition of HCV had less impact on the ICER (£14,812 to £12,788). When all parameters were added to the model (HIV, HCV, Mortality and Productivity) simultaneously, it reduced the ICER from a healthcare perspective by 70% (£14,812 to £4,509). From a societal perspective, when the analysis was restricted to each of these parameters no single one had a substantial impact on the ICER, although when they were all combined it was increased by 30%.

### CONCLUSIONS:

It has been found that the inclusion of additional variables in an existing model is not only possible but that they also have a substantial impact on the model outputs. This could have an impact on HTA decisions. Once this project is finished the code for the model will be made publically available. It is hoped this will lead to a greater consensus on future modelling.

### REFERENCES:

Barnett PG. The cost-effectiveness of methadone maintenance as a health care intervention. *Addiction*. 1999;94:479-88.

Barnett PG, Zaric GS, Brandeau ML. The cost-effectiveness of buprenorphine maintenance therapy for opiate addiction in the United States. *Addiction*. 2001;96:1267-78.

Masson CL, Barnett PG, Sees KL, Delucchi KL, Rosen A, Wong W et al. Cost and cost-effectiveness of standard methadone maintenance treatment compared to enriched 180-day methadone detoxification. *Addiction*. 2004;99:718-26.

Negrin MA, Vazquez-Polo FJ. Bayesian cost-effectiveness analysis with two measures of effectiveness: the cost-effectiveness acceptability plane. *Health Econ*. 2006;15:363-72.

Schackman BR, Leff JA, Polsky D, Moore BA, Fiellin DA. Cost-effectiveness of long-term outpatient buprenorphine-naloxone treatment for opioid dependence in primary care. *J Gen Intern Med*.

2012;27:669-76.

Sheerin IG, Green FT, Sellman JD. What is the cost-effectiveness of hepatitis C treatment for injecting drug users on methadone maintenance in New Zealand? *Drug Alcohol Rev*. 2004;23:261-72.

Stephen JH, Halpern CH, Barrios CJ, Balmuri U, Pisapia JM, Wolf JA et al. Deep brain stimulation compared with methadone maintenance for the treatment of heroin dependence: a threshold and cost-effectiveness analysis. *Addiction*. 2012;107:624-34.

Tran BX, Ohinmaa A, Duong AT, Nguyen LT, Vu PX, Mills S et al. The cost-effectiveness and budget impact of Vietnam's methadone maintenance treatment programme in HIV prevention and treatment among injection drug users. *Glob Public Health*. 2012;7:1080-94.

Zaric GS, Barnett PG, Brandeau ML. HIV transmission and the cost-effectiveness of methadone maintenance. *Am J Public Health*. 2000;90:1100

Zaric GS, Brandeau ML, Barnett PG. Methadone maintenance and HIV prevention: A cost-effectiveness analysis. *Manage Sci*. 2000;46:1013-31.

Zarkin GA, Dunlap LJ, Hicks KA, Mamo D. Benefits and costs of methadone treatment: results from a lifetime simulation model. *Health Econ*. 2005;14:1133-50.

Miller CL, Schechter MT, Wood E, Spittal PM, Li K, Laliberte N et al. The potential health and economic impact of implementing a medically prescribed heroin program among Canadian injection drug users. *Int J Drug Policy*. 2004;15:259-63.

Adi Y, Juarez-Garcia A, Wang D, Jowett S, Frew E, Day E et al. Oral naltrexone as a treatment for relapse prevention in formerly opioid-dependent drug users: a systematic review and economic evaluation. *Health Technol Assess*. 2007;11:iii-iv, 1-85.

Connock M, Juarez-Garcia A, Jowett S, Frew E, Liu Z, Taylor RJ et al. Methadone and buprenorphine for the management of opioid dependence: a systematic review and economic evaluation. *Health Technol Assess.* 2007;11:1-171, iii-iv.

Schering-Plough. Manufacturer's submission. Cited in Connock et al. *Health Technol Assess.* 2007;11:1-171, iii-iv.

Scottish Medicines Consortium. Buprenorphine/naloxone 2mg/0.5mg, 8/2mg sublingual tablet (Suboxone). No. 355/07. 2007. [https://www.scottishmedicines.org.uk/files/buprenorphine\\_naloxone\\_sublingual\\_tablet\\_\\_Suboxone\\_\\_355-07\\_.pdf](https://www.scottishmedicines.org.uk/files/buprenorphine_naloxone_sublingual_tablet__Suboxone__355-07_.pdf). Accessed 3 Jun 2015.

Clay E, Kharitonova E, Ruby J, Aballea S, Zah V. Medicaid population budget impact analysis of buprenorphine/naloxone film and tablet formulation. *Value Health.* 2014;17:A212.

Clay E, Khemiri A, Ruby J, Aballea S, Zah V. A studies-based private insurance budget impact analysis of buprenorphine/naloxone film and tablet formulations. *Value Health.* 2014;17:A213.

Fowler J, Emerson J, Allen A, Dilley S, Gideonse N, Rieckmann T et al. Buprenorphine vs methadone for maintenance of opioid addiction during pregnancy: A cost-effectiveness analysis. *Am J Obstet Gynecol.* 2013;208 (1 SUPPL.1):S65-6.

.....

## Poster 72A Using A Method Of Indirect Comparison In Network Meta-Analysis To Compare Efficacy In Randomized Clinical Trials That Include Patient Groups With Different Attributes

### DESCRIPTION:

Indirect comparison is considered a useful way; however, it may be problematic because of differences in attributes among the patient groups in each randomized clinical trial. In this study, we developed a method in which the attributes could be adjusted to conduct indirect comparison scientifically using network meta-analysis and applied it to evaluate angiotensin II receptor antagonists.

### PRESENTING AUTHOR:

Yusuke Nakamura, Milliman, Inc, China

### AUTHORS:

Kosuke Iwasaki, Yujiro Otsuka, Tomomi Takeshima, Yusuke Nakamura, Yukio Shimasaki, Akihito Uda, Kaoru Yamabe, Hiroyo Kuwabara, Shinzo Hiroi

### BACKGROUND AND OBJECTIVES:

Network meta-analysis (NMA) is considered one of the useful ways to compare the efficacy of various treatments indirectly when data is not available from direct comparison. However, indirect comparison may be problematic because of differences in demographics among the patient groups in each randomized clinical trial (RCT). In this study, we developed a method in which the attributes of patients in RCTs could be adjusted so as to conduct indirect comparison scientifically using NMA.

### METHODS:

We developed a regression model where the efficacy-ratio among treatments is described

as a function of patient attributes. In the model, attributes are treated as unobservable state variables to be estimated. Using data from direct comparison RCTs, we estimated the efficacy-ratio function coefficients of attribute and also estimated the attributes. As a case study, we conducted a comparison among several angiotensin II receptor antagonists used for treatment of hypertension.

**RESULTS:**

Efficacy-ratios among treatments where direct comparison data were available were obtained as probability distributions with each attribute. Subsequently, the attributes of the patient groups were adjusted, and indirect comparison could be performed using NMA, as the patient groups from different RCTs had a common attribute. We were able to apply this method successfully to the evaluation of angiotensin II receptor antagonists .

**CONCLUSIONS:**

By introducing an efficacy-ratio function for patient attributes and using direct comparison networks for efficacy data, we applied regression analysis to estimate attributes for each RCT and their relationship to the efficacy-ratio among treatments. Our model enabled scientifically indirect comparison of efficacy among multiple treatments by NMA even though the attributes for each RCT were different. Our method could improve the validity of drug efficacy evaluation by indirect comparison, providing improved information for Health Technology Assessment.

.....

## Poster 73A Acceptability Of The Comparator Used In Global Development In The Local HTA Submission Across 7 Diverse Jurisdictions

**DESCRIPTION:**

While companies may have only one global development plan with consolidated data package, there are multiple HTA agencies assessing the evidentiary package, the question is how well the global comparator meets the divergent requirements at jurisdictions. This research was conducted to investigate the inclusion of comparators in the global development for new medicine, and the impact on the HTA submissions.

**PRESENTING AUTHOR:**

Tina Wang, Centre for Innovation in Regulatory Science, United Kingdom

**AUTHORS:**

Tina Wang

**BACKGROUND AND OBJECTIVES:**

Requirements for clinical evidence on the safety and efficacy of a new medicine versus a placebo are being supplanted by a growing interest from regulatory agencies in requesting or undertaking a relative efficacy evaluation, whilst HTA agencies request or undertake a relative effectiveness assessment of new medicines to ascertain the added therapeutic value of a new product compared with existing treatments or standard of care. Therefore, it is important for companies to choose the right active comparators in the development phase to ensure the scientific validity of trial designs and to be able to provide the evidence for the value proposition of a new product. However, while a company may have only one global development plan with one consolidated data package, there are multiple HTA agencies considering the submission package,

each with diverging evidentiary needs and local standards of care. The question is how well the comparator choice of companies during the global development meets these divergent evidentiary requirements by local jurisdictions. Objective: To investigate the inclusion of active comparators in the global development for new medicine, and the impact on the local HTA submissions.

#### **METHODS:**

54 compounds collected directly from 8 major pharmaceutical companies were studied to determine if active comparators were included into their global development. Analysis were conducted looking at the roll out status of those products, the first regulatory approval of these products varied between Oct 2007 and Jul 2015, a comparative analysis was conducted to assess the extent of acceptance (fully, partially, not accepted) on the global comparator by HTA agencies across 7 jurisdictions (Australia, Canada, England, France, Germany, Spain and Italy), and whether additional comparators were required by the HTA agencies for assessment.

#### **RESULTS:**

Fifty four percent of the 54 compounds studied included an active comparator during global development. The full acceptance of the comparator used in global trials varied at the jurisdictional level from 31% (Australia) to 71% (Italy and Canada); Spain showed the highest acceptance rate on submission without further requests of comparators (77% of submissions). All jurisdiction required for some compounds additional comparators in addition to the global comparator with Australia and England requesting the highest proportion of compounds (50% and 33% respectively), Germany rejected the highest proportion of submissions (17%) based on the global comparator choice and requested a local relevant comparator.

#### **CONCLUSIONS:**

Good acceptance of the comparator used in the

global clinical trials at the jurisdictional level was identified. However additional comparators were often requested for HTA review in addition to or instead of the global comparator. The key reason for additional comparators to be requested was the jurisdictions need for a local relevant comparator, which does emphasis that divergence in standard of care across jurisdictions needs to be factored in for local submissions. Early dialogue with HTA agencies prior to HTA submission will lead to identification of the most appropriate comparators, and result in better submissions that meet the local needs.

---

## **Poster 74A Health Technology Performance Assessment: Real-World Evidence Guiding Disinvestment**

#### **DESCRIPTION:**

SUS Collaborating Centre for Technology Assessment and Excellence in Health (CCATES) developed a Guideline for Disinvestment in cooperation with the Ministry of Health of Brazil and the Pan-American Health Organization. An international workshop was held to discuss the preliminary version and to propose improvements. The discussion of two case studies showed the importance of continuous assessment of financed technologies.

#### **PRESENTING AUTHOR:**

Augusto Afonso Guerra Junior, SUS Collaborating Centre for Technology Assessment and Excellence in Health, Brazil

#### **AUTHORS:**

Livia Lemos, Brian Godman, Clarice Petramale, Björn Wettermark, Wallace Barbosa, Murilo Contó, Gaizka Benguria-Arrate, Carlos Vassallo, Marion Bennie, Francisco Acurcio, Augusto Guerra

## **BACKGROUND AND OBJECTIVES:**

After technology assessment and incorporation, little is done in most countries to assess the continued impact and performance of a health technology in light of more recent developments. In Nov/2015 the SUS Collaborating Centre for Technology Assessment and Excellence in Health (CCATES) held an international workshop to discuss disinvestment and propose improvements for the Guideline for Disinvestment CCATES developed in cooperation with the Department of Management and Incorporation of Technologies of the Ministry of Health of Brazil and the Pan-American Health Organization. Participants discussed two case studies building on the draft Guideline and real-world studies conducted by CCATES.

## **METHODS:**

Guests were divided in groups to discuss whether or not to use the term 'disinvestment', and two disinvestment proposals: 1) There is no evidence that insulin glargine is more effective than the standard treatment, and in Brazil it costs 20 times more; 2) There is some evidence that beta-interferon-1A-30?g is less effective than the other beta-interferons also provided for multiple sclerosis. After group discussions, one representative of each group presented the results to all guests and all participants were invited to comment the issues raised and others relevant to the subject.

## **RESULTS:**

All agreed that 'disinvestment' should be avoided whenever possible - it is misunderstood by politicians and society. For all, glargine should be a candidate for disinvestment. The Guideline for Glargine Use was considered sufficiently restrictive; therefore strategies to successfully implement it should be a priority together with price renegotiation. Academic Detailing was suggested for enhancing Guideline compliance (as recommended in the Guideline for Disinvestment). For beta-interferon-1A-30?g, all agreed that more information is needed. One issue raised was the

possibility of financing oral medicines ultimately leading to decreased use of beta-interferon-1A-30?g; showing the relevance of horizon scanning for disinvestment decisions.

## **CONCLUSIONS:**

It is imperative to evaluate the impact of financed technologies. 'Performance evaluation' means assessing the results of a technology using real-world-evidence and thus reassessing its value and providing managers with information to continue or not financing it (a different approach to 'disinvestment'). The discussion also raised other important issues to be urgently debated worldwide, such as the necessity (or not) of economic threshold for financing new technologies and the public dissemination of this value (should the seller know how much the buyer is willing to pay?); and the policy conflict of interest when the health sector finances R&D among private companies.

---

## **Poster 75A Impact Of Integral Team For High-Risk-High-Complexity-High-Cost Material Management**

### **DESCRIPTION:**

Minimally invasive methods have provided benefits to patients and challenged specific health teams' skills development. Also, this development required strategies to preserve the specific high-risk-high-complexity-high-cost materials (HR2HCM). Follow-up indicators pointed to HR2HCM increased use without incidents. Examples of the program's economic gains are presented. Lessons and strategies from a São Paulo State Transplantation Reference Hospital may contribute for other services.

### **PRESENTING AUTHOR:**

Dr. Evelinda Trindade, São Paulo State Health Secretariat, Brazil

## **AUTHORS:**

Deyvid-Fernando Mattei-da-Silva, Evelinda Trindade

## **BACKGROUND AND OBJECTIVES:**

Traditional open surgical methods have migrated to the minimally invasive methods. Lessening invasiveness has provided benefits to patients, and reduced the risk of infection. However, these less invasive procedures required the development of program logistics. Management of fragile materials and surgical equipment used in laparoscopy and endoscopy are key to ensure their useful life. This program involves many institutional sectors such as materials management and sterilization centers (MM&SC), as well as the operating theatre (OR). Moreover, this changed scenario requires specific health teams' skills development. Amid these, specific skills are required to manipulate, reprocess and work with, in order to preserve such high-risk-high-complexity-high-cost materials (HR2HCM). Lessons and strategies learned at a São Paulo State Transplantation Reference Hospital may contribute for other services to improve their program. Objectives: To report the impact of an integral approach to prepare and maintain a work team for high-risk-high-complexity-high-cost materials (HR2HCM) management.

## **METHODS:**

During 2013 and 2014, a team of nurses and operating room nursing technicians carried out an initiative to build and improve the endoscopy program. Aiming to implement maximum safety and traceability standards, the team conducted a comprehensive and systematic literature review in LILACS, Health Ministry Scientific Periodicals and PUBMED databases. In parallel, a reference nurse was sent to learn in HR2HCM manufacturers' courses. Moreover, staff focus groups and meetings were realized where specific activities and responsibilities' protocols according to the standards were built, and institutional HR2HCM courses were designed.

## **RESULTS:**

The flows for materials reception, handling, preparation, sterilization, storage, transportation and dispensing for the operating room, as well as control of materials in the operating room and transportation out for the MM&SC were settled. HR2HCM institutional specific courses prepared capilarized knowledge amid all program professionals and medical team. Today it includes a reference nurse continued training for every doctor, medical trainee or surgeon who is in activity in the institution. Implementation of these processes has led to greater staff awareness for the HR2HCM preservation. Indicators followed-up pointed to HR2HCM increased use without incidents. Examples of the program economic gains are presented: in a surgical optics (4 mm 30 degrees) used for prostate resection a useful life has more than doubled (51 reprocesses vs. 20 before); and has tripled of the Flexible lithotripsy ureteroscope used in endoscopic surgery (60 reprocesses vs. 20 before). Accordingly, access increased, more candidate patients had their treatment, and surgical procedures suspension rate decreased.

## **CONCLUSIONS:**

health care organizations may benefit from HR2HCM institutional specific program. Continued courses training the team and divided responsibilities may aid to develop specific HR2HCM conservation strategies. Developing specific flows for each type of HR2HCM is essential for the sustainability of the service, contributes for the reduction of the surgical procedures suspension rate and increases the professionals' and patients' satisfaction.

## **REFERENCES:**

Graybill-D'Ercole P. Implementing AORN recommended practices for sterilization. AORN J,97(5): 521-33, 2013 May. Moresca, L.G. N.; Fonseca, L. F; Tramontini, C.C.; Avaliação dos índices de velocidade e confiabilidade de materiais reprocessados em um Centro de Material e Esterilização. Rev. SOBECC; 16(2): 34-42, abr. - jun.2011.

## Poster 76A Smoking Cessation: A Case Study Of A Pilot Integrated Programme In Qingdao, China

### DESCRIPTION:

To improve the intervention uptake and treatment outcomes, an integrated tobacco dependence management program was piloted in Qingdao.

With structural reform in different parts of the healthcare system, the program showed better smoking quit rate and cost saving in the long-run.

The proposed new management model can potentially be adopted in the management of other chronic diseases.

### PRESENTING AUTHOR:

Dongdong Liu, Pfizer, China

### AUTHORS:

Fei Qi, Junshuai Liu, Sixia Lin, Henpeng Zhu, Qiuming Gao, Dongdong Liu, Peng Dong, Yuan Jia, Zhen Wang

### BACKGROUND AND OBJECTIVES:

China is the largest producer and consumer of tobacco. A cost-of-illness study suggested that the healthcare cost and productivity loss incurred to the society due to smoking was US\$28.9 billion in 2008. China is still in the early stages of tobacco control; the government is increasingly aware of the long-term social and economic impact of smoking in recent years. Hence, various tobacco control measures have been implemented nationwide since 2009. Tobacco dependence management is an evidence-based intervention, recommended by the WHO as a way to increase cessation rates. However, the high cost of treatment might deter smokers from enrolling into the program.

### METHODS:

In order to effectively improve uptake of the intervention and overall treatment outcomes, a pilot integrated tobacco dependence management program was conducted in Qingdao with 5 key initiatives namely: 1) new collaborative model across different government agencies, 2) partnership strategy between government and the private sector, 3) funding mechanism of the program, 3) introduction of new payment method, 4) development of electronic medical records, and 5) management of associated medical risk and fraud.

### RESULTS:

The collaboration between Bureau of Human Resource and Social Security and Health and Family Planning Commission ensured sufficient finance available with copayments by individuals receiving the smoking cessation treatment for the provision of the program. Through public and private partnerships, pharmaceutical and insurance companies provided financial and technical support, training and medications. Payment mechanism was a mixture of both case-based and pay-for-performance methods. Electronic medical records system was used to enable better program delivery, risk and fraud management. The primary results found that of the completed follow-up cases (828), more than 60% of the study participants quit smoking successfully.

### CONCLUSIONS:

In China, the focus on tobacco control is still at the early stage. Our pilot experience of an integrated smoking cessation program in Qingdao that involved payers, providers and industries offered a cost saving and sustainable system in the long-run for a consideration of full scale implementation in China.

## Poster 77A Development Of HTA Implementation Strategy In Tunisia

### DESCRIPTION:

INASanté was created in 2012; HTA is one of its major missions. HTA implementation in Tunisia began with a stakeholders analysis for the development of a HTA national strategy. After a consensus meeting, it was agreed that HTA will be part of the Tunisian healthcare reform and will concern drugs, medical devices, equipments, medical procedures, and healthcare strategies and programs.

### PRESENTING AUTHOR:

Asma Ben brahem Touil, INASanté, Tunisia

### AUTHORS:

Asma Ben Brahem Touil, Mouna Jameleddine, Hela Mesmia, Reiner Banken, Khaled Mounir Zeghal

### BACKGROUND AND OBJECTIVES:

Since the revolution in 2011, tunisian institutions have been adapted to the new concept of democracy. The new constitution of 2014 includes the right to health and mentions that the means for healthcare quality and security must be provided [1]. In this context, the national instance for accreditation in healthcare (INASanté) was created by decree in 2012. INASanté is a public, non for profit, scientific authority which has two principal missions : Health technology assessment (HTA) and accreditation. The first step of implementation of HTA has consisted in a stakeholders analysis with the support of WHO in order to develop HTA strategy in Tunisia.

### METHODS:

A stakelohders analysis has been conducted with the support of HTA expert in two steps. During the first step, INASanté team has identified 36 stakeholders. 23 meetings were organized in April 2015 to introduce INASanté and its HTA mission.

Each stakeholder expressed his point of view and potentiel role concerning HTA implementation. The second step, in May 2015, consisted in a consensus meeting involving all the stakeholders including policy makers. Five workshops were conducted: 1- HTA and universal health coverage, 2- HTA processes and stakeholders' collaboration modalities, 3- Problems and solutions in implementing HTA in Tunisia, 4-INASanté organization, 5-HTA and drugs. Each workshop group was based on some questions related to each topic [2].

### RESULTS:

Stakeholders have expressed their commitment to the HTA implementation and have highlighted the importance of scientific and financial independance of INASanté. HTA will be part of the tunisian healthcare reform and will concern drugs, medical devices, equipments, medical and surgical procedures and healthcare strategies and programs [3]. INASanté HTA reports will be public. Moreover, HTA will have an essential role in the reimbursement process in Tunisia. Drugs pricing may also be based on HTA reports [2]. Currently many issues should be discussed such as drugs classification and health products reimbursement rates.

### CONCLUSIONS:

HTA has key implications for universal health coverage in Tunisia [3, 4]. It offers views on the relevance, effectiveness and efficiency of the use of health technologies. INASanté should have an impact on policies and decisions and involve all stakeholders to insure a correct implementation of HTA. Furthermore, international collaboration is required to be in accordance with international standards [5].

### REFERENCES:

- [1] Constitution de la république tunisienne. Journal officiel de la république tunisienne : Tunis ; 2015.
- [2] Banken R. 'Appui au développement d'une

stratégie d'évaluation des technologies de la santé en Tunisie. Rapport pour l'organisation Mondiale de la Santé', The National Instance for Accreditation in Health Care: Tunis; 2015.

[3] Ben Salah F, Bouzidi R, Champagne F, Guisset AL and all. Pour une meilleure santé en Tunisie faisons le chemin ensemble. Dialogue sociétal pour les politiques, programme conjoint EU-OMS pour la couverture sanitaire universelle : Tunis ; 2014.

[4] Abdelfatteh S, Ayadi I, Ben Abbes R, Ben Salem H and all. Quel chemin vers la couverture sanitaire universelle ? Ministère de la santé : Tunis ; 2014.

[5] EUnetHTA Handbook on HTA Capacity Building : Spain ; 2008.

---

## Poster 78A Experience Of Using The EUnetHTA Core Model For National HTA Production 'Implantable Left Ventricular Assist Device (LVAD) In Addition To Guideline Directed Medical Therapy (GDMT) In End Stage Heart Failure': Experience And Lessons Learned.

### DESCRIPTION:

Experience of using the EUnetHTA core model for national HTA production implantable left ventricular assist device (LVAD) in addition to guideline directed medical therapy (GDMT) in end stage heart failure': experience and lessons learned.

### PRESENTING AUTHOR:

Dr. Francesca Gillespie, Agenas, Italy

### AUTHORS:

Gillespie F, Abraha I, Amicosante AMV, Caimmi P P, Chiarolla E, Corio M, Paone S, Jefferson T, Cerbo M

### BACKGROUND AND OBJECTIVES:

Left ventricular assist device (LVAD) in end stage acute or chronic left ventricular congestive heart failure (HF) improve the allocation of transplants, alleviating the shortage of donors. We assessed the effect of using a LVAD in addition to guideline directed medical therapy (GDMT) in adult patients with end stage heart failure who are not eligible for cardiac transplant.

### METHODS:

We used the Agenas model and structure derived from the EUnetHTA Core Model® for seven domains: Health problem and current use of technology (CUR), Description and technical characteristics of technology (TEC), Regulatory status (REG), Clinical effectiveness (EFF), Safety (SAF), Organisational aspect (ORG), Costs and economic evaluation (ECO). We included evidence from systematic reviews and contextual data from manufacturers and from available national projects. The target population of the technology is represented by adults with end stage heart failure who are not eligible or immediately eligible for cardiac transplant in stage D of the ABCD classification of the American College of Cardiology (ACC)/American Heart Association (AHA), and class III-IV of the New York Heart Association (NYHA) functional classification.

### RESULTS:

In Italy the absolute number of VAD procedures carried out in national health services was equal to 165 (between 2012 and 2013). Around 75% of these procedures are performed on males aged between 25 and 74. Moreover, around 68% of VAD procedures are performed in Lombardia, Veneto and Lazio Regions. Evidence from two included studies showed a consistent improvement in 1-year overall survival in favor of patients that received LVAD. Both studies were affected by selection bias and the overall sample size was limited. In the 5 included full economic evaluations, LVAD patients had higher mean costs with higher survival benefits compared to GDMT; however continuous-flow

LVAD is not cost-effective. LVAD cost-effectiveness estimates were sensitive to several variables (e.g. technology improvement, length of follow up and cost). We used the Agenas model as a checklist.

### CONCLUSIONS:

LVAD is a promising technology considering the shortage of donor hearts, the increase in survival and quality of life. The technology is the only alternative treatment in patients who are temporarily or definitively not eligible for transplant. The use of Agenas' model contributes to a standardization of content. Fragmentation of information was partially avoided by identifying the relevant research questions in each section.

### REFERENCES:

Long EF, Swain GW, Mangi AA. Comparative survival and cost-effectiveness of advanced therapies for end-stage heart failure. *Circ Heart Fail.* 2014;7(3):470-8.

Moreno SG, Novielli N, Cooper NJ. Cost-effectiveness of the implantable HeartMate II left ventricular assist device for patients awaiting heart transplantation. *J Heart Lung Transplant.* 2012;31(5):450-8.

Neyt M, Van den Bruel A, Smit Y, De Jonge N, Erasmus M, Van Dijk D, et al. Cost-effectiveness of continuous-flow left ventricular assist devices. *Int J Technol Assess Health Care.* 2013;29(3):254-60.

Rogers G J, Butler J, et al. Chronic Mechanical Circulatory Support for Inotrope-Dependent Heart Failure Patients Who Are Not Transplant Candidates *Journal of the American College of Cardiology* Vol. 50, No. 8, 2007

Rogers JG, Bostic RR, Tong KB, Adamson R, Russo M, Slaughter MS. Cost-effectiveness analysis of continuous-flow left ventricular assist devices as destination therapy. *Circ Heart Fail.* 2012;5(1):10-6.

Rose E A, Gelijns A C et al. (2001). 'Long-term mechanical left ventricular assistance for end-stage heart failure.' *New England Journal of*

*Medicine*, 345 (20), 1435 -1443.

Sutcliffe P, Connock M, Pulikottil-Jacob R, Kandala NB, Suri G, Gurung T, et al. Clinical effectiveness and cost-effectiveness of second- and third-generation left ventricular assist devices as either bridge to transplant or alternative to transplant for adults eligible for heart transplantation: systematic review and cost-effectiveness model. *Health Technol Assess.* 2013;17(53):1-499, v-vi.

The International Classification of Diseases (9th Edition) - Clinical Modification (ICD9-CM)

---

## Poster 79A The Evaluation Of Da Vinci Surgical System

### DESCRIPTION:

The evaluation of Da Vinci surgical system is to help the government decision-maker to make evidence-based policy of configuration, procurement, and regulation; health technology assessment need to be used to evaluate Da Vinci surgical system. As the forefront technology of minimally invasive surgical, Da Vinci is greatly demanded in China currently situation. However, in the basis of high cost and clinical evidence of Da Vinci, indications-based capital procurement and funding is recommended.

### PRESENTING AUTHOR:

Liwei Shi, China National Health Development Research Center, China

### AUTHORS:

Liwei Shi, Xue Li, Yuzhao Li, Xueran Qi

### BACKGROUND AND OBJECTIVES:

With the development of the medical technology, minimally invasive surgical robot has been gradually used in the world, da Vinci surgical system is a kind of new minimally-invasive technology. As a high-end intelligent surgical equipment, it is no doubt that Da Vinci surgical robot is costly. Meanwhile,

the training, regulation, payment etc. of the robot have become key contents of health system regulation in various countries. During the 12th Five-Year Plan period, the Chinese government has paid great attention to improve people's livelihood. In order to meet people's health demands in different groups, the government gradually increased the investment of high and new technology application. Da Vinci surgical system became a key procurement item. To help the government decision-maker to make evidence-based policy of configuration, procurement and regulation, health technology assessment need to be used to evaluate Da Vinci surgical system. First, using literatures which has been combined with domestic hospital data to analyze main technical characteristics, clinical effects, cost effectiveness and other social impacts of Da Vinci surgical system. Then, identifying its clinical safety, effectiveness, economics and ethicality to provide policy advice for surgical system's introduction, operation and regulation.

#### **METHODS:**

Literature review has been combined with expert consultancy and field investigation in domestic hospital, to collect data on regulation, uptake, diffusion, pricing, payment in various countries which have settings of the Da Vinci surgical system. Moreover, based on systematic literature review fully assess the available of clinical safety, effectiveness, cost-effectiveness and economics evidence. In addition, 38 domestic hospital cost and effectiveness data is being used to do cost-effectiveness analysis. Finally, budget impact analysis has been used to analyze the system uptake prospect in China and potential impact on the health budget.

#### **RESULTS:**

Clinical and costs evidences show that as a very expensive technology, Da Vinci assisted surgery is a superior over open surgery in terms of certain peri-operative clinical outcomes. However its comparative advantages over laparoscopic surgeries are hard to be evidenced with current studies. Also

there are some ethical and moral concerns with the introduction of the technology in Chinese context. Budget impact analysis findings show that the introduction of the Da Vinci surgical robot will have big impact on the local government budget and may cause problems for public health insurance schemes.

#### **CONCLUSIONS:**

As the forefront technology of minimally invasive surgical, Da Vinci is greatly demanded in China currently situation. However, in the basis of high cost and clinical evidence of Da Vinci, Indications-based capital procurement and funding is recommended. Moreover, long-term multi-centered follow-up study on clinical effectiveness and cost-effectiveness is calling for collecting more evidence.

---

## **Poster 80A Assessing Therapy Versus Enhancement - Does It Matter At All?**

#### **DESCRIPTION:**

The same interventions can be used for both therapy and enhancement. This study addresses the differences between therapy and enhancement in the HTA setting in order to provide just health care.

#### **PRESENTING AUTHOR:**

Bjørn Hofmann, University of Oslo, Norway

#### **AUTHORS:**

Bjørn, Hofmann

#### **BACKGROUND AND OBJECTIVES:**

The difference between therapy and enhancement is blurred. The same interventions can be used both for therapy and for enhancement. The same improvement in health can be enhancement in one patient, but not in another. Moreover, both therapy and enhancement share the same goal: increased

health and wellbeing. The objective of this study is to address the differences between therapy and enhancement in the HTA setting in order to provide just health care.

#### **METHODS:**

Literature search of the philosophical, bioethical, and medical literature for debates, arguments, and suggested solutions to the issue of therapy versus enhancement.

#### **RESULTS:**

A wide range of arguments were identified, e.g., referring to naturalness, rehabilitation, species-typical potential, normality, sustainability, responsibility. On closer scrutiny few of these arguments do the job in bolstering the therapy-enhancement distinction.

#### **CONCLUSIONS:**

It is difficult to defend the difference between therapy and enhancement. The reason for this is that we already use a wide range of means to extend human abilities. The therapy-enhancement distinction raises a wide range of ethical issues that are relevant for the assessment of a number of emerging health technologies.

---

## **Poster 81A Committee For Health Technology Incorporation Into The SUS And The Legalization Of Access To Health Care**

#### **DESCRIPTION:**

The quantity of judicial decisions made to provide health technologies has experienced a growing trend since the Constitution of 1988, creating difficulties for the Brazilian public health system. A study was conducted by means of quantitative and qualitative approach towards that took place

between 2012 and 2015. The data analyses indicate that CONITEC (National Committee for Technology Incorporation) has contributed to prevention of judicialization.

#### **PRESENTING AUTHOR:**

Eliete Maia Gonçalves Simabuku, Brazilian Ministry of Health, Brazil

#### **AUTHORS:**

Eliete Maia Gonçalves Simabuku, Izamara Damasceno Catanheide, Carla de Agostino Biella, Roberta Buarque Rabelo, Vania Cristina Canuto Santos, Clarice Alegre Petramale

#### **BACKGROUND AND OBJECTIVES:**

The quantity of judicial decisions made to provide health Technologies, especially drugs, has experienced a growing trend since the Federal Constitution of 1988, creating some difficulties for the Brazilian Public Health System (SUS). This study's goal is to describe experiences of the National Committee for Health Technology Incorporation (CONITEC), its communication with the Federal Prosecutors, the Attorney General of the Union and the Judiciary Power.

#### **METHODS:**

A case study was conducted by means of a quantitative and qualitative approach using as a data source, information submitted by CONITEC Executive Secretariat in response to the Judiciary Power requests, Federal and State Prosecutors, Public Defenders, Attorney General of the Union, Legislative Power, Health Secretaries, medical and patient associations that took place between 2012 and 2015.

#### **RESULTS:**

During this period, 889 responses and 260 technical reports as assistance to the requests for information on health technology incorporation, involving medicines, medical devices or procedures. Most requests were about treatments

for diseases, like diabetes, blood pressure, osteoporosis and epilepsy, for which there are several treatment options in SUS.

### **CONCLUSIONS:**

The data analyses indicate that CONITEC has contributed to the prevention of judicialization, to the extent that it identified that (i) the Prosecutors Office has been increasingly requesting information before beginning judicial actions; (ii) during the period from 2012 to 2014 there was a drop in the number of requests for information aiming to defend the Union in judicial actions that were already established; and (iii) the Judiciary Power has increasingly used communications channels via email before deciding about the concession of injunctions.

.....

## **Poster 82A The Results Of Educational Workshop On Health Technology Assessment In The Russian Federation And CIS Countries**

### **DESCRIPTION:**

A survey among the healthcare decision-makers in Commonwealth of Independent States (CIS) countries on the possibility of implementing health technology assessment into the healthcare systems was conducted during the educational workshop on HTA. The results reflect the interest of these specialists in HTA and show the importance of educational programs on HTA in CIS countries.

### **PRESENTING AUTHOR:**

Prof. Roza Yagudina, Department of Organization of Medicinal Provision and Pharmacoeconomics, Russia

### **AUTHORS:**

Roza Yagudina, Dzhumber Ugrehelidze

.....

### **BACKGROUND AND OBJECTIVES:**

Despite the fact that HTA is a globally recognized tool for evidence-based decision making in health care and has been used successfully in the most economically developed countries (USA, Canada, Australia, UK and other EU countries), Commonwealth of Independent States (CIS) countries still have a long way of introducing HTA in their healthcare system. One of the steps necessary to disseminate HTA in CIS countries is the exchange of experience and best practices. One of the examples of educational programs and workshops is the educational workshop "Modern requirements for conducting pharmacoeconomic studies" for decision makers (DM) in the healthcare of the CIS countries, which was held on 15 - 19 December 2014 in Moscow at the Department of organization of medicinal provision and pharmacoeconomics of I.M. Sechenov First Moscow State Medical University. It was attended by officials from the ministries of health and insurance organizations, higher educational institutions of 8 CIS countries (Russia, Uzbekistan, Kyrgyzstan, Moldova, Tajikistan, Belarus, Azerbaijan, Armenia).

### **METHODS:**

The survey contained questions on the possibility of implementation of HTA in CIS countries, types of HTA and organizational structure of future agencies.

### **RESULTS:**

As a result of the conducted survey all DM note that HTA is necessary for decision-making in their countries. The majority of respondents note that the most important sphere for assessment is medicinal drugs (17 respondents), 13 respondents chose diagnostics and medical devices as a priority for HTA. 7 respondents payed attention to rehabilitation programs and 6 ones proposed organizational systems as the key area for HTA. 65% of respondents suppose that HTA agency should be financed by the Ministry of Health, 20% consider the key role of pharmaceutical companies, 15 %

suppose that insurance companies should finance HTA agencies. However 65% of respondents suppose that HTA agency in their country should be a part of Ministry of Health and 35% ones consider the independent role of HTA agency more appropriate for their country. The following factors were identified as inhibiting the development of HTA in their countries: limited budget, lack of qualified personnel, lack of political will, lack of information about the HTA methodology and its benefits, unstable socio-political situation. It should be noted that the decision-makers approve the implementation of regional HTA in their countries (82% of respondents) and implementation of mini-HTA (100%). 53% of the respondents preferred the establishment of committees for HTA in health facilities, 47% prefer the request of expert evaluation consultants from other institutions (the Ambassador model).

#### **CONCLUSIONS:**

All participants of the educational program noted the importance of educational programs on HTA and stressed the need for further training of decision-makers in the CIS countries.

---

## **Poster 83A RENEM - National List Of Equipments And Permanent Materials For The SUS**

#### **DESCRIPTION:**

The Ministry of Health (MoH) of Brazil supports institutions linked to the Public Health System (SUS) to improve their technological infrastructure, financing the acquisition of medical equipment. As resources are always finite, a selection of the most cost-effective equipment is required. The National List of Equipment and Materials (RENEM) consists of a database with technical-economic information and financing values.

#### **PRESENTING AUTHOR:**

Murilo Contó, PAHO-WHO, Brazil

#### **AUTHORS:**

Murilo Contó, Clarice Alegre Petramale

#### **BACKGROUND AND OBJECTIVES:**

The Ministry of Health (MoH) of Brazil supports institutions linked to the Public Health System (SUS) to improve their technological infrastructure, financing the acquisition of medical equipment. As resources are always finite, a selection of the most cost-effectiveness equipment is required.

#### **METHODS:**

It consists of a descriptive report of the actions taken by the MoH to refine the process of incorporation and investment in medical equipment, through participant observation during the period from 2008 to 2014.

#### **RESULTS:**

RENEM was adopted stemming from the standardization of technical terminology according to the nature/complexity of the equipment, made it possible to develop a computerized system (SIGEM) for the distribution of technologies according to the type of service, also maintaining databases of technical-economic information to create specifications and financing values. The equipment began to be demanded in accordance with the profile of the institution, with technical specifications and clear amounts in accordance with their nature/complexity.

#### **CONCLUSIONS:**

Managers from all over country began to have access to information that is relevant to the constitution of investment projects, promoting a better allocation of technologies, optimizing the efficiency in the use of health-related resources.

#### **REFERENCES:**

Brasil. Cartilha para Apresentação de Propostas ao Ministério da Saúde. Brasília: Ministério da Saúde,

Fundo Nacional de Saúde; 2014 Brasil. Portaria nº 448, de 13 de setembro de 2002. Divulga o detalhamento das naturezas de despesas 339030, 339036, 339039 e 449052. Brasília: Presidência da República, Ministério da Fazenda; 2002. Brasil. Critérios para Análise de Investimentos em Saúde. Brasília: Ministério da Saúde, Fundo Nacional de Saúde; 2005.

Brasil. Decreto nº 7.508, de 28 de junho de 2011. Institui a Relação Nacional de Ações e Serviços de Saúde & RENASES. Brasília: Presidência da República, Casa Civil; 2011.

Brasil. Portaria GM nº 3.134, de 17 de dezembro de 2013. Institui a Relação Nacional de Equipamentos e Materiais permanentes financiáveis para o SUS & RENEM. Brasília: Ministério da Saúde; 2013.

Brasil. Lei nº 12.401, de 28 de abril de 2011. Altera a Lei nº 8.080, de 19 de setembro de 1990, para dispor sobre a assistência terapêutica e a incorporação de tecnologia em saúde no âmbito do Sistema Único de Saúde & SUS. Diário Oficial União nº 81 seção 1:1. Velazquez-Berumen, A. Development of Medical Device Policies. WHO Medical Device Technical Series, WHO & Organização Mundial da Saúde; 2011.

---

## Poster 84A The Impact On Health Services Of Mobile Applications In The Context Of Transaction Costs

### DESCRIPTION:

The impact on health services of mobile applications in the context of transaction costs.

### PRESENTING AUTHOR:

Huseyin Demir, Izmir Katip Celebi University, Turkey

### AUTHORS:

Huseyin Demir

### BACKGROUND AND OBJECTIVES:

Transaction costs shows an upward trend in health organizations for Turkey as another countries. This problem is pull attention of the Ministry of Health and minimization of transaction costs per one person has been studied in recent years. Therefore, the reduction of transaction costs and overall total cost in public hospitals concerned all stakeholders and the future of the health care system poses a major problem of sustainability point. In this study, the role of mobile health technologies impact on cost and effective healthcare is investigated. Improving of coverage of healthcare with the use of health technology like smartphone and tablet is the aim of this study.

### METHODS:

The international features of the mobile application are indicated with the developers perspective and literature review. E-Nabiz is investigated as sample application. The developers emphasize that a mobile app is usable, can data visualisation, video-conference, reliable, privacy, easy to use, affordable and accessible. After the research at this topic, it was determined that E-Nabiz is not have a video-conference and accessible properties.

### RESULTS:

It should be guaranteed that there is no difference between go to healthcare institution and connect by mobile apps. Face to face communication is essential for patient-physician relationships. This properties should added to E-Nabiz. As a result, it should be said that the mobile apps can be used for decreasing cost on healthcare institution.

### CONCLUSIONS:

It should be guaranteed that there is no difference between go to healthcare institution and connect by mobile apps. Face to face communication is essential for patient-physician relationships. This properties should added to E-Nabiz. As a result, it should be said that the mobile apps can be used for decreasing cost on healthcare institution.

---

## Poster 85A Estimation Of Needs Of Immune Suppressant Medicines Financed By The Government Budget For Patients With Organ Transplants

### DESCRIPTION:

In Mongolia, the 64.0% of persons who had been taken organ transplants covered to government subsidized free immuno suppressant drugs in 2013. By this trend, in 2020 users of immuno suppressants will increase by 5.2 times, the amount of immune suppressant drugs will increase by 3.2-6.4 times, and budget will increase by 7.8 times from 2013.

### PRESENTING AUTHOR:

Unurtsetseg Takhad, Center for Health Development, Mongolia

### AUTHORS:

Unurtsetseg Takhad, Shirnen, Lkhamsuren

### BACKGROUND AND OBJECTIVES:

Ministries of Health and Finance jointly approved the list of outpatient medicines funded by government budget as per joint order 129/100 in 2012. This list includes Tacrolimus and Cyclosporine to be taken after undergoing transplantation surgeries. In 2013, 272 persons had been taken organ transplants and of which 174 or 64.0% covered to government subsidized free immuno suppressant drugs due to lack of resources. This survey aimed to undertake projection of needs and utilization up to 2020 of immuno suppressant drugs after organ transplantation and provide evidence to decision makers for improve the further planning of the medicine.

### METHODS:

Medicine and drug utilization projections are

based on population morbidity data. We also used related pharmacophie, mode and dosage; methods and technology of treatment of the selected conditions and health statistics. For this study we conducted quality and facts and evidence based interviews to gather information on current and potential utilizations of selected medicines. Disease prognosis was estimated using structural and regression analysis model. On the other hand, per capita average dosage and portion was estimated using the simple statistical averages.

### RESULTS:

The determination coefficient of square regression model of the time series data until 2013 for patients received organ transplantation was the highest from other models.  $R^2=0.779$  for kidney transplantation and  $R^2=0.877$  on liver transplantation by square regression. Therefore we used this model to project organ transplantation cases up to 2020. In 2020, Mongolia will use immune suppressant drugs in total for 1425 persons in volumes of 330,792 capsules of 25 mg cyclosporine, 1,380,370 capsules of 1 mg prograf, 238,504 capsules of 0.5mg prograf, 239,751 capsules of 1 mg pangraf, 14,786 capsules of 1mg advagraf. Trend analyze showing, in 2020, persons who would be use immuno suppressants will be increase by 5.2 times and necessary budget will be increase by 7.8 times compare with 2013.

### CONCLUSIONS:

Government could not provide immuno suppressant medicines for all patients with organ transplants due to lack of financing resources. For that reason, need to rationalize the ratio of financing sources (e.g. government budget, health insurance and out of pocket) of high costed health care services as well as organ transplants based on estimation of real cost of health care.

### REFERENCES:

1. Joint order 129/100 of Ministries of Health and Finance in 2012

2. Minister of Health order 74 in 2014
3. Minister of Health order 177 in 2014
4. Drug catalog, 2007
5. Health Statistics of Mongolia, 1996-2013
6. Immune suppressant drug spending reports of First clinical hospital.

---

## Poster 88A Analysis Of Drug Related Problems In Hypertension Treatment

### DESCRIPTION:

Prescribed drugs should have therapeutic effect on comorbidities and not have contraindications for underlying diagnosis. We identified 44 drug related problems (DRP) for treatment of hypertension. The cost of duplicated drugs could be saved and spent on improving the life quality and on the acquisition of other life-saving medicines. The program was created of assistance for medical appointments drug interactions, forecast of the likely risk of complications.

### PRESENTING AUTHOR:

Dr. Oksana Blavatska, Danylo Galytskyj Lviv National Medical University, Ukraine

### AUTHORS:

Oksana Blavatska, Ulyana Yanyshyn, Ihor Blavatskyj

### BACKGROUND AND OBJECTIVES:

The presence of comorbidity (? 3 diseases) provides individualized pharmacotherapy: prescribed drugs should have beneficial therapeutic effect on comorbidities and have no contraindications to treatment of underlying diagnosis, or vice versa. Medication process includes: assigning drugs, pharmacotherapy, monitoring of drugs use, cancellation and replacement drugs (at

each stage can occur DRP). To determine the DRP above category we take into account: the presence of indications for treatment of the basic disease (hypertension) and pharmacotherapy comorbidity. We identified 44 DRP in this category. The next stage was to identify DRP in safety-related pharmacotherapy. Revealed contraindications to the drug use by primary and related nosology found, that patients with hypertension with concomitant diagnosis of heart failure in 42.85% cases were assigned to pharmacotherapy drugs with contraindications to their use: the 33.33% comorbidities heart failure and peptic ulcer disease; 14,3% ? coronary heart disease; 9,5% ? thyroid and hepatitis.

### METHODS:

The analysis was conducted using Good Clinical Practice assignments drugs. Monitoring comorbidities avoids unwanted DRP when evaluated patient drug list and detection contraindications to the use of drugs, including primary and concomitant diagnoses in time to prevent and eliminate unwanted complications of pharmacotherapy. Inadequate duplication from one pharmacotherapy group was observed in 44 cases in observed 4 healthcare institutions. Actions of pharmacist should be directed in particular to eliminate the problem of duplication of drugs irrational combinations to reduce the side effects of drugs, improving patient QOL during and after drug therapy and avoid polypharmacy.

### RESULTS:

The results of the comparative analysis revealed the prescribed drugs that contain the same active substance, of the same pharmacotherapy group, have a similar mechanism of action. Such analysis can prevent occurrence or worsening of side effects of drugs. The results of the analysis highlights the main pharmacotherapy group and the number of cases that are used in patients with hypertension: in 27% of cases was the combination of drugs of the group of angiotensin-converting enzyme (S09AA, C09BA, C09BB). Pharmacotherapy

group angiotensin II (SO9SA) amounted to 13.6% of identified DRP. Such combinations are irrational, since they lead to unnecessary increase in cost pharmacotherapy and increased side effects. As a result of calculating the cost of duplicated drugs (n = 44), we have established the amount of money that could be saved and spend on improving the life quality and the acquisition of other life-saving medicines.

### **CONCLUSIONS:**

To improve quality of pharmacotherapy we created the program of assistance for medical appointments by providing information about drug interactions, possibility of negative impact of drug combinations on patient health, forecast of the likely risk of complications. We consider it is appropriate to: provide complex medical and pharmaceutical care on purpose, dosage and application of medicines, characteristics of dosage forms, pharmacological drug interactions, identify and determine ways to eliminate DRP (unreasonable and irrational prescriptions drugs) and pharmacotherapy rationalization by reducing the number of DRP.

---

## **Poster 89A A Comparison Of Critical Disease Insurance Schemes In Different Areas Of China**

### **DESCRIPTION:**

The rationale of implementing critical disease insurance (CDI) in China is to expand the coverage of current health care insurance system, and to further relieve the burden of catastrophic medical spending for patients. This study aims to evaluate the framework of four different CDIs, and to provide early experience gained from these CDIs to support the CDI implementation in other regions.

### **PRESENTING AUTHOR:**

Li Chen, Abbvie, China

### **AUTHORS:**

Li Chen, Yi Li, Jun Feng, Andrew Eggleston

### **BACKGROUND AND OBJECTIVES:**

Basic public medical insurance plays a significant role in the health care financing system in China. Currently, basic medical insurance for urban and rural people can generally cover 50 percent of medical expenses (NHFPC, on 22 Dec 2015). Despite nearly universal public insurance coverage, out-of-pocket (OOP) co-payments are substantial under the current health insurance plans (Alexander et al 2012). Furthermore, relatively low cap for total reimbursement amount resulted in: 1. higher portion of healthcare OOP payment for patients with serious acute and chronic conditions 2. limited access for innovative drugs and novel treatment such as biologics for autoimmune disease Therefore, National Development and Reform Commission (NDRC), Ministry of Health (MoH) and four other ministries and commissions of China issued 'Guidance about implementation of urban and rural residents' critical disease insurance (CDI) system' on August, 2012. The CDI system aims to expand the coverage of the country's health care insurance system to include the treatment of critical illness, aiming to relieve urban and rural families of the heavy burden of catastrophic medical spending.

### **METHODS:**

CDI schemes in 4 areas including Qingdao, Shenzhen, Gansu as well as Karamay were identified for analysis. The objectives of this study are twofold: 1) To compare and evaluate the design and implementation of CDI schemes in four different places in China under different social and economic circumstances; 2) to provide early experience and insights gained from current CDI system to further support CDI reimbursement discussion between sponsors and local government in other areas of China.

## RESULTS:

Analysis of these CDI schemes indicated that the regulation, operation and management, funding of CDIs are different according to their regional economic level, stage of social development, health care needs and extent of insurance pooling fund. These differences also resulted in the difference in reimbursement rate, population coverage as well as disease/product coverage.

## CONCLUSIONS:

Due to the differences in economic development, population structure, funding source, each area has designed and implemented their own CDI schemes. Although there is no structured, standardized single CDI system throughout the country, it is clear that the CDI program provides a special access mechanism to improve patient access to innovative drugs and accelerate the reimbursement process of innovative drugs including biologics.

## REFERENCES:

Alexander N, Claudia SD, Florian T. Private health insurance in China: finding the sinning formula. Health International 2012; Nov 12: 75-82. National Health and Family Planning commission of the PRC (NHFPCC). State Council General Office on critical illness insurance for urban and rural residents, en.nhfpcc.gov.cn, accessed on 22nd Dec 2015.

---

## Poster 90A Assessment Of Detecting Number Of Individuals And Medical Costs By CKD Severity Using Annual Health Checkup Data And Medical Claims Data In Japan

### DESCRIPTION:

It is important to identify chronic kidney disease (CKD) patients and start earlier intervention for those patients in Japan. We assessed the detection

of CKD and evaluated medical costs using health checkup and claims data. 1.1% of individuals were identified as medium to high severity of CKD and the presence of advanced CKD and/or complication of diabetes were associated with higher medical costs.

### PRESENTING AUTHOR:

Rie Nishikino, Japan Medical Data Center Company Ltd., Japan

### AUTHORS:

Rie Nishikino, Chie Ito, Shinzo Hiroi, Hiroyo Kuwabara, Kaoru Yamabe, Yukio Shimasaki

### BACKGROUND AND OBJECTIVES:

Despite being costly to treat end stage kidney disease (ESKD) or dialysis, there has been a rapid increase in the number of patients with ESKD or on dialysis in Japan. It is important to identify patients with chronic kidney disease (CKD) and start earlier intervention for those patients. This study was to assess number of individuals with CKD at annual health checkup, and evaluate their medical cost.

### METHODS:

Annual health checkup data and medical claims data from Japan Medical Data Center (JMDC) were used for this study. We obtained laboratory value results of serum creatinine and uric protein from their annual health checkup data and assessed severity of CKD based on "Evidence-Based Clinical Practice Guidelines for Chronic Kidney Disease 2013" by Japanese Society of Nephrology. Individuals who already received diagnosis of systemic lupus erythematosus(SLE) or received dialysis were excluded from the analysis. We then evaluated presence or absence of previous kidney-related treatment history, type of diagnosis, and medical costs by merging annual health checkup data and medical claims data by unique identifiers. Additionally, medical costs were assessed by the presence or absence of diabetes.

**RESULTS:**

Among 565,148 of insured individuals between April 2009 and March 2010, 88,156 individuals were identified as a final cohort. Population of individuals categorized in green stage (G1A1, G2A1) was 93.7%, yellow stage (G1A2, G2A2, G3aA1) was 5.2%, orange stage (G1A3, G2A3, G3aA2, G3bA1) was 0.9%, red stage (G3aA3, G3bA2, G3bA3, G4A1, G4A2, G4A3, G5A1, G5A2, G5A3) was 0.2%. Among individuals with stage orange and red, one fourth of them were already received some kinds of kidney-related diagnosis. The proportion of patients with diabetes was 4.2% in green stage, 10.2% in yellow stage, 20.8% in orange stage, and 40% in red stage. The presence of advanced CKD stage and/or complication of diabetes were both associated with higher medical costs.

**CONCLUSIONS:**

Numbers of individuals and medical costs categorized by the CKD severity can be detected using annual health checkup data and medical claims data.

**REFERENCES:**

Evidence-Based Clinical Practice Guidelines for Chronic Kidney Disease 2013

**Poster 91A Amniopatch Procedure For The Treatment In Preterm Premature Rupture Of The Membranes: Systematic Review**

**DESCRIPTION:**

To evaluate the safety and effectiveness of amniopatch procedure for the treatment in preterm premature rupture of the membranes.

**PRESENTING AUTHOR:**

Ryeojin Ko, National Evidence-based Healthcare

Collaborating Agency, Korea

**AUTHORS:**

Ryeojin Ko

**BACKGROUND AND OBJECTIVES:**

To evaluate the safety and effectiveness of amniopatch procedure for the treatment in preterm premature rupture of the membranes.

**METHODS:**

The searches were conducted via electronic databases including Ovid-MEDLINE, Ovid-EMBASE, the Cochrane Library and 8 Korean DB. In study design, up to randomized controlled trials, case report study of which patients received amniopatch procedure were included. Two reviewers independently selected data in standardized form and assessed the methodological quality. Quality evaluation was performed by SIGN method.

**RESULTS:**

Total 11 studies (2 cohort studies, 1 case series, 8 case report) were included. There were no serious maternal or fetal related complications. There were reported lower maternal chorioamnionitis after the amniopatch relative to conservative treatment(control). Mean gestational age at delivery was 27.7 weeks(total 70 cases in 10 studies) (spontaneous group : 27.6 weeks, iatrogenic group : 27.8 weeks). Amniopatch was successful in 46.6%(33/71 cases in 11 studies). Overall neonatal survival was 55.3%(52/94 cases in 11 studies). Neonatal morbidity was 23.4%(11/47 cases in 7 studies).

**CONCLUSIONS:**

In a systematic review, although there is no clear evidence, the amniopatch procedure is a viable treatment option to prolong a pregnancy with previable PROM.

## Poster 92A Network Meta-Analysis For HTA: Review Of HTA Body Guidelines Globally

### DESCRIPTION:

The checklist aims to provide practical support to health technology manufacturers and serve as a quality tool to critically appraise the reporting of network meta-analysis/indirect comparison (NMA/IC) for HTA, particularly for HTA submissions in countries where specific guidance is not available.

### PRESENTING AUTHOR:

Sarah Batson, DRG, United Kingdom

### AUTHORS:

Sarah Batson, Gemma Greenall

### BACKGROUND AND OBJECTIVES:

Network meta-analysis (NMA) is an important and developing method of evidence synthesis for Health Technology Assessment (HTA). NMA and indirect comparisons (ICs) should be conducted and reported according to methodological guidelines which vary by HTA body. The objective of this study was to review the methodological guidelines specifically for NMA/IC issued by HTA bodies globally.

### METHODS:

Country-specific pharmacoeconomic guidelines were identified by reviewing the web-based repository of guidelines maintained by ISPOR in addition to supplementary hand-searching.

### RESULTS:

Specific HTA guidelines from 39 countries were identified (38 from the repository maintained by ISPOR and 1 from hand-searching). Of these, ten were not available in English, 16 did not make reference to NMA/IC and 5 made reference only to the use of IC/NMA. Guidelines from 9 countries providing guidance for the use of NMA/IC in HTA

submissions were identified and reviewed (Australia, Belgium, Canada, England and Wales, Germany, Ireland, New Zealand, Scotland and South Africa). Five main themes were noted: the data included in analyses, the statistical methodologies used, the analyses to be performed, the presentation of the results, and technical issues surrounding NMA/IC.

### CONCLUSIONS:

This study highlights a general lack of country specific methodological guidance around NMA/IC for HTA. We present a reporting checklist, based upon the review of guidance from 9 countries. The checklist aims to provide practical support to health technology manufacturers and serve as a quality tool to critically appraise the reporting of NMA/IC for HTA, particularly for HTA submissions in countries where specific guidance is not available.

---

## Poster 93A The Use Of Non-Randomised Evidence In Health Technology Assessments: A UK Perspective

### DESCRIPTION:

We present the current policy on the use of non-randomised evidence in UK's National Institute for Health and Care Excellence (NICE) Technology Appraisal programme. We highlight key areas where the use of real-world data may help to inform assessment of new technologies and provide additional information to the National Health Service.

### PRESENTING AUTHOR:

Dr. Pall Jonsson, National Institute for Health and Care Excellence, United Kingdom

### AUTHORS:

Pall Jonsson, Sarah Garner

### BACKGROUND AND OBJECTIVES:

The UK's National Institute for Health and Care Excellence (NICE) is tasked with providing guidance to the National Health Service (NHS) on clinical and cost effectiveness of health technologies. In the development of NICE's guidance, various data sources are required for modelling of clinical and economic scenarios and to inform decisions. In addition to randomised controlled trials (RCTs), this often involves use of non-randomised 'real-world data' from observational studies, databases, datasets and clinical registers. We present the current policy on the use of non-randomised evidence in NICE's Technology Appraisals and outline areas where the use of real-world data could help meet NICE's overall strategic objectives.

**METHODS:**

N/A

**RESULTS:**

Current use of non-randomised data in NICE's Technology Appraisals is guided by the programme's methods guide. It is primarily limited to use in health economic modelling, such as for supporting extrapolation of health effects over time, and to inform assessments of quality adjusted life years (QALYs). Other frequent use of such data is to inform costing and implementation tools. Considering potential future developments, we have identified five key uses of real-world data that could help the organisation meet its objectives.

**CONCLUSIONS:**

Real-world evidence may have a greater role in flexible licensing pathways, such as the European Medicine Agency's Medicines Adaptive Pathways to Patients (MAPPs) and, for instance, in health technology assessment where new treatments are covered on the condition of additional evidence generation. Here we have identified five key areas where the use of real-world data and evidence could help inform assessment of new technologies and provide additional information to the NHS.

.....

.....

## Poster 94A Overview Of The Cardiac Implant Registry In The Last Decade

**DESCRIPTION:**

The aim of this study is to overview the existing cardiac implant registries worldwide in the last decade, and then to investigate the registry structure. 64 cardiac implant registries were identified from this study. Data of 'registry name and topic, geography and duration, research type and data collection basement, initiator or funding, research objectives, and public access' were identified.

**PRESENTING AUTHOR:**

Prof. Peter Kolominsky-Rabas, Centre for HTA and Public Health, University of Erlangen, Germany

**AUTHORS:**

Shixuan Zhang, Sandra Schaller, Peter L Kolominsky-Rabas

**BACKGROUND AND OBJECTIVES:**

According to a systematic overview of recall reports identified from eleven national regulatory authorities, a total of 103 cases of cardiac implant adverse event have been reported last decade. The effect of cardiac implant adverse event is usually comparatively serious, like the Sprint Fidelis Defibrillator Leads manufactured by Medtronic, which caused by a small number of fractures on the device being detected and causing five deaths in 2007. With the cardiac implants increasing worldwide, the need for monitoring 'real-world' data is increased. Medical devices registries can provide a real-world data of clinical outcome, device indications, cost and effectiveness of the device, as well as adverse event. The aim of this study is to overview the existed cardiac implant registries worldwide in the last decade, and then to investigate the registry structure.

## **METHODS:**

A systematic search was employed in line with the PRISMA guidelines about cardiac implant registries from 2005 to 2015 in the following databases were searched: the PubMed (Medline), the ScienceDirect (EMBASE). A deductive approach will be used to explore the criteria emerging in the identified registries. Data of 'registry name and topic, geography and time duration, research type and data collection basement, initiator or funding, as well as research objectives and public access' will be extracted from the identified articles.

## **RESULTS:**

To summarize the cardiac implant registries from the identified articles, the following 64 registries were achieved: 16 pure ICD registries, five pure CRT registries, five pacemaker registries, and four CIED registries which combined ICD, pacemaker and CRT implantation data; as well as 21 coronary stent registries and 11 TAVI registries. Cardiac implant registries mainly distributed in US and Europe. 46 registries collect data prospectively from different centers; in addition eight registries collect data prospectively from single center. 18 registries were funded by public organizations. Six registries can be accessed via web page, in addition they release annual report.

## **CONCLUSIONS:**

Registries provide a clear 'real-world' picture for the patients, physicians, manufacturers, payers, decision-makers and other stakeholders. The importance of cardiac implants registry has been recognized and approved, the next step is to investigate how to complete the structure of the registry, to balance the distribution of the registries and to improve the transparency of the registry.

---

## **Poster 95A Added Direct Inpatient Costs Of Antimicrobial Resistant (AMR) Infections In China**

### **DESCRIPTION:**

We used a systematic review process to select publications and pick some relevant data from them, then, according to our model (formula), estimated the added direct hospital inpatient costs of antimicrobial resistant (AMR) infections in China. We found that the percentage of the added direct inpatient costs of AMR infections over the total health expenditures were from 18.24% in 2008 to 3.55% in 2012. Its mean share of the gross domestic product was 0.49%, from 0.84% in 2008 to 0.19% in 2012. However, from 2008 to 2012, multidrug resistant (MDR) infections are becoming increasingly serious.

### **PRESENTING AUTHOR:**

Xuemei Zhen, Zhejiang University, China

### **AUTHORS:**

Xuemei Zhen, Hengjin Dong

### **BACKGROUND AND OBJECTIVES:**

Antimicrobial resistant (AMR) infections result in huge costs to individuals and society globally. The use of antibiotics in China is exceptionally high, about half of the total world consumption, resulting in what has been reported as the world's fastest growth of AMR infections. Yet few studies have examined the costs of AMR infections in China. This study estimated the added added direct inpatient costs of AMR infections in China at the national level.

### **METHODS:**

China Health Statistical Yearbook and national and international databases were systematically searched. The search period was from January 1, 2000 to July 1, 2015. The keywords are

---

infection surveillance system, antimicrobial usage, antimicrobial resistant bacteria, multi-drug resistant bacteria, inpatients, length of stay (LOS), China or Chinese. The main indicator is added direct inpatient costs of AMR infections in entire China. Other indicators are percentage of antimicrobial usage, percentage of AMR infections and added LOS per AMR infection. Articles were included if the above mentioned indicators were identified. We excluded studies where data could not represent whole general hospitals.

### RESULTS:

A total of 55 studies were included covering the years from 2008 to 2012. The total added direct inpatient costs of AMR infections peaked in 2010 at ¥322.30 billion with a remarkable drop to the lowest level in 2011 at ¥87.93 billion, with a modest increase again in 2012. The percentage of GDP absorbed by the added direct inpatient costs of AMR infections showed a drop, going from 0.84% in 2008 to 0.19% in 2012. The incidence of AMR infections which were MDR infections constituted an increase over the years, with a correlation coefficient ( $r$ ) of 0.97.

### CONCLUSIONS:

The percentage of the total health expenditures (THE) caused by added direct inpatient costs of AMR infections dropped from 18.24% in 2008 to 3.55% in 2012. The percentage share of the gross domestic product (GDP) dropped from 0.84% in 2008 to 0.19% in 2012. MDR infections are becoming increasingly serious. The added direct inpatient costs of AMR infections are still huge, in spite of some reduction in the overuse of antibiotics. Further measures need to be taken to reduce the inappropriate use, thus curtailing the speed of antibiotic resistance and multi-drug resistance in order to further reduce the economic costs.

.....

## Poster 96A Moving Towards Better Outcomes In Multiple Sclerosis By Addressing Policy Change

### DESCRIPTION:

This study aims to estimate the societal economic burden and health-related quality of life (HRQoL) of patients with multiple sclerosis (MS) and evaluate the role of receiving early disease modifying treatment (DMT) (i.e., within 12 months of a single neurological attack) towards better disease outcomes.

### PRESENTING AUTHOR:

Prof. Panos Kanavos, London School of Economics, United Kingdom

### AUTHORS:

Michela Tinelli, Panos Kanavos, Jean Mossman, Olina Efthymiadou

### BACKGROUND AND OBJECTIVES:

MS is associated with a high cost of illness, both in terms of direct and indirect costs. Given that the onset of MS is in early adult life (average onset at 29 years of age) lasting over an individual's lifetime, there are huge costs relating to productivity losses. At global level in 2012, MS was estimated to cause 1,165,000 disability-adjusted life years (DALYs), of which 387,000 were attributable to the European region and 282,000 in the Americas (WHO data). There is also a significant impact on the families of people with MS (PWMS). There are therapies which modify the course of the illness, known as disease modifying treatments (DMTs); that is, their effect is to slow disability and disease progression. However, considerable neurological damage can occur if people with MS are not given the appropriate treatment early enough. There is increasing focus on finding ways to identify disease progression as early as possible so that treatments can be adapted to prevent or delay further

## **METHODS:**

A bottom-up, cost-of-illness, retrospective analysis of 246 individuals and their informal caregivers in Germany, France, Romania, UK and North America was conducted to approximate the global, social and economic impact of MS. Data on demographic variables and clinical characteristics such as time between diagnosis and treatment, consumption of Disease Modifying Drugs (DMDs), healthcare resource and informal care utilization, as well as data on productivity losses and HRQoL (using the EQ-5D-5L instrument) were collected by means of two online, self-completed questionnaires distributed to non-institutionalized MS patients and their informal caregivers respectively.

## **RESULTS:**

Using 2014 as a reference price, we found that the average annual cost for a patient with MS was 38,820, with mean annual direct health care costs amounting up to 20,631 (53% of total costs). On average, the largest share on total costs was that of Disease Modifying Drugs (DMDs) consumption (47%), followed by indirect costs due to productivity losses (41.3%), non-medical costs from formal/informal care required (5.5%), inpatient care (3.9%) and ambulatory care (2.9%). Statistically significant differences existed between countries on total costs (p0.05).

## **CONCLUSIONS:**

Our analysis highlights the importance of the economic and quality of life consequences of MS from a societal perspective. A significant utility loss of 25% was observed for individuals with MS, when compared to the general population. In addition, MS was found to introduce a significant global economic burden for societies, with DMD costs and indirect costs due to permanent work disability representing 88% of the total average annual costs of MS. Early initiation of treatment yielded promising results in terms of reducing the overall burden of the disease, although further economic evaluations are required in this field.

---

## **Poster 99A HTA In Rare Diseases: A Snapshot Of Current Approaches, Implications And Recommendations**

### **DESCRIPTION:**

Health technology assessment (HTA) in rare diseases is associated with a number of complexities and challenges. The current study aimed at reviewing the HTAs conducted worldwide in a rare disease area, to facilitate understanding of HTA approaches, challenges, as well as HTA/payer evidence requirements. Similarities and differences of approaches were noted. Implications and recommendations are discussed.

### **PRESENTING AUTHOR:**

Dr. Ruzan Avetisyan, Sanofi Genzyme, United States

### **AUTHORS:**

Ruzan Avetisyan, Alicia Granados

### **BACKGROUND AND OBJECTIVES:**

New therapies commonly undergo health technology assessment (HTA) before their adoption on the national or regional levels. Assessments of therapies for rare diseases are often associated with additional complexities and uncertainties, as some of the traditional approaches and criteria (such as cost-effectiveness thresholds) used for common conditions, may not be applicable in the rare diseases context. Sometimes these challenges can lead to longer assessment times with uncertain outcomes, resulting in delayed or restricted patient access to much needed and effective health technologies. The objective of this presentation is to use a case study in a specific rare disease to review and discuss HTA done in various countries. The discussion will include topics around methods, challenges, implications and opportunities. Recommendations are suggested related to the

assessment criteria and approaches, as well as in general the HTA role in development and adoption of therapeutic innovations.

#### **METHODS:**

We performed a qualitative review of HTAs performed worldwide for a rare disease indication. The therapy has been approved for more than a decade, providing a unique opportunity to scan the landscape for the assessments and re-assessments done throughout the period 2001-2015. A broad definition for HTA sources was applied. The aim was to understand key findings related to evidence frameworks and assessment criteria used, and the HTA/ payer agency requirements and preferences for additional evidence. Additionally, the review provided an opportunity to understand commonalities and differences among the HTAs in their approaches and criteria, and recommendations for decision-making.

#### **RESULTS:**

We identified 38 HTAs performed globally, including 19 completed by national/ regional agencies. There were some differences and similarities among HTAs in the use of evidence sources, but there was a clear focus on randomized-controlled trials over single-arm and observational studies. These latter sources often provide the only evidence available for some requested data (i.e., subpopulations and long-term outcomes); however their use was highly variable in the evaluations. In some cases, data from multiple products were merged to perform analyses for a therapeutic class. The majority of HTA included also data on economic analyses focusing on cost-effectiveness and budget impact.

#### **CONCLUSIONS:**

HTA in rare diseases is an important and active policy topic globally, especially so because of the increasing number of therapies in these areas of substantial unmet medical need. We found commonalities and differences among the agencies in their criteria and assessments, which illustrate the complexity of evaluating rare disease therapies.

The findings indicate that common and consistent criteria of assessment would be beneficial. This can help industry generate evidence that is most helpful to the stakeholders, ultimately leading to efficient development and assessment of these therapies. Most importantly, this would result in faster access to life-changing therapies for patients.

---

## **Poster 101A International Variability Of Factors Influencing The Reimbursement Decisions In Asia Pacific: A Case Study Of Targeted Oncology Medicines**

#### **DESCRIPTION:**

Lack of studies to determine factors influencing the reimbursement decisions in Asia Pacific. We examined factors by selecting 15 high unmet need and costly medicines for 6 countries. To determine the factor, we applied systematic review and regression for statistical analysis. We found that common factors that have been used in many countries are clinical evidence, cost-effectiveness, and budget impact. However, key challenges are transparency and transferability of the reimbursement results.

#### **PRESENTING AUTHOR:**

Dr. Nathorn Chaiyakunapruk, Monash University, Malaysia

#### **AUTHORS:**

Nathorn Chaiyakunapruk, Rosarin Sruamsiri, Jittrakul Leartsakulpanitch

#### **BACKGROUND AND OBJECTIVES:**

Previous studies showed different factors included in the reimbursement decisions with varied influence on the final decision. However no specific study was done in Asia Pacific where the health technology assessment has been evolving and this

makes this region interesting on how their HTA development in different mechanisms results in the coverage decisions and policy implication.

#### **METHODS:**

The targeted oncology drugs including Trastuzumab, Pertuzumab, Lapatinib, Everolimus, Bevacizumab, Erlotinib, Afatinib, Cetuximab, Gefitinib, Crizotinib, Rituximab, Ipilimumab, Vemurafenib, Dabrafenib, Ofatumumab, were purposively chose as case study to reflect the high unmet need and costly treatment. We selected 6 countries with different reimbursement systems including fully reimbursement with health economics based (Korea, Australia) and relative effectiveness-based (Japan, Taiwan), and semi-reimbursement (Thailand, Malaysia). A systematic review of publicly available literature and government reports was undertaken from interception until September 2015. Descriptive statistics were used to describe the reimbursement and factors reported affecting the decision. The hierarchical logistic regression was further used to examine the relationship of different factors and decision taken.

#### **RESULTS:**

We found different reimbursement status of all chosen 15 oncology drugs. There are only in Korea and Australia where all drugs are covered. Factors affecting the decision are relatively consistent in same country group especially in HE-based countries where the cost-effectiveness is one major factor driving decision, however, the explicit willingness to pay threshold was not clearly specified. The relative effectiveness was mainly used in Taiwan and Japan while in Thailand and Malaysia both factors are used in combination. There was no statistically difference among varied system on role of main factors on reimbursement decisions.

#### **CONCLUSIONS:**

Reimbursement decisions for newly targeted cancer medicines vary among countries due to

many factors. A combination of clinical evidence, cost-effectiveness, and budget impact analysis have been used in many countries. There remains unclear evidence on the role of individual factor in the same products across countries and across products in same countries. Key challenges of making decision are transparency and transferability of the reimbursement results. Documented evidence including process and result is needed to improve transparency and also create knowledge for HTA advancement.

---

### **Poster 102A** Effects Of China's Essential Medicine System On Improving Rational Drug Use In Village Clinics: An Empirical Study In Shandong Province, China

#### **DESCRIPTION:**

A retrospective comparative study was performed among village clinics in Shandong province after the implementation of China's Essential Medicine System (NEMS), aimed to evaluate effectiveness on improving rational drug use in village clinics. According to the results, the NEMS improved the rationality of drug use in rural primary hospitals of China.

#### **PRESENTING AUTHOR:**

Zhongming Chen, Weifang Medical University, China

#### **AUTHORS:**

Zhongming Chen, Mengqi Tang, Haihong Cao, Muye Ma, Hui Tan, Hongwei Guo, Kui Sun, Dongmei Huang, Wenqiang Yin

#### **BACKGROUND AND OBJECTIVES:**

Irrational use of drugs in primary health facilities is a common and serious problem of China, especially

in rural. The National Essential Medicine System (NEMS) was implemented to protect patients against insecurity and irrational use of drugs. At the same time several measures had been taken to strengthen the trainings and inspections of doctors about rational drug use. This study aims to assess the effect of NEMS on rational drug use at village clinic.

**METHODS:**

A retrospective comparative study was performed among village clinics in 2012. A total of 1724 prescriptions from 45 village clinics in 2009 and 2012 were analyzed in this study. Among them, 808 prescriptions belong to 2009, 916 prescriptions belong to 2012. Drug use indicators were determined to comparing the rationality of drug use. Then descriptive analysis for the drug use was presented by means and proportion. Student's t-test and chi-square test were performed respective to compare the means and the proportion between the two periods.

**RESULTS:**

Average number of drugs/prescription (ANDPP) decreased from 4.3 to 3.5 ( $p<0.01$ ). Percentage of drugs prescribed from the essential drug list (PED) increased from 62.05% to 69.11% ( $p<0.01$ ). Percentage of prescriptions containing antibiotics (PPA) decreased from 67.8% to 59.8% ( $p<0.01$ ). Percentage of prescriptions containing injections (PPI) decreased from 61.1% to 51.7% ( $p<0.01$ ). Average medical charges for per prescription (AMCP) decreased from 33.51 to 17.16 ( $p<0.01$ ). For elderly patients, ANDPP decreased from 4.24 to 3.54 ( $p<0.01$ ). PPI decreased from 68.9% to 48.7% ( $p<0.01$ ). AMCP decreased from 33.51 to 19.67 ( $p<0.01$ ). For chronic patients, PPI decreased from 57.9% to 33.3% ( $p<0.01$ ). AMCP decreased from 50.88 to 28.58 ( $p<0.01$ ).

**CONCLUSIONS:**

The NEMS improved the rationality of drug use in rural primary hospital of China. But the polypharmacy and the overuse of antibiotics and

injections remain common. Measures should be taken to optimizing the NEMS and improving the rationality of drug use of village clinic doctors and patients.

**Poster 103A Defensive Retreat And Function Differentiation - An Empirical Study On Operation Models Of Township Health Centers Under The New Health Care**

**DESCRIPTION:**

As the result of the New Health Care System Reform of China, the township health centers adopted a defensive retreat operating strategy, which causes function differentiation tendency. These are not suitable with the orientation of the policy of enhancing grassroots construction.

**PRESENTING AUTHOR:**

Zhongming Chen, Weifang Medical University, China

**AUTHORS:**

Wenqiang Yin, Dongmei Huang, Hongwei Guo, Qianqian Yu, Yan Wei, Xin Ma

**BACKGROUND AND OBJECTIVES:**

Chinese government implemented the New Health Care System Reform aims to reduce economic burden of patients. In this study, we analyzed the Operation Models of Township Health Centers under the New Health Care System Reform systematically and gave proposal to improve the role of Township Health Centers.

**METHODS:**

Principal-Agent Theory, combining with the structure of National Health System in rural grassroots, was used to study the business strategy

and function differentiation of Township Health Centers under the New Health Care System Reform theoretical. Then quantitative and qualitative analytical methods were used to validate the theoretical models.

**RESULTS:**

Principal-Agent Relation based Authoritarian political regime exists between county government and Township Health Centers. According principal-agent theory?under the compensation model and actual earnings of medical health service and public health services, The Township Health Centers adopt Defensive Retreat strategy, and Function Differentiation generates four behavior models which include 'medical health service centered, balance public health services model', 'medical health service centered, public health services retreat model'; 'public health services centered, medical service retreat model'; 'medical service and public health services maintained model'.

**CONCLUSIONS:**

The Township Health Centers adopt defensive retreat operating strategy, which causes function differentiation tendency. These are not suitable with the orientation of the policy of enhancing grassroots construction. Furthermore it perhaps will induce new Health inequality. To improve the Township Health Centers' role, measures should be taken, such as establish division of labor and coordination mechanism among the Township Health Centers, the sharing ratio of the public health services' compensation should adjust with the local economic development, accelerate the policy promotion, introduce supervisory mechanism, and stimulate the residents' participation.

.....

## Poster 104A The Efficacy Of Fluoride Toothpastes To Reduce Dental Caries In Preschool Children.

**DESCRIPTION:**

Worldwide, primary tooth decay is a public health problem that can negatively affect children's quality of life. Regular exposure to fluoride could help decrease children's caries levels. This study evaluates the scientific evidence on the efficacy of fluoride toothpastes to reduce dental caries in preschool children and how the Brazilian government is disseminating this evidence to the population.

**PRESENTING AUTHOR:**

Dr. Gisele Alexandre, UFF - Universidade Federal Fluminensense, Brazil

**AUTHORS:**

Gisele Alexandre, Patricia de Soarez, Branca Vieira

**BACKGROUND AND OBJECTIVES:**

Worldwide, primary tooth decay is still a public health problem that can lead to pain and tooth loss. WHO suggests that 80% of 5-year old children should be caries free or have less than 1 decayed, missing or filled tooth (dmft) in 2010. According to the latest national report on Brazilian's Oral Health (2010), dental caries prevalence in 5-year olds is 53% and their mean dmft is 2,4. The National Oral Health Policy Guidelines ensure the articulation of collective promotion activities and prevention with treatment and health recovery for the assisted population, and the use of toothpaste is considered a collective practice of obtaining fluoride. However, for preschool children there is a great resistance by decision makers, health professionals and society in the recommendation or use of Fluoride toothpastes with 1000 ppm or more. The rationale is that this group ends up swallowing about 50% of toothpaste and there are studies that correlate the use of Fluoride toothpaste with the risk of dental

fluorosis in permanent teeth. This study evaluates the scientific evidence on the efficacy of Fluoride toothpastes to reduce dental caries in preschool children and how the Brazilian government is disseminating this evidence to the population.

#### **METHODS:**

Fluoridated toothpastes are already in wide circulation, thus we have developed a technical and scientific report to summarize the information on its efficacy available in Systematic Reviews of Controlled Trials published in the last 10 years. Databases searched were Cochrane Library, Medline, CRD, LILACS and NHS Evidence in 2015. The target population was preschool children. The intervention evaluated was the use of Fluoride toothpaste with 1,000 ppm or more compared to Fluoride toothpaste with less than 1,000 ppm. The outcome was dental caries incidence. The included studies were assessed using the Grading of Recommendation, Assessment, Development and Evaluation (GRADE).

#### **RESULTS:**

It was found 79 studies. Twenty-two duplicates and 39 that did not meet inclusion criteria were excluded. There were included 2 Systematic Reviews, assessed for evidence quality and classified according to methodological characteristics using GRADE approach. The quality of evidence produced by the studies was classified as moderate when assessed through the Cochrane tool. Their recommendations were classified as strong in favor of technology because the methodology met the criteria for classification GRADE. The studies had good methodological quality and were classified as having produced moderate quality of evidence and strong recommendation for the use of the technology studied.

#### **CONCLUSIONS:**

Results pointed to strong recommendation for 1,000 ppm or more Fluoride toothpaste use in preschool children to prevent tooth decay.

There is confidence that the benefits of using it outweigh the possible risks of fluorosis in permanent dentition. It is necessary to spread the results to stakeholders - health professionals, policy makers and society. The results reinforce the recommendations of the Fluoride Guide of the Ministry of Health. National campaigns should guide the parents about benefits of rational use of 1,000 ppm or more Fluoride toothpaste. It is vital to conduct Economic evaluation studies on the technology for this population.

#### **REFERENCES:**

ANVISA, 2005. Agência Nacional de Vigilância em Saúde. Disponível em: <http://portal.anvisa.gov.br>, acessado em 19/06/2013.

ATKINS, D et al. Systems for grading the quality of evidence and the strength of recommendations I: Critical appraisal of existing approaches.

BMC Health Services Research. 2004; 4:38.

Brasil. MS.SAS.DAB.Guia de recomendações para o uso de fluoretos no Brasil / Ministério da Saúde, Secretaria de Atenção à Saúde, Departamento de Atenção Básica.

Brasília : Ministério da Saúde, 2009; 56 p.

Brasil. MS.SCTIE.DCT. Diretrizes Metodológicas: elaboração de pareceres técnico-científicos - 4 ed - Brasília : Ministério da Saúde, 2014; 80 p.

---

## **Poster 105A Assessing The Incremental Cost Of TAVR And SAVR Complications In Contemporary, Real-World Clinical Practice**

#### **DESCRIPTION:**

The purpose of this study was to assess the incremental hospital resource consumption associated with complications in Medicare

beneficiaries receiving TAVR and SAVR in a contemporary, real-world setting.

**PRESENTING AUTHOR:**

Seth Clancy, Edwards Lifesciences, United States

**AUTHORS:**

Seth Clancy, Dhara Intwala

**BACKGROUND AND OBJECTIVES:**

The hospital costs associated aortic valve replacement via transcatheter (TAVR) or surgical (SAVR) approaches are driven, in part, by complications during and after the procedure. The purpose of this study was to assess the incremental hospital resource consumption associated with complications in Medicare beneficiaries receiving TAVR and SAVR in a contemporary, real-world setting.

**METHODS:**

Using the Medicare Provider Analysis and Review File (MedPAR), we retrospectively analyzed 129,606 Medicare beneficiaries receiving TAVR (n=24,455) and SAVR (n=105,151) in the United States during the 2012-2014 fiscal years. Hospital costs were estimated from charges using the hospital's overall cost-to-charge ratio. Complications were identified using appropriate ICD-9-CM codes. The incremental hospital resource consumption (cost and length of stay) was estimated for patients experiencing any of the selected complications during the index TAVR or SAVR hospitalization. Both observed and adjusted incremental cost estimates were generated. Multivariate regression models were used for the adjusted cost estimates controlling for patient demographics, comorbidities and complications.

**RESULTS:**

The mean index hospitalization cost for TAVR and SAVR procedures with no complications was \$48,820 and \$41,919, respectively. At least one of the selected complications occurred in

38% of TAVR patients and 40% of SAVR patients. The incremental cost of complications was \$18,752 and \$24,121 for TAVR and SAVR patients, respectively. The incremental hospital length of stay in complicated cases was +4.5 days for TAVR procedures and +5.7 days for SAVR procedures. In both cohorts, the most common complication was acute kidney failure, occurring in 14% of TAVR cases and 18% of SAVR cases. The unadjusted incremental cost of acute kidney failure was \$20,304 for TAVR and \$23,203 for SAVR. The regression adjusted incremental cost of acute kidney failure was \$9,150 in TAVR cases (p<0.001) and \$7,576 in SAVR cases (p<0.001). Table 1 reports the incremental cost and length of stay for each of the selected complications.

**CONCLUSIONS:**

Complications substantially increase resource use after TAVR and SAVR procedures. The avoidance of complications should improve the cost-effectiveness of both valve replacement approaches. These findings may serve as an important benchmark to assist in prioritizing quality improvement initiatives and assessing the potential cost savings of reduced complications through technological or device related improvements.

---

**Poster 106A Data Governance For Real-World Evidence: Cross-Country Differences And Recommendations For A Governance Framework**

**DESCRIPTION:**

There are significant differences across countries in how health data are collected and used. With insights generated from eight country case studies, we develop an illustrative framework of a top-performing data governance model. We thereby provide recommendations on the core principles that should govern how real-world data (RWD)

is accessed or generated, and used credibly to generate real-world evidence (RWE).

### **PRESENTING AUTHOR:**

Dr. Amanda Cole, Office of Health Economics, United Kingdom

### **AUTHORS:**

Amanda Cole, Louis Garrison, Jorge Mestre-Ferrandiz, Adrian Towse

### **BACKGROUND AND OBJECTIVES:**

Real-world data (RWD) is information collected outside of an experimental clinical trial setting, and is a term that is becoming increasingly widespread in health economics and health services research. The environment for collecting RWD to support decision-making is changing. Increasingly, regulators are monitoring benefits and risks throughout a medicine's lifecycle; RWD is essential to support this. Payers are similarly being challenged to conduct earlier value assessments under greater uncertainty, and re-visiting assessments as further RWD is collected. Moreover, managed entry agreements and performance-based payments require data collection alongside clinical practice. These themes are central to many emerging health system policies that aim to make treatment access more sensitive to the evolving evidence base. For these purposes, RWD must become real-world evidence (RWE) by a series of activities that transform raw data into analysis and results. Robust and appropriate data governance, applied at each step, are essential to realising the value of RWD and its derivative RWE. In this study we analyse the current data governance arrangements in eight countries, and propose an aspirational governance framework.

### **METHODS:**

We investigate the core governance arrangements for how RWD is accessed or generated, and used credibly to provide evidence, in eight countries: the UK, France, Italy, Sweden, Germany, the Netherlands, Australia, and the U.S. We used a

structured pro-forma to assess: core legislation for the collection and use of (both routinely-collected and de novo) data, data linkage opportunities, the data access environment, data use, and imminent changes to this landscape. By identifying strengths and weaknesses, we develop an illustrative framework of a top-performing data governance model to support a favourable environment for RWE development and use.

### **RESULTS:**

Appropriate and facilitative information governance, along with public trust, is key to realising the benefits of scientific research. Patient consent has a central role, alongside transparent mechanisms for data linkage, anonymisation, and authorisation. For example, where data collection is on a routine basis across a large patient cohort, an opt-out system of consent may be appropriate. Current governance arrangements compare more/less favourably against our recommendations depending on the country and criteria. For example, in Italy data collection is strong but access is poor. National data linkage networks, such as that established in Australia, offer huge potential. However, transparency is essential: the UK and Netherlands provide examples of public trust breaking down, thus impeding RWD programmes. Sweden and the U.S. perform well across our proposed framework; Germany and France are more restrictive.

### **CONCLUSIONS:**

Restrictive data governance impedes the contribution of RWD and thus RWE to improving the quality and efficiency of healthcare. The core objective is to balance public and privacy interests: in advancing our understanding of medical treatments through evaluation and research, on the one hand, and protecting individuals' privacy, on the other. Countries have different approaches, and in most cases the legal framework is not completely prescriptive: this makes a clear governance framework essential. We propose recommendations to work towards international standards for a more facilitative environment for the transformation of RWD into RWE.

---

## Poster 107A Assessment Of Pneumococcal Vaccines For The Immunization Of Elderly In Germany

### DESCRIPTION:

To identify the optimal vaccination strategy for the prevention of pneumococcal diseases in elderly in Germany, a comprehensive assessment of a 13-valent pneumococcal conjugate vaccine and a 23-valent pneumococcal polysaccharide vaccine was conducted. The analysis included a meta-analysis on vaccine efficacy and a dynamic model of pneumococcal carriage to calculate the population-level impact of vaccination.

### PRESENTING AUTHOR:

Alexander Kuhlmann, Center for Health Economics Research Hannover (CHERH), Germany

### AUTHORS:

Alexander Kuhlmann, Marina Treskova, Bernd Ultsch, Felix Weidemann, Ole Wichmann, Gerd Falkenhorst, J.-Matthias Graf von der Schulenburg

### BACKGROUND AND OBJECTIVES:

In Germany, vaccination of infants with a 13-valent pneumococcal conjugate vaccine (PCV13) and of individuals  $\geq 60$  years with a 23-valent pneumococcal polysaccharide vaccine (PPSV23) is recommended to prevent pneumococcal diseases. Recently, PCV13 was also approved for individuals  $\geq 50$  years. The study assesses the epidemiologic effects and the cost-effectiveness of three vaccination strategies targeting adults  $\geq 60$  years in Germany: vaccination with PCV13, vaccination with PPSV23, and sequential-vaccination (PCV13+PPSV23).

### METHODS:

A dynamic transmission model of pneumococcal

carriage was developed to capture the epidemiological impact of childhood PCV13-vaccination (herd and serotype replacement effects) on incidence and serotype mix among adults. The model compartments were further stratified by age- and pneumococcal serotype-groups. A meta-analysis on vaccine effectiveness was conducted. Other model parameters were either retrieved from the literature or obtained by fitting against local incidence data. Epidemiologic and health economic outcomes were calculated for four (epidemiologic/effectiveness) scenarios. The robustness of the model results was assessed through sensitivity analyses regarding uncertain input data.

### RESULTS:

The sequential vaccination of 60 years old people in the period 2016-2020 could prevent 50-560 additional hospitalizations and 10-70 additional deaths compared with PPSV23 only or 540-1,820 additional hospitalizations and 90-220 additional deaths due to pneumococcal diseases compared with PCV13 only. The ICER of the sequential vaccination compared to PPSV23 ranges from 132,000- 561,000 per QALY gained. PPSV23 vaccination vs. no vaccination resulted in additional costs of 14,000- 48,000 per QALY gained. Immunization with PCV13 was dominated by PPSV23. The main reason for this domination of PCV13 was a sharp decline in pneumococcal diseases caused by PCV13-serotypes among adults as an indirect result of the infant PCV13-vaccination.

### CONCLUSIONS:

The sequential vaccination was the most effective vaccination strategy but incurred substantial additional costs per QALY gained. From the health economic perspective, PPSV23 would be the preferred vaccine to be used for prevention of pneumococcal diseases in adults in Germany.

---

## Poster 108A Clinical Effectiveness Of Immunosuppressive Therapy For Renal Transplantation In Children And Adolescents: A Systematic Review

### DESCRIPTION:

The clinical effectiveness of induction and maintenance therapy in children and adolescents was systematically reviewed. Three RCTs were identified, two which evaluated induction therapy (basiliximab vs. placebo/no induction) and one which evaluated maintenance therapy (immediate-release tacrolimus vs. ciclosporin). From the paucity of evidence available, immediate-release tacrolimus appeared to offer superior effectiveness over ciclosporin, however, more research is needed.

### PRESENTING AUTHOR:

Dr. Jo Varley-Campbell, University of Exeter, United Kingdom

### AUTHORS:

Jo Varley-Campbell, Marcela Haasova, Tristan Snowsill, Tracey Jones-Hughes, Louise Crathorne, Chris Cooper, Ruben Mujica-Mota, Helen Coelho, Jenny Lowe, Jan Dudley, Stephen Marks, Chris Hyde, Mary Bond, Rob Anderson

### BACKGROUND AND OBJECTIVES:

End stage kidney disease is an irreversible decline in kidney function, requiring renal replacement therapy (renal transplantation, haemodialysis, or peritoneal dialysis). The gold standard therapy is renal transplantation utilising induction and maintenance immunosuppressive therapy to reduce the risk of renal graft rejection and loss. We systematically reviewed the clinical effectiveness evidence for basiliximab and rabbit anti-human thymocyte immunoglobulin as induction therapy

and immediate-release tacrolimus, prolonged-release tacrolimus, belatacept, mycophenolate mofetil, mycophenolate sodium, sirolimus, and everolimus as maintenance therapy in children and adolescents undergoing renal transplantation. This systematic review was commissioned on behalf of the National Institute for Health and Care Excellence (NICE) as part of a larger project updating the NICE guidance (TA99).

### METHODS:

Searches were conducted to 7th January 2015 in Medline (OVID), Embase (OVID), CENTRAL (Wiley) and Web of Science (ISI), CDSR, DARE and HTA (The Cochrane Library via Wiley) and HMIC (OVID). Searches returned 5,079 unique titles and abstracts that were independently screened against predefined inclusion criteria, subsequent full texts of identified studies were also screened. Included studies were extracted and quality appraised. Data were tabulated, discussed narratively and meta-analysed (where appropriate).

### RESULTS:

Three RCTs were included: two studies evaluating basiliximab and one study evaluating immediate-release tacrolimus. No statistically significant differences in key outcomes were found between basiliximab and their comparators (placebo/no induction). Renal graft function was significantly better ( $p < 0.01$ ) and fewer biopsy-proven acute rejections ( $OR = 0.41$ ;  $95\%CI: 0.16$  to  $1.00$ ) were found for immediate-release tacrolimus when compared to ciclosporin. However, all three studies based their power calculation on biopsy proven acute rejection (with outcomes such as mortality, graft loss, and graft function being potentially underpowered). In addition the induction studies failed to achieve their targeted power.

### CONCLUSIONS:

There is a paucity of high-quality randomised control trial evidence available assessing the clinical effectiveness of immunosuppressive therapy for kidney transplantation in the child and

adolescent population. From the evidence that was available, immediate-release tacrolimus appeared to offer superior effectiveness over ciclosporin. Recommendations for further research include an analysis of the NHS Blood and Transplant UK Transplant registry for comparative effectiveness evidence and a systematic review of controlled (non-randomised) clinical trials.

---

## Poster 109A Cost-Effectiveness Of Sequential Use Of ELF Test/ARFI And ELF Test Alone Versus Biopsy To Assess Liver Fibrosis In Chronic Alcoholic Liver Disease (ALD)

### DESCRIPTION:

Non-invasive methods to diagnose liver fibrosis are being considered as an alternative to liver biopsy. We estimated the cost-effectiveness of sequential use of enhanced liver fibrosis (ELF) test/ acoustic radiation force impulse (ARFI) and ELF test alone compared to biopsy to assess liver fibrosis in alcoholic liver disease (ALD) patients from the perspective of a hospital in Spain. The incremental cost-effectiveness ratios (ICERs) were respectively 280\$ and 189\$ per quality-adjusted life year.

### PRESENTING AUTHOR:

Dr. Marcelo Soto, Hospital Clinic Barcelona, Spain

### AUTHORS:

Marcelo Soto, Laura Sampietro-Colom, Luis Lasalvia, Aurea Mira, Wladimiro Jiménez, Miquel Navasa

### BACKGROUND AND OBJECTIVES:

Non-invasive diagnosis of liver fibrosis (LF) has rapidly evolved in recent years. Though biopsy is used to stage most cases of liver disease, it is well known that this procedure has several limitations.

First, sampling errors can occur, especially when smaller sized biopsies are analysed. In addition, histological examination is prone to intra- and inter-observer variation, which may occur even when widely validated systems are used to score liver damage. Finally, liver biopsy is an invasive procedure with associated morbidity and mortality. Most non-invasive methods have shown good diagnostic accuracy to detect LF. In addition, non-invasive tests can be repeated over time, and in cases of indeterminate results two or more methods can be combined. The sequential use of ELF test (as a blood test for patients with suspected liver disease), and ARFI (as a specific tool to confirm the presence and severity of liver disease) has been proposed. However, health and economic implications

### METHODS:

A Markov model simulating LF progression in ALD was developed to estimate health outcomes and costs during lifetime for a cohort of 40-year-old men with abnormal levels of transaminases. The analysis was performed from the perspective of a University Hospital in Barcelona. Clinical data were obtained from published literature. Costs were sourced from administrative databases of the Hospital. Three different testing alternatives were studied: a single liver biopsy; annual ELF test followed by ARFI if ELF test is positive; annual ELF test without ARFI as a confirmation test. Deterministic and probabilistic sensitivity analyses were carried out to examine the robustness of the results.

### RESULTS:

Annual sequential ELF test/ARFI and annual ELF test alone increased the number of quality-adjusted life years (QALYs) relative to biopsy by 1.33 and 2.39, respectively. Incremental costs were 372\$ and 452\$, respectively. The cost-effectiveness ratios (ICERs) for sequential ELF test/ARFI and ELF test alone were respectively 280\$ and 189\$ per QALY. The sensitivity analysis showed that sequential ELF test/ARFI dominated biopsy when the assumed cost of detoxification therapy was low (173\$ per patient)

and when individuals diagnosed with LF had a high probability of abstinence (43%) or a low probability of relapse (17%) within a year. The remaining parameters of the model had a minor impact

### **CONCLUSIONS:**

Testing for liver fibrosis annually with non-invasive methods resulted in a substantial reduction in the number of events (cirrhosis, hepatocellular carcinoma and fibrosis-related death) and a significant increase in QALYs for HCV patients, compared with a single liver biopsy. In particular, the low incremental cost associated with ELF test alone and its large health gains make it a highly cost-effective option. The present results were obtained with limited evidence on the accuracy of ELF test and ARFI in ALD patients. Additional studies are required to address these limitations. (NOTE: The ELF test is not available for sale in the U.S.)

.....

## **Poster 110A Missing The Value Of Herd Immunity In Cost-Effectiveness Analyses Of Vaccines. A Systematic Review.**

### **DESCRIPTION:**

Exclusion of herd immunity in economic evaluation is problematic because we are not capturing the full value of vaccines and this represents a wasted opportunity. The objective of this review is to identify current economic evaluations of vaccines where the model reflects herd immunity effects and to assess which model properties have been used.

### **PRESENTING AUTHOR:**

Tarang Sharma, Nordic Cochrane Centre, Denmark

### **AUTHORS:**

Liv Solvår Nymark, Tarang Sharma, Ulla Griffith

### **BACKGROUND AND OBJECTIVES:**

Cost-effectiveness is increasingly considered when deciding whether or not to increase vaccination coverage. It is usually recommended that cost-effectiveness analyses (CEAs) of vaccines account for the indirect effects of herd immunity. However, we have limited knowledge of economic evaluations of vaccines that routinely consider these effects. This is problematic because we are not capturing the full value of vaccines and this represents a wasted opportunity. It is quite clear that improving vaccine uptake is costly and takes extra resource but there are also benefits to increased levels of coverage. The optimal rate of coverage occurs where the marginal benefit of extending coverage is equal to the marginal cost of extending coverage. Exclusion of herd immunity in economic evaluation will lead to the marginal benefit being underestimated. Including the benefits of herd immunity effects in economic evaluation would free up resources that may be used to increase vaccination coverage.

### **METHODS:**

Kim and Goldie (2008) conducted a systematic review from 1 January 1976 - 31 May 2007 detailing the modelling approaches used in CEAs of vaccination programmes. We will adopt their search strategy and search databases EMBASE and MEDLINE from 1 June 2007- present for CEAs for vaccines. Duplicates will be removed. Two reviewers will independently screen abstracts for inclusion of CEAs. Relevant full-text articles will be retrieved and reviewed. Included studies will be reviewed for inclusion of herd immunity. Disagreements will be resolved with a third reviewer. Kim & Goldie identified 275 CEAs. These were screened for inclusion of herd immunity.

### **RESULTS:**

The results are forthcoming and will include the number of retrieved articles, the number of excluded duplicates, the number of titles and abstracts screened include a CEAs and the number of studies which qualify upon review of full-text articles. A breakdown by number of vaccine type, percent of studies performed for monovalent

vaccines and percent of studies conducted for multivalent vaccines will be presented. The initial result of the screening of the 275 full-text CEAs articles identified by Kim & Goldie (2008) from 1976-2007 shows that 38 articles considered herd immunity.

### CONCLUSIONS:

The preliminary results demonstrate that 38/275 of the eligible studies in the Kim & Goldie's review from 1976-2007 accounted for the affects arising from indirect effects of herd immunity. This finding implies that many studies may be underestimating the marginal benefit of vaccines. This reinforces the need to improve cost-effectiveness analyses for vaccination programmes. The full results of the systematic review conducted from 2007-2015 will be presented and discussed at the conference.

### REFERENCES:

Kim, S. Y., & Goldie, S. J. (2008). Cost-effectiveness analyses of vaccination programmes. *Pharmacoeconomics*, 26(3), 191-215.

---

## Poster 111A Hyperbaric Oxygen Therapy As Adjuvant Treatment Of Diabetic Foot: A Systematic Review

### DESCRIPTION:

Hyperbaric oxygen therapy (HBO) has been used for the treatment of diabetic foot, which has been one of the main leading causes of prolonged hospitalisations worldwide. This study evaluates whether HBO as adjuvant treatment for diabetic foot ulcers improves complete healing and amputation rates. The SRs results showed inconsistencies regarding efficacy outcomes, as well as no description of subgroups that would be the highest benefited by HBO use. Methodologic biases and high heterogeneity between studies compromise a clearly evidence based decision.

### PRESENTING AUTHOR:

Dr. Leila Moreira, Hospital de Clínicas de Porto Alegre-UFRGS, Brazil

### AUTHORS:

Fernanda d A. Rodrigues, Maria Angélica P. Ferreira , Leila B. Moreira

### BACKGROUND AND OBJECTIVES:

The hyperbaric oxygen therapy (HBO) has been used for the treatment of diabetic foot, which has been one of the main leading causes of prolonged hospitalisations worldwide.<sup>1, 2</sup> This treatment aims to improve efficacy with increasing in complete healing rates, as well as, decreasing of major complications, such as amputations.<sup>3</sup> Consequently, it is expected to reduce the health services expenditure, in addition to the social impact. However, its utility remained controversial. This study evaluates whether HBO as adjuvant treatment for diabetic foot ulcers improves complete healing and amputation rates.

### METHODS:

This systematic review included a combination of the search terms 'hyperbaric oxygen', 'diabetic foot' e 'wound healing'. Medline (Pubmed), Cochrane Central Register of Controlled Trials, Embase, Lilacs and Centre for Reviews and Dissemination databases were searched to find relevant articles published. Other sources including guidelines, white papers from government agencies, mini-HTAs and visits to a HBO services were also performed. Inclusion criteria: systematic reviews (SR), meta-analysis and randomized clinical trials (RCT); HBO as adjunctive treatment of diabetic foot ulcers compared with sham procedure added to clinical and surgical conventional treatments. Two investigators independently screened the search results, assessed trial quality (GRADE) and extracted data.

### RESULTS:

A total of 155 abstracts were screened, and five

systematic reviews fulfilled the inclusion criteria. The SR with higher methodologic quality observed benefits with the use of HBO after 6 weeks (RR: 2.35; IC95% 1.19-4.62). The effect was not maintained over time (RR: 9.53; IC95% 0.44-207.7). No association was found with major amputations rates, (RR: 0.36; IC95% 0.11-1.18). The SRs results showed inconsistencies regarding efficacy outcomes, as well as, no description of subgroups that would be the highest benefited by the HBO use. Methodologic biases and high heterogeneity between studies compromise a clearly evidence based decision.

### CONCLUSIONS:

According to our study, evidences of the technology's benefits regarding the outcomes analyzed were considered of low quality. The magnitude of the effect, if any, is probably small. There is uncertainty about the HBO safety and, also, its cost-effectiveness has not yet been established. It is not possible, thus, to support a favorable recommendation of the technology. There is a need for better designed studies to analyze the effectiveness of HBO relevant outcomes more accurately.

### REFERENCES:

1. BENNETT, M. H. The evidence basis of diving and hyperbaric medicine - a synthesis of the high level clinical evidence with meta-analysis. Prince of Wales Clinical School, University of New South Wales, Sydney, 2006.
2. Reiber GE, LeMaster JW. Epidemiology and economic impact of foot ulcers. In: Boulton AJM, Cavanagh P, Rayman G (eds). The Foot in Diabetes 4th edition. John Wiley and Sons (Chichester). 2006; 1:1-16.
3. Löndahl M. Hyperbaric oxygen therapy as adjunctive treatment for diabetic foot ulcers. Int J Low Extrem Wounds. 2013 Jun;12(2):152-7.

## Poster 112A Using Health Technology Assessment To Design And Evaluate Clinical Pathways: The Essential HTA Template For Clinical Pathways

### DESCRIPTION:

The paper describes an HTA report template designed for the assessment and the construction of clinical pathways. The template derives from a critical review of national and international best practices and the cooperation of difference competences.

### PRESENTING AUTHOR:

Dr. Silvia Coretti, Università Cattolica del Sacro Cuore, Italy

### AUTHORS:

Cicchetti A, Coretti S, Fiore A

### BACKGROUND AND OBJECTIVES:

The widespread culture of patient centered care and the increasing attention to the rational allocation of healthcare resources draws the attention of many scholars on healthcare pathway design as a tool to optimize the integration of care and improve the quality of assistance. Health Technology Assessment (HTA) proved to be an evaluable tool for the assessment of health technologies, but even the best-established methods may be insufficient when assessing clinical pathways, which may be considered as a set of technologies. The aim of this study is to build an analytic tool to design and assess clinical pathways.

### METHODS:

The Essential HTA template is being developed starting by the EuNetHTA Core Model 2.1 and based on a review of previous national and international experiences. During its development, the template is being tested as a tool to develop a clinical pathway for patients with head and neck cancer.

Such a process includes a strict cooperation between health economists, clinical engineers and physicians, coherent with the logic underlying HTA.

**RESULTS:**

In its preliminary structure, the Essential HTA template is made up of 7 chapters: 1) Clinical problem and current management of disease, 2) characteristics of the technology, 3) safety, 4) efficacy, 5) economic domain, 6) organizational domain, 7) ELS domain. The chapters 1) and 7) are discussed only once and refer to the whole pathway, while chapters 2)-6) are discussed separately for diagnosis, treatment and follow up phases and they involve a set of issues relevant to the specific step of the clinical pathway. For each domain the template indicates the data sources and the type of analysis. The template can be utilized to assess a clinical partway or to show evidence concerning different management strategies systematically.

**CONCLUSIONS:**

This pilot experience allowed to build up an evidence- based template for the technology assessment of clinical pathways. It is being improved gradually thanks to the feedback of relevant stakeholders and can be considered as a step forward towards the harmonization of methods.

.....

## Poster 113A Social Demographic Characteristics And Direct Medical Costs For Patients With Fecal Incontinence In Korea: Big Data Analysis From The National Health Insurance Claims Dataset

**DESCRIPTION:**

This study is to figure out the real status with Claim

data such as prevalence, medical cost, and patients' characteristics for fecal incontinence in Korea using the National Health Insurance Claim Dataset.

**PRESENTING AUTHOR:**

MinJeong Kwak, Medtronic Korea Ltd., Korea

**AUTHORS:**

MinJeong Kwak

**BACKGROUND AND OBJECTIVES:**

Fecal incontinence (FI) is defined as the involuntary loss of solid or liquid feces that is a social or hygienic problem. Fecal incontinence is a major burden to both patients and society. Patients are often significantly embarrassed as a result of accidents or soiling of clothing. Unfortunately, many of these patients suffer in silence as they are afraid even to discuss it with their own family or physician. Patients suffer from the effects incontinence has on their lifestyle in avoidance of certain social activities, changes in employment, and the strain placed on personal relationships. According to Netherlands study, annual cost to health care system, society in general and patients and families is \$2,380 per patient. The 33% of the total cost consisted of health care visits and drugs, and 16% was dietary changes due to the purchase of absorbent and protective material. The 18% of the total cost of FI was due to productivity loss and absence from work. The research is to analyze social demographic characteristics and health service use nature of Fecal Incontinence in Korea by using Korean National Health Insurance Claims dataset (HIRA-NPS 2013), which is one of the secondary sources of health and medical treatment provided by reimbursement authority, and to measure a direct medical costs of Fecal Incontinence.

**METHODS:**

Patients with primary or secondary disease code for Fecal Incontinence according to Korean Standard Classification of Disease (KICD-10 code : R15) are selected from National Patients Sample Dataset.

The characteristics of age, sex, length of stay for inpatients, the number of outpatient visit and medical cost were analyzed based on the patient dataset extracted. SAS 9.2 (SAS Institute Inc., Cary, NC, USA) was used for statistical analysis.

### RESULTS:

The number of patients with Fecal Incontinence for the analysis was 6,742, and that of claims cases for 12 months was 24,557. The average age of the patients was 71.3 years old and the female patients composed 61.46%, which was about 1.59 times that of the male patients. The prevalence rate of Fecal Incontinence per 1,000 populations was 0.13 in 2013. Based on 1-year claims dataset, annual average visit days of outpatients were 2.48 and annual average days of inpatient hospitalization were 10.65. The annual average of direct medical costs was USD 90 for an outpatient and USD 1,335 for an inpatient.

### CONCLUSIONS:

This study is to know the real status with Claim data such as prevalence, medical cost and patients characteristics for Fecal Incontinence in Korea. However I found two limitations. First, the sample data used for the research is smaller than the raw data should be considered. Second, as patients are reluctant to report FI, the prevalence is underestimated in this study. Therefore further analysis on Fecal Incontinence is needed in various way.

---

## Poster 114A Cost Effectiveness Of Pulmonary Artery Pressure Guided Management Of Chronic Heart Failure In The Australian Healthcare Setting

### DESCRIPTION:

CardioMEMS, a pulmonary artery pressure monitoring system, can detect worsening heart

failure (HF) prior to symptom onset in NYHA class III patients. Results can guide proactive, individualised medical management. The addition of CardioMEMS to usual care has been found to significantly reduce the rate of HF hospitalisations and is cost effective in the Australian healthcare setting.

### PRESENTING AUTHOR:

Margaret McBride, St Jude Medical, Australia

### AUTHORS:

Margaret McBride, Philip Adamson, Derek Chew, Carmine de Pasquale, Christopher Hayward, Scott McKenzie, Amit Shah, Simon Stewart, Colman Taylor

### BACKGROUND AND OBJECTIVES:

Heart failure (HF) is a progressive and complex syndrome characterised by insufficient cardiac output and congestion. Patients frequently experience acute episodes of fluid accumulation, leading to functional decompensation and consequent hospitalisation. Monitoring changes in pulmonary artery pressure (PAP) allows the early detection of fluid accumulation prior to the onset of decompensation symptoms. The information obtained can guide early intervention and proactive management of patients. CardioMEMS (St Jude Medical) is a PAP monitoring system incorporating a passive, wireless, implanted sensor which can transmit data for remote monitoring. The CHAMPION Trial (NCT00531661) confirmed the addition of CardioMEMS to usual outpatient management of NYHA class III HF patients resulted in a 28% reduction in the rate of HF-related hospitalisations at 6 months (84/270 [0.32] vs. 120/280 [0.44];  $p=0.0002$ ), while also improving patient quality of life.<sup>1</sup> The number needed to treat (NNT) to prevent one HF hospitalization in 6 months was 8 patients. Over the extended access period (mean 18 months),<sup>2</sup> CardioMEMS monitoring was found to be cost effective in the US medical system (ICER \$30,167).<sup>3</sup> We report on the cost-effectiveness of PAP-guided HF management in the Australian healthcare setting.

## METHODS:

Extrapolating results from the CHAMPION trial, assuming treatment aligned with local clinical guidelines<sup>4</sup> and applying local costs for procedures and complications, a stepwise Markov model was developed to estimate the trial-based and expected long term costs and consequences associated with CardioMEMS compared with standard care. The model incorporated 4 health states (device implantation or Standard care, stable HF, HF hospitalisation, dead) and employed a cycle length of one month and a lifetime horizon (for the base case). The economic analysis takes a third party payer perspective with costs and effects discounted at 5% per annum. The base case assumptions were modified in multiple, conservative one-way sensitivity tests.

## RESULTS:

Over the modelled time horizon, the estimated cost of adding PAP monitoring to standard HF management (\$53,041) exceeded the cost of standard HF management alone (\$27,536), but the QALYs gained (4.14 and 3.13 respectively) resulted in an ICER of \$25,163 per QALY. The ICER was most sensitive to assumptions of quality of life utility, mortality and HF-related hospitalisations, but remained below \$40,000 per QALY for all tests.

## CONCLUSIONS:

With increasing pressure on healthcare budgets globally, governments and payers are tasked with finding ways to contain expenditure, efficiently allocate scarce healthcare resources and improve overall patient outcomes. The CardioMEMS system has a potential role in achieving these objectives. When compared to current standard of care, proactive management of HF by PAP monitoring with CardioMEMS has proven to reduce HF hospitalisation rates and improve patient quality of life in appropriate patients. Despite the additional upfront cost associated with the implanted sensor, these analyses suggest CardioMEMS is cost-effective and economically attractive in the Australian healthcare setting.

## REFERENCES:

- 1 Abraham WT et al., (2011). Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: A randomised controlled trial. *Lancet*;377(9766):658-66
- 2 Abraham WT et al., (2015). Sustained efficacy of pulmonary artery pressure to guide adjustment of chronic heart failure therapy: Complete follow-up results from the CHAMPION randomised trial. *The Lancet* (in press). [http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(15\)00723-0.pdf](http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(15)00723-0.pdf)
- 3 Martinson M et al., (submitted). Pulmonary Artery Pressure Guided Heart Failure Management in Chronic Heart Failure: Cost effectiveness Results from the CHAMPION Trial. *Eur Heart Journal*.
- 4 National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand (Chronic Heart Failure Guidelines Expert Writing Panel). Guidelines for the prevention, detection and management of chronic heart failure in Australia. Updated October 2011. [https://heartfoundation.org.au/images/uploads/publications/Chronic\\_Heart\\_Failure\\_Guidelines\\_2011.pdf](https://heartfoundation.org.au/images/uploads/publications/Chronic_Heart_Failure_Guidelines_2011.pdf)

---

## Poster 115A Breast Cancer Risk Prediction Model For Identifying Those At Risk: The Malaysian Context

### DESCRIPTION:

The growing awareness of breast cancer and its risk factors, with availability of medical and surgical risk reduction options has created alarm on women's breast cancer risk. Given variance in its risk, surveillance and primary prevention adapted to individual risk level may be the most effective use of resources in preventing, detecting and improving breast cancer survival. Opportunistic screening policy is being practiced for breast cancer in Malaysia. Introduction of risk prediction model to address the unmet needs in identifying high risk individuals is timely in the local context. Therefore,

a review of breast cancer risk prediction model was conducted to assess performance of these models.

### **PRESENTING AUTHOR:**

Dr. Junainah Sabirin, MaHTAS, Medical Development Division, Ministry of Health, Malaysia

### **AUTHORS:**

Junainah Sabirin, Roza S, Izzuna MMG, Rugayah B, Nor Aina E, Junainah S

### **BACKGROUND AND OBJECTIVES:**

Breast cancer imposed significant public health problem worldwide.<sup>1</sup>In Malaysia, it was the commonest cancer in women with incidence rate higher than other developing countries and a substantial proportion presented at a later stage of disease.<sup>2,3,4</sup> The growing awareness of breast cancer and its risk factors, with availability of medical and surgical risk reduction options has created alarm on women's breast cancer risk. Given variance in its risk, surveillance and primary prevention adapted to individual risk level may be the most effective use of resources in preventing, detecting and improving breast cancer survival.<sup>5</sup> Opportunistic screening policy is being practiced for breast cancer in Malaysia.<sup>6</sup> Introduction of risk prediction model to address the unmet needs in identifying high risk individuals is timely in the local context. Therefore, a review of breast cancer risk prediction model was conducted to assess its effectiveness (predictive accuracy), safety, cost-effectiveness and organizational implication among women.

### **METHODS:**

Electronic databases were searched including PubMed, Medline, EBM Reviews - Cochrane Database of Systematic Reviews, Health Technology Assessment, Cochrane Database of Controlled Trial, National Horizon Scanning, and other websites; INAHTA, ARSENIP-S, CADTH, FDA and MHRA for published reports from 1990 to 2nd Quarter 2015. Literatures were critically appraised using Critical Appraisal Skills Programme checklist,

effectiveness evidences follow the US/Canadian Preventive Services Task Force Level of Evidence (2001) grading.

### **RESULTS:**

There was limited good level of evidence retrieved which demonstrated that Gail model is the most widely studied and validated risk prediction model in various population out of the six models identified. The Gail model appeared to have good calibration in validation studies done cross-population with considerable heterogeneity across studies. However, it showed moderate performance in terms of discriminatory ability. Other risk prediction models (CARE model, model by Petracci, model by Pfeiffer, Vermont model, model by Anothaisintawee and BWHS model) demonstrated to be well calibrated in the validated population however, were modest in its discrimination. These models also appeared safe without any reported adverse issues. No evidence retrieved on its cost-effectiveness.

### **CONCLUSIONS:**

Although the above review showed that the Gail model had good calibration and moderate discriminative ability, it is not suitable to be introduced as one of the strategy in the prevention of breast cancer under the Malaysian National Cancer Control Programme yet as it needs further validation to develop a well-fitted model that would have better predictive ability tailored to Malaysian population. This model then needs continual validation to ensure the consistency of its performance. This review is limited by majority of available evidences were from Caucasian study population which restrict its generalizability into local context. There is currently neither standard quality assessment tool nor standard reporting for risk prediction studies such as CONSORT guidelines for RCT.

### **REFERENCES:**

1. World Health Organisation. International Agency for Research on Cancer. Globocan 2012; Estimated

cancer incidence, mortality and prevalence worldwide in 2012. Available online at <http://globocan.iarc.fr/Default.aspx>

2. O Zainal Ariffin, IT Nor Saleha. National Cancer Registry Malaysia Report. 2007; Cancer statistics: data and figure, Peninsular Malaysia. Ministry of Health, Malaysia. 2011

3. Ferlay J, Bray F, Parkin DM, P eds 2001. Globocan. 2000. IARC Press, Lyon

4. Yip CH, Ibrahim M. Epidemiology of breast cancer in Malaysia. Asian Pac J Cancer Prev. 2006;7;7

5. Anderson EE, Hoskins K. Individual Breast Cancer risk assessment in Underserved Populations: Integrating empirical Bioethics and Health Disparities Research. Journal of health care for the poor and underserved. 2012;23(40):10.1353/hpu.2012.0178. doi:10.1353/hpu.2012.0178.

---

## Poster 116A Quantifying The Burden Of Pain: A Tool For Assessing Pain Severity Burden In Those Diagnosed With Pain

### DESCRIPTION:

The purpose of this work was to develop a tool for quantifying a patient's pain given his or her demographic characteristics and reported level of pain severity in the past week. The resultant tool uses results from a large population study to estimate the burden of pain severity on work productivity loss, healthcare resource use, and health-related quality of life.

### PRESENTING AUTHOR:

James Kenworthy, Mundipharma International, United Kingdom

### AUTHORS:

James Kenworthy, Edward A. Witt, William C. Dunlop, Gina Isherwood

### BACKGROUND AND OBJECTIVES:

Although chronic pain is a common occurrence, the quantification of the burden of chronic pain has been under-studied. The aim of the current study was to use a large population-based study to develop a series of equations to estimate patient, health system and productivity burden based on their pain severity scores and demographic characteristics.

### METHODS:

The data in this study came from the 2013 5EU National Health and Wellness Survey (France, Germany, Italy, UK, and Spain). Generalized linear models were used to estimate coefficients for pain severity in the past week, demographics, and health characteristics with regard to the domains of work productivity loss, quality of life, and healthcare resource use.

### RESULTS:

The sample for this analysis were patients diagnosed with at least one form of pain (of 25 conditions) in the 2013 NHWS survey (n = 14,459). Patients' self-reported pain scores in the past week were entered into generalized linear models along with their age (in years), gender (male/female), education (university degree yes/no), and their Charlson Comorbidity Index score (CCI), predicting the outcomes of quality of life (mental, physical, and health utilities), work productivity loss (absenteeism and presenteeism), and healthcare resource use (ER visits, hospitalizations, and HCP visits). The resulting coefficients were used to create a tool that can quantify an individual patient's burden based on his or her characteristics and his or her self-reported pain in the past week. For instance, an average patient with a pain severity score of 4 out of 10 would have a health utilities score of 0.53, 19.1% absenteeism in the past 7 days, and 0.53 ER visits over the past six months whereas

the same patient with a pain severity score of 5 would have a health utilities score of 0.51, 23.6% absenteeism, and .66 ER visits. The accuracy of these estimates is improved the more information about the key patient characteristics is provided to the tool.

### **CONCLUSIONS:**

The tool developed in this study can be used to estimate patient burden with just his or her self-reported pain severity in the past week and can further quantify that burden with a few additional pieces of patient demographic information. This tool can be a valuable resource for health technology assessment when assessing the full impact of a patient's pain.

---

## **Poster 117A Costs On Procedures And Health Technologies Used By Patients Diagnosed With Schizophrenia During Eleven Years Of Follow-Up**

### **DESCRIPTION:**

This study describes costs on procedures and health technologies used by patients diagnosed with schizophrenia and attended by SUS, from January 2000 to December 2010.

### **PRESENTING AUTHOR:**

Augusto Afonso Guerra Junior, SUS Collaborating Centre for Technology Assessment and Excellence in Health, Brazil

### **AUTHORS:**

Wallace Barbosa, Augusto Guerra, Lívia Lemos, Rosângela Gomes, Juliana Costa, Francisco Acurcio

### **BACKGROUND AND OBJECTIVES:**

Schizophrenia is a severe mental disorder, chronic

and debilitating, affecting 0.3 to 0.7% of the population(1) and is associated with a significant financial and social impact on patients, families, caregivers and society in general.(2) Schizophrenia treatment includes the use of antipsychotics and psychosocial therapies.(3) In Brazil, the Public Health System (SUS) have been focusing at the inclusion of patients in the community and their dehospitalization. The strategy is to progressively substitute care at the psychiatric hospital to alternatives in hospitals, such as psychiatric units in general hospitals, and to outpatient care(4). In addition, to inpatient and outpatient treatment the SUS provides typical, or first-generation (FGA), antipsychotics, such as chlorpromazine and haloperidol, and atypical, or second generation (SGA), medicines, such as clozapine, olanzapine, quetiapine, risperidone and ziprasidone. These are considered high-cost or specialized medicines and are dispensed to patients after an analysis of compliance with requirements of the national clinical protocol for schizophrenia.(5) This study describes costs on procedures and health technologies used by patients diagnosed with schizophrenia and attended by SUS, from January 2000 to December 2010.

### **METHODS:**

We analyzed a nationwide cohort developed through deterministic-probabilistic linkages of administrative records of SUS national databases(6,7). The included patients received the following antipsychotics: clozapine, olanzapine, quetiapine, risperidone and ziprasidone; had the diagnosis ICD-10 for schizophrenia and were treated between January 2000 and December 2010. We stratified the individual costs by groups of procedures and we describe on median. Monetary values were adjusted for inflation to January 2015. Brazilian Reais (BRL) were converted to United States Dollars (USD) using the purchasing power parity of the World Bank at a conversion factor for 2014 (USD1 = 1.69 BRL).

### **RESULTS:**

We included 241,079 patients and drugs accounted

for 82.9% of costs and median spending per patient USD 490.56, followed by clinical procedures (14.7% of expenditures and median spending USD 311.36); surgical procedures (1.1% and USD 395.92); complementary actions of health care (0.6% and USD 50.60); orthoses, prostheses and special materials (0.3% and USD 305.53); procedures for diagnostic purposes (0.2% and USD 28.58) and organs, tissues and cells transplantations (0.2% and USD 241.28).

### CONCLUSIONS:

The spending on drugs accounted for the greatest impact on overall expenditure, as well as presenting the biggest spending median. This finding may be related to the cost of medicines to the healthcare system and its continuous use. The procedures (orthoses, prostheses and special materials and organs, tissues and cells transplantations) did not impact much on overhead, but stood out for their spent median values. What must be directly related to the values of health technologies used. Although this cohort was built secondary data, this study encourages more rational use of medicines and rational hospital services.

### REFERENCES:

1. American Psychiatric A. Diagnostic and Statistical Manual of Mental Disorders (DSM-5®). American Psychiatric Pub, 2013.
2. Knapp M, Mangalore R, Simon J. The global costs of schizophrenia. *Schizophr Bull.* 2004; 30: 279-93.
3. Lehman AF, Lieberman JA, Dixon LB, et al. Practice guideline for the treatment of patients with schizophrenia. *The American journal of psychiatry.* 2004; 161: 1-56.
4. Brasil. Ministério da Saúde. Secretaria de Atenção à Saúde. DAPE. Reforma psiquiátrica e política de saúde mental no Brasil. Brasília, novembro de 2005.
5. Brasil. Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Componente Especializado da Assistência Farmacêutica: inovação para a garantia do acesso

a medicamentos no SUS. Brasília: Ministério da Saúde, 2014. 163p.

6. Coeli CM, Camargo Jr KRd. Evaluation of different blocking strategies in probabilistic record linkage. *Rev Bras Epidemiol.* 2002; 5: 185-96.
7. Cherchiglia ML, Guerra Júnior AA, Andrade EIG, et al. A construção da base de dados nacional em terapia renal substitutiva (TRS) centrada no indivíduo: aplicação do método de linkage determinístico-probabilístico. *Revista Brasileira de Estudos de População.* 2007; 24: 163-6

---

## Poster 145A Mapping The Disability Assessment Scale To Preference-Based Health Utilities In Patients With Upper Limb Spasticity

### DESCRIPTION:

Mapping the disability assessment scale to preference-based health utilities in patients with upper limb spasticity.

### PRESENTING AUTHOR:

Ryan Hansen, University of Washington, United States

### AUTHORS:

Ryan N. Hansen, Solomon J. Lubinga, Jerome Dinet, Sylvie Gabriel, Sean D. Sullivan

### BACKGROUND AND OBJECTIVES:

The disability assessment scale (DAS) has been validated as a measure of functioning in patients with upper limb spasticity. Our goal was to compare algorithms estimating EQ-5D and SF-6D preference-based health-related quality of life from DAS scores.

### METHODS:

We used data from a double-blind, placebo-controlled, randomized trial of abobotulinumtoxinA in 243 hemiparetic patients with upper limb spasticity following stroke or brain trauma. Baseline data included DAS domain scores, SF-36 and EQ-5D-5L measures, which were used to estimate EQ-5D and SF-6D scores (utilities). We examined correlations between the DAS scores and utilities. Data were randomly split into training and validation samples to map DAS scores to utilities. We fit linear regression models in the training sample, adjusting sequentially for age, sex, prior botulinum toxin use, spasticity etiology, physiotherapy, other medications, and baseline scores on modified Ashworth, modified Frenchay, Tardieu and the active range of motion scales. We used each model to predict utilities in the validation sample, compared observed and predicted utilities using the Student's t-test, and computed mean absolute percentage error (MAPE).

**RESULTS:**

We found that the DAS domain scores and both utility measures were negatively correlated. The largest correlation was observed between the pain domain of the DAS and SF-6D ( $r = -0.46, p < 0.001$ ), and lowest between the hygiene domain and the SF-6D ( $r = -0.1490, p = 0.02$ ). R2 values for EQ-5D models ranged from 2% to 29%, while those for SF-6D models ranged from 0.02% and to 41%. There were no differences between observed and predicted utilities in the validation sample. MAPEs were higher in the EQ-5D models (ranging from 161.01 to 238.04) and lower in the SF-6D models (ranging from 12.03 to 14.16).

**CONCLUSIONS:**

The DAS appears to map more accurately to SF-6D in patients with upper limb spasticity. In this population, the results suggest that utilities from SF-6D appear to yield more robust estimates than those obtained by EQ-5D for economic evaluations.

## Poster 146A A Cost-Utility Analysis Of Bevacizumab For Treatment Of Recurrent Ovarian Cancer In Canada

**DESCRIPTION:**

Using a 3-year time horizon, a 3-health state cohort-based partitioned survival model was developed to assess the cost-utility of bevacizumab plus chemotherapy versus chemotherapy alone in Canada. The results of our analysis suggest that the addition of bevacizumab to single-agent chemotherapy treatment, while improving patient outcomes, is unlikely to be cost-effective in the Canadian patient population.

**PRESENTING AUTHOR:**

Graeme Ball, McMaster University, Canada

**AUTHORS:**

Graeme Ball, Feng Xie, Jean-Eric Tarride

**BACKGROUND AND OBJECTIVES:**

Ovarian cancer is a leading cause of cancer-related mortality in Canada among women. It is a rare disease but carries a disproportionately large morbidity burden. There are a limited number of chemotherapies available in Canada for treatment of ovarian cancer, though many of these treatments are old and have been in use for many years. Previous trials have shown that combining chemotherapy agents results in increased toxicity without improving efficacy, implying the need for new therapies. Approximately 85% of patients who achieve full remission after completion of first line therapy will develop recurrent disease, and optimal treatment for recurrent disease has not yet been established.

Bevacizumab (AVASTIN®) is a recombinant humanised monoclonal antibody that selectively binds to and neutralises the biologic activity of vascular endothelial growth factor (VEGF), reducing the vascularisation of tumours, thereby inhibiting

tumour growth. The purpose of this economic analysis is to analyze the expected costs, effects, and cost-effectiveness of bevacizumab versus other currently available chemotherapeutic options for patients with recurrent ovarian cancer from a Canadian healthcare system perspective.

#### **METHODS:**

Using a 3-year time horizon, a 3-health state cohort-based partitioned survival model was developed to assess the cost-utility of bevacizumab plus chemotherapy (BEV+CT) versus chemotherapy alone (CT). We used recently developed techniques to reconstruct individual patient data from published Kaplan-Meier curves. Clinical parameters, including progression-free survival and overall survival, were derived from the AURELIA phase III randomized controlled trial. The model was populated using costs, resource utilization and utility values from recent Canadian sources. Results were presented in the form of estimated costs, quality-adjusted life-years (QALYs), and incremental cost-utility ratios (ICURs). Uncertainty was examined through univariate and probabilistic sensitivity analyses.

#### **RESULTS:**

The reconstructed individual patient data was observed to match the results from the AURELIA trial. Total 3-year costs for the BEV+CT and CT treatment arms were \$85,034 and \$51,281, respectively. Total estimated QALYs were 1.0631 and 0.9366 for the BEV+CT and CT arms, respectively. The ICUR for BEV+CT versus CT was estimated to be \$266,851 per QALY gained. At a willingness-to-pay threshold of \$100,000 per QALY gained, the probability of BEV+CT being cost-effective was 0. Univariate sensitivity analyses indicated that the model was most sensitive to changes in bevacizumab unit cost and the cost of managing serious adverse events.

#### **CONCLUSIONS:**

The results of our analysis suggest that the addition of bevacizumab to single-agent chemotherapy

treatment, while improving patient outcomes, is unlikely to be cost-effective in this Canadian patient population. The results also provided validation for the use of individual patient data reconstruction techniques in pharmacoeconomic evaluation.

#### **REFERENCES:**

Alberta Health Service. (2013). EPITHELIAL OVARIAN , FALLOPIAN TUBE , AND PRIMARY PERITONEAL CANCER, (April).

Health Canada. (2015). AVASTIN Product Monograph.

Pujade-Lauraine, E., Hilpert, F., Weber, B., Reuss, A., Poveda, A., Kristensen, G., Ray-Coquard, I. (2014). Bevacizumab combined with chemotherapy for platinum-resistant recurrent ovarian cancer: The AURELIA open-label randomized phase III trial. *Journal of Clinical Oncology*, 32(13), 1302-1308."

---

## **Poster 1B** A Comparative Cost Analysis Of Robotic-Assisted Surgery Versus Laparoscopic Surgery And Open Surgery Considering A Set Of Urologic Surgical Procedures

#### **DESCRIPTION:**

This study explains the potential economic implications of introducing robotic-assisted surgery compared to laparoscopic and open surgeries for a range of pediatric urologic surgical procedures. Break-even analysis and cost-minimization analysis were performed.

#### **PRESENTING AUTHOR:**

Martina Andellini, Bambino Gesù Children's Hospital, Italy

#### **AUTHORS:**

Giorgia, Tedesco, Francesco, C. Faggiano, Martina,

Andellini, Erica, Leo, Mario, De Gennaro, Pietro, Derrico, Matteo, Ritrovato

## **BACKGROUND AND OBJECTIVES:**

A decision on a high-impact technology investment (as the case of minimally invasive robotic surgery) requires tailored information to fulfil hospital decision-makers' needs, which could be delivered through a sharper and more structured assessment's output. Moreover, with the recent rise in the worldwide use of innovative health technologies to deliver high-quality and patient-oriented care, the importance of achieving a balance between the innovations' benefits and their impact on hospital budgets has increased. The purpose of this study is to describe the potential economic implications of introducing the robotic-assisted surgery (RS) compared to laparoscopic and open surgeries (LS and OS, respectively), for a range of pediatric urologic surgical procedures (e.g. gastroesophageal reflux, hydronephrosis).

## **METHODS:**

Fixed and variable costs were identified to carry out the break-even analysis and cost-minimization analysis, using hospital management system, the team expertise and robotic system's manufacturer proposals. Asking surgeons to supply data pertaining to the volume and time of actual (LS, OS) or hypothetical (RS) surgical activities, made it possible to obtain all the cost drivers. The initial capital expenditure and annual maintenance fees were also taken into account. Revenues were calculated as the weighted average of DRG associated with each procedure considered. We provided a view of the relationship between RS, LS and OS on the contribution margins (CMs).

## **RESULTS:**

Considering that the mean value of the selected DRGs refunded by the Italian Healthcare System is actually 7.399, the break-even point (BEP) would be achieved performing 298 annual urologic procedures, at which thereby the robotic technology does not generate neither profit

nor loss. The cost-minimization analysis was conducted to compare the costs of RS with those of LS and OS in order to identify the less expensive alternative: it showed that, assuming equal efficacy among all the alternatives, RS is the more expensive procedure than the two surgical alternatives (in terms of CMs).

## **CONCLUSIONS:**

Results showed that it is now difficult to make up for the initial investment with RS. It implies increased hospital costs (initial investment, maintenance costs, and the procedures costs, which often exceeded the tariffs for reimbursement). Open and laparoscopic surgical procedures offer greater economic convenience in terms of the contribution margin. Therefore, in the short run, economic data do not seem to support the decision to introduce the robotic system within our hospital.

## **REFERENCES:**

1. Drummond MF, Sculpher MJ, Torrance GW, et al. *Metodi per la valutazione economica dei programmi sanitari*. Rome: Il Pensiero Scientifico Editore; 2010.
2. European Network for Health Technology Assessment (EUnetHTA). HTA core model for medical and surgical interventions. Available at: <http://www.eunetha.eu/sites/5026.fedimbo.belgium.be/files/HTA%20Core%20Model%20for%20Medical%20and%20Surgical%20Interventions%201.0r.pdf>. [Accessed September 5, 2014].
3. Camps JI. The use of robotics in pediatric surgery: My initial experience. *Pediatr Surg Int*. 2011;27(9):991-996.
4. Luebbe BN, Woo R, Wolf S, et al. Robotically Assisted Minimally Invasive Surgery in a Pediatric Population: Initial Experience, Technical Considerations, and Description of the da Vinci® Surgical System. *Pediatric Endosurgery & Innovative Techniques*. 2003;7(4).
5. Meehan JJ, Elliott S, Sandler A. The robotic

approach to complex hepatobiliary anomalies in children: Preliminary report. J Pediatr Surg. 2007;42:2110-2114.

6. Cundy TP, Shetty K, Clark J, et al. The first decade of robotic surgery in children. J Pediatr Surg. 2013;48(4):858-865.

7. Ballini L, Minozzi S, Negro A. et al. La chirurgia robotica: il robot da Vinci. Regione Emilia Romagna. Dossier 167; 2008.

8. De Lambert G, Fourcade L, Cent J. How to successfully implement a robotic pediatric surgery program: lessons learned after 96 procedures. Surg Endosc. 2013;27:2137-2144.

9. Dangle PP, Kearns J, Anderson B, et al. Outcomes of infants undergoing robot-assisted laparoscopic pyeloplasty compared to open repair. J Urol. 2013;190(6):2221-2227.

10. Cabot JC, Lee CR, Brunaud L, et al. Robotic and endoscopic transaxillary thyroidectomies may be cost prohibitive when compared to standard cervical thyroidectomy: a cost analysis. Surgery. 2012;152(6):1016-1024.

11. Anderberg M, Kockum CC, Arnbjornsson E. Paediatric robotic surgery in clinical practice: a cost analysis. Eur J Pediatr Surg. 2009;19(5):311-315.

12. Casella DP, Fox JA, Schneck FX, et al. Cost analysis of pediatric robot-assisted and laparoscopic pyeloplasty. J Urol. 2013;189(3):1083-1086.

13. Chaussy Y, Becmeur F, Lardy H, et al. Robotic-assisted surgery: current status evaluation in abdominal and urological pediatric surgery. J Laparoendosc Adv Surg Tech A. 2013;23(6):530-538.

14. Ho C, Tsakonas E, Tran K, et al. Robot-Assisted Surgery Compared with Open Surgery and Laparoscopic Surgery: Clinical Effectiveness and Economic Analyses. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2011 (Technology report no.137).

15. AGENAS, Nucleo Tecnico Health Technology Assessment Regione Sicilia. Supporto consulenziale del NHTTA alla richiesta dell-A.R.N.A.S. Civico di Palermo sul Robot da Vinci; April 2013.

16. Turchetti G, Palla I, Pierotta F, et al. Economic evaluation of Da Vinci-assisted robotic surgery: a systematic review. Surg Endosc. 2012;26:598-606

---

## Poster 2B Vitamin D And Atopic Dermatitis: A Systematic Review And Meta-Analysis

### DESCRIPTION:

Despite the evidence supporting the use of vitamin D supplements for managing atopic dermatitis (AD), no meta-analysis providing definite conclusions in this field has been reported. The purpose of the current study was to conduct a systematic review and meta-analysis of all controlled studies of vitamin D for treating AD to elucidate the efficacy of vitamin D for alleviating the symptoms of AD.

### PRESENTING AUTHOR:

Gaeun Kim, Keimyung University, Korea

### AUTHORS:

Gaeun, Kim, Ji-Hyun, Bae

### BACKGROUND AND OBJECTIVES:

Objectives: Despite the evidence supporting the use of vitamin D supplements for managing AD, no meta-analysis providing definite conclusions in this field has been reported. The purpose of the current study was to conduct a systematic review and meta-analysis of all controlled studies of vitamin D for treating AD to elucidate the efficacy of vitamin D for alleviating the symptoms of AD.

### METHODS:

Methods: Literature searches were conducted using Ovid-MEDLINE, EMBASE, Web of Science,

Cochrane Library, Korean databases, and Chinese database. Search terms used were: 'vitamin D', 'atopic dermatitis', 'randomized', 'controlled trial', and 'clinical trial'. Random effects models were used to calculate the mean difference (MD), with 95% confidence intervals (CI) to analyze the effects of vitamin D supplementation for severity of AD.

### RESULTS:

Results: Initial searches yielded 266 citations. Of these original results, nine met specific selection criteria. Four of the RCTs compared the efficacy of vitamin D with a placebo on severity of AD and were included in the meta-analysis. The vitamin D supplementation interventions showed a higher mean difference in severity of AD symptoms (MD = -5.81, 95% CI: -9.03, -2.59,  $p = 0.0004$ ,  $I^2 = 50\%$ ).

### CONCLUSIONS:

Conclusions: Vitamin D has a potentially significant role for improving the symptoms of AD. The results from this study indicate that vitamin D supplementation may help ameliorate the severity of AD, and can be considered as a safe and tolerable therapy. However, larger-scale studies over a longer duration of treatment are needed to confirm this conclusion.

---

## Poster 3B High-Dose-Rate Brachytherapy As Monotherapy In Localized Prostate Cancer: A Systematic Review Of Its Safety And Efficacy

### DESCRIPTION:

Systematic review to assess the efficacy and safety of high-dose-rate brachytherapy as monotherapy for prostate cancer.

### PRESENTING AUTHOR:

Dr. Luis M Sánchez-Gómez, AETS. ISCIII, Spain

### AUTHORS:

Luis Sánchez-Gómez, Mar Polo-deSantos, Setefilla Luengo-Matos, Antonio Sarria-Santamera

### BACKGROUND AND OBJECTIVES:

New therapeutic technologies are improving the efficacy and safety of the treatment for prostate cancer. In recent years, there is a growing interest in the use of high-dose-rate brachytherapy (HDR-BT) as monotherapy in prostate cancer. The treatment is complex and requires a high technical and planning expertise level to perform the procedure. The choice of treatment implies to make an adequate selection of the patient and assess not only the characteristics of the tumor but also the patient's risk factors. The objective of this work is to assess the efficacy and safety of high-dose-rate brachytherapy as monotherapy for prostate cancer.

### METHODS:

Systematic review of the scientific literature. The searched databases were: MEDLINE (PubMed), CRD, Clinicaltrials, EuroScan and Cochrane Library. Studies using the HDR-BT as monotherapy published in French, Spanish or English until 30 May 2015 were reviewed. Outcomes measures of efficacy (local control, PSA progression free survival (PSA-PFS), and survival) and safety (appearance of acute and late adverse effects, its location and severity, particularly gastrointestinal and genitourinary complications) were collected. The selection, review of studies and data extraction was carried out by two reviewers independently.

### RESULTS:

2 systematic reviews including 12 studies were retrieved. Selection criteria were different in the studies. A variety of dose and fractionation schedules were reported. Regarding efficacy, 6 studies included local control of the disease with rates varied from 97% to 100%. Regarding PSA-PFS the results were good, rates over 85% for low and medium risk patients and rates over 79% for high risk patients were reported. The overall

survival rates were over 95%. Regarding safety, there were few acute and late genitourinary (dysuria, hematuria, urgency) and gastrointestinal (rectal pain, rectal bleeding, tenesmus, diarrhea) complications. The majority of them were Grade I/II.

### CONCLUSIONS:

The HDR-BT as monotherapy seems to be a good therapeutic alternative for patients with prostate cancer. Short to medium-term, HDR-BT achieved high levels of local control of the disease, biochemical control, and overall survival, with few severe complications. Further research is needed, especially regarding selection of patients and dose and fractionation schedules, as well as on long-term results and cost effectiveness analysis.

---

## Poster 5B Health Technology Assessment For The Reorganization And Automation Of The Medical Laboratory Of Bambino Gesù Children's Hospital

### DESCRIPTION:

The article describes a virtuous cycle of integration and consolidation of LAB activities in order to ensure high safety standards through a reorganization of work in synergy with the new technological solutions available on the market

### PRESENTING AUTHOR:

Giorgia Tedesco, Bambino Gesù Children's Hospital, Italy

### AUTHORS:

Gerardina Masucci, Liliana De Vivo, Giorgia Tedesco, Pietro Derrico, Alessandra Martino, Matteo Ritrovato, Erica Leo, Francesco C. Faggiano

### BACKGROUND AND OBJECTIVES:

Services provided by the Medical Laboratory (LAB) are fundamental elements for the proper management of patients, while complying with cost containment strategies, resource rationalization and quality improvement. New spaces recently became available; as a consequence, Bambino Gesù Children's Hospital (OPBG) has started a virtuous cycle of integration and consolidation of LAB activities in order to ensure high safety standards, effectiveness and efficiency through a reorganization of work in synergy with the new technological solutions available on the market.

### METHODS:

The complexity of the project must necessarily be seen as a result of a multidisciplinary teamwork within several corporate divisions; methodological approach can be drawn from Health Technology Assessment with particular reference to professional safety aspects due to the future location in the basement.

### RESULTS:

The team has shared a multiphase work project:

1. Analysis of context, clinical-technological needs i.e., spaces, standard offer, transport of samples, equipment, mapping of carcinogens, organizational flows, human resources and consolidation proposals
2. Analysis of hypothesized locations for different analytical procedures and evaluation of available spaces
3. Definition of performance and basic qualitative/quantitative parameters, according to doHTA methodology
4. Analysis and evaluation of submitted offers, and identification of the solution more suitable for expressed needs
5. Planning of interventions and transfers
6. Implementation of structural interventions and

installations

7. Transfer of activities

### CONCLUSIONS:

The reorganization and automation of LAB activities will surely lead to a better use of available resources, especially in the event of consolidation and transfer in shared spaces. To achieve the best solution for the OPBG reality, it is essential for the preliminary analysis of current organizational model to be related to economic, logistical and human availability.

.....

## Poster 6B Efficacy Of The MICA Antibody For Transplant Patients

### DESCRIPTION:

- i) There were no significant differences in the graft survival rate and incidence of organ rejection;
- ii) It is difficult to determine whether the different results for the graft survival rate and incidence of organ rejection reported;
- iii) The results cannot be generalized as it is probable that they will change in case of including all the patients fitting the description;
- iv) Kidney transplantation is presently performed even if the results of the histocompatibility test of the donor and the patient do not conform to each other;
- v) Heart and lung transplantations are performed based on anatomical compatibility without a histocompatibility test.

### PRESENTING AUTHOR:

JinA Mo, National Evidence-Based Health Care Collaborating Agency & Inha University, Korea

### AUTHORS:

JinA Mo

.....

### BACKGROUND AND OBJECTIVES:

MICA antibody identification is a test performed on transplant patients to check for the presence of donor-specific MICA for the purpose of predicting the incidence of organ rejection among transplant patients. The purpose of this assessment was to evaluate the effectiveness.

### METHODS:

The literature search was performed using 8 domestic research databases and 3 core databases. A total of 9 papers that remained. Each of the stages from literature search to application of selection criteria and data extraction was independently by 2 researcher. The SIGN was used for the quality assessment.

### RESULTS:

There were 5 studies reporting on the medical results of kidney transplant patients. 2of the studies reported no significant differences in the graft survival rate and incidence of organ rejection( $p=.67$ ). However, 3studies reported a low graft survival rate and a significantly lower incidence of organ rejection in MICA(-)patients compared to the MICA (+)patients. There were 3studies reporting of heart transplant patients. 2studies reported an incidence of organ rejection of 23.1~62.5% and 1study reported a 5~10year graft survival rate of 94.7%( $p=ns$ ). There was one study reporting of lung transplant patients. The incidence of organ rejection was reported to be 42.0%( $p=ns$ ).

### CONCLUSIONS:

MICA Identification lacked clinical effectiveness for the following reasons: i)there were no significant differences in the graft survival rate and incidence of organ rejection; ii)it is difficult to determine whether the different results for the graft survival rate and incidence of organ rejection reported; iii) the results cannot be generalized as it is probable that they will change in case of including all the patients fitting the description; iv)kidney transplantation is presently performed even if the results of the histocompatibility test of the donor

and the patient do not conform to each other; v) heart and lung transplantations are performed based on anatomical compatibility without a histocompatibility test.

---

## Poster 7B Revisiting Role Of HTA In Drug Pricing And Reimbursement In China: A Government Perspective

### DESCRIPTION:

The study aims to provide updates on roles of HTA in drug pricing and reimbursement in China.

### PRESENTING AUTHOR:

Chunyang Hu, Astrazeneca, China

### AUTHORS:

Chunyang Hu, Qian Zhang, Liping Xu

### BACKGROUND AND OBJECTIVES:

HTA has been a hot research field, which also draws closer and closer attentions from decision makers in governmental agency in China. Descriptions or requirements related to HTA have been written into published official documents or regulations ever since the new healthcare reform in 2009. Analysis of these documents is of great importance to understand government's attitude toward HTA. However, such summary or analysis is rarely seen in publications. Our study aims to provide updates on roles of HTA in drug pricing and reimbursement in China.

### METHODS:

comprehensive search of related literature or official documents was conducted within 'CNKI' and 'Wanfang data', which are biggest database for published Chinese journals, and on government's official websites. In addition, expert interviews were carried out. All published governmental documents

or regulations with descriptions or requirements related to HTA for drug pricing and reimbursement were included for further analysis.

### RESULTS:

5 governmental documents were included. For drug pricing, there are 3 documents related to HTA: in 2009, 'state council's opinions on deepening healthcare reform' released by state council first says 'pharmacoeconomic evaluation should be gradually implemented in pricing of new drugs'. Then in 2010, NDRC (National Development and Reform Commission) published 'administration of drug pricing (exposure draft)', saying 'price adjustment can refer to results of pharmacoeconomic evaluation'. Recently in 2015, NHFPC's (National Health and Family Planning Commission) 'pilot scheme for establishing drug price negotiation system (exposure draft)' pointed out 'negotiation team should perform EBM and pharmacoeconomic evaluation and integrate international price information before official negotiation.' For drug reimbursement, there are also 2 documents: for NRDL (National Reimbursement Drug List) review, 'working scheme for NRDL review (2009)' by MOHRSS (Ministry of Human Resources and Social Security) says 'for inclusion of drug, pharmacoeconomic principle should be used to compare price and efficacy; for exclusion, drugs demonstrated to be not cost-effective should be excluded'; for NEDL (National Essential Drug List) review, 'administration methods on NEDL (2015)' by NHFPC says 'advisory expert group must conduct technology assessment on included drugs following EBM and pharmacoeconomic principles'.

### CONCLUSIONS:

HTA has not been mandatory in drug pricing and reimbursement in China, however, government have realized the great importance of scientific decision making, which would regard HTA as a useful tool. Pharmacoeconomic evaluation, which is an important component of HTA, is expected to play an important role in pricing and reimbursement in the future.

---

## Poster 8B Effectiveness Of Interventions To Solve Emergency Department Overcrowding

### DESCRIPTION:

Emergency department overcrowding is a global problem that massively violates human and health right.

### PRESENTING AUTHOR:

Tatiana Yonekura, Hospital do Coração, Brazil

### AUTHORS:

Tatiana Yonekura, Patricia Albuquerque, Armando De Negri Filho

### BACKGROUND AND OBJECTIVES:

Emergency department overcrowding is a global problem that massively violates human and health right. Numerous studies have shown the association between emergency department overcrowding and worse outcomes for patients, dissatisfaction of patients, families and health workers and increased hospital costs. However, effective interventions to address emergency department overcrowding are not well known and used in the practice of health services and systems. The aim of this study was to identify the effectiveness of interventions to solve emergency department overcrowding.

### METHODS:

It was conducted an overview of reviews with the following inclusion criteria: review that aimed to identify effective interventions in prevention, control and management of emergency department overcrowding, published at any time in Portuguese, English or Spanish. The following databases were checked: Cochrane library, Joanna Briggs database, LILACS, Evidence Portal, PubMed

and Scopus. The following descriptors were used: Crowding, Emergency, Medicine Department, Hospital Overcrowding, Intervention and Solution.

### RESULTS:

A total of four reviews were identified using the described databases and terms, of which 134 references were included. The management of emergency department overcrowding is complex, diversified and multifaceted, while also reduce overcrowding. Most of the interventions were developed in the US, France and the UK and used in case studies and before and after designs. The interventions were classified according to: (1) input, throughput and output interventions (2) Increase resources, management of demand and operational research, and (3) decreased use of service, increased resources, improvement of hospital admission and discharge. There are differences of concepts, measures of length of stay and methodologies, which does not allow statistical comparisons and general recommendations for all contexts. While overcrowding is an international problem, not all solutions are equally appropriate to all countries.

### CONCLUSIONS:

The literature of interventions to solve emergency department overcrowding is large and shows effectiveness in short-time, related to decrease of length of stay, increase hospital bed access and decrease demand. Studies in other realities are required, in addition to evaluate the interventions in long-term to ensure the quality of care and human and social rights.

---

## Poster 9B Liposomal Amphotericin B Or Amphotericin B Lipid Complex: Which Is The Best Alternative Among Patients With Previous Renal Impairment Or Unacceptable Toxicity To Conventional Amphotericin B Treatment?

### DESCRIPTION:

Lipid formulations of amphotericin B (lipid complex and liposomal) constitute an innovation in antifungal therapy, presenting superior safety profiles when compared with conventional amphotericin B (AmB). However, defining utilization criteria is necessary to reduce the associated economic burden, specially in low and middle income settings. The comparative effectiveness of the different lipid formulations in patients with previous renal impairment or unacceptable toxicity to AmB is not established in clinical practice. We aimed to compare both formulations efficacy and safety in this specific population, in order to contribute to evidence-based decisions. This systematic review included Medline (PubMed), Cochrane Central Register of Controlled Trials (CENTRAL), Embase, and LILACS databases.

### PRESENTING AUTHOR:

Dr. Maria Angélica Pires Ferreira, Hospital de Clínicas de Porto Alegre, Brazil

### AUTHORS:

Maria Angélica Pires Ferreira, Luiza Grazziotin, Leila Beltrame Moreira

### BACKGROUND AND OBJECTIVES:

Lipid formulations of amphotericin B (lipid complex and liposomal) constitute an innovation in antifungal therapy, presenting superior safety profiles when compared with conventional

amphotericin B (AmB).<sup>1</sup> However, defining utilization criteria is necessary to reduce the associated economic burden, specially in low and middle income settings. The comparative effectiveness of the different lipid formulations in patients with previous renal impairment or unacceptable toxicity to AmB is not established in clinical practice. We aimed to compare both formulations efficacy and safety in this specific population, in order to contribute to evidence-based decisions.

### METHODS:

This systematic review included Medline (PubMed), Cochrane Central Register of Controlled Trials (CENTRAL), Embase and Lilacs databases. The search terms were a combination of 'liposomal amphotericin B' and 'amphotericin B lipid complex' terms. Inclusion criteria: randomized clinical trials and observational studies; patients with previous renal impairment or unacceptable toxicity to conventional amphotericin B; treatment comparing L-AmB with ABLC. Two investigators independently screened the search results, assessed trial quality (GRADE) and extracted data.

### RESULTS:

A total of 459 abstracts were screened, and five observational studies were selected for full-text reading. Four studies included patients with normal renal function; only one study evaluated exactly the population of interest: Wade and colleagues<sup>2</sup> reviewed the medical records of 327 patients and found that creatinine elevation (double of basal value or >1,2 mg/dL) was more than twice as common among ABLC patients versus L-AmB (p=0.020). In contrast, no significant difference was found in clinical relevant outcomes as dialysis (p=0.916) or mortality (p=0.700).

### CONCLUSIONS:

The quality of available studies is low. Therefore, we concluded that there is no robust evidence, particularly considering significant outcomes in clinical practice, to embase clinical decisions

regarding one or another lipid formulation in this specific scenario. Further studies are necessary to elucidate whether there is a role for choosing between them despite economic value.

#### REFERENCES:

<sup>1</sup> Safdar A, Ma J, Saliba F, Dupont B, Wingard JR, Hachem RY, et al. Drug-induced nephrotoxicity caused by amphotericin B lipid complex and liposomal amphotericin B: a review and meta-analysis. *Medicine (Baltimore)* 2010;89(4):236-44.

<sup>2</sup> Wade R, Chaudhari P, Natoli J, Taylor R, Nathanson B, Horn D. Nephrotoxicity and other adverse events among inpatients receiving liposomal amphotericin B or amphotericin B lipid complex. *Diagnostic Microbiology and Infectious Disease* 2013; 76(3):361 - 367.

---

## Poster 11B Volume-Outcome Relationships In Peripheral Vascular Surgery: An Overview Of Reviews Introduction

#### DESCRIPTION:

An overview of systematic reviews of the relationship between the volume of procedures undertaken and outcomes in peripheral vascular disease was conducted, this identified 11 relevant reviews. Quality was assessed using AMSTAR; the reviews were judged to be of low quality and dated, the most recent being from 2010, suggesting the need for a new, high quality systematic review.

#### PRESENTING AUTHOR:

Patrick Phillips, The University of Sheffield, United Kingdom

#### AUTHORS:

Phillips Patrick, Poku Edith, Essat Munira, Woods Helen B, Goka Edward A, Kaltenthaler Eva C, Shackley Phil, Michaels Jonathan

#### BACKGROUND AND OBJECTIVES:

The debate regarding the relationship between volume and outcomes has been informed by suggestions that clinicians and hospitals that perform high volumes of procedures achieve better outcomes as a result of 'practice making perfect' or 'preferential referral'. Either way the potential re-configuration of vascular services requires a sound evidence base if services are to be provided in a clinically and cost effective way. As a preliminary stage of a proposed systematic review investigating the volume outcome relationship in peripheral vascular surgery an overview of reviews was conducted. The objective was to identify and evaluate the evidence from existing systematic reviews of the relationship between the volume of vascular procedures undertaken (by individual clinicians or hospitals) and outcomes including mortality, stroke and amputation, with the intention of identifying existing relevant, high quality and contemporary reviews that would negate the need for a new review.

#### METHODS:

Electronic database searches, including MEDLINE, EMBASE and the Cochrane Library, supplemented by reference list and citation searches were conducted to March 2015. Reviews were eligible for inclusion if they self-identified as a systematic review or used systematic review methodology to investigate the volume outcome relationship in the treatment of peripheral vascular disease. Study selection, data extraction and quality assessment were conducted by a single reviewer, the AMSTAR tool (1) was used for quality assessment; a narrative synthesis was performed. A pre-registered protocol is publicly available at: [http://www.crd.york.ac.uk/PROSPERO/display\\_record.asp?ID=CRD42014014850](http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42014014850)

#### RESULTS:

Of 710 screened records 11 relevant systematic reviews were identified examining the volume outcome relationship in three disease areas; abdominal aortic aneurysm, carotid procedures and

lower limb procedures. Results were suggestive of an inverse volume outcome relationship in AAA repair, but there was less evidence for such a relationship for the other vascular procedures. The most recent review was published in 2010 and the majority of included studies used US data and/or pre-dated recent technological advances (specifically the increasing use of endovascular procedures). Overall the quality of reviews was low with particular issues relating to protocol registration, quality assessment and study selection. Subsequent preliminary searches for primary studies have identified several relevant UK and European studies which were not included in the previously published reviews. It is anticipated that such evidence, more directly relevant to the UK and European context, will reflect recent technological advancements in vascular procedures and inform the ongoing volume-outcome debate in vascular surgery.

**CONCLUSIONS:**

There is a need for a new, high quality systematic review of this topic.

**REFERENCES:**

1. Shea BJ, Grimshaw JM, Wells GA, Boers M, Andersson N, Hamel C, et al. Development of AMSTAR?: a measurement tool to assess the methodological quality of systematic reviews. *BMC Med Res Methodol.* 2007;7(10).
- .....

## Poster 13B Impact Of Emerging Medical Evidence On Clinician Behaviour: A Pilot Study Of Low Risk Prostate Cancer Treatments Over a 10-Year Period

**DESCRIPTION:**

Evidence from RCTs in 2011 and 2013 confirmed that subgroups with low risk prostate cancer failed to gain a prostate cancer specific survival advantage with radical prostatectomy compared with watchful waiting. Furthermore, watchful waiting was associated with less morbidity, more quality adjusted life years, and reduced costs. We wished to determine if such information impacted clinical practice in New Zealand.

**PRESENTING AUTHOR:**

Caroline McAleese, Auckland District Health Board, New Zealand

**AUTHORS:**

Caroline McAleese, Anita Fitzgerald, Stephen Munn

**BACKGROUND AND OBJECTIVES:**

Evidence from two recent randomized controlled trials confirmed that subgroups of patients with low risk prostate cancer failed to gain a prostate cancer specific survival advantage with radical prostatectomy compared with watchful waiting (no further surveillance or treatment unless or until symptoms develop). Furthermore, cost-effectiveness analysis indicated that watchful waiting was associated with less morbidity; more quality adjusted life years and reduced costs. These studies were published between 2011 and 2013. We wished to determine if such information impacted clinical practice in New Zealand.

**METHODS:**

Medical records of all patients with a new diagnosis of prostate cancer in 2003, 2008 and 2013 from Auckland and Northland District Health Boards

were scrutinized to determine the proportion of patients with low risk disease and their treatment dispositions: radical prostatectomy, external beam radiation therapy, brachytherapy, active surveillance (conservative management but with regular PSA measurements, digital rectal examinations and repeated prostatic biopsy), or watchful waiting. The first three treatments were grouped as 'Curative intent'.

**RESULTS:**

Around one third of all patients with newly diagnosed prostate cancer had low risk disease. Tables 1 and 2 show the dispositional data for all low risk patients, as well as those both low risk and 65 years or older, for the years 2003, 2008 and 2013. (see tables as attached)

**CONCLUSIONS:**

These results show that there has been a significant change in the disposition of patients over time, consistent with the emerging evidence regarding conservative management of low risk prostate cancer. However, the evidence from the randomized controlled trials and the cost-effectiveness analysis favored watchful waiting whereas the change in treatment disposition was to active surveillance, a more expensive and less well-proven strategy. Reasons for the adoption of this strategy will be discussed.

**REFERENCES:**

Wilt et al, 2012 Prostate Cancer Intervention versus Observation Trial (PIVOT) trial New England Journal of Medicine 367: 203-213, 2012. Hayes et al, 2013 Observation Versus Initial Treatment for Men With Localized, Low-Risk Prostate Cancer, a Cost-Effectiveness Analysis Annals of Internal Medicine 158(12): 853-860, 2013. Anna Bill-Axelson et al, 2014 Radical Prostatectomy or Watchful Waiting in Early Prostate Cancer Scandinavian Prostate Cancer Group Study Number 4 (SPCG-4) N Engl J Med 2014; 370:932-942, March 6, 2014.

.....

.....

## Poster 14B Cost-Effectiveness Analysis Of DAA Based Treatment For Untreated Patients With Genotype 1 Chronic Hepatitis C In China

**DESCRIPTION:**

The study used decision tree and Markov modelling to determine the cost effectiveness of new hepatitis C virus (HCV) treatment drugs in China, providing evidence for decision makers.

**PRESENTING AUTHOR:**

Weiwei Hou, China National Health Development Research Center, China

**AUTHORS:**

Wei Wei Hou, Kun Zhao, Ying Peng, Qiu Esther Chang, Bingyan Sui, Xueran Li, Xiaochun Wnag, Lai, Wei, Jidong Jia, Ming Wu, Polin Chan

**BACKGROUND AND OBJECTIVES:**

Several highly effective new direct-acting antiviral (DAA) drugs with high sustained virologic response rate for the treatment of chronic hepatitis C (CHC) recently has made available in high-income countries. There was no evidence of their cost effectiveness in China.

**METHODS:**

This study compared the clinical outcome and cost effectiveness of DAA based treatment with current best available treatment and no treatment in China, using a decision analytic Markov model. The study was conducted at payer's perspective. Direct medical cost was used. The target cohort was treatment-naïve genotype 1 CHC Chinese patient aged 55.

**RESULTS:**

With DAA drug price of around Chinese yuan (RMB) 520,000 per 12 week treatment, the average life

time direct medical cost was RMB 591,167 for a CHC patient, with incremental cost effectiveness ratio (ICER) = RMB 184,685 /QALY compared to no treatment, and ICER = RMB 1.3 million /QALY compared to current treatment, both much higher than the willingness to pay level of China (1\*GDP/capita). With DAA drug price of RMB 6,000 per 12 week treatment, the average life time direct medical cost was RMB 77,166. DAA based treatment was cost saving compared with both current and no treatment. Deterministic and probabilistic sensitivity analysis confirmed the robustness of results.

### CONCLUSIONS:

For untreated genotype 1 CHC patients in China, DAA-based treatment can achieve better clinical outcome compared with current treatment regimen. However, the cost-effectiveness of DAA-based treatment depends heavily to the drug price. At US price, DAA-based treatment is not cost-effective in China. Negotiation to lower the price is strongly recommended.

---

## Poster 15B Growing Trend Analysis Of New And Emerging Health Technologies: Based On Euroscan Database

### DESCRIPTION:

The study was to analyze the development status of emerging health technologies (EHT) based on the 2000-2015 EuroScan database. We believe it is strategically significant to provide an earlier identification and alert HTA for EHTs.

### PRESENTING AUTHOR:

Dr. Ping Zhou, Key Laboratory of Health Technology Assessment, School of Public Health, Fudan University, China

### AUTHORS:

Ping Zhou, Xunyouzhi Chi

### BACKGROUND AND OBJECTIVES:

As one of the most significant collaborative network, the EuroScan aims to assess and share information regarding new and emerging health technologies (EHT). The database of the EuroScan is probably the international information source with the largest number of records concerning EHT. The study was to analyze the development status of EHTs based on 2000-2015 EuroScan database.

### METHODS:

Data of interest was exported from the EuroScan Database to Excel. A descriptive trend analysis depending on the agency, type of technology, and speciality through Jan.2000~Nov. 2015 was conducted. Frequency distributions of the different types of technology for various specialities and for various agencies were made with SAS 9.2.

### RESULTS:

During the past 16 years, the amount of the EHTs in the last five years has increased nearly twice than that in the first five years. Four agencies introduced the great majority of the technologies (77.0%), with drugs representing 53% of the total, followed by devices (22%). But the growth rate of every five years for combination is the largest (about 85%). The new techniques applied in the field of oncology and radiotherapy occupied nearly 33% of all, followed by those in the field of cardiovascular disease and vascular surgery (nearly 13%). The new techniques used in men's health and sexual health have risen most rapidly, followed by those for rehabilitation and disability. Some agencies were found to focus on drugs, whereas others focused mainly on devices.

### CONCLUSIONS:

Based on EuroScan's Database, a rough developing map of EHTs has been described since the beginning of the 21th century. We believe it is a strategically significance to provide an earlier identification and alert HTA for EHTs.

---

## Poster 16B The Efficacy And Safety Of Scopolamine For The Treatment Of Adult Depression: A Mini-HTA

### DESCRIPTION:

This is research about the efficacy and safety of scopolamine as an antidepressant agent used for the treatment of adult depression. The study is a literature review (a systematic one) which focused on the clinical outcomes in order to analyze and predict the effects and the rate of clinical response of the drug for the disease.

### PRESENTING AUTHOR:

Gabriela Brito, University of Brasilia, Brazil

### AUTHORS:

Gabriela Vilela de Brito, Pablo Estevam, Marcus Tolentino, Tais Galvão, Maurício Gomes Pereira

### BACKGROUND AND OBJECTIVES:

Depression is a common disorder, which has been affecting millions of people worldwide. The disease is responsible for one of the main global burden of disease, rising from third to second cause of global years lived with disability in the last years (from 1990 to 2013). Nowadays, there is evidence suggesting that hypersensitivity of the cholinergic system plays a role in the pathophysiology of depression. Thus, scopolamine could produce antidepressant effects. Based on that, we conducted a research in order to retrieve the best evidence available about the theme (possibility of this new clinical application of the drug). The objective was to evaluate the efficacy and safety of scopolamine for the treatment of adult depression.

### METHODS:

A wide systematic search was conducted in October of 2015 in the following databases:

PubMed, Embase, Web of Science, Cochrane Library, BVS (Virtual Health Library) and Scopus, with the intention of retrieving randomized clinical trials (RCT) about the subject. Clinical Trials website was also included in the search. The RCT chosen presented clinical outcomes. The selected studies were evaluated according to GRADE system and quality assessment form criteria contained in the Brazilian Ministry of Health's Methodological Guidelines.

### RESULTS:

From 1961 assessed references, only six RCT were included. The majority of assessed references are preclinical studies and some of them are duplicated. All of selected studies were crossover, open-label, placebo-controlled trials and represented a small sample, varying from 8 to 50 patients on average. In general, the studies selected were RCT phase II or III of lower methodological quality, which determined poor outcomes, with little clinical expression. Furthermore, the majority of the studies were conducted by the same group of researchers (Furey and Drevets). Therefore, clinical evidence is restricted, regarding both the quantity of studies and their quality.

### CONCLUSIONS:

Although the use of antimuscarinic agent is being investigated as one more therapeutic option for the treatment of depression, the clinical supportive data remain limited, which does not allow us to make inference about the rate of clinical response or how many patients would respond to scopolamine. It is not possible to claim long-term benefits about the drug in patients with chronic illness, be it improving patient's quality of life or reducing the risk of complications of the disease. For that, more good quality methodological studies about the subject are needed.

---

## Poster 17B The Patient Experience Of Colchicine Resistant-Familial Mediterranean Fever (Cr-FMF): Patients' Views Of Their Disease Journey

### DESCRIPTION:

This patient-focused study examined the impact of Familial Mediterranean Fever on patients resistant to the first line treatment, colchicine, and what role patients want to play and what information patients need so they can help guide their treatment.

### PRESENTING AUTHOR:

Jill Gregson, Novartis Pharma AG, Switzerland

### AUTHORS:

Karen Durrant, Kathleen Lomax, Jill Gregson

### BACKGROUND AND OBJECTIVES:

Background: Familial Mediterranean Fever (FMF) is a genetic disorder characterized by recurrent attacks of fever and pain, which is most common in those of Sephardic Jewish, Armenian, Turkish or Arabic descent. Colchicine is the mainstay of treatment for FMF,<sup>1</sup> but 5-15% of patients have an incomplete response to colchicine (e.g. colchicine-resistant FMF [cr-FMF]).<sup>2</sup> Objectives: To determine the impact of cr-FMF on patients'/caregivers' lives, to describe patient's journey from first onset of symptoms to present, and to identify areas for improvement in cr-FMF patient care.

### METHODS:

Patients with cr-FMF or their caregivers were recruited through disease experts in rare fever syndromes and patient support groups. Patients/caregivers completed a 20 page pre-interview questionnaire and a 90 minute interview covering symptoms, diagnosis process, treatment experience, treatment needs and impact on well-

being.

### RESULTS:

Sixteen cr-FMF patients were recruited. In-person interviews were completed in 2012. The majority were adults (87.5%) with a family history of FMF (63%). The disease generally started in childhood for these patients, with 65% experiencing symptoms before 10 years. A key feature was the delay in diagnosis ranging from 3 months to 30 years, with 50% experiencing a delay of around 5 years and many receiving earlier misdiagnoses. Attacks occurred with variable frequency, ranging from weekly to every 3-4 months, and the typical duration was up to 10 days in length. The most commonly reported symptoms were stomach/belly pain, fever, and joint pain. Flares were reported to be extremely debilitating and patients were often bed ridden during a flare due to severe pain. Patients reported the attack may occur spontaneously or be triggered by stress or menstruation. Work was regularly affected and children frequently missed school leading to disrupted education. Patients are often dependent on family for support and finance. The entire family was impacted. Parents who have passed the condition to their child expressed guilt and regret. Most patients (94%) in this survey continued to be treated only with colchicine despite partial response while reporting distressing side-effects. They identified the need for a well-tolerated treatment to prevent or reduce attacks, and one that was fast-acting to reduce attack symptoms. They also described having little information provided to them at diagnosis, causing the patients to search on their own for answers.

### CONCLUSIONS:

FMF patients in this survey reported a significant impact of the disease on physical, social, emotional, and practical/financial aspects of their lives. They commonly experienced diagnostic delays and misdiagnoses. Almost all patients in this cohort remain on monotherapy with colchicine. Patients said that therapeutic options with improved efficacy and fewer side-effects are needed for the

treatment of cr-FMF. Once the diagnosis is given, patients require educational materials to better understand their disease including the causes of their condition, the associated symptoms and the treatment options.

**REFERENCES:**

[1] Jacobs Z et al. Curr Allergy Asthma Rep. 2010;10(6):398-404 [2] Ben-Chetrit E et al. Clin Exp Rheumatol. 2008;26(4 Suppl 50):S49-S51

.....

## Poster 18B The Influence Of The Medical Insurance Payment Policy In Health Technology Assessment and The Empirical Analysis Based On China's Rural Residents Borrowing Medical Disease

**DESCRIPTION:**

Medical insurance payment policy is a key aspect of HTA. As a developing country, the medical insurance of China has space to improve. The government needs to make health technology assessment, according to national condition and development model.

**PRESENTING AUTHOR:**

Li Yunfei, Huazhong University of Science and Technology, China

**AUTHORS:**

Li Yunfei

**BACKGROUND AND OBJECTIVES:**

Medical insurance payment policy is a key aspect of HTA. As a developing country, the medical insurance of China has space to improve. The government needs to make health technology assessment, according to national condition

and development model. Objective: We set foot on medical lending for disease in Chinese rural residents to make empirical analysis, in order to provide scientific policy assessment basis for medical insurance payment system.

**METHODS:**

The amount of surveyed population was 6502, which includes 3240 poor people and 3262 non-poor people, and each family was a team. the relevant information was collected through household survey, and the rural family who were born into poverty and not born into poverty were analyzed from medical lending and lending channels.

**RESULTS:**

Poor households borrowing probability was higher, which means its disease economic risk is bigger, and the influence of the economic burden on the family economy is bigger; lending and there is no difference between the poor families and non-poor families. Although there is a larger lending requirements in poor families, they subject to a narrow social relation network. besides, the channels of medical lending in rural residents are focused on bank, Chinese Rural Credit and usurious loan.

**CONCLUSIONS:**

To strengthen the protection of rural poverty population, which should focus on medical care, consider prepaid compensation, breaks up the pay line, etc. To adhere to the principle of "the comprehensive arrangement for serious disease", and give priority to the hospital compensation, and secondary compensation of high medical costs, etc. To construct a system of participation in social risk management.

## Poster 19B Infant Mortality, Risk Factors And Causes

### DESCRIPTION:

The main causes of infant mortality were premature birth, stillbirth, hypoxia, and congenital anomaly. Some of the main risk factors are: lack of experienced midwives, inexperienced or general practitioners provide emergency service in intensive care units, and early or wrong transportation of critical neonates. Results suggest that the mother's general health, their socioeconomic status, health care provider's competency, human resource capacity, and inspection and regulation of health service quality have an effect on neonatal mortality rate.

### PRESENTING AUTHOR:

Narangerel Natsagnyam, Center for Health Development, Mongolia

### AUTHORS:

Bat-Erdene Chuluunbat, Shirnen Lkhamsuren, Narangerel Natsagnyam

### BACKGROUND AND OBJECTIVES:

The cause of death of the newborn and main risk factors infant mortality rate in Mongolia is as follows: the poverty of the population, malnutrition of mothers' in low socioeconomic families, lack of health education, poor service, and quality of health care. As per 2014 infant mortality rate of 65.3% were neonatal deaths, of which 81.4% occurred in the prenatal period, 18.6% for 7-28 days. It follows from this high demand the causes and factors of infant mortality, especially in the early period. Aimed to investigate the causes and risk factors of infant mortality

### METHODS:

The study used the quantitative and qualitative research methods. For example, interviews, documents and questionnaire survey.

### RESULTS:

The study covered a national scale, and research conducted in 1196 among obstetricians, gynecologists, pediatricians and medical staff. The main causes of infant mortality were premature birth, stillbirth, hypoxia, and congenital anomaly. Infant mortality rate directly relates to the health of mothers, their socioeconomic status, and quality of healthcare for mothers and newborns. Some of the main risk factors are: lack of experienced midwives, inexperienced or general practitioners provide emergency service in the intensive care units, and early or wrong transportation of critical neonates. And there is still a lot of complications and poignancy sort of secondary infection due to improper organization of chambers and patient care rooms. In connection with the failure and the implementation of standards of care and treatment management of newborns, lack of SCBA and insufficient training of medical workers, improper usage of medical equipments also affect the care and services in case of emergency. There is very high demand and urgent needs of breathing apparatus, ECG, anesthesia machine, phototherapy machine, oxygen machine, ultrasound machine and monitors in the all neonatal units and newborn departments.

### CONCLUSIONS:

The main underlying causes of infant death related to premature birth, stillbirth, hypoxia, and congenital anomaly. Above results suggest that, mothers general health, their socioeconomic status, health care providers' competency, human resource capacity, inspection and regulation of health service quality have an effect on neonatal mortality rate.

.....

## Poster 20B Cost Effectiveness Analysis On Universal Hearing Impairment Screening (UHS) Associated With DNA Screening (UHS-DNA), Compared To UHS

### DESCRIPTION:

Newborns with hearing impairment will benefit from early detection and intervention, lessening the negative impact of hindered language development. According to the 2006 Chinese census on population with disability, 27% of people with disability suffer from hearing impairment and verbal dyspraxia. In this study, we will examine and compare cost, effectiveness, and accuracy of universal hearing impairment screening (UHS) associated with DNA screening (UHS-DNA) and UHS. A decision-analytic Markov model was conducted to evaluate the effectiveness of the two hearing impairment screening strategies and a multi-way sensitivity analysis was performed using the Monte Carlo simulation.

### PRESENTING AUTHOR:

Yuzhao Li, China National Health Development Research Center, China

### AUTHORS:

Yuzhao Li, Yanzh, Chen, Rui Zhao

### BACKGROUND AND OBJECTIVES:

Newborns with hearing impairment will benefit from early detection and intervention, lessening the negative impact of hindered language development. According to the 2006 Chinese census on population with disability, 27% of people with disability suffer from hearing impairment and induced verbal dyspraxia. There are currently no models to compare the effectiveness of UHS versus UHS-DNA in China. The objective of this study is to compare the cost-effectiveness and accuracy of the two hearing impairment detection strategies with follow-ups of 0 to 6 months, 6 to 12 months, and 12 to 18 months.

### METHODS:

More than 80,000 newborns in Wuhan, Hubei Province are enrolled in the study. To assess accuracy, the proportions of false negative and false positive rates were examined to evaluate the accuracy of UHS and UHS-DNA. To assess effectiveness, the Disability Adjusted Life Years (DALYs) were utilized as outcome indicator. A decision-analytic Markov model was conducted to evaluate the effectiveness of the two hearing impairment screening strategies and a multi-way sensitivity analysis was performed using the Monte Carlo simulation.

### RESULTS:

Main part of the result in this study is in progress. The current preliminary results indicate that true positive cases among 76,146 newborns are 2,222 (2.9%). The rest of the results are expected to be finalized by March, 2016.

### CONCLUSIONS:

It is currently in progress and is expected to be finalized by March 2016.

---

## Poster 21B Determining The Time Of Sending Appointment SMS Text Messaging Reminders To Patients On Antiretroviral Therapy (ART): Pilot Study At TASO Jinja, Uganda.

### DESCRIPTION:

TASO Jinja is one of the 11 Centers of Excellence of TASO Uganda Ltd. It provides antiretroviral therapy (ART) to over 7000 patients. ART refill is provided using the appointment system, however, we noted 59% out of 3414 returned on the scheduled appointment for review. We introduced sending SMS reminders to patients with the aim of reminding patients of scheduled appointments.

**PRESENTING AUTHOR:**

Darius Kato, TASO Uganda Ltd,TASO Jinja Centre, Uganda

**AUTHORS:**

Darius Kato, Seruma Emmanuel, Stephen Okoboi

**BACKGROUND AND OBJECTIVES:**

TASO Jinja provides ART to over 7000 patients. ART refill is provided using the appointment system however we observed that of the 3414 that was given the appointment for review only 59% returned on the scheduled appointment. We introduced sending SMS reminders to patients with the aim of reminding patients to keep scheduled appointment and to determine the perfect timing for sending an appointment SMS reminder.

**METHODS:**

We collected client’s telephone contacts and developed a telephone database that was linked to appointment system. A simple reminders text message in the local language was developed, we randomized 1000 patients to receive reminders text messages 24 hours before the scheduled appointment while other 1000 to receive text messages 48 hours before the appointment. we used the A chi-square test in order to establish the relationship between those who wanted to receive reminders 24 hours before the appointment due date and 48 hours before the appointment date.

**RESULTS:**

1522 clients consented and enrolled, 71.3% females, with mean age of 40 years (1QR=35), 55% were married. Out of 292 interviewed,99% (F, 69%; M, 32%) received the text message reminders for their appointment schedule and 99.3% received on time, 94.5% of those who received reminders have never missed their appointments, with 50.4% of those who received reminders 48 hours kept their appointment and 48.9% who received reminders 24 hours kept their appointments.50.9% preferred receiving SMS reminders 48 hours before the

appointment which helps them to plan, save and reminds them the return date. 49.1% preferred 24 hours before the appointment.

**CONCLUSIONS:**

Sending SMS reminders to patients helps patients to plan for their scheduled visits and it helps to reduce on missed appointments hence facilitating proper planning of services by the service provider. For better appointment keeping SMS reminders should be sent 48 hours before.

**Poster 22B Budget Impact And Cost-Effectiveness Of An Innovative Blood Glucose Measurement Device Using Pattern Alert Technology In Insulin-Treated Diabetics In Japan**

**DESCRIPTION:**

The authors conducted an economic model, comparing a conventional blood glucose measurement device (CBGM) and an innovative blood glucose measurement device (IBGM) with PatternAlert® technology. The objective was to determine (i) the number of potentially avoidable sHes through deployment of IBGM, compared to CBGM (ii) the IBGM device net costs (iii) and its impact on overall management costs.

**PRESENTING AUTHOR:**

Julia Krumreich, Econ-Epi, Germany

**AUTHORS:**

Julia Krumreich, Nadine Froehlich, Marion Schauf, Jack H Wang, Reiko Toho,York Zoellner

**BACKGROUND AND OBJECTIVES:**

Hypoglycemic events (HEs) are important acute

complications in patients with diabetes mellitus, especially when insulin-treated. Severe HEs (sHEs) cause high treatment costs and have a major impact on patients' quality of life. A newly available, innovative blood glucose measurement (IBGM) device, using PatternAlert® technology (PAT) automatically identifies patterns of low blood glucose and alerts the patient about the potential for having a future sHE. This economic model is conducted to determine (i) the number of avoidable sHEs through deployment of IBGM device using PAT, compared to a conventional blood glucose measurement (CBGM) device, (ii) the IBGM device net costs, and (iii) its impact on overall management costs.

#### **METHODS:**

Values attached to epidemiologic, cost and behavioral input variables were taken from scientific literature and authoritative sources. A decision-analytic, one-year model comparing direct costs (payer perspective) and sHE outcomes between IBGM device and CBGM device was developed, and budget impact and cost-effectiveness calculations were performed, reflecting the Japanese insulin-treated diabetic population.

#### **RESULTS:**

On an overall population level, in the base-case scenario (sHE incidence 8.99%, likelihood of taking action based on PAT 84%), usage of the IBGM device could lead to an extra 13,493 avoided sHEs annually, compared to a CBGM device. Assuming price parity of test strips across both devices (¥148/strip referring to Japan's National Reimbursement Scheme Rates 2008), its implementation is cost-neutral. At an average treatment cost of ¥95,827 per single sHE, this would lead to overall net cost savings of ¥1,276,334,077 per year. In alternative model scenarios, achievable savings range from ¥28,855,960 (sHE incidence 0.41%, likelihood of taking action based on PAT 80%) to nearly ¥2,816,159,323 (sHE incidence 16.3%, likelihood of taking action based on PAT 90%) per year. In terms of incremental cost-effectiveness, the IBGM device is considered dominant, as it features higher effectiveness (extra sHEs avoided) at lower overall

costs compared to a CBGM device.

#### **CONCLUSIONS:**

An innovative blood glucose measurement device with PatternAlert® technology can avoid a sizeable number of severe hypoglycemic events and may lead to considerable cost savings, if implemented widely in the target population.

---

## **Poster 23B The Factors Affecting Hospitalization Cost Analysis Of Acute Myocardial Infarction**

#### **DESCRIPTION:**

Analysis of the change of acute myocardial infarction from 2010 to 2014 and the main influence factors, providing the basis for reasonable control of medicare patients in hospital fees. Hospitalized patients' total cost has no obvious growth, but the cost of raw materials increase obviously. The main influence factors include the cost of raw materials composition ratio, number of days in hospital and the proportion of out-of-pocket.

#### **PRESENTING AUTHOR:**

Na Li, Fudan University; Shanghai Jiaotong University, China

#### **AUTHORS:**

Na Li

#### **BACKGROUND AND OBJECTIVES:**

Analysis of the change of acute myocardial infarction from 2010 to 2014 and the main influence factors, providing the basis for reasonable control of medicare patients in hospital fees.

#### **METHODS:**

Collecting patients with acute myocardial infarction

in shanghai a grade A tertiary hospital from 2010 to 2014, on admission diagnosis of acute myocardial infarction, patients with the form of insurance of medical insurance for urban workers, a total of 529 cases. Including, age, gender, situation, hospitalization days, outcome, hospital cost, the cost of raw materials and the proportion of out-of-pocket. Using descriptive analysis and multiple linear stepwise regression analysis and other methods to analyze the influence factors of the total cost in hospital.

### RESULTS:

Five years, hospitalized patients' total cost has no obvious growth, but the cost of raw materials increase obviously. Hospitalized accounted for the proportion of the total cost rise year by year. Multiple stepwise linear regression results show that the factors for the cost of raw materials accounts for a ratio, hospitalization days and in turn pay scale, gender and admitted to hospital affected the hospitalization cost. The main influence factors include the cost of raw materials composition ratio, number of days in hospital and the proportion of out-of-pocket.

### CONCLUSIONS:

Shorten the hospitalization days and had a rational use of intravascular stent to reduce the cost of raw materials, and having a appropriate pay scale can effectively reduce the total cost in hospital.

---

## Poster 24B Measuring Caregiver Quality Of Life: Which Aspects Really Matter?

### DESCRIPTION:

This is a web-based study, to generate new data on health related quality of life (HRQoL) based on patients and informal caregivers rather than the general population, with particular focus on whether EQ-5D-5L adequately captures the aspects of health that really matter for patients and

their informal caregivers.

### PRESENTING AUTHOR:

Olina Efthymiadou, Medical Technology Research Group - London School of Economics and Political Science, United Kingdom

### AUTHORS:

Olina Efthymiadou, Jean Mossman, Panos Kanavos

### BACKGROUND AND OBJECTIVES:

Ageing societies, together with pressures to restrain the growth of healthcare expenditure, introduces fears that by 2017, caregiver burden is likely to escalate to an extent where the responsibilities facing informal caregivers will largely exceed what these individuals can feasibly provide. Caregiver research has largely studied stress, depression and the burden, arising as the direct consequences of caregiving, but there is little research assessing the aspects that truly impact on Quality of Life (QoL) and wellbeing of long-term caregivers. Since the effectiveness of a technology in healthcare economic evaluations is routinely valued at a cost per QALY paradigm, it is imperative that the QALYs generated by the EQ-5D-5L should accurately reflect the aspects that really matter for the end users of the respective technology. As there are only five dimensions of health represented by EQ-5D-5L we aimed to identify whether there are other, important domains of informal caregivers wellbeing which may be missed by a standardised QoL measure such as the EQ-5D-5L.

### METHODS:

We conducted a retrospective, online survey of patients and their informal caregivers across a range of chronic conditions. In Europe, 278 national and 30 Pan-European patient associations were invited to circulate the survey to their network of patients and informal caregivers. Similarly, 12 international organisations were also approached in Australia, Brazil, China, Japan, Malaysia and Singapore. The survey collected data on caregivers' demographics and QoL (EQ-5D-5L). Caregivers

were also asked to say if there were any aspects of their health which have had a major impact on their wellbeing that were not captured by the EQ-5D-5L and if so, to define what those aspects were.

## RESULTS:

77 responses were received from informal caregivers across 17 disease areas and 18 countries, including UK (51%), Denmark (8%), Australia (6.4%), Croatia (5%), Greece (4%), Germany (4%) and South Africa (4%). Caregivers had 15% ( $\pm 23\%$ ) utility loss compared to the general population. HRQoL worsening was mostly attributed to problems with anxiety/depression (77%), pain/discomfort (55%) and performance of usual activities (53%). 40% of respondents considered EQ-5D-5L insufficient in capturing important wellbeing aspects and of these aspects the most commonly reported were 'neglecting personal needs' (21.5%), 'time limitation' (16.7%), 'Issues with health care services/professionals' (10.5%), 'sleep deprivation' (9.5%), 'financial burden' (7%) and 'fatigue' (7%).

## CONCLUSIONS:

Regardless of its sampling limitations (for example, respondents were largely drawn from UK based patient organisations), our study showed that caregivers experience a worsening of their QoL compared to the general population, and that EQ-5D-5L does not capture all the health aspects which are important for shaping the wellbeing of these individuals. We conclude that utilisation of EQ-5D-5L may raise potential inconsistencies in caregiver QoL measurement, although further investigations are required to strengthen our understanding on caregivers' experiences and QoL preferences.

## REFERENCES:

Carers Trust, 2012. 'Concern at lack of Social Care White Paper in Queen's speech to Parliament,' 2012. Available online at: <https://www.carers.org/news/concern-lack-social-care-white-paper-queen-s-speech-parliament> Rand, S. and Malley, J. (2014), Carers' quality of life and experiences

of adult social care support in England. Health & Social Care in the Community, 22: 375-385.

## Poster 27B Growth Factors For Angiogenesis In Peripheral Arterial Disease (PAD): A Cochrane Review

### DESCRIPTION:

We conducted the Cochrane review to evaluate the clinical effects of growth factors (delivered as proteins or over gene expression) in patients with peripheral arterial disease (PAD) of the lower extremities. The protocol of the review has been published and 20 trials were identified in the literature search up-to-date. The results will be presented at the HTAi meeting.

### PRESENTING AUTHOR:

Vitali Gorenoi, Hannover Medical School, Germany

### AUTHORS:

Vitali Gorenoi, Michael U Brehm, Armin Koch, Anja Hagen

### BACKGROUND AND OBJECTIVES:

Treatments to alleviate PAD are of high societal importance. The use of growth factors which may be delivered directly as proteins or indirectly over their gene expression has emerged as a promising strategy to treat PAD patients. The aim of this systematic review is to evaluate the efficacy and safety of growth factors promoting angiogenesis as a treatment option in patients with PAD of the lower extremities.

### METHODS:

Study search was performed in the Cochrane Peripheral Vascular Diseases (PVD) Group's Specialised Register (including MEDLINE, EMBASE, CINAHL etc.) and the Cochrane Central Register of

Controlled Trials (CENTRAL). Some additional trial databases (ClinicalTrials.gov etc.) were searched for details of ongoing and unpublished studies. Reference lists of relevant publications were also checked to identify additional studies. We included randomized controlled trials (RCTs) comparing growth factors (delivered directly or indirectly, s. above) with no intervention or placebo in patients with PAD. The investigated primary outcomes are: limb amputation, level of pain and death; the secondary outcomes are: severe complications, pain-free walking time/distance, hemodynamic measures of blood flow (e.g. ankle brachial index) and level of ulceration. The eligibility of the retrieved publications for inclusion in the review will be assessed independently by two review authors. Two review authors will also independently assess the risk of bias of each trial. The results of the risk of bias assessment will be used to select studies with low risk of bias for the main meta-analyses (vs. all studies in the sensitivity meta-analyses). We will evaluate clinical heterogeneity and calculate statistical heterogeneity of the studies using the I<sup>2</sup> statistic and chi-squared test. If possible, we will summarise the results of the studies calculating the odds ratio (OR) for dichotomous outcomes or mean difference (MD) for continuous outcomes with the corresponding 95% confidence intervals (CIs). If pooling is not possible, we will undertake a narrative synthesis of the results. We will also assess the quality (i.e. strength) of the evidence for each endpoint using the system developed by the Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group. The judgments about applicability of the evidence will be performed separate from assessments of the quality of evidence.

## **RESULTS:**

898 hits were identified by the literature search. After the selection procedure, 20 trials were found for 3 different growth factors: 8 for fibroblast growth factor (FGF), 5 for hepatocyte growth factor (HGF) and 7 for vascular endothelial growth factor (VEGF). The protocol of the review has been published in June 2015. The results will be

presented at the HTAi meeting.

## **CONCLUSIONS:**

The conclusions will be presented at the HTAi meeting.

## **Poster 28B Anti-TNF Drugs For The Treatment Of Rheumatoid Arthritis In The Public Health System, Brazil: A Prospective Cohort**

### **DESCRIPTION:**

In this real-world drug utilization study, half of rheumatoid arthritis (RA) patients achieved the target of remission or low disease activity with adalimumab and etanercept use, demonstrating that the biological disease-modifying anti-rheumatic drugs (bDMARDs) are feasible alternatives for the treatment of RA. The remaining patients should have their therapeutic options reviewed.

### **PRESENTING AUTHOR:**

Francisco de Assis Acurcio, Federal University of Minas Gerais, Brazil

### **AUTHORS:**

Jéssica Santos, Alessandra Almeida, Haliton Oliveira Junior, Francisco Acurcio, Adriana Kakehasi, Augusto Guerra Junior, Marion Bennie, Brian Godman, Juliana Alvares

### **BACKGROUND AND OBJECTIVES:**

Rheumatoid arthritis (RA) is a systemic, chronic and progressive inflammatory disease which affects the synovial membrane of joints, and which may lead to bone and cartilage destruction. Treatment of RA includes non-steroidal anti-inflammatory, corticoids and synthetic (sDMARD) and biological (bDMARD) disease-modifying antirheumatic drugs. bDMARD has demonstrated efficacy for the treatment of rheumatoid arthritis and are

considered costly. Consequently, the study evaluates the effectiveness of bDMARD in clinical practice on a cohort of patients with rheumatoid arthritis in the Public Health System (SUS), Brazil.

## METHODS:

Individuals with a diagnosis of rheumatoid arthritis treated with anti-TNF $\alpha$  agents, adalimumab and etanercept, were included in the open prospective cohort study. To assess the effectiveness of the TNF $\alpha$  agents, the Clinical Disease Activity Index (CDAI) was applied, comparing results at baseline and after 6 and 12 months of follow-up. The drug was considered effective when the patient achieved remission or low disease activity and not effective when in moderate or high disease activity.

## RESULTS:

One hundred and thirty-seven patients completed one year of follow-up. The most widely used bDMARD was adalimumab (75.9%), with etanercept used by 24.1%. Both drugs, adalimumab and etanercept, significantly reduced disease activity as measured by CDAI during a 1-year of follow-up (p

## CONCLUSIONS:

In this real-world drug utilization study, half of RA patients achieved the target of remission or low disease activity with adalimumab and etanercept use, demonstrating that the bDMARD are feasible alternatives for the treatment of RA. The remaining patients should have their therapeutic options reviewed. In view of the high cost of the bDMARD to SUS and, consequently, to society, versus sDMARD continuous pharmacotherapeutic monitoring should be performed by a multidisciplinary team. This could achieve better results, assuring the quality of use of the bDMARD, and will be subject of further research.

## REFERENCES:

Lee DM, Weinblatt ME. Rheumatoid arthritis. Lancet 2001; 15; 358(9285):903-11. da Mota LM,

Cruz BA, Brenol CV et al. 2012 Brazilian Society of Rheumatology Consensus for the treatment of rheumatoid arthritis. Rev Bras Reumatol 2012; 52: 152-74.

Smolen JS, Landewé R, Breedveld FC et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs. Ann Rheum 2010; 69: 964-75. doi: 10.1136/ard.2009.126532.

Singh JA, Furst DE, Bharat A et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care Res 2012; 64: 625-39. doi: 10.1002/acr.21641.

---

## Poster 29B Hepatitis C Infection Drugs Pricing: Evolution Over Time

### DESCRIPTION:

Hepatitis C treatments evolved dramatically during the past 25 years, reaching an unprecedented 99% cure rate, although marketed at very high prices. We found that the market access price of all regimens per achieved cure remained constant over time, consistent with a value based pricing model. This strong correlation held true for both Switzerland (R<sup>2</sup>=0.956) and the United States (R<sup>2</sup>=0.943).

### PRESENTING AUTHOR:

Nathalie Vernaz, University of Geneva Hospital, Switzerland

### AUTHORS:

Nathalie Vernaz, François Girardin, Nicolas Goossens, Urs Brügger, Marco Riguzzi, Arnaud Perrier, Francesco Negro

**BACKGROUND AND OBJECTIVES:**

Hepatitis C virus (HCV) treatment was introduced in the early 1990s and evolved in a stepwise manner with the interferon-alfa (IFN-alfa) monotherapy (step 1), followed by its combination with ribavirin (RBV)(step 2), then by the introduction of pegylated IFN-alfa associated with RBV (step 3). The landscape evolved drastically with the marketing of the first direct acting antivirals in 2011, i.e. the first generation serine protease inhibitors boceprevir and telaprevir and, later, simeprevir (step 4). Finally, the first IFN-free regimens became available, based on the nucleotidic NS5B polymerase inhibitor sofosbuvir, associated or not with ledipasvir, and the combination of ombitasvir/paritaprevir/ritonavir and dasabuvir (step 5). Each step was associated with an increased sustained viral response (SVR). We aimed to determine the potential association between the stepwise increase in SVR and drug prices over 25 years for all regimens registered by the official Swiss guidelines for treatment-naive, genotype 1 chronic hepatitis C patients.

**METHODS:**

We performed a linear regression analysis and a mean costs analysis. We then conducted a sensitivity analysis using United States (US) prices at the time of US drugs licensing. We selected exclusively randomised clinical trials of drugs approved for use in Switzerland from 1997 to July 2015 involving treatment-naïve patients with HCV infection of genotype 1. The main outcome measures were the proportion of patients achieving SVR, the market access price and the costs per SVR.

**RESULTS:**

We found a statistically significant positive association between the costs of HCV regimens and the rate of SVR both in Switzerland (R2 = 0.956) and in the US (R2=0.943). We also analyze total costs and costs per SVR for each individual treatment regimen and show a steady cost increase paralleling an increase in SVR rate for each treatment step. This resulted in a relatively stable cost per achieved SVR for each treatment step

except step 1(interferon only). The incremental cost per additional percentage of SVR was 634 USD in Switzerland and 963 USD in the United States.

**CONCLUSIONS:**

The value-based HCV treatment pricing model over 25 years exhibits a stable cost per achieved SVR. However, the costs per treatment increased substantially due to higher effectiveness of newer drugs. Health care systems even of wealthy countries such as Switzerland or the US are still struggling with the high budget impact of these new agents.

**Poster 30B Building Efficient Healthcare Systems Through Integrated Health Care Decision Making In Low And Middle Income Countries**

**DESCRIPTION:**

Resource allocation decisions are made at various levels of healthcare systems (national or regional; disease or technology level). Inconsistencies in the objectives of decision makers at these different levels could lead to inefficiency in the healthcare system. We explore whether such inconsistencies exist in low and middle income countries, and identify policy options to improve the efficiency of resource allocation.

**PRESENTING AUTHOR:**

Grace Marsden, Office of Health Economics, United Kingdom

**AUTHORS:**

Grace Marsden, Martina Garau, Adrian Towse

**BACKGROUND AND OBJECTIVES:**

Health technology assessment (HTA) and other tools for decision making are used around the

world to promote efficient resource allocation within healthcare systems (HCS). Such resource allocation decisions are made at various levels (for example national or regional level; disease or technology level), yet it seems that the objectives of decision makers at the different levels do not always align with one another, leading to inefficiencies in the health system. We explore whether these inconsistencies exist in current processes in low and middle income countries (LMICs), and identify policy options which could be used to improve the efficiency of resource allocation processes in these regions. We concentrate on LMICs as HCS in these countries are more open to options for design and organisation than other more established systems, thus there is an opportunity to prevent inefficiencies creeping in by design if the three levels are aligned.

#### **METHODS:**

Three strands of literature were reviewed: current approaches for priority setting in LMICs; health service delivery and integrated care (including disease management programmes (DMPs)); future of healthcare systems. Specific case studies illustrating examples of DMPs and healthcare system reforms implemented in LMICs were identified. Interviews were conducted with global health experts to gather further information on existing priority setting processes in LMIC and the different levels of decision making. Experts were asked to identify additional case studies where possible.

#### **RESULTS:**

We discuss three key levels of decision making: macro, intermediate and micro level. The macro level is concerned with the design and organisation of the healthcare system; Intermediate level decisions relate to the configuration of service delivery, payment and incentive schemes, and health workforce for specific conditions; Micro level resource allocation is about the reimbursement and/or funding of individual health technologies. We found substantial between-country variation

in priority setting at all levels: some LMICs have implemented formal processes at the micro level (e.g. Thailand), whilst others have implemented major reforms at the macro level (e.g. Rwanda). In many other LMICs, priority setting remains informal. We found evidence of fragmentation and inconsistency between the different levels of decision making. For example, criteria for priority setting ranges from equity and affordability at the macro level, to clinical improvements at the intermediate level, to cost-effectiveness at the micro level. Such fragmentation and misalignment between levels of decision making means that decision maker's objectives are not consistent, and is highly likely to lead to inefficiencies in the health system.

#### **CONCLUSIONS:**

Based on our literature review and interviews, we identified a number of policy options and tools which could be, or have been, used to realign decision making at the different levels in LMICs. These fall into three main categories 1) a consistent principle of value being used to inform decision making at all levels, 2) strengthening decision making at the disease (or intermediate) level, and 3) monitoring data on health and economic consequences of decisions at all levels. Such policy options could be used to align the objectives of decision making throughout governments and health services, and could be invaluable enablers for healthcare decision making in Asia. However further research is required to develop an integrated decision making framework that could align all levels of decision making.

---

### **Poster 31B A Cost-Effectiveness Analysis Of Islet Transplantation Compared With Intensive Insulin Therapy For The Treatment Of Type 1 Diabetes**

#### **DESCRIPTION:**

The economic analysis developed a cohort simulation model to compares the costs and health outcomes between islet transplantation (IT) compared to intensive insulin therapy (IIT) alone for the treatment of type 1 diabetes (T1DM). Clinical data were derived from the Clinical Islet Program (CIP) database that tracks clinical outcomes in 138 consecutive IT recipients who received 301 islet infusions.

**PRESENTING AUTHOR:**

Dr. Charles Yan, Institute of Health Economics, Canada

**AUTHORS:**

Charles Yan, Anderson Chuck

**BACKGROUND AND OBJECTIVES:**

The objective of the economic analysis was to estimate the costs and cost effectiveness of islet transplantation (IT) compared to intensive insulin therapy (IIT) alone for the treatment of type I diabetes (T1DM). We developed a cohort simulation model to compares the costs and health outcomes between IT and IIT for eligible IT patients with T1DM. The model simulates the natural progression of T1DM under IIT and alternatively under IT represented through a sequence of health states including IT, Full Graft Function (FF), Partial Graft Function (PF), No Graft Function (NF), Secondary Complications, IIT, Skin Cancer, Renal Failure and Death.

**METHODS:**

Given that diabetes is a chronic disease that is associated with long-term morbidity, it is important that the time horizon for the analysis allow relevant costs and consequences of each intervention to be captured. The model thus starts with a cohort of patients at 19 years of age and was conducted at a time horizon of 20 years and lifetime, respectively. Data required for the economic analysis are broad and include epidemiologic, clinical, cost and health outcome data. All of them were from a variety of disparate sources including published

research literature, administrative health databases and clinical program data. Clinical data on islet transplantation were derived from the Clinical Islet Program (CIP) in Edmonton. The program houses a database that tracks the clinical outcomes in 138 consecutive IT recipients who received 301 islet infusions from March 11, 1999 to July 4, 2011.

**RESULTS:**

The total health system cost per patient at a 20-year time horizon is \$35,769 for IIT compared to \$410,373 for IT translating into an incremental cost of \$374,604. The QALYs per patient is 5.17 for IIT compared to 7.23 for IT translating into an incremental QALY gained of 2.05. Hence, the cost per additional QALY gained for IT compared to IIT is \$182,584. The total health system cost per patient at a lifetime horizon is \$50,277 for IIT compared to \$410,373 for IT translating into an incremental cost of \$429,062. The QALYs per patient is 6.61 for IIT compared to 8.96 for IT translating into an incremental QALY gained of 2.35. Hence, the cost per additional QALY gained for IT compared to IIT is \$160,952.

**CONCLUSIONS:**

IT is associated with clinically significant improvements in health outcomes but it is not cost saving compared to IIT. Hence, IT does not dominate IIT (i.e. less costly and more effective) and its cost effectiveness depends on whether its associated health benefit is worth its additional cost. A prohibitive factor in the value of IT is its high associated cost per additional QALY gained.

.....

**Poster 32B Professional And Health Technology Assessment Core Development By The Paulista HTA Network - REPATS - Of The São Paulo State Health Secretariat Brazil**

## **DESCRIPTION:**

The Health Secretariat of the São Paulo State Network REPATS, professionals envisage solutions, and produce or test knowledge to subsidize decision-making for healthcare planning. Through hospital-based units specific thematic working groups monthly meetings and workshops, multicenter clinical trials and HT assessments, members succeed to list pharmaceuticals, medical devices and surgical procedures, or public policy innovations adoptions. Examples will be presented.

## **PRESENTING AUTHOR:**

Dr. Evelinda Trindade, São Paulo State Health Secretariat, Brazil

## **AUTHORS:**

Evelinda Trindade, Patricia Nieri Martins, Sergio Muller, Andrea Zamberlan, Teresa Toma, David Uip

## **BACKGROUND AND OBJECTIVES:**

The Brazilian Science and Technology Policy dictated the development of thematic research networks aiming to realize strategic studies required for healthcare planning. This directive was adopted at the São Paulo State Health Secretariat to invite hospitals aiming to multiply the Health Technology Assessment Hospital-Based Units. The Health Secretariat of the São Paulo State Network - REPATS, healthcare professionals can envisage solutions for issues and daily logistics, and can suggest and produce or test relevant knowledge required to subsidize decision-making for the healthcare planning at various levels. Through improved efficiency in the provision of services this strategy may optimize the use of the healthcare scarce resources. Objectives: to formalize the HTA thematic working groups in order to improve the quality of health care; to study the cost-effectiveness of existing

## **METHODS:**

the REPATS has several groups producing systematic reviews with or without meta-analyses,

observational clinical studies, randomized controlled trials, micro costing for economic evaluations, budget impact assessments, preparation of Technical Scientific Reports - PTCs, complete or complex welfare surveys about new and/or existing technologies, in order to support decision-making. The monthly meetings are streamed live and videos are available in the Health Virtual Library of the State Secretariat of Health of São Paulo aiming to facilitate access, and participation of professionals and services to the generated knowledge and the dissemination of culture of ATS.

## **RESULTS:**

REPATS thematic working groups are specific. Pharmacology, Oncology, Diabetes, Transplantation, Osteoporosis, Neurology, Hospital Infection Control, Palliative Care, Scientific Evidence Resources or Materials Prequalification Groups have been producing structured knowledge according to the Brazilian Health Ministry guidelines. REPATS includes 35 hospitals and institutions linked to education and health care in several multiprofessional and medical disciplines, interested in incorporating new technologies, discontinue use of obsolete ones, using HTA methods to share solutions or public policy innovations. Examples of REPATS members-PTCs assessments that succeed to list pharmaceuticals, medical devices and surgical procedures, or to adopt public policy innovations will be presented.

## **CONCLUSIONS:**

REPATS is expanding the number of hospital-based HTA centers-NATS, inviting hospital managers to participate and/or send representatives to the meetings and monthly HTA methods workshops. These meetings are promoting the exchange of experience enabling partnerships between researchers for the development of multicenter studies as well as enable healthcare professionals, physicians or others, to conduct HTA research.

## **REFERENCES:**

Evelinda Trindade, Patrícia Nieri Martins, Andrea Gomes O. Neias Zamberlan, Paula Araujo Opromolla, Tereza Setsuko Toma, Sérgio Swan Muller; Décio Mion, José Manuel Camargo, Roberto Kalil, Antonio José Pereira, Eloísa Dutra Bonfá, David Everson Uip, Clarice Petramale, EQUIPE DGITS /CONITEC/MS. São Paulo state HTA network experience with CONITEC. Revista Eletrônica Gestão & Saúde (ISSN: 1982-4785) 2015 Outubro; 6 (Supl.4):3297-12.

---

## Poster 33B Indirect Cost Of Rheumatoid Arthritis In Poland: How Value Is Societal Perspective

### DESCRIPTION:

Rheumatoid arthritis (RA) is a chronic disease, affecting over 200 000 people in Poland, 56% of whom are in productive age (30+), and unequivocally restricting their activities, leading to relatively rapid impairment or premature death. The costs calculated with FC method amounted to 1,2 billion PLN and are twice lower than the costs calculated with the HC method (2,8 billion PLN).

### PRESENTING AUTHOR:

Dr. Magdalena Wladysiuk, HTA Consulting, Poland

### AUTHORS:

Wladysiuk Magdalena, Szmurlo Daria, Kostrzewska Daria, Bebrysz Magdalena

### BACKGROUND AND OBJECTIVES:

RA is a chronic disease, affecting over 200 000 people in Poland, 56% of whom are in productive age (30+), and unequivocally restricting their activities, leading to relatively rapid impairment or premature death. Direct cost are consider are the most driver of reimbursement decision in Poland. Objectives: To comapre the relation the annual direct and indirect costs of RA in Poland.

---

### METHODS:

Data collected from public sources, such as SII (The Social Insurance Insitution), NHF (The National Health Fund) and the available literature (own survey data) were used to estimate the cost from the public payer's and social perspective. The indirect costs were assessed using both the friction cost method (FC) and the human capital method (HC). All costs referred to 2012 and were presented in PLN.

### RESULTS:

The direct cost related to RA from public payer's perspective amounted to 400 million PLN. The largest part in the direct cost had pharmaceutical treatment (mainly biologics) reaching almost 55%, while hospitalization nearly 22%. The social benefits, offered to RA patients by SII. not the public payer's budget, accounted for another 200 million PLN. The cost of short term absenteeism (sick leaves) amounted to 577 million PLN, and the cost of informal care 251 million PLN. The long term absenteeism cost (work disability) varied from 9 million PLN (FC) to 1554 million PLN (HC).

### CONCLUSIONS:

The burden of RA in Poland is high when considering the direct as well as the indirect costs. The burden of disease from the societal perspective allow to assess real impact on disease due to early disability and shorter survival of RA patients in comparison in general population. The costs calculated with FC method amounted to 1,2 billion PLN and are twice lower than the costs calculated with the HC method (2,8 billion PLN).

---

## Poster 34B Measuring The Impact Of Positive HTA Assessments: Investigating The Factors That Affect Implementation

**DESCRIPTION:**

Once a HTA organisation makes a positive recommendation or concludes there is strong clinical and/or economic evidence for a medical technology - what then? As a consequence of the many influencing factors involved, measuring the impact directly attributable to HTA is challenging. We aimed to explore the direct and indirect impact of HTA and to investigate the implementation and subsequent impact of positive HTA evaluations on selected medical technologies in different healthcare settings.

**PRESENTING AUTHOR:**

Dr. Liesl Strachan, Medtronic, Australia

**AUTHORS:**

Liesl Strachan, John Gillespie

**BACKGROUND AND OBJECTIVES:**

Once a HTA organisation makes a positive recommendation/advice - or concludes there is strong clinical and/or economic evidence for a medical technology - what then? As a consequence of the many influencing factors involved, measuring the impact directly attributable to HTA has several challenges. In countries where HTA reports are directly transferable to policy making, adoption into clinical practice is often not observed. Where access and appropriate uptake of the technology is achieved, can we attribute this to the HTA itself? What other factors influence implementation of a positive HTA recommendation? In environments where HTA has little impact on patient access or more appropriately little improvement in health outcomes, what then is the role of HTA? The objective of this investigation was twofold: 1.To explore the body of research that examines the direct and indirect impact of HTA. 2.To investigate the implementation and subsequent impact of positive HTA evaluations on selected medical technologies in different healthcare settings: including assessment of the factors that may affect implementation - and what this ultimately means

for patients.

**METHODS:**

A systematic search of the published literature was undertaken to identify reviews and studies that discuss or attempt to measure the impact of HTA. HTA-specific databases and several major HTA organisation websites were searched in order to identify HTAs that positively recommended the use of selected medical technologies in several geographies where HTA organisations are well established. Impact of these selected HTA's was assessed by measuring a number of factors such as uptake of the technology over time; change in population health such as improved patient outcomes (morbidity or mortality).

**RESULTS:**

There remains a paucity of research into the impact of HTA. The vast majority of research on HTA has focussed on the characteristics of the various systems, processes and best practice methodology with the aim of identifying what essential elements are required to achieve a positive HTA review. Obviously measuring HTA impact beyond the direct processes of dissemination is extremely challenging and demands significant resource. While certain frameworks that assess HTA impact have been published(1), their use has been sporadic or inconsistent and their transferability to various healthcare systems untested. In regards to our second objective, positive HTA reports for several medical technologies, such as Deep Brain Stimulation for Parkinson's disease, Endovascular endograft repair of abdominal aortic aneurysm and catheter ablation for the treatment of atrial fibrillation have been preliminary investigated for their broader impact.

**CONCLUSIONS:**

Ultimately, implementing HTA recommendations based on robust evidence-based medicine methodology and cost effectiveness data should

result in better health outcomes, contributing to sustainability by improving outcomes per dollar spent. Measuring the impact of this however, requires more planning and priority afforded to it than current efforts.

#### REFERENCES:

INAHTA. Framework for reporting on impact of HTA reports. December 2003. Available: <http://www.inahta.org/>

---

## Poster 35B The Cost Of Severe Haemophilia In Five European Countries: The CHES Study

#### DESCRIPTION:

This abstract provides an introductory insight into a larger scale burden of severe haemophilia study across the EU5. This evidence base developed will help the medical and patient community, as well as policymakers, to better understand the costs and wider societal burden associated with severe haemophilia.

#### PRESENTING AUTHOR:

Jamie O'Hara, University of Chester, United Kingdom

#### AUTHORS:

Jamie O'Hara, David Hughes, Charlotte Camp, Tom Burke

#### BACKGROUND AND OBJECTIVES:

Haemophilia is a genetic disorder that causes a deficiency of a clotting factor in the blood of which there are two main forms; A and B, which can be classified as mild, moderate or severe. Individuals with severe haemophilia represent approximately one-third of the haemophilia population in Europe [1,2] and can experience recurrent, spontaneous bleeds, often in the absence of any trauma event. In many cases, recurrent joint inflammation

(arthropathy) leads to joint deformity, reduced mobility, and chronic pain. Initiation of prophylactic factor replacement therapy at an early age is considered critical to reducing the frequency and severity of bleed events, and subsequent arthropathy. However, uptake of prophylaxis varies substantially across European countries, and the cost-effectiveness of prophylaxis remains unclear [3-5]. In 2014, a major study was initiated to quantify the Cost of Haemophilia across Europe from a socioeconomic perspective (CHES). The study took a societal perspective and employed a 'bottom-up' methodology with the aim of quantifying the annual direct and indirect costs of severe haemophilia A and B in adults across France, Germany, Italy, Spain, and the UK (EU5).

#### METHODS:

A cross-section of haematologists (surveyed January-April 2015) provided demographic and clinical information and 12-month ambulatory and secondary care activity for patients via an online survey. The physicians completed a patient record form (PRF) for the next 8-10 eligible patients and invited each patient to complete a corresponding patient self-completion (PSC). In turn, patients provided corresponding direct and indirect non-medical cost information, including work loss and out-of-pocket expenses, as well as quality of life and adherence information. A cost database was developed for each country using publically-available information. The project was governed and approved by the University of Chester Ethics Committee.

#### RESULTS:

One hundred and thirty nine physicians participated in the study from across the EU5, capturing information on 1,285 patients (996 A and 289 B patients representing approximately 16% and 28% of the respective target populations). Five hundred and fifty one patient completed PSC questionnaires. Preliminary results indicate that the annual total cost of severe haemophilia in the EU5 was over EUR1.4billion. Per-patient costs were estimated at just under EUR 200,000 per annum,

with direct costs accounting for the vast majority of the burden.

## CONCLUSIONS:

Findings were consistent with a similar US study [6] where cost of factor replacement outweighed other costs, representing 95%-99% of direct costs. However, 60% of the remaining cost was attributed to indirect resource use, predominantly resulting from work loss due to ill health. The CHES study has produced a detailed resource, cost and patient outcome database from which a comprehensive burden of disease study can be developed on a scale far greater than previous studies. This evidence base will help medical and patient communities, as well as policymakers, to better understand costs and wider societal burden associated with severe haemophilia.

## REFERENCES:

1. Stonebraker JS, Bolton-Maggs PHB, Soucie JM, Walker I, Brooker M. A study of variations in the reported haemophilia A prevalence around the world. *Haemophilia*. 2010 Jan;16:20-32.
2. Stonebraker JS, Bolton-Maggs PHB, Michael Soucie J, Walker I, Brooker M. A study of variations in the reported haemophilia B prevalence around the world. *Haemophilia*. 2012 May;18:e91-4.
3. Miners AH. Economic evaluations of prophylaxis with clotting factor for people with severe haemophilia: why do the results vary so much? *Haemophilia*. 2013;19:174-80.
4. Fischer K, Steen Carlsson K, Petrini P, Holmström M, Ljung R, van den Berg HM, et al. Intermediate-dose versus high-dose prophylaxis for severe hemophilia: comparing outcome and costs since the 1970s. *Blood*. American Society of Hematology; 2013 Aug 15;122:1129-36.
5. IQWIG. Therapie von Hämophilie- Patienten Impressum. 2015.
6. Lippert B, Berger K, Berntorp E, Giangrande P, van den Berg M, Schramm W, et al. Cost

effectiveness of haemophilia treatment: a cross-national assessment. *Blood Coagul Fibrinolysis*. 2005;16:477-85.

---

## Poster 36B Pricing And Reimbursement Of Biosimilars In Kazakhstan.

### DESCRIPTION:

The high cost of pharmaceuticals has become an important issue in the battle to control healthcare costs. Because a biosimilar is likely to be less expensive, the assessment of the cost-effectiveness of a biosimilar depends on the relative effectiveness. The cost-effectiveness of a biosimilar needs to be calculated at multiple time points throughout the life cycle of the product.

### PRESENTING AUTHOR:

Dr. Alexander Kostyuk, Kazakh Agency for Health Technology Assessment, Kazakhstan

### AUTHORS:

Alima Almadiyeva, Alexander Kostyuk, Amangaly Akanov

### BACKGROUND AND OBJECTIVES:

The high cost of pharmaceuticals, especially biologics, has become an important issue in the battle to control healthcare costs. The key driver for the biosimilars market is likely to be cost containment pressures in healthcare systems in the context of aging populations and of the current financial and economic crisis. Because the medicines involved are so expensive, even a modest price reduction in percentage terms generates savings in the millions of USD over for Kazakhstan's healthcare system. Given that biosimilars are agents that are similar but not identical to the reference biopharmaceutical, this study aims to introduce and describe specific issues related to the economic evaluation of biosimilars by

focusing on the relative costs, relative effectiveness, and cost-effectiveness of biosimilars. The assessment of cost-effectiveness of a biosimilar is complicated by the fact that evidence needed to obtain marketing authorization from a registration authority does not always corre

#### **METHODS:**

The literature review did not wish to identify and discuss all economic evaluations of biosimilars, but rather drew on published economic evaluations with a view to identify and illustrate the factors affecting the cost-effectiveness of biosimilars. As such, the literature review of economic evaluations was not systematic. Overall, studies estimating the short to mid-term savings from biosimilars arrive at a range of 10 to 50 percent reduction in unit price. In other words, if all else is held constant, and if every patient is transitioned to a biosimilar, spending on biologics will fall by between 10 and 50 percent.

#### **RESULTS:**

Some of these studies separately estimate the impact on total spending on biologics. The very patient will transition from originator to biosimilar products. One study estimates how lower biosimilar unit prices and cost sharing could encourage patients and payers to increase utilization. Because a biosimilar is likely to be less expensive than the comparator, the assessment of the cost-effectiveness of a biosimilar depends on the relative effectiveness. If appropriately designed and powered clinical studies demonstrate equivalent effectiveness between a biosimilar and the comparator, then a cost-minimization analysis needs to be carried out and the least expensive medicine is chosen.

#### **CONCLUSIONS:**

If there are differences in the effectiveness of a biosimilar and the comparator, other techniques of economic evaluation need to be employed, such as cost-effectiveness analysis or cost-utility analysis. Given that there may be uncertainty

surrounding the long-term safety and effectiveness of a biosimilar, the cost-effectiveness of a biosimilar needs to be calculated at multiple time points throughout the life cycle of the product. Future research in these areas will provide helpful context for policymakers, patients, and providers and will strengthen the foundation for future cost savings estimates and analyses.

---

## **Poster 37B Conditional Coverage With Evidence Development In South Korea From 2009 To 2016: ESD In Early Gastric Cancer**

#### **DESCRIPTION:**

This study is the first study conducted in terms of conditional coverage with evidence development in Korea. Although the research is until being conducted, our study may serve to inform developments CED in the future.

#### **PRESENTING AUTHOR:**

Na Rae Lee, NECA, Korea

#### **AUTHORS:**

Na Rae Lee, Ji Young Kim, Chan Mi Park, Da Hyun Lyu, Youngju Cha

#### **BACKGROUND AND OBJECTIVES:**

CED (Coverage with Evidence Development) is a specific way to coverage for promising technologies for which the evidence remains uncertain. In Korea, Endoscopic submucosal dissection (ESD) for early gastric cancer (EGC) was conditionally covered only in specific indication in 2008, so additional evidence generation was required for reimbursement. The aim of the study is to report the prospective long-term outcomes after ESD compared with open surgery within the context of the CED.

**METHODS:**

This study was performed in collaboration with Korean society of gastrointestinal endoscopy, National Evidence-based Healthcare Collaborating Agency (NECA) and the Korean society of pathologists. The primary outcome was 5-year survival rate. Secondary outcome were short-term outcomes, recurrence rates and quality of life. Five-year survival rate of ESD in patients with EGC will be compared to open surgery published 2010 in Korea.

**RESULTS:**

In 2008, ESD was determined as 'conditional coverage' by Health Insurance Policy Review Committee. Ministry of health and welfare has requested a five-year long-term follow-up study to the KSGE, the NECA and the KSP cooperated. Therefore a multicenter, prospective cohort study was started in 2010 to evaluate long- and short-term outcomes of ESD on EGC. From May 2010 to December 2011, patients who had planned ESD were prospectively enrolled from 12 university hospitals nationwide in Korea. In 2011, ESD was determined as covered according to retrospective study in Korea and Japan. However, long-term outcomes of our study will be reported after the 5-year follow-up of the last enrolled patient, which is expected to be in December 2016.

**CONCLUSIONS:**

This study is the first study conducted in terms of conditional coverage with Evidence Development in Korea. Although the ESD was determined as coverage on the basis of retrospective studies, our research is still in progress and may serve to provide prospective and long term evidence about decision making.

.....

**Poster 39B Membership Retention In The National Health Insurance Scheme In Ghana**

**DESCRIPTION:**

This abstract examines how members of the Ghana's National Health Insurance Scheme (NHIS) are retaining their membership. It focused on the last five years, 2010-2014 due to availability and reliability of membership data. In all, membership increased by 29% over the period under study. Membership retention also increased from 44% to 75% between 2010 and 2013 but dropped to 70% in 2014.

**PRESENTING AUTHOR:**

Eric Nsiah-Boateng, National Health Insurance Authority, Ghana

**AUTHORS:**

Eric Nsiah-Boateng, National Health Insurance Authority, Ghana

**BACKGROUND AND OBJECTIVES:**

Ghana, a lower middle income country in Sub-Saharan Africa implemented National Health Insurance Scheme (NHIS) in 2004. The Scheme is aimed at removing out-of-pocket payment by providing financial access to health care for all residents. It is currently operational in 155 districts across the country in an effort to achieve the overarching aim of universal health coverage. However, little is known about the membership retention in the NHIS; therefore, this paper seeks to analyze membership retention in the NHIS over the last five years, 2010-2014.

**METHODS:**

Membership data for the 2010-2014 period were retrieved from the NHIS membership database and analyzed. First, the overall retention rate was analyzed, followed by analysis of membership

.....

retention at the regional level.

**RESULTS:**

Over the 2010-2014 period, the NHIS increased its membership by 29% from 8.2 million in 2010 to 10.5 million in 2014. The number of subscribers who renewed their membership also increased from 44% in 2010 to 75% in 2013 and dropped to about 70% in 2014. At the regional level, the Volta region recorded the highest percentage change of membership subscription (80%) between 2010 and 2014, followed by Brong-Ahafo (57%). Four out of the 10 regions recorded consistent increase in membership retention rate over the last three years, 2012-2014 with Brong-Ahafo region recording the highest of 89% in 2014.

**CONCLUSIONS:**

There was a consistent increase in membership subscription over the last five years of the NHIS; however, the number of members retaining their membership has started declining. Further research would be necessary to ascertain the reasons for this negative trend in membership retention.

.....

## Poster 40B Safety And Effectiveness Of Thermal Pulsation Treatment For Obstructive Meibomian Gland Dysfunction: Systematic Review

**DESCRIPTION:**

Safety and effectiveness of thermal pulsation treatment for obstructive meibomian gland dysfunction: systematic review.

**PRESENTING AUTHOR:**

Wonjung Choi, National Evidence-based Healthcare Collaborating Agency

**AUTHORS:**

Won Jung Choi, Kyung Min Lee

**BACKGROUND AND OBJECTIVES:**

The main objective of this study is to assess the safety and effectiveness of thermal pulsation treatment for obstructive meibomian gland dysfunction

**METHODS:**

**RESULTS:**

Total 4 studies were included. No severe complication was reported for both of the groups. In randomized clinical trial, the intervention group displayed more statistically significant improvement in the symptoms than the control group in terms of OSDI

**CONCLUSIONS:**

Conclusion: Thermal Massage Therapy for the Treatment of Dry Eye Syndrome was deliberated to be a health technology with grounds for the safety and effectiveness in improving the dry eye symptom by alleviating the obstructed meibomian glands through application of heat and vibration to the areas the eyes of patients with dry eye syndrome.

.....

## Poster 41B Advancing The Development Of A General Practitioner System In Hainan Province, China: A Stakeholder Analysis Among Township Health Center Directors

**DESCRIPTION:**

We conducted a survey among 140 directors of township health centers from the entire province of Hainan, China, to analyze the current state of development and existing problems related to

the implementation of general practitioner ( GP) system development , and to inform health care system decision-making using both a qualitative and quantitative analysis of stakeholder values and involvement in GP system implementation.

### **PRESENTING AUTHOR:**

Prof. Hong Zhou, Hainan Medical University, China

### **AUTHORS:**

Hong Zhou, Yu Zeng, Shaoxing Chen, Zhonghua Zhou, Timothy N Stephens

### **BACKGROUND AND OBJECTIVES:**

'Instructional Views on Establishing a General Practitioner System by the State Council' (No. 23, 2011) was issued by the Chinese central government to stimulate the national establishment of a high-quality GP system in order to alleviate the problem of 'difficult and expensive healthcare access'. A more thorough understanding of the perspectives of GPs, postgraduate trainees, and directors of township health centers on the implementation of GP System development will facilitate 'promoting the combination of system design and practice exploration at a grass roots level', as emphasized by China's President Xi Jinping in December 2014. The goals of our research on 'GP System Development for Hainan Province' were as follows: to analyze the current state of development and existing problems related to the implementation of a GP system in Hainan Province, and to inform health care system decision-making using both a qualitative analysis of stakeholder values and a quantitative analysis of stakeholder involvement in GP system implementation.

### **METHODS:**

In August 2014, we conducted a survey among 140 directors of township health centers from the entire province of Hainan, China, during a training program on Essential Public Health Service. The questionnaire was designed to reflect the key aspects of the 'Instructional Views' document (No.

23, 2011). Data was processed using Epidata3.1 and analyzed using SPSS13.0.

### **RESULTS:**

29% of township health centers carried out training programs for currently practicing GPs, and 49% received funding from their administration unit for GP continuing professional development. 70% conducted Specialist retraining program for practice-based GPs. 46% expressed interest in participating in a rural oriented free training program. 57% trained GPs through specialist retraining program, and 39% through standardized training programs. 75% provided a practice-based Continuing Medical Education Training Program for GPs, and 64% used the training results as important evidence for position employment, annual evaluation, and bonus recommendations. 78% conducted open recruitment for directors of township health centers. On improvement of incentive schemes, 99% have a position performance salary scheme in place. In 96% health centers, grass roots level health professionals were enrolled in social insurance. 99% had carried out regional health talent pool allocation. 71% had established a GP Qualification System, and 60% had set up a scientific performance evaluation mechanism.

### **CONCLUSIONS:**

We conducted a stakeholder analysis to explore feedback from the directors of township health centers on the development of a GP system in Hainan province. Development of a high-quality GP system should be emphasized as an important task of health care reform and included as a target for evaluation and an indicator of government performance. Multiple measures, including standardization of the GP training model, quality improvement, and continuing medical education need to be implemented to promote high-quality GP training. During this period of transition to the new GP system model, multiple avenues of training qualified GPs need to be adopted, including postgraduate standardized training, practice-based training, rural oriented free training programs

and degree advancement. Further needs include strengthening supervision, further establishment of a GP incentive scheme, and formulation of health system policy to promote the rational planning of training and allocation of GPs to meet local population needs.

---

## Poster 42B Challenge For The Health Technology Assessment And The Evidenced-Based Decision Making In Korea

### DESCRIPTION:

This study provides an overview of health technology assessment and decision making in Korea. We suggest future framework for decisions of resource allocation to improve performance of HTA in Korea.

### PRESENTING AUTHOR:

Yoon Jung Choi, Health Insurance Review and Assessment Service, Korea

### AUTHORS:

Yoon Jung Choi, Youn Song,Choi

### BACKGROUND:

Background: Korea implemented the health technology assessment (HTA) as the NHI required the system from 2007.

### OBJECTIVES:

The study provides an overview of the health technology assessment and decision making in Korea. We suggest the future framework for decisions of resource allocation to improve performance of HTA in Korea.

### METHODS:

We systematically collected and reviewed relevant information to describe the HTA process and

reimbursement systems.

### RESULTS:

New medical procedures should be assessed their safety and effectiveness by the HTA Committee to be listed to 'Benefit Schedule' in Korea. After that, the Expert Assessment Committee in Health Insurance Review and Assessment service (HIRA) reviews cost-effectiveness (economic value, substitutability) and benefit appropriateness (coverage principle, budget impact). From 2008 to 2011, a total of 691 applications were submitted and 304 applications (44.0%) were eligible to be assessed. Among 106 cases in 2011, 20 cases were accepted as reimbursement, 62 cases were rejected and the others were in progress. In Korea, the result of decision making is dichotomous, 'Covered' or 'Not covered'. There is lack of the flexibility by the level of evidences of the medical procedures and devices in decision making. We should consider followings to increase efficiency and transparency in the evidence-based decision making. Firstly, we need to develop the flexible process of the new medical procedures and devices reflected on the technology's characteristics. There is an increasing demand of intermediate decision such as conditional coverage, risk-sharing agreement, etc. Secondly, we consider improving the transparency in HTA reimbursement decision: engagement with patients, industry and citizen. And lastly, we need to set the monitoring and re-evaluation evidence-based system for assessing new or potentially obsolete technologies

### CONCLUSIONS:

The process of HTA and decision making in Korea should improve efficiency and transparency. Engagement of stakeholders, development of the detail and explicit process in evidence-based decision making, and setting re-evaluation system should be considered. Further study should work out a strategy in detail.

### REFERENCES:

2014. The Review of health technology Assessment

and decision making in Korea. HIRA 2013. Reassessment in HTA, Yoon Jung Choi.

---

## Poster 43B The Economic Evaluation About The Cost Estimation Of The Clinical Pathway In China

### DESCRIPTION:

In order to achieve the county-level public hospital reform, the China National Health Development Research Center (CNHDRC) has received technical support from the National Institute for Health and Care Excellence (NICE) of the UK to launch the project named "Strengthening evidence-based policy making in support of universal healthcare: the practice and dissemination of China integrated clinical pathway and payment reform" (hereafter referred to as 'the project').

### PRESENTING AUTHOR:

Yanzhu Chen, China National Health Development Research Center, China

### AUTHORS:

Yanzhu Chen, Yuzhao Li

### BACKGROUND AND OBJECTIVES:

In order to achieve the county-level public hospital reform, the China National Health Development Research Center (CNHDRC) has received technical support from the National Institute for Health and Care Excellence (NICE) of UK to launched project named, 'Strengthening evidence-based policy making in support of universal healthcare: The practice and dissemination of China integrated clinical pathway and payment reform' (here in after referred as 'the project'). The project is funded by

the Department for International Development and coordinated by the Center for Project Supervision and Management of the National Health and Family Planning Commission of China.

### METHODS:

The project use standard cost method to implement payment reform that provided incentive mechanisms and established information management systems in pilot areas. We used Statistic Package for Social Science (SPSS) to calculate the minimum cost, the maximum cost and the midpoint.

### RESULTS:

Our project team selected Qianjiang of Chongqing, Hanbin of Shaanxi, Wenxian of Henan and Huangdao of Shandong as four pilot areas for integrated management pathway (prevention, treatment and rehabilitation) for four chronic diseases: Chronic obstructive pulmonary disease (COPD), cerebral hemorrhage, cerebral infarction and transient ischemic attack (TIA). In addition to implementing integrated pathways.

### CONCLUSIONS:

In the first half of 2014 to 2015, the project produced 16 cost estimation reports. The cost estimation included cost of drugs, examination, recovery, consumption and labor. The statistical range for each cost was calculated, in addition to the proportion of each cost to the total. According to the total costs of the treatments based on the new pathway reforms and comparing to the costs before the pathway implementation, several pilot hospitals negotiated with health care institutions and New Rural Cooperative Medical System (NCMS) to adjust regional policies to set up a payment standard and reimbursement measurement.

## Poster 44B Health Advice By Mobile Alerts Improves Management Of Diabetes Patients In Suburbs Of Kampala District, Uganda

### DESCRIPTION:

A patient-centric initiative aiming to support and improve management of diabetes patients in Kampala district, Uganda. It uses common mobile phone technology based on interactive voice response to support health outcomes through adherence of 182 diabetes patients through mobile technology for community health, implemented by Uganda Network of AIDS Service Organizations and Uganda Alliance of patients' organizations.

### PRESENTING AUTHOR:

Joshua Wamboga Magawa, Uganda Network of AIDS Service Organisations (UNASO), Uganda

### AUTHORS:

Joshua Wamboga, Robert Mwesigwa, George Okwir

### BACKGROUND AND OBJECTIVES:

Health Advice by Mobile Alerts is a patient-centric initiative aiming to support and improve management of diabetes patients in Kampala district, Uganda. It uses common mobile phone technology based on interactive voice response to support health outcomes through adherence of 182 diabetes patients through mobile technology for community health implemented by Uganda Network of AIDS Service Organizations and Uganda Alliance of patients' organizations. Improve treatment adherence by providing health voice messages and generating relevant clinical data to better inform treatment decision making for 182 patients accessing diabetes treatment in suburbs of Kampala district in Uganda

### METHODS:

Collected treatment information of 182 diabetes patients between clinic visits at public health units, provided daily health information through interactive voice based services via common mobile phones to support appointment reminders, health education, weekly adherence and feedback, pill reminders, provided preliminary diagnosis in relation to patient's history. Supported interactive services for counseling, self-monitoring and accountability interventions. Provided education and training tailored to needs and individual diabetes patients.

### RESULTS:

Collected treatment information of 182 diabetes patients between clinic visits at public health units, provided daily health information through interactive voice based services via common mobile phones to support appointment reminders, health education, weekly adherence and feedback, pill reminders, provided preliminary diagnosis in relation to patient's history. Supported interactive services for counseling, self-monitoring and accountability interventions. Provided education and training tailored to needs and individual diabetes patients.

### CONCLUSIONS:

Health Advice by Mobile Alerts leads to cost-effective and sustainable adherence for patients and can easily be linked to health care system in Uganda

---

## Poster 45B An Assessment Of A Text Messaging-Based Disease Surveillance In Health Care In Vietnam

### DESCRIPTION:

In recent years, the number of developing countries that are using mobile technology to address health needs is growing. However, rigorous evidence of

the use of mobile technology in health care and its practicalities and efficiency remain unknown. This assessment aims to bring up in-depth evaluation on a text messaging-based infectious disease surveillance system implemented in Vietnam.

**PRESENTING AUTHOR:**

Cuong Nguyen, Institute of Population, Health and Development, Vietnam

**AUTHORS:**

Cuong Nguyen

**BACKGROUND AND OBJECTIVES:**

In Vietnam, infectious disease surveillance data is collected through a paper-based system with four government tiers leading to a large delay. Meanwhile, mobile phones are abundant and very popular in the country, and known to be a useful tool in healthcare worldwide. Therefore, there is the great potential for the development of a timely disease surveillance system through the use of mobile phone text messages. This project aimed to explore insights about the feasibility and practicalities of the utilization of text messaging-based interventions in health care in Vietnam by identifying potential challenges and barriers, bringing up ethical issues as well as assessing its cost-effectiveness.

**METHODS:**

A text messaging-based disease tracking system was set up in Vietnam with patient reports texted by clinic staff. Two six-month trials utilizing this disease tracking system were designed and implemented in two northern provinces of Vietnam to report two infectious diseases: diarrhea and influenza-like illness. A semi-structured self-reported questionnaire survey was developed to measure the feasibility and practicalities of the system from the participants. An in-depth evaluation of system together with the potential to enhance current paper-based system, including its cost-effectiveness, was carried out. Statistical analysis was performed using Stata software.

**RESULTS:**

Most participants were female, and nearly half (44%) were head of commune health center. Around two thirds (63%) of participants retained the basic structure of the Short Message Service (SMS) report, and there is a strong influence of those people on the time they spent texting the information. Most (86%, 69/80) believed that they can report all 28 infectious diseases asked for by the Ministry of Health by using SMS, and this highly influences the performance of their work.

**CONCLUSIONS:**

Most participants were female, and nearly half (44%) were head of commune health center. Around two thirds (63%) of participants retained the basic structure of the Short Message Service (SMS) report, and there is a strong influence of those people on the time they spent texting the information. Most (86%, 69/80) believed that they can report all 28 infectious diseases asked for by the Ministry of Health by using SMS, and this highly influences the performance of their work.

---

**Poster 46B** The Policy, Law And Legal Environment Related To Supplying, Distribution And Financing Of Medication And Medical Devices For Reproductive Health

**DESCRIPTION:**

The laws and regulations are now set up to ensure the stability for distributing and supplying reproductive health medications and medical devices and steadily creating an environment to easily distribute and deliver the medications and supplies to the rural areas. The funding for the drugs and equipment are going towards being fully funded by the government and the drug importation and humanitarian aid have been

increasing in the recent years.

**PRESENTING AUTHOR:**

Takhad Unurtsetseg, Center for Health Development, Mongolia

**AUTHORS:**

Shirnen Lkhamsuren, Unurtsetseg Takhad

**BACKGROUND AND OBJECTIVES:**

As of 2013, there have been 61132 reported cases of complications during pregnancy, delivery, and postnatal stage and if we compare this number to total deliveries, 77.0% were reported to have had some sort of complications. Additionally, the number of sexually transmitted diseases has been steadily increasing with 14904 cases reported in 2013, the syphilis accounting for 41.9% as well as 23 new cases for HIV/AIDS. These numbers can confirm the need for continuous improvement of the access and quality of reproductive healthcare, including the supply and distribution of reproductive health medication and medical equipment. Thus, this study aimed to provide necessary evidence and information to decision makers on the financial policy and legal framework of the supply and distribution of reproductive health medication and medical equipment.

**METHODS:**

The research was studied using content analysis method by collecting and analyzing health policies and legal framework articles related to the supply, distribution, and financing of reproductive health medication, and medical equipment.

**RESULTS:**

We have analyzed total of 37 legal documents consisting of 5 healthcare policies, 5 laws, 7 strategies, 2 national programs, 13 regulations and decisions and 4 healthcare service technology studies to make our research conclusion. Currently, the rights and obligations to order national level reproductive health drugs lies solely with

the Ministry of Health, and the responsibility to distribute the drugs are implemented by the provincial and city health departments. Accredited pharmaceuticals and drug supply organizations licensed from the state administrative are in charge of the supply and distribution of reproductive health medication and medical equipment. The government is responsible for the repayment of the reproductive health medication and medical supplies and the financing is approved by the Cabinet member in charge of healthcare finance. The investment for the reproductive health drugs and medical supplies should be increased in phased steps and it has been reflected in the policies and legal documents that the financing will be fully funded by the government by 2016. The legal framework of the reproductive healthcare has been leaning towards discounting the prices for reproductive health care medication. Starting from 2015, there will be 7 medications that will be discounted from the essential reproductive health care medications list.

**CONCLUSIONS:**

The Mongolian National Policy on drugs and medications are on the stage for reform and so are the financial policies and legal framework regarding the supply and distribution for reproductive health medication. The laws and regulations are now set up to ensure the stability for distributing and supplying reproductive health medication and medical equipment and steadily creating an environment to easily distribute and deliver the medications and supplies to the rural areas. The funding for the drugs and equipment are going towards being fully funded by the government and the drug importation and humanitarian aid have been increasing in the recent years.

## Poster 47B Impact Of The InFormation On Shared Decision Making (SDM) In The Early Diagnosis Of Alzheimer's Disease

### DESCRIPTION:

Investigate the impact of the information on the shared decision making regarding the early diagnosis of Alzheimer's disease.

### PRESENTING AUTHOR:

Dr. Joo Youn Kim, National Evidence-based Healthcare Collaborating Agency, Korea

### AUTHORS:

Joo Youn Kim, Seong Woo Seo, Min Ji Kim, Seihee Kim, Ji Eun Choi

### BACKGROUND AND OBJECTIVES:

Background: Shared decision making (SDM) is a process whereby patients participate in health care decision together with experts, including clinicians. Objectives: The aim of this study is to investigate the impact of the information on patients' SDM on early diagnosis through expensive imaging test such as F18-Positron emission tomography (FDG-PET) for the Alzheimer's disease.

### METHODS:

Methods: To investigate the impact of SDM information, we conducted an online, cross sectional survey of 1000 healthy adults residing in Korea asking about their perception of the early diagnosis of Alzheimer's disease. The survey targeted a quota sample of 1000 subjects considering their age, sex, location, and financial condition. We asked about the participants' intention to take the imaging test, before and after providing information on the test including: the benefits and drawbacks, cost, accuracy.

### RESULTS:

Results: Of one thousand participants, 669 (67%) preferred to take the imaging test before providing SDM information. Among those 669 participants who preferred taking the imaging test, 392 (59%) changed their intention from 'Yes to No' after having received the SDM information, while 35 (11%) individuals of the 331 respondents who did not prefer the imaging test, changed their mind to take the imaging test. In the respondents group of 'Yes to No', 92% chose the reason as 'Cost is too high'. Answers such as 'Accuracy is too low' (14%), 'Can't be fully recovered' (9%) followed as closed questions with multiple choice answers.

### CONCLUSIONS:

Conclusion: Providing unbiased information is one of the essential elements of SDM. Of 669 individuals in this study who preferred to take the FDG-PET for the early diagnosis of Alzheimer's disease, a total 59% of participants turned their intention into 'No' after receiving the SDM information. From the results of this study, we can infer that providing appropriate health care information affects people's decision making.

---

## Poster 48B Factors Influencing Participation In The Screening And Detection Of Dementia (In Korean Adults)

### DESCRIPTION:

The purpose of this study is to investigate the factors influencing their decision making on the early diagnosis of dementia. The influencing factors for perception difference on dementia early diagnosis screening of Korean adults were interest in dementia, family history of dementia, dementia patient in circle of acquaintances, knowledge of dementia, self-rated cognitive dysfunction.

**PRESENTING AUTHOR:**

Seong Woo Seo, National Evidence-based Healthcare Collaborating Agency, Korea

**AUTHORS:**

Seong Woo Seo, Joo Youn Kim, Hayoung Choi, Seul Gy Choi, Ji Eun Choi

**BACKGROUND AND OBJECTIVES:**

As Korea’s population ages, it is estimated that the prevalence of dementia among older adults will double every twenty years. The number of dementia patients is predicted to be one million in 2027. The purpose of this study is to investigate the perception of early diagnosis screening among Korean adults and explore the factors influencing their decision to be screened.

**METHODS:**

In December 2014, a cross-sectional, anonymous online survey was provided to 1000 healthy adults residing in Korea. The survey included questions related to individuals’ intention to participate in screening for the detection of dementia and other related factors such as: their characteristics; interest in dementia; family history of dementia; whether they have a dementia patient in their circle of acquaintances; experience in caregiving, knowledge of dementia; self-reported cognitive function; and, depression status. The responses of the completed survey were analyzed using descriptive statistics and preliminary univariate analyses were conducted using a Chi-square test. Then multiple logistic regression was performed using independent variables as identified by Chi-square test (p<0.05).

**RESULTS:**

Of the 1000 subjects who completed the questionnaire, 54.6% had the intention to participate in screening for dementia, including having a brief neurological examination for themselves or a member of their family. The result of the Chi-squared test, for questions related to:

income level; current health status; interest in dementia; family history of dementia; having a dementia patient in their circle of acquaintances; experience in caregiving; knowledge of dementia; and, cognitive dysfunction in independent variables showed statistically significant differences. Multivariate logistic regression analysis indicated that the following subjects were more likely to have the intention to participate in screening for dementia including a brief neurological examination: those who (i) are interested in dementia (P<0.001); (ii) have family history of dementia (P=0.002); (iii) have a dementia patient in circle of acquaintances (P=0.006); (iv) have knowledge of dementia (P=0.005); and (v) have cognitive dysfunction (P=0.007).

**CONCLUSIONS:**

The influencing factors for perception difference on dementia early diagnosis screening of Korean adults were interest in dementia; family history of dementia; dementia patient in circle of acquaintances; knowledge of dementia; self-rated cognitive dysfunction. Therefore, it is important to provide information about dementia to encourage early diagnosis screening.

**Poster 49B Conditional Coverage With Evidence Development In Spain**

**DESCRIPTION:**

Four health technologies have been selected for Conditional Coverage with Evidence Development in Spain in 2015. The aim is obtain information to define the conditions of use and the specific therapeutic indications for reimbursement. The technologies are: Endobronchial valve for prolonged air leak; Biodegradable stents for benign oesophageal stenosis; Percutaneous mitral valve repair with Mitraclip ® device; and percutaneous left atrial appendage closure.

**PRESENTING AUTHOR:**

Inaki Imaz-Iglesia, ISCIII (Instituto De Salud Carlos III), Spain

**AUTHORS:**

Iñaki, Imaz-Iglesia, Jesús, González-Enríquez, Antonio, Sarría-Santamera

**BACKGROUND AND OBJECTIVES:**

The Spanish Health Ministry updated the Spanish health care services portfolio of the surgical implants and prosthesis in 2015 supported by the Spanish Health Technology Assessment Network. As a result of this process the Health Ministry decided to initiate Conditional Coverage with Evidence Development (CCWED) on four health care technologies in order to define the conditions of use and the therapeutic indications for reimbursement of the technologies.

**METHODS:**

Description of existing rules and procedures of CCWED in Spain. Description of characteristics of the decision process for selection of four technologies to be studied under Conditional Coverage with Evidence Development in Spain during 2015. Description of intended designs for those four specific CCWED studies.

**RESULTS:**

The selected technologies for CCWED are the following: Endobronchial valve for prolonged air leak; Biodegradable stents for benign oesophageal stenosis; Percutaneous mitral valve repair using the Mitraclip ® device; and Devices for percutaneous left atrial appendage closure. All of them are health care devices already introduced in the Spanish Health System. The scientific evidences regarding those technologies are variable. The Health Ministry is currently defining studies protocols and designated centers. The design of the studies is observational, prospective and non-comparative. A software application to register all administrative and clinical data of the studies is being developed.

**CONCLUSIONS:**

CCWED is being used in Spain for health care devices assessment. CCWED is being used to gather real world evidence of already introduced technologies, in order to monitor health care outcomes in real practice, not necessarily referred to new or promising health care technologies.

**Poster 50B Multi Criteria Decision Analysis In Russian Healthcare System**

**DESCRIPTION:**

Performed abstract describes capability of multi criteria decision analysis in medicine approval process in Russian healthcare system.

**PRESENTING AUTHOR:**

Vyacheslav Serpik, Sechenov M.I. First Moscow State Medical University, Russian Federation

**AUTHORS:**

Vyacheslav Serpik

**BACKGROUND AND OBJECTIVES:**

Russian Federation Healthcare system faced with the problem of rare disease and orphan medicines. Current procedure of approving medicines for reimbursement lists is based on pharmacoeconomic evaluation. Budget impact analysis has the highest priority in medicine’s pharmacoeconomic evaluation. Therefore, it’s unlikely that orphan medicines may pass through such applied procedure. So it’s actual topic to solve the problem of orphan medicine approval for reimbursement by developing special procedure. Multi criteria decision analysis is one of the tools for solving this problem. Then we provide framework to adopt existing multi criteria decision analysis approaches for Russian healthcare system reality.

**METHODS:**

none (policy topic)

**RESULTS:**

On the first step methodology approaches of multi criteria analysis decision analysis for Russian federation were adopted. Traditionally, two criteria domains were defined: for disease and for medicine. Four criteria for each domain were identified: clinical, economic, investment and epidemiology for disease and clinical, pharmaco-economic, innovative and ease of use for medicine. Four key stakeholders were defined: clinicians, patients, HTA specialists and decision makers. After that pilot study to provide multi criteria analysis for tuberculosis was carried out. By taken into account pilot character of the study we used naïve integrative approach to calculate multi criteria decision analysis score.

**CONCLUSIONS:**

We found out that developed approach for multi criteria decision analysis is applicable for Russian healthcare system. However, during providing multi criteria decision analysis pilot study we faced with unpreparedness of decision makers to participate in such kind of surveys. This fact underlays the importance of multi criteria decision analysis to improve quality (transparency) the decision making process in Russian health care system.

.....

## Poster 51B Analysis Of Technological Innovation Produced Within The Italian NHS: An HTA Approach

**DESCRIPTION:**

The aim of this project is to provide an extended description of cost-saving innovations produced within the Italian NHS

**PRESENTING AUTHOR:**

Dr. Valentina Iacopino, Graduate School of Health

Economics and Management, Italy

**AUTHORS:**

Americo Cicchetti, Gianni Lorenzoni, Alessandra Fiore, Valentina Iacopino, Ilaria Morelli, Marcella Marletta

**BACKGROUND AND OBJECTIVES:**

The Italian NHS is facing major challenges in the management of healthcare services, given the economic pressures and the consequent decrease of expenditure. One of the possible solution to maintain the balance between the quality of services provided and the general sustainability has been recognized in the HTA approach, aimed at identifying good value technologies as well as their potential cost saving and cost-effectiveness. One relevant opportunity for modern systems has also identified in the ability of healthcare providers themselves to contribute to the creation of knowledge and innovative products. The aim of this project is to provide an extended description of this contribution, by the identification of those cost-saving innovations produced within the Italian NHS.

**METHODS:**

This study is part of a project carried out by the Graduate School of Health Economics and Management (ALTEMS) and funded by the Italian Ministry of Health. Both quantitative and qualitative methodologies have been applied in the study. First, a survey across hospital organizations and Research Institutes has been performed in order to collect information about the organizational model running by NHS organizations for technology transfer and their research products, in terms of research projects, patents, spin offs. Later, a sample of innovations produced within the NHS candidate to evaluation will be selected for HTA process. Case studies (adoption guide) on them will be realized in order to appreciate their cost-saving and cost-effectiveness potential.

**RESULTS:**

Expected results will provide a detailed description

of the amount of innovative technologies emerging by the research activity and technology transfer within the Italian NHS. Results will also contribute to investigate successful examples of organizational models for technology transfer, which can accelerate the impact of research activities conducted.

#### **CONCLUSIONS:**

The study will promote the role of the Italian NHS as an innovative system able to create new opportunity to exploit knowledge and products that can be beneficial to the system itself. HTA, is confirmed as a valuable approach to support researchers and executives in the identification of technology's value and potential impact at different level of decision making.

---

## **Poster 52B** The Impact Of Shared Decision Making On The Length Of Hospital Stay And The Health Expenditure

#### **DESCRIPTION:**

The aim of the present work is to perform a cross-sectional study in order to investigate the impact of shared decision making (SDM) on the length of hospital stay and the health expenditure.

#### **PRESENTING AUTHOR:**

Stefano Passi, Department of Public Health Sciences, University of Turin, Italy

#### **AUTHORS:**

Stefano Passi, Maria Rosaria Gualano, Davide Minniti, Flavio Boraso, Roberta Siliquini

#### **BACKGROUND AND OBJECTIVES:**

In times of economic crisis, with important consequences on health care, alternative solutions are required to reduce the length of hospital stay

and the health expenditure. It is necessary to identify possible variables in order to hypothesize strategies to reach this objective. The Shared Decision-Making (SDM) is an approach based on shared clinical choices between the physician and the patient. The aim of the present work is to perform a cross-sectional study in order to investigate the impact of SDM on the length of hospital stay and the health expenditure.

#### **METHODS:**

The patients were selected after admission to clinical and surgical units at the Rivoli Hospital (Piedmont, Italy). Data were collected through a questionnaire and the Hospital Discharge Register. Statistical analyses were performed using t-test and chi-square test. Significance level was set at  $p=0.05$ .

#### **RESULTS:**

In the sample analyzed (N=178; 86 males and 92 females; 20-94 age range) 51% were married, 5% graduate and 59% have already been hospitalized to treat the same disease. General health status was reported as positive by 61% of the patients. The women ( $p=0.04$ ) and the young people ( $p=0.04$ ) are more inclined to share clinical choices. In patients (38.2% N=68) who declared to refrain from medical decision the average length of stay and health expenditure were 14.25 days (Standard Deviation (SD):  $\pm 10.64$ ) and 2747.94 euro (SD:  $\pm 2050.62$  euro) respectively. Otherwise, the average length of stay and health expenditure were 13.84 days (SD:  $\pm 13.95$ ) and 2981.45 euro (SD:  $\pm 1576.95$  euro) in the sample supporting to SDM (N=110 61.8%). However, using t-test, this difference is not statistically significant ( $p=0.831$  e  $p=0.423$ ).

#### **CONCLUSIONS:**

A model of care, based on the SDM, seem to have no impact on the length of hospital stay and the health expenditure. At European level, further studies are needed to address this critical issue.

---

## Poster 53B What Is Real World Data? A Review Of Definitions Based On Literature And Stakeholder Interviews

### DESCRIPTION:

Despite increasing recognition of the value of real-world data (RWD) for relative effectiveness assessment, consensus on its definition is lacking. A literature review and stakeholder interviews were used to compile RWD definitions from 8 groups of relevant stakeholders. Considerable variability in stakeholder definitions of RWD exists, subsequently leading to confusion among stakeholders when discussing the use of RWD in decision-making.

### PRESENTING AUTHOR:

Dr. Wim Goettsch, National Healthcare Institute (ZIN), Netherlands

### AUTHORS:

Amr Makady, Anton de Boer, Hans Hillege, Olaf Klungel, Wim Goettsch

### BACKGROUND AND OBJECTIVES:

Although randomised controlled trials provide valuable data on drug efficacy, their results cannot easily be extrapolated to reflect conditions in routine clinical practice. As a result, stakeholders such as HTA agencies are increasingly exploring methods to incorporate Real-World Data (RWD) in relative effectiveness assessments to better reflect drug effectiveness under real-life conditions. However, despite increasing recognition of the value of real-world data (RWD) for drug development and relative effectiveness assessment, consensus on the definition of RWD is lacking. In order to shed light on similarities and differences between available RWD definitions, we aimed to review definitions for RWD from the perspective of different stakeholders.

### METHODS:

A literature review and stakeholder interviews were used to compile data from 8 groups of relevant stakeholders. Outputs from documents and interviews were pooled and subjected to coding analysis. Definitions identified were classified into one of four pre-defined categories: 1-Data collected in a non-RCT setting, 2-Data collected in a non-interventional/non-controlled setting, 3-Data collected in a non-experimental setting (i.e. no de novo data collection based on a pre-established study protocol), and 4-Other (i.e. do not fit into three categories above). The frequency of definitions identified under each category was recorded.

### RESULTS:

In total 52 documents and 20 interviews were assessed. 38 definitions were identified: 20 out of 38 definitions (53%) were category 1 definitions, 9 (24%) were category 2 definitions, 5 (13%) were category 3 definitions and 4 (11%) were category 4 definitions. Differences were identified both between, and within, definition categories. For example, opinions differed on the aspects of intervention (treatment assignment, patient selection and patient follow-up) with which non-interventional/non-controlled settings should abide. No definitions were provided in 2 interviews or identified in 32 documents.

### CONCLUSIONS:

The majority of definitions assessed defined RWD as data collected in a non-RCT setting. However, a considerable number of alternative definitions diverged from this concept. Moreover, a significant number of authors and stakeholders did not have an official, institutional definition for RWD. Persisting variability in stakeholder definitions of RWD may lead to confusion among different stakeholders when discussing the use of RWD in decision-making.

## Poster 54B Real-World Data Use In Health Technology Assessment: A Policy Review

### DESCRIPTION:

Real-world data (RWD) may offer HTA agencies with more robust sources for data on the effectiveness of medicines in routine clinical practice. However, it is not yet known to what extent HTA agencies request RWD for submissions, nor its impact on decision-making. This study aims to review current policies on use of RWD in 6 HTA agencies.

### PRESENTING AUTHOR:

Dr. Wim Goettsch, National Healthcare Institute (ZIN), Netherlands

### AUTHORS:

Amr Makady, Anton de Boer, Hans Hillege, Olaf Klungel, Wim Goettsch

### BACKGROUND AND OBJECTIVES:

Health Technology Assessment (HTA) agencies increasingly require robust evidence on relative effectiveness of products in routine clinical practice. Although Randomised Controlled Trials (RCT's) provide robust evidence on the efficacy of medicines, they do not provide robust evidence on their effectiveness. Real-World Data (RWD) may provide HTA agencies with alternative sources for effectiveness data. However, it is not yet known to what extent HTA agencies request RWD for submissions, nor the impact of RWD on decision-making. The aim of this study is to review the policies of 6 HTA agencies on use of RWD in HTA.

### METHODS:

A literature review and stakeholder interviews were used to collect information about RWD policies of HTA agencies in the following countries: the United Kingdom (NICE), Sweden (TLV), France (HAS),

Germany (IQWiG), Italy (AIFA) and the Netherlands (ZIN). The following policy contexts were reviewed for the 6 agencies: initial reimbursement discussions (i.e. general HTA methodology), guidance on pharmacoeconomic analysis, and conditional reimbursement schemes. Within each context, policies focusing on RWD requested and the appraisal of RWD in HTA submissions were analysed.

### RESULTS:

In total, 20 documents were identified and 6 interviews were conducted. For all 6 agencies, policies for general HTA methodology state that RWD is welcome (but not mandatory) in all submissions and may be used to provide evidence on treatment effects (e.g. when RCT data is absent) or other parameters (e.g. epidemiological data). For pharmacoeconomic analyses, all agencies directly request RWD for epidemiological data, evidence on costs, and resource use. However, in both policy contexts above, conclusions regarding treatment effects based on RWD merely play a supplementary role to RCT evidence in decision-making. Only 3 agencies implement conditional reimbursement. RWD requested by the 3 agencies in the context of conditional reimbursement is highly case-specific. Agencies participate in identifying evidence gaps to be informed by RWD and developing subsequent study protocols to collect it. Adherence to agencies' recommendations on study protocols should increase the impact of RWD on decision-making at re-assessment.

### CONCLUSIONS:

Policies on RWD requested in HTA differ significantly between the three policy contexts assessed. Similarly, policies for RWD appraisal differ notably across contexts. Moreover, considerable variations exist between HTA agencies regarding the use and appraisal of RWD. This has numerous negative implications for technology producers and might discourage use of RWD for HTA. HTA agencies across Europe should move towards harmonising policies on RWD use for HTA. Guidelines recently developed by EUnetHTA may

provide a starting point to do so.

---

## Poster 55B Coordinate System For Intercepting New Technologies Using App In AIIC HTA Network

### DESCRIPTION:

The Italian Association of Clinical Engineers (AIIC) implemented an App to support mainly clinical engineers in the evaluation process.

### PRESENTING AUTHOR:

Emilio Chiarolla, Italian Association of Clinical Engineers (AIIC), Italy

### AUTHORS:

Emilio Chiarolla, Lorenzo Leogrande, Umberto Nocco, Paolo Cassoli, Giovanni Guizzetti

### BACKGROUND AND OBJECTIVES:

The adoption of new technologies is continuously proposed both to Regional and moreover to Hospital level. Resources for evaluation are limited and often many organizations are concentrated in the evaluation of the same technology at the same time. The Italian Association of Clinical Engineers (AIIC) implemented an App to support mainly clinical engineers, but other professionals too, in the evaluation process, to alert AIIC HTA network members of technologies that are candidate for an evaluation and eventually as a support for the Italian Ministry of Health 'Cabina di regia for HTA' ('HTA leading group') providing a list of technologies collected through the App.

### METHODS:

AIIC represents more than 1,500 members working in almost all Italian Hospitals. Association members were invited by email to provide the scheme used in their institution (be it Hospital or local health

organization) to collect information and then used to take decisions. Recurrent issues, present in local forms, were collect in three Items: Clinical, Management and Economic. The EUnetHTA HTA Core Model was then consulted to complete the panel of information. All items were consequently implemented in an iOS and Android compatible App.

### RESULTS:

The App will be presented next April in Bari during the National AIIC Congress and will be available for free to all AIIC member. The App has the vantage to promote HTA approach, the discussion among members and to know the demand of new technologies

### CONCLUSIONS:

Many technologies are proposed and adopted in our Hospital without an appropriate assessment due scarcity of resources and competence, and often we register a duplication of report on the same technology. The App can be used as a guideline for HTA, as a tool for informing and promote discussion among AIIC members on the same technology. Moreover the list of new technology requested by clinicians can be used by Italian Ministry of Health for prioritizing technology evaluation.

---

## Poster 56B Dealing With A Lack Of Data Relevant For Taking Decisions On Hospital Formularies

### DESCRIPTION:

Hospital based HTA experiences on assessment of new drugs show how lack of evidence should have context specific solutions and request not only data collection and analysis efforts. Early generation of hospital relevant data should be addressed in Early Dialogue initiatives.

**PRESENTING AUTHOR:**

Dr. Rossella Di Bidino, A.Gemelli Teaching Hospital, Italy

**AUTHORS:**

Rossella Di Bidino, Marco Marchetti, Americo Cicchetti

**BACKGROUND AND OBJECTIVES:**

Starting from July 2013, the Health Technology Assessment Unit of 'A. Gemelli' Hospital in Rome started to carry out rapid assessments for new pharmaceuticals submitted to the Hospital Committee for Drugs and Technologies (COFT). The HTA Unit conducts rapid assessments given its expertise due a collaboration with the Italian Medicines Agency, while the Hospital Pharmacy provides support in terms of knowledge of internal needs and clinicians requests. These HTA assessments are a strategic tool to support COFT decisions on the introduction of drugs in the Hospital Drug Formulary (HDF). Main data sources are scientific evidence, pharmacoeconomic studies and Hospital Pharmacy's data.. The main effort is not only to mediate clinical needs and budget constraints but to provide all data requested by COFT members to adopt informed decisions. Absence of context specific data and evidence on organizational impact are the main issues of debate. Critical is the choice of hospital level comparators and the availability of consumption data when estimating the budget impact. For some categories of pharmaceuticals, as innovative drugs or those in the C(nn) (drugs not reimbursed by NHS and not yet negotiated at national level), the lack of data is more evident.

**METHODS:**

To cope with these information gaps a two level approach have been adopted. In the long run, efforts have been dedicated to empower data collection system and its internal analysis. In the short run, COFT suspends its decision for lack of information or approve the introduction into HDF with conditions. About 16% of 63 HTA evaluated

drug have been conditionally approved.

**RESULTS:**

About 16% of 63 HTA evaluated drug have been conditionally approved. Conditions could be linked to external (ie. regional reimbursement decisions) or internal factors. Internal conditions could refer to limitation of clinical conditions and/or identification of prescribing hospital units and/or annual number of treated patient and/or single patient requests and/or the activation of an internal monitoring system. The aim is to avoid just to duplicate national or regional reimbursement decisions given different hospital perspective, internal policies and the duty to monitor and promote appropriate prescription.

**CONCLUSIONS:**

Short run approaches are motivated by the need to take an immediate decision despite lack of data. Long run solutions will provide a partial response to data absence. A more complete answer could come only by dealing with the hospital dimension in Early Dialogues programs, as those conducted by EMA. Hospital based HTA experiences on assessment of new drugs show how lack of evidence should have context specific solutions and request not only data collection and analysis efforts.

**Poster 57B Medical Personnel's Demands For The InFormation Of New And Emerging Health Technologies: Based On A Pilot Survey In Shanghai And Gansu, China**

**DESCRIPTION:**

To survey medical personnel's usual practice of searching and using the information of emerging health technologies (EHT) and their demands for

the prospective horizon scanning system (HSS), our study investigated 837 medical staff members in 10 healthcare institutions in Shanghai and Gansu, China by using a self-designed anonymous questionnaire. It was shown that medical personnel thought it was necessary to establish a HSS and they also provided many suggestions and expectations for the future HSS.

**PRESENTING AUTHOR:**

Dr. Ping Zhou, Key Laboratory of Health Technology Assessment, School of Public Health, Fudan University, China

**AUTHORS:**

Ping Zhou, Chong-yang Jiang, Fei Bai, Xue-feng Wei, Yi-lu Lin, Zhi-yuan Xia

**BACKGROUND AND OBJECTIVES:**

Nowadays, a number of countries worldwide have established a horizon scanning system(HSS) to early assess new health technologies. The development and application of new and emerging health technologies (EHT) in China has significantly increased since the beginning of this century. Lots of hospitals actively introduce new health technologies in order to promote their reputation and competitive power. HSS has not been set up in China yet. However, it is believed to be promising and important for health care stakeholders in the Chinese context. Objectives: Medical personnel are one kind of the most significant populations to use the HSS. Their demands for the related information and requirements for the HSS are very important. The purpose of this study was to survey the medical personnel’s usual practice of searching and using the information of EHT and their demands for the prospective HSS, so as to provide a reference to establish a HSS in China.

**METHODS:**

10 healthcare institutions including 6 tertiary general hospitals and 4 secondary hospitals in Shanghai and Gansu were selected by using the convenience sampling method. The self-

designed anonymous questionnaires survey was processed in medical staff. A descriptive analysis on the frequency to scan the information of EHT, the concerned content, the main information resources, how well they know the HSS requirements and expectations of HSS, and so on was conducted with SAS 9.2.

**RESULTS:**

837 medical staff responded the questionnaires. More of the respondents were female(57%),physicians(62%) and nurses(25%),with master degree or above(79%) and the average age of 36 years old.The respondents with senior title were about 23%. More than 56% of the respondents paid very much and much attention to EHT in their field and 37% would scan or update the EHT information more than once every three months. Half of the respondents would concern the EHT before the approval of market access but with some evidence of clinical trials. The top three information resources were 1) domestic academic journals, 2) domestic academic conferences, 3) international academic journals. Only 28% of the respondents thought that the current information resources could totally or almost meet their need for EHT. More than 60% considered it was very much or much necessary to establish a HSS in China and more than 91% said they would use this kind of system. The three most expected characteristics of the HSS were 1) maintaining independence and justice, 2) having effective methods for assessment, 3) involving clinicians and technical experts.

**CONCLUSIONS:**

Based on this pilot survey,we found that medical personnel had a strong demand for a HSS and they also provided many ideas and suggestions about the future HSS.This study only investigated 10 hospitals located in two provinces,but we believe this pilot study could also give us some valuable reference.

## Poster 58B Cost-Benefit Of Innovative Teliagnosis Technology In Low-Resource Settings

### DESCRIPTION:

This study analyzed the results of a pilot project using teliagnosis tools implemented in all remote regional and district hospitals in Paraguay. A cost-benefit of implementing an innovative teliagnosis technology that addresses universal coverage for remote tomography, ECG and ecography diagnosis and that are likely to be appropriate and affordable for low-resource settings.

### PRESENTING AUTHOR:

Dr. Pedro Galvan, Research Institute in Health Sciences / Ministry of Public Health, Paraguay

### AUTHORS:

Pedro Galvan, Miguel Velazquez, Gualberto Benítez, Antonio Barrios, Enrique Hilario Asunción

### BACKGROUND AND OBJECTIVES:

Clinical background: In low- and middle-income countries many people suffer because they don't have access to appropriate health technologies. In the context of universal coverage and the efficient use of available resources in public health which should be directed towards greater equity in the provision of services, greater concern for the effectiveness and usefulness of health technologies, there is a favorable opportunity to develop telemedicine in both developing and industrialized countries as a tool to improve health care in remote locations without access to specialists. This study, performed by the Telemedicine Unit of the Ministry of Public Health (MoH) in collaboration with the Dept. of Biomedical Engineering, Research Institute in Health Sciences of the National University of Asunción (IICS-UNA) and the University of the Basque Country (UPV / EHU) served as a pilot project to evaluate the potential cost-benefit of a telemedicine system in

public health. However, despite the huge growth of scientific and technological development, the availability and access to appropriate, affordable, and high-quality medical services in low- and middle-income countries are still inadequate. For these purposes, we analyzed the results of a pilot project using innovative health technologies implemented in all remote regional and district hospitals in Paraguay. Objective: this study aims to evaluate the cost-benefit of implementing teliagnosis that address universal coverage for remote tomography, ECG and ecography diagnosis and that are likely to be appropriate, sustainable and affordable for low-resource settings.

### METHODS:

Methodology: This is a prospective study, where we analyzed the cost-benefit results of a pilot project over two years 2014-15, using telemedicine for diagnosis implemented in all remote regional and district hospitals as innovative health technologies in the public health in Paraguay. For these purposes, the cost-benefit analysis was carried out by comparing the cost of performing a tomography, electrocardiography (ECG) and ecography using a teliagnosis tool versus the cost of performing it by patient referral to a qualified and comparable diagnosis center in the capital city.

### RESULTS:

During the pilot project time 2014-15, 34.096 remote diagnostics were conducted in the main 16 regional and 9 district hospitals using the teliagnosis tool. Of all remote diagnostics modalities performed, 38.0% (12966) corresponded to tomography studies, 61.9% (21111) to electrocardiography (ECG) and 0.1% (19) to ultrasound studies. The project costs were classified into three categories, implementation cost, maintenance cost and evaluation cost. The average cost of a tele tomography, tele ECG and tele ecography in the teliagnosis project was 2.6 USD. Meanwhile, the average diagnostics cost performed by medical specialist 'face to face' in the capital city for tomography, ECG and ecography

was 68.6 USD, 11.8 USD and 21.5 USD respectively. The cost reduction through the telediagnosis was 26.4 times for tomography, 4.5 times for ECG and 8.3 times for ecography. The cost-benefit analysis performed demonstrates the economic benefit of 2.4 Million USD for the 25 communities included in

## CONCLUSIONS:

Despite the potential cost-benefit of the innovative telediagnosis technology implemented in the public health to decrease referrals, to improve access and to optimize the use of scarce health financial resources in low incoming countries, other important aspects such as acceptance of the technology by the physicians and health workers, patient satisfaction and a widespread use-assessment should be considered before a large diffusion of these tools in the health care system is accepted.

## REFERENCES:

1. Ferreira AC, O'Mahony E, Oliani AH, Araujo Júnior E, da Silva Costa F. Teleultrasound: historical perspective and clinical application. *Int J Telemed Appl*. 2015;2015:306259. doi: 10.1155/2015/306259. Epub 2015 Feb 24. Review. PubMed PMID: 25810717; PubMed Central PMCID: PMC4355341.
2. de la Torre-Díez I, López-Coronado M, Vaca C, Aguado JS, de Castro C. Cost-utility and cost-effectiveness studies of telemedicine, electronic, and mobile health systems in the literature: a systematic review. *Telemed J E Health*. 2015 Feb;21(2):81-5. doi: 10.1089/tmj.2014.0053. Epub 2014 Dec 4. PubMed PMID: 25474190; PubMed Central PMCID: PMC4312789.
3. Hsieh JC, Li AH, Yang CC. Mobile, cloud, and big data computing: contributions, challenges, and new directions in telecardiology. *Int J Environ Res Public Health*. 2013 Nov 13;10(11):6131-53. doi: 10.3390/ijerph10116131. Review. PubMed PMID: 24232290; PubMed Central PMCID: PMC3863891.
4. Al-Zaiti SS, Shusterman V, Carey MG. Novel technical solutions for wireless ECG transmission & analysis in the age of the internet cloud. *J Electrocardiol*. 2013 Nov-Dec;46(6):540-5. doi: 10.1016/j.jelectrocard.2013.07.002. Epub 2013 Aug 29. Review. PubMed PMID: 23992916.
5. Silva E 3rd, Breslau J, Barr RM, Liebscher LA, Bohl M, Hoffman T, Boland GW, Sherry C, Kim W, Shah SS, Tilkin M. ACR white paper on teleradiology practice: a report from the Task Force on Teleradiology Practice. *J Am Coll Radiol*. 2013 Aug;10(8):575-85. doi: 10.1016/j.jacr.2013.03.018. Epub 2013 May 17. PubMed PMID: 23684535.
6. de Waure C, Cadeddu C, Gualano MR, Ricciardi W. Telemedicine for the reduction of myocardial infarction mortality: a systematic review and a meta-analysis of published studies. *Telemed J E Health*. 2012 Jun;18(5):323-8. doi: 10.1089/tmj.2011.0158. Epub 2012 Apr 2. Review. PubMed PMID: 22468983.
7. McBeth PB, Crawford I, Blaivas M, Hamilton T, Musselwhite K, Panebianco N, Melniker L, Ball CG, Gargani L, Gherdovich C, Kirkpatrick AW. Simple, almost anywhere, with almost anyone: remote low-cost telementored resuscitative lung ultrasound. *J Trauma*. 2011 Dec;71(6):1528-35. doi: 10.1097/TA.0b013e318232cca7. Review. PubMed PMID: 22182864.
8. Birati E, Roth A. Telecardiology. *Isr Med Assoc J*. 2011 Aug;13(8):498-503. Review. PubMed PMID: 21910377.
9. Andrade MV, Maia AC, Cardoso CS, Alkmim MB, Ribeiro AL. Cost-benefit of the telecardiology service in the state of Minas Gerais: Minas Telecardio Project. *Arq Bras Cardiol*. 2011 Oct;97(4):307-16. Epub 2011 Jul 29. English, Portuguese. PubMed PMID: 21808852.
10. Sutherland JE, Sutphin D, Redican K, Rawlins F. Telesonography: foundations and future directions. *J Ultrasound Med*. 2011 Apr;30(4):517-22. Review. PubMed PMID: 21460152.
11. Backman W, Bendel D, Rakhit R. The telecardiology revolution: improving the

management of cardiac disease in primary care. *J R Soc Med.* 2010 Nov;103(11):442-6. doi: 10.1258/jrsm.2010.100301. Epub 2010 Oct 19. Review. PubMed PMID: 20959351; PubMed Central PMCID: PMC2966883.

12. Ekeland AG, Bowes A, Flottorp S. Effectiveness of telemedicine: a systematic review of reviews. *Int J Med Inform.* 2010 Nov;79(11):736-71. doi: 10.1016/j.ijmedinf.2010.08.006. Review. PubMed PMID: 20884286.

13. Hsieh JC, Lo HC. The clinical application of a PACS-dependent 12-lead ECG and image information system in E-medicine and telemedicine. *J Digit Imaging.* 2010 Aug;23(4):501-13. doi: 10.1007/s10278-009-9231-7. Epub 2009 Aug 27. PubMed PMID: 19711129; PubMed Central PMCID: PMC3046657.

14. Phabphal K, Hirunpatch S. The effectiveness of low-cost teleconsultation for emergency head computer tomography in patients with suspected stroke. *J Telemed Telecare.* 2008;14(8):439-42. doi: 10.1258/jtt.2008.080603. PubMed PMID: 19047455.

15. Hailey D, Ohinmaa A, Roine R. Published evidence on the success of telecardiology: a mixed record. *J Telemed Telecare.* 2004;10 Suppl 1:36-8. Review. PubMed PMID: 15603604.

---

## Poster 59B Sutureless Aortic Valve Replacement For Aortic Valve Stenosis

### DESCRIPTION:

Sutureless aortic valve replacement (Su-AVR) is proposed as an alternative to traditional aortic valve replacement (AVR) or transcatheter aortic valve implantation (TAVI). We present the results of a rapid assessment of Su-AVR versus traditional sutured bioprostheses and TAVI in terms of effectiveness, safety, and economic impact with focus on the Italian context.

### PRESENTING AUTHOR:

Antonio Migliore, AGENAS, Italy

### AUTHORS:

Simona Paone, Antonio Migliore, Iosief Abraha, Anna Maria Vincenza Amicosante, Alessandra Lo Scalzo, Chiara Rivoiro, Anna Cavazzana, Philippe Caimmi, Tom Jefferson, Marina Cerbo

### BACKGROUND AND OBJECTIVES:

Aortic stenosis is one of the most common and most serious valve disease problems consisting in a narrowing of the aortic valve opening. Sutureless aortic valve replacement (Su-AVR) is proposed as an alternative to traditional aortic valve replacement (AVR) or transcatheter aortic valve implantation (TAVI). We present the results of a rapid assessment of Su-AVR versus traditional sutured bioprostheses and TAVI in terms of effectiveness, safety, and economic impact with focus on the Italian context.

### METHODS:

We performed systematic review of literature on effectiveness, safety and cost analyses. Context information was also gathered by involvement of national clinical experts and manufacturers.

### RESULTS:

Two sutureless aortic valve bioprostheses are currently marketed in Italy and they present different technical characteristics and implantation approaches: Edwards INTUITY Elite and Sorin Perceval. No randomized clinical trials were identified. Evidence on effectiveness and safety of Su-AVR as an alternative to AVR or TAVI is limited to 3 non-randomized comparative studies. Outcomes were not uniformly and completely reported across the 3 studies. Differences in terms of overall mortality, cause-specific mortality, and adverse events (bleeding and transfusion requirement, arrhythmias and permanent pacemaker implantation, renal insufficiency) between the two groups were not statistically significant. In our country, Su-AVR are mainly performed in a few

large regions (in the North and Centre). The cost analysis performed was based on data from two Italian centers suggesting that the main difference between Su-AVR and AVR depends on the cost of the device. We found that the estimated total costs using traditional valve is 13,642 calculated as mean of the total costs for the two centers involved in the analysis, while for sutureless valves the mean value is 17,785.

**CONCLUSIONS:**

Available data show that the potential benefit is not supported by well-designed randomized trials. Given the lack of good quality data on the clinical performance, we were only able to perform a cost analysis based on secondary data.

**Poster 60B High Prevalence Of Hypovitaminosis D In Patients With Chronic Low Back Pain: Evidence From Systematic Review And Meta-Analysis**

**DESCRIPTION:**

While several observational studies have investigated the association between vitamin D status and chronic low back pain (CLBP), we are aware of no comprehensive meta-analysis in this regard. The present systematic review and meta-analysis aims at assessing the prevalence of hypovitaminosis D in patients with CLBP.

**PRESENTING AUTHOR:**

Boya Chandrasekhar, NIPER, India

**AUTHORS:**

Chandra Sekhar Boya, Kapil Gudala, Dipika Bansal

**BACKGROUND AND OBJECTIVES:**

Introduction Vitamin D refers to a group of fat-soluble secosteroids responsible for intestinal

absorption of calcium, iron, phosphate and zinc. It is involved in bone formation, resorption, and mineralization and in maintaining neuromuscular function. Patient with chronic low back pain (CLBP) are at high risk vitamin D deficiency. Several observational studies have investigated the association between vitamin D status and chronic low back pain (CLBP), we are aware of no comprehensive meta-analysis in this regard. Objectives The present systematic review and meta-analysis aims at assessing the prevalence of hypovitaminosis D in patients with CLBP

**METHODS:**

A systematic research on all published articles until August 2015 was conducted in PubMed, EMBASE, and CINAHL. We considered the studies that are eligible for this systematic review and meta-analysis were all observational studies include cohort, cross sectional and case-control studies that evaluated the prevalence of hypovitaminosis D in LBP and published in English language. We excluded articles if they were reviews, letters to the editor, editorials, case reports.. According to the level of 25-OHD, vitamin D deficiency was defined as a 25-OHD level of < 20 ng/mL and vitamin D insufficiency as 21 to 29 ng/mL, and normal level as above 30 ng/mL. 25-OHD level of > 50% for Q statistic test and I2 statistic respectively. The Publication bias was assessed by using funnel plot and Beggs test.

**RESULTS:**

A total of 64981 articles were retrieved from different databases by using the search strategy. After analyzing the title, abstract and full texts 12 relevant studies were included according to inclusion criteria. Among 12 studies included 4 were case-control, 7 were cross sectional and one was case series. A total of 2190 participants were included in all 12 studies with individual sample sizes ranging from 60 to 360. Results from the meta-analysis on the pooled prevalence of hypovitaminosis in CLBP patients was 79.9% (95% CI 66.2 %-89.2%). Subgroup analyses based on study design, study quality, and study location

did not explain between-study heterogeneity; however, cut off point for biomarker assessed [25-hydroxyvitamin D3] showed some degree of heterogeneity.

**CONCLUSIONS:**

We found a strong association between vitamin D deficiency and CLBP. This study indicates a strong association between vitamin D deficiency and CLBP and justifies serum 25-OHD assessment in patients with CLBP. Vitamin D supplementation may be used as an adjuvant treatment for patients with CLBP. However, randomized clinical trials are required to confirm our findings.

**REFERENCES:**

Ghai B, Bansal D, Kapil G, Kanukula R, Lavudiya S, Sachdeva N. High Prevalence of Hypovitaminosis D in Indian Chronic Low Back Patients. *Pain Physician*. 2015;18(5):E853-62.

.....  
**Poster 61B Regulation Problems Of Pharmaceutical Price Control In Kazakhstan**

**DESCRIPTION:**

Price controls can seem more noticeable in Kazakhstan, where pharmaceutical companies are currently focusing as sales have slowed down in the rest of the world. In Kazakhstan, the government conducts audits to set the upper-ceiling for patented and generic drugs reimbursed by the government. Under the highly price-regulated market in Kazakhstan, competition from generic and therapeutic competitors did decrease pharmaceutical prices.

**PRESENTING AUTHOR:**

Dr. Alexander Kostyuk, Kazakh Agency for Health Technology Assessment, Kazakhstan

**AUTHORS:**

Alexander Kostyuk, Amangaly Akanov, Talgat Nurgozhin

**BACKGROUND AND OBJECTIVES:**

Globally, healthcare costs are coming under scrutiny like. Everywhere in the world - more pharmaceutical products, medical devices and services are competing for fewer healthcare costs while governments seek to alleviate economic pressure by imposing price controls and looking for ways to implement value-based pricing on a grand scale. These price controls can seem more noticeable in Kazakhstan where pharmaceutical companies are currently focusing as sales. In Kazakhstan conducts government audits to set the upper-ceiling for patented and generic drugs reimbursed by the government and has apparently intensified its pricing audits. Arriving at this balance is the challenge, particularly as many countries turn to national organizations to determine public reimbursement of drug therapies based on patient outcomes. More countries are using health technology assessments in reimbursement decisions and healthcare payers are increasingly demanding real-world evidence of value on pharmaceutical

**METHODS:**

We conducted semi-structured interviews with senior representatives from key national organizations involved in pharmaceutical care. The captured data were coded and analysed using the predetermined themes of pricing, reimbursement, prescribing, dispensing and cost sharing. Data from public medical organizations in Kazakhstan from 2012 to 2015 were used to explore the effect of generic and therapeutic competition on prices of pharmaceutical products. A quasi-hedonic regression model was employed to estimate the impact of competition. The inputs to our model were specific attributes of the products and manufacturers, with the exception of competition variables.

## RESULTS:

We identified several key issues, including high medicine prices, underuse of generic medicines and high out-of-pocket drug spending. Our results suggest that pharmaceutical prices are inversely related to the number of generic and therapeutic competitors, but positively related to the number of therapeutic classes. In addition, the product prices of leading local manufacturers are not only significantly lower than those of global manufacturers, but are also lower than their non-leading counterparts when other product attributes are controlled.

## CONCLUSIONS:

In Kazakhstan, if the unified national health system is going to provide universal health coverage in a sustainable fashion, then the national government must address the current issues in the pharmaceutical sector. Importantly, the country will need to increase the market share of generic medicines to contain drug spending. Under the highly price-regulated market in Kazakhstan, competition from generic and therapeutic competitors did decrease pharmaceutical prices. Further research is needed to explore whether this competition increases consumer welfare in Kazakhstan's healthcare setting.

---

## Poster 62B Patient Profile From The First International Burden Of Illness Study In Inadequately Controlled Chronic Spontaneous Urticaria: ASSURE-CSU

### DESCRIPTION:

ASSURE-CSU is the first real-world international study to assess the clinical profile of diagnosed chronic spontaneous urticaria (CSU) patients in those inadequately controlled with current

treatments. This study showed that CSU patients were silently suffering for 2 years before it was diagnosed. More than half of them had angioedema and/or were assessed to have moderate to severe form of diseases.

### PRESENTING AUTHOR:

Dr. Maria-Magdalena Balp, Novartis Pharma AG, Switzerland

### AUTHORS:

Karsten Weller, Clive Grattan, Mohamed Abuzakouk, Frederic Berard, Gordon Sussman, Giorgio Walter Canonica, Andre Knulst, Javier Ortiz de Frutos, Alla Nakonechna, Ana Giménez-Arnau, Joanne Nicola Gertrude Oude Elberink, Maria-Magdalena Balp, Sam Khalil, Haijun Tian, Kelly Hollis, Carolyn Sweeney, Christina Radde, Doreen McBride, Marcus Maurer

### BACKGROUND AND OBJECTIVES:

ASSURE-CSU study (ASsessment of the Economic and Humanistic Burden of Chronic Spontaneous/Idiopathic Urticaria PatiEnts) is the first international study to quantify the humanistic and economic burden of illness of patients with chronic spontaneous urticaria (CSU). Herein, we report, the pooled results describing the profile of CSU patients with inadequate control to treatment.

### METHODS:

This observational, non-interventional, multinational, and multicentre study was conducted in 7 countries (Canada, France, Germany, Italy, Netherlands, Spain and United Kingdom). Patients with CSU, aged ≥18 years, with disease persisting for ≥12 months, symptomatic despite current treatment were recruited. The study involved a retrospective medical chart review, a cross-sectional patient survey, and a 7-day patient diary to evaluate outcomes. Demographic and clinical characteristics of CSU patients were extracted from the medical charts, including age, sex, ethnicity, disease duration, severity, diagnosis, angioedema and diagnostic tests. After recruitment

patients completed the Urticaria Activity Score over 7 days (UAS7). All study measures were summarised using mean values and standard deviations for continuous variables and counts and proportions for categorical variables.

### RESULTS:

A total of 64 sites recruited 673 eligible patients for which chart data were extracted and among them 614 (91.2%) returned the UAS7. The mean (SD) age of patients at enrolment was 48.8 (15.47) years, at symptom onset was 42.3 (16.54) years and at the time of diagnosis 44.2 (15.92) years. Mean (SD) disease duration between symptom onset and diagnosis was 24.0 (63.63) months and 57.7 (77.79) months from diagnosis to enrolment. The majority of enrolled patients were female (72.7%) and White/Caucasian (90.4%). Diagnostic testing for triggers was performed in 75.1% of patients. At diagnosis 75 (11.2%), 211 (31.4%) and 245 (36.5%) of patients were assessed by physician as having mild, moderate and severe disease respectively (for 21% data were not available). The most used severity criteria were number of flares, medication requirements or impact on quality of life. More than half of the patients (58.5%) had ever experienced angioedema with an average mean of 19.0 episodes/patient over 12 months. The mean (SD) UAS7 score was 17.3 (10.49) and 49.4% of patients had a score  $\geq$  16 reflecting moderate to severe disease.

### CONCLUSIONS:

Patients recruited in this first real-world international study had a diagnosed disease duration of almost 5 years on average but had experienced symptoms for 2 years before diagnosis. More than half of them were assessed as moderate to severe; angioedema was present in 58.5%. After recruitment half of the patients with UAS7 data were still experiencing moderate-severe symptoms despite being treated.

.....

## Poster 63B Time Series Analysis Of Hospitalization And Material Cost Of Hip Replacement

### DESCRIPTION:

To analyse hospitalization and material cost and its trend for Hip Replacement. Hospitalization costs in 2010-2014 have a tendency to increase, and the cost of raw materials is on the decline. Predicting the future three years, hospitalization costs will continue to grow, but materials costs have no obvious trend.

### PRESENTING AUTHOR:

Na Li, Fudan University, China

### AUTHORS:

Na Li

### BACKGROUND AND OBJECTIVES:

To analyse hospitalization and material cost and its trend for Hip Replacement. Providing references for controlling the Growth in medical costs and reducing the economic pressures of patients with hip replacement.

### METHODS:

Collecting the information of home page of medical record of patients with hip replacement in ruijin hospital .Using SPSS20.0 to make a descriptive analysis and using exponential smoothing model to make short-term forecast of average hospitalization and material cost.

### RESULTS:

Hospitalization costs in 2010-2014, has a tendency to increase, and the cost of raw materials is on the decline. Predicting the future three years, hospitalization costs will continue to grow, but materials costs have no obvious trend.

### CONCLUSIONS:

In order to achieve a win-win situation, we must

.....

guarantee the quality of medical treatment, adjust the proportion of hospitalization cost, reduce the patient economic burden.

---

## Poster 64B Role Of Low Dose Naltrexone In Crohns Disease Condition: A Systematic Review And Meta-Analysis

### DESCRIPTION:

The use of low dose naltrexone (LDN) in Crohns disease (CD) condition is controversial. So we assessed the efficacy of LDN to treat pain in patients with CD.

### PRESENTING AUTHOR:

Dr. Dipika Bansal, National Institute of Pharmaceutical Education and Research, India

### AUTHORS:

Dipika Bansal, Priyamvada Bharadwaj

### BACKGROUND AND OBJECTIVES:

The use of low dose naltrexone (LDN) in Crohns disease (CD) condition is controversial. So we assessed the efficacy of LDN to treat pain in patients with CD.

### METHODS:

Systematic literature search was done using PubMed, Cochrane library and EMBASE databases from inception to June 2015, looking for Randomized Controlled Trials (RCT) and cohort studies reporting the safety and efficacy of LDN in CD. Number of subjects with Crohns disease activity index (CDAI) score

### RESULTS:

Meta analysis of 6 (4 RCT and 2 case-control) studies indicated a significantly higher percentage of patients improved according to CDAI when

compared to placebo (OR, 4.0, 95% CI, 1.9 - 8.5). All included studies are of high quality.

### CONCLUSIONS:

Our meta-analysis supports the hypothesis that LDN may be used for treatment of pain patients with CD. Nevertheless, further RCTs with larger sample size are required to assess the safety and efficacy of LDN for CD.

### REFERENCES:

Segal D, Macdonald JK, Chande N. Low dose naltrexone for induction of remission in Crohn's disease. Cochrane Database Syst Rev. 2014; 21;2:CD010410.

---

## Poster 65B What Are We Missing By Limiting The Outcome Of Cost Effectiveness Analyses Of Diagnostic Tests To Cost Per Correct Result?

### DESCRIPTION:

When cost-utility analyses are not possible, a commonly reported outcome for the economic evaluation of a diagnostic test is cost per correct test result. However, such analyses do not consider patient relevant downstream actions, including re-testing and whether the test enacts a change in management. A case study is presented where different conclusions may be reached depending on the outcome presented.

### PRESENTING AUTHOR:

Skye Newton, Adelaide Health Technology Assessment, School of Public Health, The University of Adelaide, Australia

### AUTHORS:

Arlene Vogan, Camille Schubert, Skye Newton, Tracy Merlin

**BACKGROUND AND OBJECTIVES:**

Cost per correct diagnosis is a commonly reported outcome of economic evaluations of diagnostic tests. While such analyses may be structured to capture the cost implication of an incorrect test result, the health outcome implications are not captured in this measure. While cost utility analyses may be more appropriate, as these can take into account both the cost and health outcome implication of incorrect results, these are not always possible. A case study is reviewed that reports the results of an economic evaluation of a diagnostic test using two different cost-effectiveness analyses outcomes.

**METHODS:**

An economic evaluation comparing cardiac magnetic resonance imaging (CMRI) to single photon emission computed tomography (SPECT) for the diagnosis of coronary artery disease (CAD) was performed. Two outcomes for the economic evaluation were presented: (i) cost per correct test result and (ii) cost per unnecessary invasive coronary angiography (ICA) avoided. The latter outcome was chosen as avoidance of unnecessary ICA was considered a clinically relevant patient outcome, and this outcome would also take into account the impact of downstream confirmatory testing in the diagnostic pathway and indicate whether or not there was ultimately a change in management.

**RESULTS:**

Compared to SPECT, CMRI was associated with a reduction in false positive test results, however was also associated with a higher re-testing rate. For the outcome of cost per correct test result, CMRI was dominated by SPECT, due to the higher proportion of tests that required re-testing. However, a more favourable ICER was observed for CMRI in the outcome of cost per unnecessary ICA avoided (ICER

**CONCLUSIONS:**

Economic evaluations of diagnostic tests should

note the potential limitations of reporting outcomes in terms of cost per correct test result. If cost-utility analysis is not possible, patient relevant downstream actions, including re-testing and whether the test does enact a change in management should still be considered when selecting the outcome of interest to model. The case study presented displays that substantially different conclusions regarding the cost-effectiveness of a diagnostic test may be reached depending on the outcome presented.

**Poster 67B Dealing With Structural Uncertainty In Model-based Submissions To National Funding Bodies?**

**DESCRIPTION:**

Funding decision under uncertainty: managing structural uncertainty in decision making.

**PRESENTING AUTHOR:**

Dr. Hossein Afzali, The University of Adelaide, Australia

**AUTHORS:**

Hossein Afzali

**BACKGROUND AND OBJECTIVES:**

Increasingly, decision analytic models are used to inform decisions about whether or not to publicly fund new health technologies (e.g. pharmaceuticals). Given the inherent uncertainty in model predictions, the assessment of uncertainty in model-based evaluations is an essential part of the decision-making process. Ideally, all sources of uncertainty should be fully presented and characterized within the decision-making process. Two major types of uncertainty associated with decision modelling including parameter uncertainty and structural uncertainty. Recent studies have shown that structural uncertainty can

have a greater impact on model predictions than parameter uncertainty. Although the impact of making incorrect structural assumptions on model predictions is noted, relatively little attention has been paid to this issue in guidelines developed by national funding bodies such as the Australian Pharmaceutical Benefits advisory Committee (PBAC) and The National Institute for Health and Care Excellence (NICE) in the UK, with potential impact on quality of funding decisions. This presentation will provide an opportunity to discuss four questions (1) what is structural uncertainty? (2) Does structural uncertainty matter? (3) How do national funding bodies address structural uncertainty in their guidelines? (4) How guidelines should be revised to deal with structural uncertainty more appropriately?

#### **METHODS:**

A review and analysis of the literature and guidelines developed by major national funding bodies including: PBAC, the UK National Institute for Health and Care Excellence (NICE), the Canadian Agency for Drugs and Technologies in Health (CADTH), and the New Zealand Pharmaceutical Management Agency (PHARMAC).

#### **RESULTS:**

Key sources of structural uncertainty include the conceptual model and assumptions and methods that are used to estimate model inputs (i.e. by imposing structural relationship between inputs and outputs). In guidelines developed by national funding bodies, there is non-specific guidance on how to systematically present and characterise all key sources of structural uncertainty. It is recommended that all key structural aspects of a model (as potential sources of uncertainty) be explicitly defined in guidelines. Submissions to funding bodies should explicitly report and justify the conceptual model development process and all other underlying structural assumptions. It is recommended that structural uncertainty be characterised using the parameterization approach.

#### **CONCLUSIONS:**

It is important to consider the potential impact of structural uncertainty on model predictions and methods to characterise this type of uncertainty in guidelines and submissions to national funding bodies. This presentation represents a contribution to the good modelling practice within the decision-making process. Addressing structural uncertainty in a more transparent and systematic way can result in better informed public funding decisions with consequential impact on population health.

#### **REFERENCES:**

Haji Ali Afzali H, Karnon J. Exploring structural uncertainty in model-based economic evaluations. *PharmacoEconomics* 2015; 33: 435-443.

---

## **Poster 68B** Volume-Outcome Relationships In The Treatment Of Abdominal Aortic Aneurysm In Europe: A Systematic Review

#### **DESCRIPTION:**

The centralisation of vascular services is based on the theory that high volume providers achieve improved outcomes for patients. This systematic review evaluates the evidence for this in abdominal aortic aneurysm and concludes that while there is some evidence of an inverse relationship between procedure volume and mortality, the quality of the evidence, evaluated using ACROBAT-NRSI, is low.

#### **PRESENTING AUTHOR:**

Edward Goka, University of Sheffield, United Kingdom

#### **AUTHORS:**

Phillips Patrick, Poku Edith, Essat Munira, Woods Helen B, Goka Edward A, Kaltenthaler Eva C, Shackley Phil, Michaels Jonathan.

## BACKGROUND AND OBJECTIVES:

Searches for evidence of a relationship between the volume of patients treated for an abdominal aortic aneurysm (AAA) and outcomes identified nine relevant systematic reviews which were generally supportive of an inverse relationship for mortality. However the evidence base was of low quality, dated and more relevant to the context of the USA than Europe. Subsequent scoping searches identified a number of relevant primary studies from Europe which were not included in the identified reviews, thus establishing a need for a new systematic review in this area. The objective of this review was to evaluate the relationship between the volume of AAA surgery undertaken by individual clinicians or hospitals and outcomes (primary outcome mortality). A publicly available and pre-registered protocol is available at: [http://www.crd.york.ac.uk/PROSPERO/display\\_record.asp?ID=CRD42014014850](http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42014014850)

## METHODS:

Literature Searching: Comprehensive electronic searches were conducted in multiple databases, including MEDLINE and EMBASE to March 2015, using MESH and free text terms, these searches were supplemented by reference list and citation searches. Inclusion criteria: studies, published in the last ten years, of European populations of adults undergoing elective or emergency abdominal aortic aneurysm treatment where the effect of hospital or operator volume on outcomes is reported. Data Extraction was conducted independently by two authors, quality assessment was conducted using a modified version of ACROBAT-NRSI (1). Synthesis by meta-analysis was planned in the event that there was sufficient clinical, methodological and statistical homogeneity in included studies; alternatively a narrative synthesis was planned.

## RESULTS:

Thirteen full-text papers (n =181,932 participants) were included, 9 from the UK, 3 from Germany and 1 from Norway. All the included studies used observational designs; using a combination of

prospective, retrospective, administrative and clinical data. There is a high degree of heterogeneity in terms of clinical and procedural groups investigated which is compounded by; variety in the methods used to define volume groups, in the analysis of outcomes and by different studies using overlapping data sources making meta-analyses inappropriate. Overall, included studies were of low methodological quality, particularly in relation to the risk of selection bias. Preliminary synthesis of adjusted and unadjusted data suggests a relationship between high volumes of procedures conducted in hospitals and reduced mortality. The relationship between surgeon volume and mortality and other relevant outcomes could not be established due to insufficient evidence.

## CONCLUSIONS:

Current evidence suggests the existence of an inverse relationship between the volume of AAA procedures conducted in hospital and mortality, though this conclusion is tentative based on the relatively low quality of the evidence. There is insufficient evidence to reach conclusions regarding other outcomes and relationships.

## REFERENCES:

1. Sterne JAC, Higgins JPT RB on behalf of the development group for A-N. A Cochrane Risk Of Bias Assessment Tool?: for Non- Randomized Studies of Interventions ( ACROBAT-NRSI ) Version 1.0.0. 2014.

---

## Poster 70B Risperidone For Aggressiveness In Adults With Autism Spectrum Disorders In Brazil: A Budget Impact With Probabilistic Sensitivity Analysis.

### DESCRIPTION:

The aim of this study is to estimate the budget impact of extending the access to risperidone for adults with autism spectrum disorders (ASD) and

aggressiveness in SUS. Adopting the Ministry of Health's perspective, with direct medical costs, we estimated the budget impact for a 3 year time horizon. Uncertainty was handled with one-way and probabilistic sensitivity analysis on the key parameters.

#### **PRESENTING AUTHOR:**

Ivan Ricardo Zimmermann, National Committee for Technology Incorporation - CONITEC, Brazil

#### **AUTHORS:**

Ivan Ricardo Zimmermann, Vania Cristina Canuto Santos, Clarice Alegre Petramale

#### **BACKGROUND AND OBJECTIVES:**

Autism, a chronic neuropsychiatric disorder that develops in early childhood, is part of a group referred as autism spectrum disorders (ASD). In this context, irritability, despite being a nonspecific manifestation of ASD, can manifest itself in pathological form converging in hostile and aggressive responses, even to common stimuli. Risperidone, an atypical antipsychotic, is available to treat aggressiveness in children and adolescents with ASD in the Brazilian National Health System (SUS). The aim of this study was to estimate the budget impact of extending the access to risperidone for adults with ASD and aggressiveness in SUS.

#### **METHODS:**

Adopting the Ministry of Health's (MoH) perspective, with direct medical costs, we estimated the budget impact for a 3 year time horizon. The target Brazilian population, with ages between 18 and 74, was based on epidemiological data. Data about dosage, resource use and clinical features were extracted from literature. Drug and test costs were based on the prices reimbursed by the MoH. Uncertainty was handled with one-way and probabilistic sensitivity analysis (Monte Carlo simulations) on the key parameters: ASD prevalence, aggressiveness incidence, non-pharmacologic interventions failure, SUS coverage

rate, hyperprolactinemia incidence, risperidone dosage and prolactin testing. Beta and gamma probability distributions were adopted according the parameter profile.

#### **RESULTS:**

In the base-case, we estimated a total budget of R\$ 12,164,094.18 to treat 97,622 adults over a 3 year time horizon. Risperidone represented 37% of the budget. The maximum amplitude identified in the one-way sensitivity analysis was related with the ASD prevalence variation (R\$ 19 million variation). After 1,000 simulations, the mean total budget estimated was R\$ 13,238,773.00 (95%CI: R\$ 12,761,473.00 to R\$ 13,716,073.00). Assuming a R\$ 10 million a year budget impact threshold, approximately 98%, 97% and 93% of the simulations would be within the threshold in the first, second and third year, respectively.

#### **CONCLUSIONS:**

Risperidone coverage expansion for adults with ASD and aggressiveness can reflect an average annual budget impact of approximately R\$ 4.5 million, with over 90% probability of it being below the R\$ 10 million a year threshold over the next 3 years.

---

## **Poster 71B** Assessment On The Benefits Of ALT Rapid Tests Before Blood Collection In Nonpaid Blood Donators Of Shanghai

#### **DESCRIPTION:**

Our study assessed the benefits of alanine aminotransferase (ALT) rapid tests before blood collection in nonpaid blood donators of Shanghai. It provides evidence and decision-making information to the decision makers in other areas in China, in other developing countries in Asia, and even all over the world.

**PRESENTING AUTHOR:**

Wei Fang, Fudan University, China

**AUTHORS:**

Wei Fang

**BACKGROUND AND OBJECTIVES:**

Alanine aminotransferase (ALT) is a main clinical indicator of liver function diagnosis and a pre-requisite test item of nonpaid blood donators before blood collection. Promoting ALT rapid tests before blood donation is considered to be able to reduce blood waste and the cost of blood collection. Shanghai started a program to implement ALT rapid test before blood collection in nonpaid blood donators. Objective: The aim of our research is to assess the benefits of ALT rapid test before blood collection in nonpaid blood donators of Shanghai and to provide evidence and decision making information to decision makers.

**METHODS:**

The research collected the monitoring data from Shanghai blood administration office during 2010 to 2013, and analyzed the allocation and utilization of the equipment for ALT rapid tests, the status of blood waste and the economic benefit that related to ALT rapid tests program in Shanghai.

**RESULTS:**

The number of the equipment for ALT rapid tests has been increased from 6 to 160 during 2010 to 2013. The number of ALT rapid tests conducted before blood collection in nonpaid blood donators has been increased by 10.15 times. After ALT rapid tests were widely used, the rate of blood waste was reduced from 7.13% to 1.96% and the cost of blood collection was reduced by 8.64 million in Shanghai.

**CONCLUSIONS:**

The utilization of ALT rapid tests before blood collection in nonpaid blood donators of Shanghai significantly reduced the rate of blood waste and have good economic benefits. We suggested that

the program of conducting ALT rapid tests before blood collection in nonpaid blood donators should be promoted nationwide.

**Poster 72B A Health Care Of Elderly In Brazilian Emergency Services: An Integrative Review**

**DESCRIPTION:**

An increased use of health services is related to aging, due to the higher prevalence of diseases, vulnerability characteristics, and health needs.

**PRESENTING AUTHOR:**

Tatiana Yonekura, Hospital do Coração, Brazil

**AUTHORS:**

Tatiana Yonekura, Jeane Roza Quintans, Mayla Youko Kato, Cesar Roberto Braga Macedo, Armando De Negri Filho

**BACKGROUND AND OBJECTIVES:**

An increased use of health services is related to aging, due to the higher prevalence of diseases and vulnerability characteristics and health needs. In Brazil, aging was accelerated and dramatically, without the provision of adequate health services. Assistance in emergency services has been insufficient to meet the needs of complex care for the elderly. The aim was to analyze the scientific literature on the health care of the elderly in the Brazilian emergency services.

**METHODS:**

An integrative review was conducted, restricted to articles of elderly health in Brazilian emergency services. Quantitative studies, qualitative and theoretical studies were included, with no date and language restrictions. We used two databases (LILACS and BDENF) and a directory of magazines (SciELO) for data collection. A tool to extract and analyze data from the included studies was

developed.

### RESULTS:

The search resulted in the identification of 1910 citations, from which 97 studies clearly addressed the topic. After the studies titles and abstracts were screened, 23 full manuscripts were retrieved for further examination. The application of the selection criteria resulted in 14 studies included. The main objective of included studies was to characterize the sociodemographic and health profiles of older people through quantitative approach. The main medical diagnostics and reasons of search medical assistance were: circulatory, respiratory, mental and behavioral disorders, neurological, misuse of drugs, injuries, poisoning, violence, trauma and fall. Recommendations for health care of the elderly in the Brazilian emergency services were described.

### CONCLUSIONS:

There are still many problems in the elderly health care in emergency departments. The provision of health care services based in health needs is important to an effective care and in accordance to principles of the health system.

### REFERENCES:

1 World Health Organization, WHO. Interesting facts about ageing. 2012. Disponível em: <http://www.who.int/ageing/about/facts/en/index.html>. Acesso em 20 Dez 2013.

---

## Poster 73B Evaluation Of Residual Bacterial Content And Trace Elements In Different Brands Of Commercially Supplied Bottled Drinking Waters In Kerala, India - A Comparative Study.

### DESCRIPTION:

An analytical study done to evaluate the bacteriological content and trace elements including fluoride, molybdenum, phosphorous, copper, vanadium, copper, selenium, magnesium, cadmium, and lead in commercially supplied bottled drinking water.

### PRESENTING AUTHOR:

Dr. Fawaz Pullishery, Educare Institute of Dental Science, India

### AUTHORS:

Fawaz Pullishery, Fadiya Moidu

### BACKGROUND AND OBJECTIVES:

Water is one of the vital elements that is required to maintain life on the earth. Microbial contamination of drinking water from pathogenic organisms is the main cause of waterborne diseases. In a country like India the chance of contamination of public water supplies is more and there is a growing trend that people tend to choose bottled drinking water as an alternative source since it is believed that it is safe for consumption than tap water. Trace elements in water like Fluoride, Molybdenum, Phosphorous, Copper, Vanadium, Copper, Selenium, Magnesium, Cadmium, Lead have been found to have effect with dental caries. Hence this study was done to evaluate the bacteriological content and trace elements in commercially supplied bottled drinking water.

### METHODS:

The study was conducted in the state of Kerala, India which included Aquafina, Bislery, Surabhi, Bailley, Kingfisher, Bindu, Kinley and Tethys. Six samples of each 8 commercially supplied bottled drinking water brand were selected randomly from different outlets in the State of Kerala and the water samples were transferred carefully to sterile containers while avoiding the touching of opening of the bottles. Inductively coupled plasma Optical Emission Spectrometer and ion-selective electrode

(Orion 94-09) were used to estimate other trace elements and fluoride content respectively.

### RESULTS:

It was found that the microbial content of the water analyzed varied from 12.5 to 108.7 CFU/ml. It was found that 8% of the water samples were having faecal coliforms ; 12% were having Aeromonas Spp; 23% of the water samples were reported to have Pseudomonas aeruginosa and 31% of the water sample were having the mesophilic aerobic bacterial content. Highly cariostatic elements like Fluoride and Phosphorous were profound be present at or lower than 0.60 mg/L and 0.15 mg/L respectively.

### CONCLUSIONS:

In our study we have found that some of the bottled water doesn't have appropriate standards as recommended by WHO and TSE, hence are not to fit for sale consumption to the public. A strong legislative action should be taken by the state government regarding the sale of these bottled drinking water henceforth to make it safe for drinking purposes

---

## Poster 74B Advances In Diabetes: Technology On The Horizon

### DESCRIPTION:

Diabetes is a disease whose prevalence is increasing about 25% annually in the Brazilian population. The disease is associated with complications that can significantly affect the quality of life of patients and has a high cost expenditure, estimated at US\$ 1,528.00 per person. Facing the numerous studies that seek alternatives for the diagnosis, prevention, and cure of diabetes, this review aims to define the current situation of research in this field, including studies in the laboratory phase, clinical trials, and patents.

### PRESENTING AUTHOR:

Dayane Silveira, Brazilian Ministry of Health, Brazil

### AUTHORS:

Dayane Gabrielle, Tamara Angelo, Rafael Mota Pinheiro, Taís Gratieri

### BACKGROUND AND OBJECTIVES:

Diabetes is a disease whose prevalence is increasing about 25% annually in the Brazilian population. The disease is associated with complications that can significantly affect the quality of life of patients and has a high cost expenditure, estimated at US\$ 1,528.00 per person. Facing the numerous studies that seek alternatives for the diagnosis, prevention and cure of diabetes, this review aims to define the current situation of research in this field, including studies in the laboratory phase, clinical trials and patents.

### METHODS:

N/A

### RESULTS:

The data can provide decision makers and the State with the opportunity to manage investment policies for the most promising technologies, in order to develop products and processes that can be made available on the market and in the local health system.

### CONCLUSIONS:

Expected that investments positively influence the quality of life and health of the population, in addition to favoring the country's economy.

### REFERENCES:

1. International Diabetes Federation. IDF Diabetes Atlas. 6th ed. International Diabetes Federation; 2013. 160 p.
2. Al-Tabakha M, Arida A. Recent challenges in insulin delivery systems: A review. Indian J Pharm Sci. 2008;70(3):278-86.

3. King H, Aubert RE, Herman WH. Global Burden of Diabetes, 1995-2025: Prevalence, numerical estimates, and projections. *Diabetes Care*. 1998;21(9):1414-31.
4. Oliveira AF de, Valente JG, Leite I da C, Schramm JM de A, Azevedo ASR de, Gadelha AMJ. Global burden of disease attributable to diabetes mellitus in Brazil. *Cad Saude Publica*. 2009;25(6):1234-44.
5. World Health Organization. World Health Statistics 2015. Luxembourg: WHO Library Cataloguing-in-Publication Data; 2015. 161 p.
6. Iser BPM, Stopa SR, Chueiri PS, Szwarcwald CL, Malta DC, Monteiro HO da C, et al. Prevalência de diabetes autorreferido no Brasil: resultados da Pesquisa Nacional de Saúde 2013. *Epidemiol e Serviços Saúde*. 2015;24(2):305-14.
7. Malta DC, Morais Neto OL de, Silva Junior JB da. Apresentação do plano de ações estratégicas para o enfrentamento das doenças crônicas não transmissíveis no Brasil, 2011 a 2022. *Epidemiol e Serviços Saúde*. 2011;20(4):425-38.
8. Hernandez M, Mollo A, Marsal J, Esquerda A, Capel I, Puig-Domingo M, et al. Insulin secretion in patients with latent autoimmune diabetes (LADA): half way between type 1 and type 2 diabetes: action LADA 9. *BMC Endocr Disord*. 2015;(doi 10.1186/1472-6823-15-1).
9. Balsells M, García-Patterson A, Solà I, Roqué M, Gich I, Corcoy R. Glibenclamide, metformin, and insulin for the treatment of gestational diabetes: a systematic review and meta-analysis. *BMJ*. 2015;350(h102):1-12.
10. Robertson KE, Glazer NB, Campbell RK. The latest developments in insulin injection devices. *Diabetes Educ*. 1999;26(1):135-8.
11. Garber AJ. Will the next generation of basal insulins offer clinical advantages? *Diabetes, Obes Metab*. 2014;16(6):483-91.
12. Mohan V, John M, Baruah M, Bhansali A. Addressing barriers to effective basal insulin therapy. *J Assoc Physicians India*. 2014;62(1 Suppl):10-4.
13. Mo R, Jiang T, Di J, Tai W, Gu Z. Emerging micro- and nanotechnology based synthetic approaches for insulin delivery. *Chem Soc Rev*. 2014;43(10):3595-629.
14. Jain S, Hreczuk-Hirst DH, McCormack B, Mital M, Epenetos A, Laing P, et al. Polysialylated insulin: synthesis, characterization and biological activity in vivo. *Biochim Biophys Acta - Gen Subj*. 2003;1622(1):42-9.
15. Uehata K, Anno T, Hayashida K, Higashi T, Motoyama K, Hirayama F, et al. Peak-less hypoglycemic effect of insulin glargine by complexation with maltosyl- $\alpha$ -cyclodextrin. *Int J Pharm*. 2012;422(1-2):33-9.
16. Nishimura A, Hayakawa T, Yamamoto Y, Hamori M, Tabata K, Seto K, et al. Controlled release of insulin from self-assembling nanofiber hydrogel, PuraMatrix(TM): Application for the subcutaneous injection in rats. *Eur J Pharm Sci*. Elsevier B.V.; 2012;45(1-2):1-7.
17. Kim BS, Oh JM, Hyun H, Kim KS, Lee SH, Kim YH, et al. Insulin-loaded microcapsules for in vivo delivery. *Mol Pharm [Internet]*. 2009;6(2):353-65. Available from: <http://dx.doi.org/10.1016/j.biomaterials.2008.10.030>
18. Peng Q, Sun X, Gong T, Wu CY, Zhang T, Tan J, et al. Injectable and biodegradable thermosensitive hydrogels loaded with PHBHHx nanoparticles for the sustained and controlled release of insulin. *Acta Biomater*. 2013;9(2):5063-9.
19. Oak M, Singh J. Chitosan-zinc-insulin complex incorporated thermosensitive polymer for controlled delivery of basal insulin in vivo. *J Control Release*. 2012;163(2):145-53.
20. Anhalt H, Bohannon NJV V. Insulin Patch Pumps: Their Development and Future in Closed-Loop Systems. *Diabetes Technol Ther*. 2010;12(S1):S 51 S 58.

21. Gu Z, Aimetti AA, Wang Q, Dang TT, Zhang Y, Veiseh O, et al. Injectable Nano-Network for Glucose-Mediated Insulin Delivery. *ACS Nano*. 2013 May 28;7(5):4194-201.
22. Veiseh O, Tang BC, Whitehead KA, Anderson DG, Langer R. Managing diabetes with nanomedicine: challenges and opportunities. *Nat Rev Drug Discov*. 2014;14(1):45-57.
23. Damgé C, Michel C, Aprahamian M, Couvreur P. New approach for oral administration of insulin with polyalkylcyanoacrylate nanocapsules as drug carrier. *Diabetes*. 1988;37(2):246-51.
24. Zijlstra E, Heinemann L, Plum-Morschel L. Oral Insulin Reloaded: A Structured Approach. *J Diabetes Sci Technol*. 2014;8(3):458-65.
25. Takeuchi H, Yamamoto H, Niwa T, Hino T, Kawashima Y. Enteral absorption of insulin in rats from mucoadhesive Chitosan-Coated liposomes. *Pharmaceutical Research*. 1996. p. 896-901.
26. Song L, Zhi ZL, Pickup JC. Nanolayer encapsulation of insulin- chitosan complexes improves efficiency of oral insulin delivery. *Int J Nanomedicine*. 2014;9(1):2127-36.
27. Mukhopadhyay P, Mishra R, Rana D, Kundu PP. Strategies for effective oral insulin delivery with modified chitosan nanoparticles: A review. *Prog Polym Sci*. 2012;37(11):1457-75.
28. Zhang X, Qi J, Lu Y, He W, Li X, Wu W. Biotinylated liposomes as potential carriers for the oral delivery of insulin. *Nanomedicine Nanotechnology, Biol Med*. Elsevier Inc.; 2014;10(1):167-76.
29. Niu M, Tan Y, Guan P, Hovgaard L, Lu Y, Qi J, et al. Enhanced oral absorption of insulin-loaded liposomes containing bile salts: A mechanistic study. *Int J Pharm*. 2014;460(1-2):119-30.
30. Zhang N, Ping Q, Huang G, Xu W, Cheng Y, Han X. Lectin-modified solid lipid nanoparticles as carriers for oral administration of insulin. *Int J Pharm*. 2006;327(1-2):153-9.
31. Liu J, Gong T, Wang C, Zhong Z, Zhang Z. Solid lipid nanoparticles loaded with insulin by sodium cholate-phosphatidylcholine-based mixed micelles: Preparation and characterization. *Int J Pharm*. 2007;340(1-2):153-62.
32. Sarmiento B, Martins S, Ferreira D, Souto EB. Oral insulin delivery by means of solid lipid nanoparticles. *Int J Nanomedicine*. 2007;2(4):743-9.
33. Chen M-C, Sonaje K, Chen K-J, Sung H-W. A review of the prospects for polymeric nanoparticle platforms in oral insulin delivery. *Biomaterials*. Elsevier Ltd; 2011;32(36):9826-38.
34. D'souza B, Bhowmik T, Uddin MN, Oettinger C, Souza MD. Development of b-cyclodextrin-based sustained release microparticles for oral insulin delivery. *Drug Dev Ind Pharm*. 2014;9045(1):1-6.
35. Sajeesh S, Sharma CP. Cyclodextrin-insulin complex encapsulated polymethacrylic acid based nanoparticles for oral insulin delivery. *Int J Pharm*. 2006;325(1-2):147-54.
36. Turcheniuk K, Khanal M, Motorina A, Subramanian P, Barras A, Zaitsev V, et al. Insulin loaded iron magnetic nanoparticle-graphene oxide composites: synthesis, characterization and application for in vivo delivery of insulin. *RSC Adv*. 2014;4(2):865-75.
37. Cho HJ, Oh J, Choo MK, Ha JI, Park Y, Maeng HJ. Chondroitin sulfate-capped gold nanoparticles for the oral delivery of insulin. *Int J Biol Macromol*. 2014;63:15-20.
38. Chaturvedi K, Ganguly K, Nadagouda MN, Aminabhavi TM. Polymeric hydrogels for oral insulin delivery. *J Control Release*. 2013;165(2):129-38.
39. Karnoosh-Yamchi J, Mobasseri M, Akbarzadeh A, Davaran S, Ostad-Rahimi AR, Hamishehkar H, et al. Preparation of pH sensitive insulin-loaded nano hydrogels and evaluation of insulin releasing in different pH conditions. *Mol Biol Rep*. 2014;41(10):6705-12.

40. Kumria R, Goomber G. Emerging trends in insulin delivery: Buccal route. *J Diabetol.* 2011;2(1):1-9.
41. Ungaro F, d'Emmanuele di Villa Bianca R, Giovino C, Miro A, Sorrentino R, Quaglia F, et al. Insulin-loaded PLGA/cyclodextrin large porous particles with improved aerosolization properties: In vivo deposition and hypoglycaemic activity after delivery to rat lungs. *J Control Release.* 2009;135(1):25-34.
42. Aguiar MMG, Rodrigues JM, Silva Cunha A. Encapsulation of insulin-cyclodextrin complex in PLGA microspheres: a new approach for prolonged pulmonary insulin delivery. *J Microencapsul.* 2004;21(5):553-64.
43. Taylor MJ, Tanna S, Sahota T. In vivo study of a polymeric glucose-sensitive insulin delivery system using a rat model. *J Pharm Sci.* 2010;99(10):4215-27.
44. Zhao Y-Z, Li X, Lu C-T, Xu Y-Y, Lv H-F, Dai D-D, et al. Experiment on the feasibility of using modified gelatin nanoparticles as insulin pulmonary administration system for diabetes therapy. *Acta Diabetol.* 2012;49(4):315-25.
45. Al-Qadi S, Grenha A, Carrión-Recio D, Seijo B, Remuñán-López C. Microencapsulated chitosan nanoparticles for pulmonary protein delivery: In vivo evaluation of insulin-loaded formulations. *J Control Release.* 2012;157(3):383-90.
46. Andrade F, das Neves J, Gener P, Jr. SS, Ferreira D, Oliva M, et al. Biological assessment of self-assembled polymeric micelles for pulmonary administration of insulin. *Nanomedicine Nanotechnology, Biol Med. Elsevier Inc.;* 2015;11(7).
47. Liu J, Gong T, Fu H, Wang C, Wang X, Chen Q, et al. Solid lipid nanoparticles for pulmonary delivery of insulin. *Int J Pharm.* 2008;356(1-2):333-44.
48. Sintov AC, Levy H V., Botner S. Systemic delivery of insulin via the nasal route using a new microemulsion system: In vitro and in vivo studies. *J Control Release.* 2010;148(2):168-76.
49. Aspden TJ, Illum L, Skaugrud O. Chitosan as a nasal delivery system: Evaluation of insulin absorption enhancement and effect on nasal membrane integrity using rat models. *Eur J Pharm Sci.* 1996;4(1):23-31.
50. Tsuneji N, Yuji N, Naoki N, Yoshiki S, Kunio S. Powder dosage form of insulin for nasal administration. *J Control Release.* 1984;1(1):15-22.
51. Furlanos S, Perry C, Gellert S a., Martinuzzi E, Mallone R, Butler J, et al. Evidence that nasal insulin induces immune tolerance to insulin in adults with autoimmune diabetes. *Diabetes.* 2011;60(4):1237-45.
52. Borgheti-Cardoso LN, Ângelo T, Gelfuso GM, Lopez RF V, Gratieri T. Topical and transdermal delivery of drug-loaded nano/microsystems with application of physical enhancement techniques. *Curr Drug Targets.* 2015;([Epub ahead of print]).
53. Rastogi R, Anand S, Koul V. Electroporation of polymeric nanoparticles: an alternative technique for transdermal delivery of insulin. *Drug Dev Ind Pharm. Informa Healthcare New York;* 2010 Nov 20;36(11):1303-11.
54. Smith NB, Lee S, Shung KK. Ultrasound-mediated transdermal in vivo transport of insulin with low-profile cymbal arrays. *Ultrasound Med Biol.* 2003;29(8):1205-10.
55. Lee S, Snyder B, Newnham RE, Smith NB. Noninvasive ultrasonic transdermal insulin delivery in rabbits using the light-weight cymbal array. *Diabetes Technol Ther.* 2004;6(6):808-15.
56. Park EJ, Werner J, Smith NB. Ultrasound mediated transdermal insulin delivery in pigs using a lightweight transducer. *Pharm Res.* 2007;24(7):1396-401.
57. Gratieri T, Kalia YN. Mathematical models to describe iontophoretic transport in vitro and in vivo and the effect of current application on the skin barrier. *Adv Drug Deliv Rev.* 2013 Feb;65(2):315-29.

58. Dubey S, Perozzo R, Scapozza L, Kalia YN. Noninvasive transdermal iontophoretic delivery of biologically active human basic fibroblast growth factor. *Mol Pharm*. 2011;8(4):1322-31.
59. RL S, TJ P, SC J. Potential novel methods for insulin administration: I. Iontophoresis. *Biomedica biochimica acta*. 1984. p. 553-8.
60. Pillai O, Borkute SD, Sivaprasad N, Panchagnula R. Transdermal iontophoresis of insulin. II. Physicochemical considerations. *Int J Pharm*. 2003;254(2):271-80.
61. Pillai O, Nair V, Panchagnula R. Transdermal iontophoresis of insulin: IV. Influence of chemical enhancers. *Int J Pharm*. 2004;269(1):109-20.
62. Malakar J, Sen SO, Nayak AK, Sen KK. Formulation, optimization and evaluation of transferosomal gel for transdermal insulin delivery. *Saudi Pharm J*. 2012;20(4):355-63.
63. Kajimoto K, Yamamoto M, Watanabe M, Kigasawa K, Kanamura K, Harashima H, et al. Noninvasive and persistent transfollicular drug delivery system using a combination of liposomes and iontophoresis. *Int J Pharm*. 2011 Jan 17;403(1-2):57-65.
64. Martanto W, Davis SP, Holiday NR, Wang J, Gill HS, Prausnitz MR. Transdermal delivery of insulin using microneedle rollers in vivo. *Pharm Res*. 2004;21(6):947-52.
65. Nordquist L, Roxhed N, Griss P, Stemme G. Novel microneedle patches for active insulin delivery are efficient in maintaining glycaemic control: An initial comparison with subcutaneous administration. *Pharm Res*. 2007;24(7):1381-8.
66. Chen H, Zhu H, Zheng J, Mou D, Wan J, Zhang J, et al. Iontophoresis-driven penetration of nanovesicles through microneedle-induced skin microchannels for enhancing transdermal delivery of insulin. *J Control Release*. 2009;139(1):63-72.
67. Tzvetanov I, D'Amico G, Bejarano-Pineda L, Benedetti E. Robotic-assisted pancreas transplantation: where are we today? *Curr Opin Organ Transplant*. 2014;19(1):80-2.
68. Robertson RP. Islet Transplantation as a Treatment for Diabetes & A Work in Progress. *N Engl J Med*. 2004;350:694-705.
69. Tiwari P. Recent Trends in Therapeutic Approaches for Diabetes Management?: A Comprehensive Update. *J Diabetes Res*. 2015;(http://dx.doi.org/10.1155/2015/340838).
70. Nose K, Pissuwan D, Goto M, Katayama Y, Niidome T. Gold nanorods in an oil-base formulation for transdermal treatment of type 1 diabetes in mice. *Nanoscale*. 2012;4(12):3776-80.
71. Orynbayeva Z, Sensenig R, Polyak B. Metabolic and structural integrity of magnetic nanoparticle-loaded primary endothelial cells for targeted cell therapy. *Nanomedicine*. 2015 May;10(10):1555-68.
72. Heath V. A crossroads for diabetes care? *Nat Rev Endocrinol*. 2010;6(3):117-117.
73. Cash KJ, Clark HA. Nanosensors and nanomaterials for monitoring glucose in diabetes. *Trends Mol Med*. 2010;16(12):584-93.
74. Claussen JC, Kumar A, Jaroch DB, Khawaja MH, Hibbard AB, Porterfield DM, et al. Nanostructuring Platinum Nanoparticles on Multilayered Graphene Petal Nanosheets for Electrochemical Biosensing. *Adv Funct Mater*. 2012;22(16):3399-405.
75. Farandos NM, Yetisen AK, Monteiro MJ, Lowe CR, Yun SH. Contact lens sensors in ocular diagnostics. *Adv Healthc Mater*. 2015;4(6):792-810.
76. Gallagher EJ, LeRoith D. The Proliferation Role of Insulin and Insulin Like Growth Factors in Cancer. *Trend Endocrinology Metab*. 2010;21(10):610-8.
77. Paudel KS, Milewski M, Swadley CL, Brogden NK, Ghosh P, Stinchcomb AL. Challenges and opportunities in dermal/transdermal delivery. *Ther Deliv*. 2010;1(1):109-31.
78. Veisheh O, Langer R. Diabetes: A smart insulin patch. *Nature*. 2015;524(7563):39-40.



Junqueira Araujo LC, da Silva VC, Sousa Junior PT de, et al. Combretum lanceolatum flowers extract shows antidiabetic activity through activation of AMPK by quercetin. Rev Bras Farmacogn. 2013;23(2):291-300.

95. Oliveira HC, dos Santos MP, Grigulo R, Lima LL, Martins DTO, Lima JCS, et al. Antidiabetic activity of Vatairea macrocarpa extract in rats. J Ethnopharmacol. 2008;115(3):515-9.

96. Janebro DI, Queiroz M do SR de, Ramos AT, Sabaa-Srur AUO, Cunha MAL da, Diniz M de FFM. Effect of the flour of the yellow passion fruit peel (*Passiflora edulis* f. *flavicarpa* Deg.) in the glycemic and lipid levels of type 2 diabetes patients. Rev Bras Farmacogn. 2008;18(supl):724-32.

97. Brasil. Instituto Nacional da Propriedade Industrial [Internet]. Ministério do Desenvolvimento, Indústria e Comércio Exterior. 2015 [cited 2015 Oct 26]. Available from: <http://www.inpi.gov.br>

---

## Poster 75B Review Of HTA Role In Drug Centralized Procurement In A Chinese Setting

### DESCRIPTION:

Drug centralized procurement is vital in health reform and became a field of HTA in 2015. In the series of new regulations, Chinese governments regard HTA as an important tool for new drugs access. Many provinces may explore their own pathways for HTA. Real-world HTA will attract more and more attention in improving clinical medicine.

### PRESENTING AUTHOR:

Chalet Zhang, AstraZeneca, China

### AUTHORS:

Chalet Zhang, Charles Hu, Liping Xu

### BACKGROUND AND OBJECTIVES:

As health care expenditures surge in China, the Chinese government has drawn close attention to HTA, which is a useful tool to rationally allocate resources. Drug centralized procurement, or tendering, is the necessary step for a drug to be sold in public hospitals in China. The centralized procurement is vital in the health reform as it covers 80% of drug sales in all public hospitals. 2015-2016 is a key stage for drug centralized procurement. In 2015, most provinces have officially published tendering working plans, many of which include parts related to HTA. Therefore, analysis of these documents is of great importance to understand government's attitude toward HTA. However, such summary or analysis is rarely seen in publications. Our study aims to provide updates on roles of HTA in drug centralized procurement in China.

### METHODS:

The findings are informed by reviewing literatures and official documents, from 'CNKI' and 'Wanfang' Database and governments' official websites. This review looks at the current developments in drug centralized procurement and the considerations and implications for using HTA in China.

### RESULTS:

27 governmental documents were included, 2 at national level and 25 at provincial level. The documents refer to HTA in two fields, new drugs and comprehensive evaluation for all drugs: (1) the state council says new drugs should be included in centralized procurement at provincial or lower level based on HTA and evidence-based medicine assessment. In the 25 provincial implementation plans, 10 include HTA for new drugs with differences. (a) After new drugs being approved by HTA and other assessments, purchasing process is different: hospital purchase directly in 2 provinces, with a report to government; Hospital purchase directly in 2 provinces, after government review; in other 6 provinces, it is similar to other drugs as centralized procurement by the provincial

government. (b) 9 documents say nothing about evaluators for HTA, and the other 1 designates public hospitals. (2) For all the drugs especially the essential drugs, a comprehensive evaluation system based on clinical practice is encouraged, including the evaluations for safety, effectiveness and efficiency. China medicine comprehensive evaluation guidelines have been published, with most recent update in 2011, which included a guideline of pharmacoeconomics.

### CONCLUSIONS:

(1) National and local governments regards HTA as an important tool for new drugs in the access to public hospitals. It is likely that in the next a few years many provinces will explore their own pathways for HTA. (2) As a part of drug comprehensive evaluation, real-world HTA will attract more and more attention in improving clinical medicine.

---

## Poster 76B Uncertainty In Health Utilities Elicited Through The EQ-5D-3L

### DESCRIPTION:

The EQ-5D is used to measure health utilities. The EQ-5D is a questionnaire whose responses are converted to utilities using a scoring algorithm. The scoring algorithm is estimated rather than known, and introduces parameter uncertainty into estimates of mean utilities. We show that this uncertainty is large enough to warrant being accounted for when using the EQ-5D in economic evaluations.

### PRESENTING AUTHOR:

Dr. Eleanor Pullenayegum, Hospital for Sick Children, Toronto, Canada

### AUTHORS:

Eleanor Pullenayegum, Kelvin Chan, Feng Xie

### BACKGROUND AND OBJECTIVES:

Parameter uncertainty in EQ-5D value sets is routinely ignored. Sources of parameter uncertainty include uncertainty in the estimated regression coefficients of the scoring algorithm and uncertainty that arises from the need to use a nonsaturated functional form when creating the scoring algorithm. We hypothesize that this latter source is the major contributor to parameter uncertainty in the value sets.

### METHODS:

We used data from the United States EQ-5D-3L valuation study to assess the extent of parameter uncertainty in the value set. We refitted the US scoring algorithm to quantify contributors to the mean square prediction errors and used a Bayesian approach to estimate the predictive distribution of the mean utilities. The impact of parameter uncertainty in the value set was assessed using survey data.

### RESULTS:

Parameter uncertainty in the estimated regression coefficients explained 16% of the mean squared prediction error; uncertainty in the functional form explained the remaining 84%. The median width of the 95% credible intervals for the mean utilities was 0.15. In estimating mean utility in our survey population, parameter uncertainty in the value set was responsible for 93% of the total variance, with sampling variation in the survey population being responsible for the remaining 7%.

### CONCLUSIONS:

EQ-5D-3L value sets are estimated subject to considerable parameter uncertainty; the median credible interval width is large compared with reported values of the minimum important difference for the EQ-5D-3L, which have been reported to be as small as 0.03. Other countries' scoring algorithms are based on smaller studies and are hence subject to greater uncertainty. This uncertainty should be accounted for when using EQ-5D health utilities in economic evaluations.

---

## Poster 77B Performance Of Second Trimester Maternal Serum Screening For Down Syndrome In China: Systematic Review And Meta-analysis

### DESCRIPTION:

This study systematically evaluated the diagnostic performance of second trimester maternal serum screening (STMSS) for Down syndrome in China. Meta-analysis reported that STMSS had a good average performance level with enormous variety in Chinese pregnant women, and suggested urgent implementation of performance optimizing tactics to achieve the attainable diagnostic performance of STMSS in middle- and low- income countries.

### PRESENTING AUTHOR:

Dr. Shiyi Tu, Fudan University, China

### AUTHORS:

Shiyi Tu, Dongze Wang, Yingyao Chen

### BACKGROUND AND OBJECTIVES:

Second trimester maternal serum screenings (STMSS) have emerged as effective prevention strategies of Down syndrome (DS) from 1980s(1). For Caucasian population in industrialized regions, satisfied diagnostic performance of STMSS in detecting DS has been achieved(2-4). In middle- and low-income regions like China, a variety of STMSS have been available since early 2000s(5). Although a national guideline with the minimum performance requirements of STMSS was published in China in 2011(6), the lack of structurally synthesized empirical evidence left the practical performance of STMSS unclear. A limited number of reviews on STMSS in China were reported. However, they either used narrative methods(7) or bibliometric methods(8), or focused on one specific

screening strategy(9). The recently launched national pilot program of noninvasive prenatal test, which is based on cell-free DNA sequencing, heated the debates on the performance and role of STMSS in prenatal care system in China. This study aims to evaluate the diagnostic performance of STMSS in detecting DS in China, using systematic review methods and meta-analysis.

### METHODS:

SEARCH STRATEGY: An exhaustive literature search of Medline, Embase, Cochrane Library, ISI Web of Science, and China BioMedical Disc. SELECTION CRITERIA: Primary studies, published from January 2004 to November 2014, which examined the diagnostic accuracy of STMSS in Chinese pregnant women, compared with a reference standard, either chromosomal verification or newborn inspection. DATA COLLECTION AND ANALYSIS: Data were extracted as screening positive/negative results for Down's and non-Down's pregnancies allowing estimation of sensitivities (SEN) and specificities (SPE). Risks of bias within and cross studies were assessed. Diagnostic accuracy measurers were pooled, using random effects coefficient binary regression model, when appropriate.

### RESULTS:

Sixty-six trials, involving 3 categories of STMSS, were included. Second trimester double serum (STDS, 58.8%) and triple serum screenings (TTTS, 36.4%) dominated the use of STMSS. STDS was reported to have a good diagnostic performance (Median SEN=80%, Median SPE=95%), while TTTS (pooled SEN=81%, pooled SPE=95%) performed comparatively well. Diagnostic performance varied enormously for both STDS (SEN varied from 50% to 100%) and TTTS (SEN varied from 57% to 100%), which suggested that the minimum national performance standard hasn't been achieved universally in China. Second trimester quadruple serum screening performed better (Median SEN=86%, Median SPE=95.5%), but was scarcely used.

## CONCLUSIONS:

Compared with prior reviews, this study covered a comprehensive spectrum of STMSS instead of any specific strategies, and used a more rigorous and well-defined systematic approach. Results suggested that STMSS has the potential to achieve satisfied diagnostic performance in middle- and low- income countries. The reported enormous variety of diagnostic performance of STMSS called for urgent implementation of performance optimizing tactics. The reported good diagnostic performances of second trimester quadruple serum screening need to be verified by more evidence from Chinese population. Future studies are needed to explore potential determinants of screening performance.

## REFERENCES:

1. Canick J. Prenatal screening for trisomy 21: recent advances and guidelines. *Clinical Chemistry and Laboratory Medicine*. 2012;50(6):1003-8.
2. Alldred SK, Deeks Jonathan J, Guo B, Neilson James P, Alfirevic Z. Second trimester serum tests for Down's Syndrome screening. *Cochrane Database of Systematic Reviews [Internet]*. 2012; (6). Available from: <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD009925/abstract>.
3. Maria Ospina, Ken Bond, Carmen Moga, Anderson Chuck, Charles Yan, Thanh Nguyen, et al. *First and Second Trimester Prenatal Screening for Trisomies 13, 18, and 21 and Open Neural Tube Defects*. Edmonton: Institute of Health Economics Alberta Canada, 2011.
4. O'Connell R, Stephenson M, Weir R. Screening strategies for antenatal Down Syndrome screening: A systematic review of the literature. *New Zealand Health Technology Assessment Report*. Christchurch, New Zealand: Christchurch School of Medicine and Science, Department of Public Health and General Practice; 2006 November. Report No.: NZHTA Report 2006; 9(4).
5. Regulation of prenatal diagnostic technology (in Chinese), Order No. 33, Ministry of Health, China (2002).
6. Bian X, Zhu B, Liu J, Wang H, Lv S, Ma L, et al. Technical standards of prenatal screening and diagnosis for fetal common chromosomal abnormalities and open neural tube defects: part1. Maternal serum prenatal screening in second trimester (in Chinese). *Chinese Journal of Prenatal Diagnosis (Electronic Version)*. 2011;3(3):42-7.
7. Shaw SW, Chen CP, Cheng PJ. From Down syndrome screening to noninvasive prenatal testing: 20 years' experience in Taiwan. *Taiwan J Obstet Gynecol*. 2013 Dec;52(4):470-4.
8. Chen Y, Wang S, Wang K, Hui W, Li X, Wu H. Bibliometric analysis on the prenatal screening and diagnosis of Down's syndrome in China (in Chinese with English abstract). *Chinese Journal of Practical Gynecology and Obstetrics*. 2013 1938-04-11;29(3):208-11.
9. Wu J, Wang Y, Zhang X, Yan G, Teng F, Qiang R, et al. Systematic evaluation of dual-marker in the second trimester for screening of Down's syndrome in Chinese (in Chinese with English abstract). *Chinese Journal of Clinicians (Electronic Edition)*. 2011 1938-03-29;5(8):2313-9.

---

## Poster 78B The 'Value' Of Safety-Engineered Medical Devices In Reducing Needlestick And Sharps Injuries

### DESCRIPTION:

Needlestick and sharps injuries (NSIs) are one of the most common hazards for many healthcare workers. NSIs are also associated with substantial cost for the Australian healthcare system. Safety-engineered medical devices (SEMDs) are cost-effective interventions that should be mandated, in which implementation of SEMDs will effectively reduce rates of NSIs and occupational exposures to bloodborne pathogens.

**PRESENTING AUTHOR:**

Alessandra Doolan, Medical Technology Association of Australia

**AUTHORS:**

Alessandra Doolan

**BACKGROUND AND OBJECTIVES:**

Needlestick and sharps injuries (NSIs) are one of the most common hazards for many healthcare workers. NSIs are also associated with substantial cost for the Australian healthcare system. The aim of the study is to determine the impact of safety-engineered medical devices (SEMDs) on healthcare expenditure in Australia, focusing on the costs and benefits for the Australian healthcare system and healthcare workers.

**METHODS:**

Evidence-based review was performed to determine the clinical and economic benefits of SEMDs. Economic evaluation was also performed to estimate the annual cost savings for the Australian healthcare system to implement the use of SEMDs in all Australian hospitals.

**RESULTS:**

The study found extensive evidence that shows the effectiveness of SEMDs in reducing rates of NSIs in healthcare facilities. Implementing SEMDs in all Australian hospitals would result in an average cost savings of \$18.6 million per year for the Australian healthcare system. Cost savings would further increase if costs of post-exposure prophylaxis (PEP) treatment and treatment costs associated with high risk NSIs were included.

**CONCLUSIONS:**

The use of SEMDs in Australian healthcare facilities should be mandated, where implementation of SEMDs will effectively reduce rates of NSIs and occupational exposures to bloodborne pathogens.

SEMDs are cost-effective interventions, in which substantial cost savings can be gained for the Australian healthcare system through the reduction in the number of injured healthcare workers requiring treatment and management of NSIs and bloodborne pathogens.

**Poster 79B Presentation Of The SR/PS-Method For Use Of Data On Primary Studies From Systematic Reviews In Health Technology Assessment**

**DESCRIPTION:**

We developed the Systematic Reviews for assessment based on Primary Studies (SR/PS) method to enable valid but time-saving assessment of healthcare technologies. SR/PS-method comprises the comprehensive use of relevant data on primary studies from systematic reviews selected with special quality criteria. If data from systematic reviews are insufficient they should be completed by the incorporation of primary studies.

**PRESENTING AUTHOR:**

Dr. Vitali Gorennoi, Hannover Medical School, Germany

**AUTHORS:**

Vitali Gorennoi, Anja Hagen

**BACKGROUND AND OBJECTIVES:**

The assessment of healthcare technologies is a time-consuming process which is commonly performed based on systematic analysis of clinical (primary) studies. In order to save time and costs, the evaluation is performed alternatively based on results of previously published systematic reviews; however, these results may be associated with a high risk of bias. We aimed to develop the SR/PS ('Systematic Reviews for assessment

based on Primary Studies') method to enable a comprehensive, transparent, valid but time-saving assessment of healthcare technologies due to the use of data on primary studies from systematic reviews.

#### **METHODS:**

1) Structuring of the HTA- process in stages according to the main information to be ascertained. 2) Working out the certain stages of the new method including corresponding quality criteria for systematic reviews to use their information on primary studies (consensus-building). 3) Comparison of the new assessment method with the conventional methods with respect to validity, precision and time consume (planned).

#### **RESULTS:**

Using the SR/PS method, the evaluation of the hits identified through the literature search is divided into three main steps: 1) an identification of all relevant studies on the research question, 2) a quality assessment of the studies, and 3) an information synthesis based on the results of the studies. This process results in the ascertainment of the three most important data sets: 1) the pool of identified primary studies, 2) the pool of primary studies of higher methodological quality, and 3) the results of the information synthesis. Each step of the evaluation using the SR/PS-method comprises the comprehensive use of relevant data on primary studies from the systematic reviews. The selection of the appropriate systematic reviews from the literature search is based on special quality criteria. Gaps in the identification of the primary studies using systematic reviews will be completed by an additional search for these studies; an incomplete or poor quality assessment of the studies by an additional assessment of the primary studies. Incorrect or missing information synthesis on the base of all relevant studies will be completed by the own information synthesis.

#### **CONCLUSIONS:**

The SR/PS method may be particularly advantageous especially in projects based on many primary studies (e.g. guidelines development).

---

## **Poster 80B Questionnaire Survey On Current Experiences And Knowledge On Health Economics Analysis In Data Science Division In Pharmaceutical Companies In Japan (2014)**

#### **DESCRIPTION:**

Anticipating HTA trial introduction from April 2016, it was of interest for the taskforce under the Data Science subcommittee 2014 in the Japan Pharmaceutical Manufacturers Association to find out current experiences, knowledge, human resources, and issues on health economics analysis among peer pharmaceutical companies in Japan. This presentation provides you the results.

#### **PRESENTING AUTHOR:**

Dr. Kenji Adachi, Bayer Yakuhin, Ltd., Japan

#### **AUTHORS:**

Kenji Adachi, Akihiro Nakajima, Kotoba Okuyama, Keiko Sato, Toshihiko Aranishi, Shinichi Takayama, Yasuyuki Matsushita, Yuichi Kawata, Tomomi Kimura, Hironori Sakai

#### **BACKGROUND AND OBJECTIVES:**

Anticipating Health Technology Assessment (HTA) trial introduction from April 2016, it was of interest for the taskforce under the Data Science (DS) subcommittee in the Japan Pharmaceutical Manufacturers Association (JPMA) to find out current experiences, knowledge, human resources, and issues on health economics analysis among

peer pharmaceutical companies in Japan.

#### **METHODS:**

A web-based survey was conducted of 67 member companies of the DS subcommittee in the JPMA, between September 26 and October 17, 2014.

#### **RESULTS:**

43 companies responded the survey (response rate 64%). 35% (n=15) companies had experience(s) on health economics analysis in the last five years (91% of 11 foreign companies and 16% of 32 domestic companies), mostly by estimating incremental cost-effectiveness ratio (ICER) using Quality-Adjusted Life Years. Health economic analysis was conducted for various purposes, such as pricing negotiation (n=6), marketing tool (n=4), and post-marketing evidence generation/publication (n=3). DS specialists had limited knowledge (e.g., ICER, one-way sensitivity analysis) and involvement in health economic analyses, except for meta-analysis. An HTA-specific division was established in 7/43 (16%) companies, while 19/43 (44%) companies had HTA specialist(s) in various divisions, such as Medical Affairs. Various data sources were used for costs and effectiveness parameter estimates but collection of additional data, specific to health economics analysis (e.g., utility value by EQ-5D), in clinical trials was limited. Issues in implementation of health economics analysis included lack of data on epidemiology and costs, internal and external capabilities and validity of models, and seemingly no impact on price negotiation.

#### **CONCLUSIONS:**

15 out of 43 companies conducted health economics analyses in 2010-2014. Considering limited response rate, this might be overestimated. DS specialists have not had many opportunities to be involved in health economics analysis, but, given their background and skills, they should have no technical challenges in understanding and conducting such an analysis, as it will help raising overall capability of the industry to generate

meaningful evidence that shows the value of product. Future collaboration with HTA specialists and contribution from scientific aspect will be expected.

---

## **Poster 81B** Evaluation Of Medical Service Efficiency Of Township Hospitals Before And After The Implementation Of The Essential Medicine System In Shandong Province, China

#### **DESCRIPTION:**

This research was conducted to evaluate the medical service efficiency of township hospitals after the implementation of the essential medicine system (EMS) by data envelopment analysis (DEA) in Shandong province, PR China, and to provide references for the development of township hospitals under the background of the essential medicine system (EMS).

#### **PRESENTING AUTHOR:**

Lili Zhu, Weifang Medical University, China

#### **AUTHORS:**

Lili Zhu, Wenqiang Yin, Zhongming Chen, Xuedan Cui, Yan Wei, Haiping Fan, Hui Guan, Jifei Zheng, Haiyi Jia

#### **BACKGROUND AND OBJECTIVES:**

In order to meet the basic medicine needs of the masses and reduce their medical expenses burden, the former Chinese Ministry of Health and other eight ministries issued the notice of establishing national essential medicine system (EMS) on Aug. 18th 2009. The establishment of national essential medicine system (EMS) was a major policy decision in the national health reform program. The implementation of the essential medicine system (EMS) had important positive effect to improve the

quality of medical care and reduce the burden of patients. But faultiness of essential medicine system (EMS) also brought huge impact to the original operating mode of medical and health institutions, and even became a major issue affecting the medical service capability of township hospitals in a negative way. This research was conducted to evaluate the medical service efficiency of township hospitals by the data envelopment analysis (DEA) in Shandong province, PR China, and to provide references for the development of township hospitals under the background of the essential medicine system (EMS).

**METHODS:**

The CCR model and BCC model of the data envelopment analysis (DEA) method was used to analyze the medical service efficiency of township hospitals before and after the implementation of the essential medicine system (EMS) in Shandong province, PR China. The software of SPSS 19.0 was used to implement data entry and analysis, the software of DEAP 2.1 was used for the medical service efficiency analysis.

**RESULTS:**

In general, the relatively effective efficiency of decision-making units (DMUs) was decreased from 66.67% to 53.33% after the implementation of the essential medicine system (EMS). The medical service efficiency of township hospitals was decreased in Shandong province, PR China. From the view of the input and the output, the non-effective decision-making units (DMUs) were all shortage in output indicators?however, several input indicators input were excessive invested after the implementation of the essential medicine system (EMS).

**CONCLUSIONS:**

In order to improve the medical service efficiency, the first priority, the government needs to perfect the policy of essential medicine system (EMS) to guarantee smooth development of medical services. Secondly, kinds of measures need to be

considered to increase the medical staff's working enthusiasm. Last but not the least: the government needs to ameliorate the compensation policy so that it can promote the continuity of the policy. All these approaches above can strengthen the function of basic medical services of townships hospitals, which enhance the equity and accessibility of medical service and stimulate the healthy development of township hospitals.

.....

## Poster 82B Social Values In Health Technology Assessment

**DESCRIPTION:**

Social values are an inherent part of any form of decision making based. To inform an update of NICE's social values policy, a systematic review was undertaken of social values relevant to health resource allocation. Eight social value types were identified which can be used as a framework for beginning to assess the social values in different resource allocation systems.

**PRESENTING AUTHOR:**

Prof. David Gough, University College London, United Kingdom

**AUTHORS:**

David Gough, Caroline Kenny

**BACKGROUND AND OBJECTIVES:**

Many health systems create guidance to inform allocation of resources and thus services. Such guidance depends on decisions about opportunity costs and thus is based on social values as to the relative importance of different priorities. In other words, the social value judgements that is combined with technical evidence to make decisions on which individuals and groups should be offered what services. Research in this area has shown international variation in these values underlying differences in priority setting systems (Littlejohns et al 2012). The National Institute for

Health and Care Excellence (NICE) in England has a policy of Social Value Judgements (2008) that informs the use of research evidence in the production of health systems guidance for the National Health Service. NICE is currently revising its social values policy. This paper reports on a review of the literature on social values commissioned to inform that revision. To identify and organise social values and related debates relevant to priority setting by health and social care systems.

#### **METHODS:**

A framework conceptual systematic review was used. As the purpose was to identify issues, a configuring rather than aggregative review methodology was adopted (Gough et al 2012). The search strategy included a priori inclusion criteria and exhaustive and iterative search components. Nearly 2000 papers were identified of which over 800 were considered highly relevant. The issues were configured using an adapted version of Clarke and Weale's (2012) typology for social values consisting of: Utility and efficiency, Justice and equity, Autonomy, Solidarity, Participation, Sustainability, Transparency and accountability, and Rigour in methods of guidance development.

#### **RESULTS:**

The review identified eighty four main issues under the eight social value categories and proposed twenty main issues to be considered in developing policies for social values in HTA type systems.

#### **CONCLUSIONS:**

The application of the evidence from health technology assessment necessarily involves social value positions. The eight social value types and ten social value themes identified in this systematic review provide a basis for appraising and planning the social values incorporated in the development of priority setting in health and social care systems in different cultures.

#### **REFERENCES:**

Clark S, Weale A, (2012) Social values in health priority setting: a conceptual framework. *Journal of Health Organization and Management*. 26: 293-316. Gough D, Oliver S, Thomas J. (2012) *Introduction to Systematic Reviews*. Sage, London.

Littlejohns P, Sharma T, Jeong K, (2012) Social values and health priority setting in England: "values" based decision making. *Journal of Health Organization and Management*. 26: 363-373. NICE (2008) *Social Value Judgement: Principles for the development of NICE guidance (2nd Ed)*. London: NICE. <http://www.nice.org.uk/media/C18/30/SVJ2PUBLICATION2008.pdf>

---

## **Poster 83B The Trade-Off Between QALY Maximisation And Social Values: A Systematic Review Of Public Opinion Surveys**

#### **DESCRIPTION:**

In Cost-utility analysis assumes all quality-adjusted life-years (QALYs) are of equal value. We conducted a systematic review to determine public opinion on the relative value of QALYs depending on factors such as patient, disease or treatment characteristics. Results show that the public do not value all QALYs equally. We suggest that this should be quantitatively accounted for when prioritising resource allocation.

#### **PRESENTING AUTHOR:**

Amy Buchanan-Hughes, Costello Medical Consulting Ltd, Switzerland

#### **AUTHORS:**

Amy Buchanan-Hughes, Jeanette Kusel

#### **BACKGROUND AND OBJECTIVES:**

A key principle of cost-utility evaluations is that quality-adjusted life-years (QALYs) have equal

value regardless of the characteristics of the patients gaining or losing them. However, this utilitarian view may not be in line with public opinion. For example, the public may prefer to fund therapies for patients with greater burden of disease, or patients at the end of life. The UK's National Institute for Health and Care Excellence (NICE) currently attempts to incorporate these social values into health technology assessment (HTA) decisions by increasing its willingness-to-pay (WTP) threshold for certain special cases, but this workaround leads to boundary effects and an inconsistent application of values. A number of studies have sought to measure the extent to which the public are willing to trade efficiency (the principle of QALY maximisation) in favour of prioritising patients, diseases or treatment with particular characteristics. We aimed to review these studies with a view to developing a formula that could be used to adjust traditional QALYs to generate a value-weighted QALY.

#### **METHODS:**

We conducted a systematic literature review to identify primary research where members of the public quantified (directly or indirectly) the relative value of QALYs or health gains depending on factors such as patient, disease or treatment characteristics. Searches of MEDLINE (via PubMed) were supplemented by hand searches of abstracts from relevant congresses and examining the reference lists of relevant reviews. We excluded studies that did not present quantitative analyses of results.

#### **RESULTS:**

A number of studies using methods such as person trade-off and discrete choice experiments were identified. Overall, the evidence did not support the principle that all QALYs are of equal value. There was a preference for treating patients with more severe disease, but mixed opinions on whether patients with shorter or longer initial life expectancies should be favoured for treatment. Some studies examined broader factors such as patients' socioeconomic status or culpability for

their own disease.

#### **CONCLUSIONS:**

Published ratings of societal value weights for cost-value analysis (eg. Nord 2015) are weighted for severity of disease or proportional QALY shortfalls, but our review suggests that public preferences may support the consideration of a wider range of characteristics when determining priority setting for resource allocation. Further analyses are needed before quantitative weighting scales can be calculated.

#### **REFERENCES:**

Nord E. Cost-value analysis of health interventions: introduction and update on methods and preference data. *Pharmacoeconomics*. 2015 Feb;33(2):89-95.

---

## **Poster 84B** Lifetime Cost-Effectiveness Of Vildagliptin Versus Sulphonylurea As Add-On Therapy In Patients With Type 2 Diabetes Mellitus (T2Dm) Inadequately Controlled By Metformin Monotherapy In Thailand

#### **DESCRIPTION:**

Currently, no DPP-4 inhibitor is listed in national formulary of Thailand. This study showed that, over a patient's lifetime, the addition of vildagliptin to metformin is cost-effective when compared with the combination of metformin and sulphonylurea for the treatment of diabetes mellitus type 2 (T2DM) patients who failed to achieve glycemic control with metformin monotherapy from the Thai payer perspective.

**PRESENTING AUTHOR:**

Kannika Numuang, Novartis (Thailand) Limited, Thailand

**AUTHORS:**

Thongchai Pratipanawatr, Kannika Numuang

**BACKGROUND AND OBJECTIVES:**

Currently, no DPP-4 inhibitor is listed in national formulary of Thailand, and evidence on local economic evaluation is limited. This study aims to evaluate the long-term cost-effectiveness of vildagliptin compared with sulphonylurea (SU) as add-on therapy to metformin in uncontrolled type 2 diabetic patients receiving metformin monotherapy from the Thai payer perspective.

**METHODS:**

A previously published patient-level simulation economic model, utilizing risk equations from the UK Prospective Diabetes Study (UKPDS) Outcomes Model, was used to project clinical outcomes, diabetes-related complications, mortality and costs over a lifetime time horizon. The model simulated health outcomes and costs for a cohort of 10,000 T2DM patients in yearly cycles in which weight gain and hypoglycemia were drug-specific events considered in the analysis. Patients were switched to alternative treatments (metformin plus basal-bolus insulin and subsequently metformin plus intensive insulin) when HbA1c level increased above the HbA1c threshold of 7% according to Thailand Clinical Practice Guidelines. Efficacy and safety data were extracted from clinical trials. Most baseline patient characteristics were derived from Thailand Diabetes Registry Project. Disease-related costs were obtained from published local studies. Vildagliptin price proposed for national formulary listing was used, and other drug prices were those published by Ministry of Public Health, Thailand. The weighted average annual cost of SU was calculated based on the 2014 market share of individual drug in SU class to reflect the real-world treatment pattern. All costs were expressed in USD 2014 values (exchange rate of 1 USD = 33 THB).

Costs and clinical outcomes were discounted at 3% annually. Univariate and probabilistic sensitivity analyses were performed by varying key input parameters.

**RESULTS:**

Compared with the combination of metformin and SU, metformin plus vildagliptin yielded an incremental life expectancy of 0.04 years and 0.07 additional quality-adjusted life years (QALY). The mean incremental cost of vildagliptin versus SU when added to metformin was USD 252 per patient. Considering the Thailand recommended threshold of 4,848 USD/QALY, metformin plus vildagliptin was cost-effective with discounted incremental cost-effectiveness ratios (ICER) of 3,816 USD/QALY. The higher drug acquisition cost of vildagliptin was partially offset by lower costs for treatment of diabetes-related complications and hypoglycemic event. The cost-effectiveness results were robust to various assumptions determined in the sensitivity analyses.

**CONCLUSIONS:**

Based on the third-party payer perspective, the addition of vildagliptin to metformin is likely to be cost-effective compared with metformin plus SU for the treatment of T2DM patients not achieving glycemic control with metformin monotherapy. Vildagliptin in combination with metformin may be considered as one of the cost-effective second-line therapies for T2DM patients in Thailand setting.

.....

**Poster 85B Dealing With Uncertainties When The Decision Has To Be Made**

**DESCRIPTION:**

An Example of an HTA for possible disinvestment within "The National System for the Introduction of New Health Technologies within the Specialist Health Care Service" in Norway. Having to make a decision based on weak evidence is challenging.

.....

Here, we present an example from Norway where the decision has to be made as to whether the current clinical practice should be changed or not. We will discuss what was taken into account in the process and why.

**PRESENTING AUTHOR:**

Dr. Katrine Fronsdal, Norwegian Institute of Public Health, Norway

**AUTHORS:**

Dr. Katrine Fronsdal

**BACKGROUND AND OBJECTIVES:**

In 2013, the "The National System for the Introduction of New Health Technologies within the Specialist Health Care Service" was launched in Norway. The reason for establishing this system was the lack of use of HTA for investments and disinvestments in Norwegian hospitals as well as divergent practices and lack of transparency in decision making processes. The aim of the system is to increase patient safety and access to effective technologies by laying the ground for making right priorities in an evidence-based, cost-effective, predictable and transparent manner. Within this system, the so called "Commissioner Forum" which includes representatives of the four Norwegian regional health authorities (RHA), asked the Norwegian Knowledge Centre for the Health Services (NOKC) to conduct an HTA which should compare the various alternatives for generation of plasma for transfusion purposes in terms of clinical effectiveness, safety and costs. Based on findings from this HTA the four RHA will make the decision to either keep the today's practice or replace it by (an)other alternative(s). Currently, all plasma used for transfusion at Norwegian hospitals is the plasma product Octaplas®. Alternative plasma products are available on the market, and there are concerns about the high costs of purchasing Octaplas®.

**METHODS:**

NOKC conducted an HTA, which has compared the various plasma alternatives for transfusion in

terms of clinical effectiveness, safety and costs. For assessing clinical effectiveness and safety, we carried out a systematic review and performed a literature search for prospective controlled trials, which had compared Octaplas® with the alternatives Intercept, Mirasol, Methylene blue, quarantine plasma and fresh frozen plasma. We also consulted registries for adverse events. Costs we evaluated using three production strategies for coverage of the demand for plasma for transfusion in Norway. The strategies included one central production, four regional productions and production at 19 local hospitals.

**RESULTS:**

According to available documentation, it is not possible to determine whether there are differences in terms of clinical effectiveness between the different plasma alternatives assessed. It seems that the various types of plasma routinely used in various European countries are safe in terms of adverse events. Pathogen inactivated plasma appears to be the safest alternative. Maybe certain methods of pathogen inactivation may lead to more allergies, but the evidence is both sparse and partly inadequate. Fresh frozen plasma has the lowest costs. Pathogen-inactivated plasma produced in-house represents the middle level of costs while purchase of Octaplas® incurs the highest costs.

**CONCLUSIONS:**

In clinical practice, it is likely that all plasma alternatives are similarly efficient. We know that Octaplas is safe, but that does not mean that the alternatives are not. On the other hand, Octaplas is the most expensive alternative with a yearly expenditure of more than 30 million Norwegian Kroner, whereas the other plasmas are up to three times cheaper. There is a lot of interest in Norway around the decision process that follows this HTA, and we will discuss what the decision has been based on and what influenced the final outcome.

## Poster 86B Systematic Review Of Economic Evaluation Of NIPT For Down Syndrome

### DESCRIPTION:

Non-invasive prenatal testing (NIPT) is a relatively new technology for diagnosis of fetal aneuploidies and more accurate than conventional maternal serum screening. This study was to systematically review the economic evaluation of NIPT for Down's syndrome. We found it could be cost-effective if designed well with existing screening strategies.

### PRESENTING AUTHOR:

Yan Xu, Fudan University, China

### AUTHORS:

Yan Xu, Raymond Pong, Yingyao Chen

### BACKGROUND AND OBJECTIVES:

Non-invasive prenatal testing (NIPT) is a relatively new technology for diagnosis of fetal aneuploidies and more accurate than conventional maternal serum screening. The aim of this study was to systematically review the economic evaluation of NIPT for Down's syndrome.

### METHODS:

The literature on economic evaluation of NIPT for Down's syndrome was searched, literatures were chose according to the inclusion and exclusion criteria, and the quality of literatures was assessed using the 24-item checklist of CHEERS, which produced a total score of 24. Descriptive analysis was used, which also reported the results of cost-effectiveness analyses of NIPT.

### RESULTS:

14 studies were included in the review. The percentage of them with a quality score over 15 was 78.6%. Three interventions were typically used: Universal NIPT screening; Contingent screening in which NIPT only in high-risk pregnancies after

conventional screening; Hybrid strategy in which NIPT was offered to all patients aged over 35 years and only to patients

### CONCLUSIONS:

NIPT is a promising new technology for pregnant women, which could be cost-effective if designed well with existing screening strategies. Costs of using NIPT will likely decrease in the future, making it more affordable to pregnant women.

---

## Poster 87B Mortality Reduction From Gastric Cancer By Endoscopic And Radiographic Screening

### DESCRIPTION:

Endoscopic screening can reduce gastric cancer mortality.

### PRESENTING AUTHOR:

Dr. Chisato Hamashima, National Cancer Center, Japan

### AUTHORS:

Chisato Hamashima, Michiko Shabana, Katsuo Okada, Mikizo Okamoto, Yoneatsu Osaki

### BACKGROUND AND OBJECTIVES:

The burden of gastric cancer cannot be ignored in Eastern Asian countries, and this also holds true in Eastern European countries and South America which also have a high incidence of gastric cancer. Recently, upper gastrointestinal endoscopy has been increasingly used in clinical practice and as a standardized examination procedure for gastrointestinal diseases. To evaluate mortality reduction from gastric cancer by endoscopic screening, we performed a population-based cohort study where both radiographic and endoscopic screenings for gastric cancer have

been conducted.

**METHODS:**

The subjects were selected from the participants of gastric cancer screening in 2 cities in Japan (i.e., Tottori and Yonago) from 2007 to 2008. The subjects were defined as participants aged 40-79 years who had no gastric cancer screening in the previous year. Follow-up of mortality was continued from the date of the first screening to the date of death or up to December 31, 2013. A Cox proportional hazards model was used to estimate the relative risk (RR) of gastric cancer incidence, gastric cancer death, all cancer deaths except gastric cancer death, and all-causes deaths except gastric cancer death.

**RESULTS:**

The numbers of subjects selected for endoscopic screening was 9,950 and that for radiographic screening was 4,324. The subjects screened by endoscopy showed a 67% reduction of gastric cancer compared with the subjects screened by radiography (adjusted RR by sex, age group, and resident city = 0.327, 95%CI: 0.118-0.908). The adjusted RR of endoscopic screening was 0.968 (95%CI: 0.675-1.387) for all cancer deaths except gastric cancer death and 0.929 (95%CI: 0.740-1.168) for all-causes deaths except gastric cancer death.

**CONCLUSIONS:**

This study indicates that endoscopic screening can reduce gastric cancer mortality by 67% compared with radiographic screening. This is consistent with previous studies showing that endoscopic screening reduces gastric cancer mortality.

.....

## Poster 88B The Costs Of Short- And Long-Term Psychotherapies And Their Effectiveness On Work Ability In The Treatment Of Depression And Anxiety: A Randomized Trial With A 5-Year Follow-Up

**DESCRIPTION:**

The costs of short-term (STP) and long-term (LTP) psychotherapies and their effectiveness on work ability in the treatment of depression and anxiety were compared. LTP was more effective in reducing absence from work, but the costs of LTP were, however, much higher than those of STP, and thus LTP cannot be regarded as cost-effective compared to STP.

**PRESENTING AUTHOR:**

Timo Maljanen, Social Insurance Institution, Finland

**AUTHORS:**

Timo Maljanen, Tommi Härkänen, Esa Virtala, Olavi Lindfors, Paul Knekt

**BACKGROUND AND OBJECTIVES:**

Several clinical trials have shown that patients with mood and anxiety disorders can be treated successfully both with short-term and long-term psychotherapy. However, our current knowledge about the cost-effectiveness of short-term therapies compared to that of long-term therapy is extremely limited. The aim of this study, which is a part of the larger Helsinki Psychotherapy Study, was to compare the direct health care costs and effectiveness of solution-focused therapy (SFT), short-term psychodynamic psychotherapy (SPP) and long-term psychodynamic psychotherapy (LPP) in the treatment of depression and anxiety during a 5-year follow-up in a design where effectiveness was measured by the number of sick-leave days, i.e. days in which patients were unable

to perform their usual activities due to illness.

#### **METHODS:**

A total of 326 outpatients aged 20-45 years suffering from mood or anxiety disorder were randomized to SFT (n=97), SPP (n=101) or LPP (n=128). The estimation of the number of sick-leave days was based on six postal surveys carried out at baseline and at 12, 24, 36, 48 and 60 months after the start of the therapy. In the self-administered questionnaires patients were asked to report the number of sick-leave days during the previous three months. All health care costs due to mental health problems incurred during the 5-year follow-up period were estimated. Both effectiveness and costs were discounted annually by 3%.

#### **RESULTS:**

In the first year after the start of therapy absence from work and studies was reduced somewhat more, on the average, among patients belonging to the short-term therapy groups, but from the second year on the situation was reversed. Taking the whole 5-year follow-up period into account and assuming that the annual number of sick-leave days is four-fold compared to the three-month period covered by the survey the 5-year mean number of sick-leave days in the LPP group was 53.5, which was 29.7 days less than in the STF group and 21.0 less than in the SPP group. The direct health care costs per patient were clearly higher in the LPP group (22 100 euros) than in the SFT (8 400 euros) or the SPP group (7 400 euros).

#### **CONCLUSIONS:**

According to this study LPP was more effective than either short-term therapy in reducing absence from work. The costs of LPP were, however, much higher than the costs of SFT or SPP. Thus, if only economic implications, i.e. the extra health care cost versus the value of lost production, are taken into account, LPP cannot be regarded as cost-effective compared to SFT or SPP if patients are randomized to different therapies. Further studies identifying patients suitable for LPP therefore seem

warranted.

---

## **Poster 89B Comparison On Diagnostic Value Between Serum CYFRA21-1 And CEA In Non-Small Cell Lung Cancer: A Meta Analysis**

#### **DESCRIPTION:**

This abstract was mainly concerned with two non small cell lung cancer testing method performance comparison using meta analysis.

#### **PRESENTING AUTHOR:**

Haiyin Wang, Shanghai Medical Technology Intelligence Institute; Shanghai Health Technology Assessment Center, China

#### **AUTHORS:**

Wang Hai-yin, Chen Min-xing, Pu Zhen-mei, Sun Li-qian, Jin Chun-lin, Zhang Xiao-xi

#### **BACKGROUND AND OBJECTIVES:**

Lung cancer is one of the most common malignant tumors in the world. According to the differentiation and morphological characteristics, the World Health Organization divided lung cancer into two categories: small cell lung cancer (SCLC) and non small cell lung cancer (NSCLC), NSCLC accounted for 80%~85% of the total number of lung cancer, 5 years survival rate was only 11%~17%. Effective examination and early diagnosis is the key to improve the survival rate of NSCLC. At present, carcinoembryonic antigen (CEA) and serum levels of cytokeratin 19 fragment (CYFRA21-1) was commonly used in NSCLC, However, their sensitivity and specificity have not been compared sufficiently. Therefore, this study aimed to evaluate the efficacy of CEA and CYFRA21-1 in the clinical diagnosis of NSCLC by using systematic review method.

## METHODS:

Databases such as the PUBMED, EMBASE, CBM, CNKI, Wanfang were searched from inception to May 2014. Articles related to the diagnostic value of serum CYFRA21-1 and CEA on NSCLC were selected, and literature quality evaluation was implemented by using quality assessment of diagnostic accuracy studies (QUADAS) criteria. Data analysis was conducted by Meta-Disc1.4 software.

## RESULTS:

Eleven studies with a total of 989 cases and 886 controls were included. The results of meta-analysis showed that the diagnostic odds ratio of CYFRA21-1 test for diagnosis of NSCLC was 22.822(95%CI:14.282~36.467), sensitivity was 59.7%(95%CI?56.6%~62.8%), specificity was 94.3%(95%CI?92.5%~95.7%), area under the SROC curve was 0.8017(SE=0.0824); The diagnostic odds ratio of CEA test for diagnosis of NSCLC was 11.978(95%CI?8.949~16.034), sensitivity was 45.5%(95%CI?42.4%~48.7%), specificity was 93.7%(95%CI?91.9%~95.2%), area under the SROC curve was 0.5928(SE=0.0809).

## CONCLUSIONS:

CYFRA21-1 test had a higher performance than CEA diagnosing NSCLC.

---

## Poster 90B Cost-Effectiveness Analysis Of Neonatal Screening Of Critical Congenital Heart Defects In China

### DESCRIPTION:

This is the first cost-effectiveness analysis on pulse oximetry as an adjunct of clinical assessment to early detect critical congenital heart defects among neonates in the developing world.

## PRESENTING AUTHOR:

Ruoyan Gai, National Center for Child Health and Development, Japan

## AUTHORS:

Ruoyan Gai, Gerard R. Martin, Fuhai Li, Rintaro Mori

## BACKGROUND AND OBJECTIVES:

Congenital heart defects (CHD) are the most common type of birth defects, and a leading cause of infant mortality in China. A quarter of this number have critical CHD (CCHD), which requires surgical or catheter-based interventions during infancy. Pulse oximetry as an adjunct to clinical assessment has shown good accuracy to additionally detect critical CHD after birth, and has been recommended as routine practice in several developed countries. The justification for adding pulse oximetry into routine practice is the ability to identify those apparently asymptomatic infants with CCHD before discharge from birth hospitals, the proportion of which cannot be neglected and depends on the prenatal diagnosis rate. Early detection is critical to prevent infant morbidity and mortality, and combined with advances in therapeutic interventions, it is now possible for the majority of children born with CHD to go on to lead normal productive lives. It has high potential benefits for developing countries. A large-scale multicenter prospective screening study recently conducted in China confirmed the feasibility and accuracy of pulse oximetry screening for detection of CCHD in neonates before discharge. However, certain barriers may impede its wider implementation. In this study, we aim to inform clinical and health policy decisions by assessing the cost-effectiveness of CHD screening in China.

## METHODS:

We developed a cohort model to evaluate the cost-effectiveness of screening all Chinese newborns annually using two possible screening options compared to no intervention: (1) clinical assessment alone, and (2) pulse oximetry as an adjunct to clinical assessment. We calculated the

incremental cost per averted disability-adjusted life years (DALYs) in 2014 international dollars to measure cost-effectiveness. One-way sensitivity analyses and multivariate probabilistic sensitivity analysis were performed to test robustness of the model.

**RESULTS:**

Clinical assessment is cost-effective with an incremental cost-effectiveness ratio Int\$ 34,673/DALY, while pulse oximetry as an adjunct to clinical assessment yielded the best health outcomes. When the proportion of timely access to both diagnosis and treatment increased up to 32%, pulse oximetry plus clinical assessment showed the better expected values compared to clinical assessment alone. Neonatal CCHD screening (by at least clinical assessment) has approximately 75% of probability to be cost-effective. The probability of the combined strategy to be cost-effective gradually increased with WTP and exceeded that of clinical assessment at a WTP threshold of Int\$77,360/DALY.

**CONCLUSIONS:**

In China, neonatal CCHD screening by clinical assessment is currently cost-effective at the national level. In the long term, however, pulse oximetry as an adjunct to clinical assessment would be the best screening strategy with improvement of access to pediatric cardiological care. Our results suggested that postnatal oximetry screening could bring potential benefits to developing countries as well. In China, public investment and insurance coverage for children with CCHD is crucial to achieve the health benefits of the screening.

.....

## Poster 91B Economic Evaluation Of Automated External Defibrillators In Japan

**DESCRIPTION:**

Sudden death from cardiac arrest is a major public health problem in the industrialized world. The rate of survival after an out-of-hospital cardiac arrest has been increasing as improvements are made in connecting the links in the 'chain of survival' . On the other hand, national health expenditure of Japan has continued to soaring. However, cost efficiency the AED has not been evaluated. This study conduct an economic evaluation of AED to suggest policy implications for accountable control of the emergency systems.

**PRESENTING AUTHOR:**

Mie Sasaki, National Institute of Public Health; Ministry of Health, Labour and Welfare, Japan

**AUTHORS:**

Mie Sasaki, Tetsuya Sakamoto, Atsushi Hiraide, Hajime Sato, Hideki Hashimoto

**BACKGROUND AND OBJECTIVES:**

In our country, there are about seventy thousands cases of out-of-hospitals cardiac arrest occurring every year. The need for out-of-hospital emergency system has become a serious problem. When cardiac arrest happened outside hospitals, if the bystanders can perform Cardiopulmonary Resuscitation (CPR) and use defibrillators, apparently the survival rate will be higher. In order to increase the survival rate, it is extremely important to increase the ability to use defibrillators by the bystanders. In Japan, from July 2004, AED has been allowed to be used by the general civil, the widespread of AED to the non-medical areas. Consequently, the resuscitation rate of defibrillation cases done by the civil has increased rapidly. However, the recent prevalence of automated external defibrillators (AEDs) in public spaces has not been fully studied in its cost-value

performance, especially in Japan. This study seeks to conduct an economic evaluation of AED to suggest policy implications for accountable control of the out-of-hospital emergency systems towards improving their societal value.

## **METHODS:**

Cost-benefit analysis were used to examine the effects of AEDs installed in various situations in Japan. Outcome data regarding prognosis of cardiac arrest cases were derived from Utstein data of Osaka city, and cost data were estimated from the public data. Moreover, actual claim data of cardiac arrest cases were collected in a tertiary emergency unit of a university-affiliated hospital for a validity check. The benefits were converted into monetized values using the Markov model. Regarding the costs side, medical costs and nursing care costs of the survivors in each case were studied with and without AEDs. Moreover, in order to assess the differences between locations where cardiac arrest occurs, the cases in different locations were separately examined. Robustness of results was confirmed by probabilistic sensitivity analysis.

## **RESULTS:**

The net benefit of locations other than stations and sports centers is negative. Throughout 6 years of AED service life, the loss in hospitals, where the net benefit is the lowest, is around 467 million yen. The benefit in stations, where the net benefit is the highest. The net losses were about 2-4 times as large as the net benefit value of the base case in the places other than stations and sports centers. Further considerations must be taken when purchasing new AEDs in the places other than stations and sports centers.

## **CONCLUSIONS:**

The benefits of promoting AEDs were strongly dependent on the types of institutions prepared with AEDs. The results of this study indicated that the system to install the AEDs should be managed and monitored by public agencies such as local

government for efficient use of AEDs to achieve societal values.

## **REFERENCES:**

Ambulance Service Planning Office of Fire and Disaster Management Agency of Japan. Effect of first aid for cardiopulmonary arrest. 2013. Available at: [http://www.fdma.go.jp/neuter/topics/kyukyukyujo\\_genkyo/h25/01\\_kyukyu.pdf](http://www.fdma.go.jp/neuter/topics/kyukyukyujo_genkyo/h25/01_kyukyu.pdf) (Accessed 27, November, 2015).

(in Japanese) Valenzuela, T. D., D. J. Roe, G. Nichol, L. L. Clark, D. W. Spaite, and R. G. Hardman. "Outcomes of Rapid Defibrillation by Security Officers After Cardiac Arrest in Casinos." *The New England Journal of Medicine* 343, no. 17. 1206-1209. Oct 26, 2000.

Page, R. L., J. A. Joglar, R. C. Kowal, J. D. Zagrodzky, L. L. Nelson, K. Ramaswamy, S. J. Barbera, M. H. Hamdan, and D. K. McKenas. "Use of Automated External Defibrillators by a U.S. Airline." *The New England Journal of Medicine*. 343. no. 17. 1210-1216. Oct 26, 2000.

Mark S. Link, Chair; Dianne L. Atkins; Rod S. Passman; Henry R. Halperin; Ricardo A. Samson; Roger D. White; Michael T. Cudnik; Marc D. Berg; Peter J. Kudenchuk; Richard E. Kerber. Part 6: Electrical Therapies Automated External Defibrillators, Defibrillation, Cardioversion, and Pacing. 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation*. 2010 Nov 2;122(18 Suppl 3):S706-19. Erratum in *Circulation*. 2011 Feb 15;123(6):e235.

Folke F, Lippert FK, Nielsen SL, Gislason GH, Hansen ML, Schramm TK, Sorensen R, Fosbol EL, Andersen SS, Rasmussen S, Kober L, Torp-Pedersen C. Location of cardiac arrest in a city center: strategic placement of automated external defibrillators in public locations. *Circulation*. 2009;120:510-517.

Weisfeldt ML, Kerber RE, McGoldrick RP, Moss AJ, Nichol G, Ornato JP, Palmer DG, Riegel B, Smith SCJ. American Heart Association Report on the

Public Access Defibrillation Conference December 8-10, 1994. Automatic External Defibrillation Task Force. *Circulation*. 1995;92:2740-2747.

Weisfeldt ML, Kerber RE, McGoldrick RP, Moss AJ, Nichol G, Ornato JP, Palmer DG, Riegel B, Smith SC Jr. Public access defibrillation. A statement for healthcare professionals from the American Heart Association Task Force on Automatic External Defibrillation. *Circulation*. 1995;92:2763.

---

## Poster 92B What Is The Clinical Effectiveness Of Cetuximab And Panitumumab For Previously Untreated Metastatic Colorectal Cancer? A Systematic Review.

### DESCRIPTION:

A systematic review assessed the clinical effectiveness of cetuximab and panitumumab in combination with chemotherapy for previously untreated metastatic colorectal cancer in patients with rat sarcoma (RAS) wild-type. Results suggest that the addition of both anti-epidermal growth factor receptors to chemotherapy have statistically significant benefits. However, results were based on post hoc subgroup analyses and must be treated with caution.

### PRESENTING AUTHOR:

Nicola Huxley, University of Exeter Medical School, United Kingdom

### AUTHORS:

Nicola Huxley, Louise Crathorne, Jo Varley-Campbell, Irina Tikhonova, Tristan Snowsill, Simon Briscoe, Jaime Peters, Mary Bond, Mark Napier, Martin Hoyle

### BACKGROUND:

Colorectal cancer is the fourth most commonly diagnosed cancer in the UK. People with metastatic

disease who are sufficiently fit are usually treated with active chemotherapy as first- or second-line therapy. Targeted agents are available, including the anti-epidermal growth factor receptor (EGFR) agents cetuximab and panitumumab. The National Institute for Health and Care Excellence conducted a multiple technology appraisal to review the clinical effectiveness and cost-effectiveness of cetuximab and panitumumab. We present the results of the systematic review conducted as part of the appraisal.

### OBJECTIVES:

To investigate the clinical effectiveness of panitumumab in combination with chemotherapy and cetuximab in combination with chemotherapy for rat sarcoma (RAS) wild-type (WT) patients for the first-line treatment of metastatic colorectal cancer (mCRC).

### METHODS:

Searches were conducted up to April 2015 in bibliographic and ongoing trials databases, as well as sources of grey literature and conference proceedings. Studies were included if they were randomised controlled trials (RCTs) or systematic reviews of RCTs of cetuximab or panitumumab in participants with previously untreated mCRC with RAS WT status. Included studies were extracted and quality appraised. Outcomes evaluated were overall survival (OS), progression free survival (PFS), response rate, adverse events (AEs) and health related quality of life (HRQoL). Data were tabulated and discussed narratively. Network meta-analyses (NMA) within a Bayesian framework were conducted as appropriate.

### RESULTS:

Five clinical trials, all reporting results for RAS WT subgroups were included in the review. Two networks were used for the NMA, based on the different chemotherapies (FOLFOX and FOLFIRI) as insufficient evidence was available to connect these networks. Results suggest there are clinical benefits from the addition of anti-EGFR therapies

to chemotherapy for first-line treatment of patients who are RAS WT. There is no evidence to suggest that cetuximab plus FOLFOX is any more effective than panitumumab plus FOLFOX for improving PFS or OS. No HRQoL data was reported for the RAS WT subgroups.

**CONCLUSIONS:**

Cetuximab and panitumumab in combination with chemotherapy appear to be clinically beneficial for RAS WT patients compared with chemotherapy alone. However, the trials only include RAS WT populations as post hoc subgroup analyses, so results must be interpreted with caution. No evidence was available for panitumumab plus FOLFIRI or to join the FOLFIRI and FOLFOX networks. It would be useful to conduct a RCT for patients with RAS WT.

---

## Poster 93B Determinants Of High Technology Medical Equipment Utilization In Chinese Hospitals: A Panel Data Analysis

**DESCRIPTION:**

In order to identify determinants of high technology medical equipment utilization in Chinese hospitals, a sample of 131 hospitals was randomly selected from six provinces in China. Panel analysis demonstrated that CT and MRI utilization were significantly affected by hospital level indicators, which need to be considered in the allocation of high technology medical equipment in China.

**PRESENTING AUTHOR:**

Yan Wei, Fudan University, Key Lab of Health Technology Assessment, Ministry of Health, China

**AUTHORS:**

Yan Wei, Yingyao Chen, Hao Yu

**BACKGROUND AND OBJECTIVES:**

The current regional health planning and allocation of high technology medical equipment in China rely on population-based models, not considering hospital level factors. This study aimed to fill the gap by identifying determinants of high technology medical equipment utilization in Chinese hospital.

**METHODS:**

The study sample of 131 hospitals was randomly selected from six provinces that are located in East, Middle, and West China. Information about CT and MRI utilization and hospital characteristics was collected from the study hospitals from 2009-2013 through a questionnaire survey. Based on the Hausman test, we chose to specify a fixed-effect model to analyze the panel data.

**RESULTS:**

The analysis confirms that the hospital indicators, such as annual discharge number (p

**CONCLUSIONS:**

CT and MRI utilization were significantly affected by hospital level indicators, such as annual discharge number, number of surgical cases, number of qualified persons, and outpatient and emergency visits. These factors need to be considered in the allocation of high technology medical equipment in China.

---

## Poster 94B Experiences Of Lung Cancer Screening Using Low Dose CT: A Meta-Analysis

### DESCRIPTION:

This article systematically reviewed the worldwide experiences of lung cancer screening using low-dose CT (LDCT) to evaluate its effectiveness. The overall detection rate was 1.30%. Baseline prevalence rate of lung cancer was 0.86%. Given that medical resources are relatively insufficient and that ethical concerns remain, the rationality of lung cancer screening in the communities using LDCT needs further study.

### PRESENTING AUTHOR:

Ying Ji, Fudan University, China

### AUTHORS:

Ying Ji, Di Xue

### BACKGROUND AND OBJECTIVES:

Lung cancer ranks highest incidence rate among all malignant tumors and has been the leading cause of cancer-related death in China since 2008. Early detection of lung cancer has been explored as a possible method of reducing its disease burden. Compared with chest X-ray, the low-dose computed tomography (LDCT) is believed to be the most promising screening technique. We systematically reviewed the worldwide experiences of lung cancer screening using LDCT to evaluate its effectiveness and to provide the information for decision makers on screening strategies for lung cancer.

### METHODS:

We searched PubMed, EMBase, China National Knowledge Infrastructure (CNKI), SinoMed (CBM) and WANFANG Database to screen eligible literature according to the inclusion and exclusion criteria. We used Meta-Analyst 3.13 to analyze the effectiveness of LDCT. Overall detection rate, baseline prevalence, annual incident rate and the

95% confidence interval (CI) of these indicators were calculated and a forest plot for overall detection rate was drawn.

### RESULTS:

A total of 195636 cases from 36 researches were used for analyses. Among all cases, 2965 cases were diagnosed as lung cancer. The overall detection rate was 1.30% (1.01%-1.68%), but it was lower in China (0.69%, 0.28%-1.68%) and higher in other countries (1.72%, 1.39%-2.13%). Baseline prevalence rate of lung cancer was 0.86% (0.63%-1.16%) and the incident rate of annual repeated screening for lung cancer was 0.53% (0.38%-0.76%). Of the 1946 cases with histopathological diagnosis, 52.00% were adenocarcinoma. Of the 2267 cases described by stage, 70.75% were defined as stage I. 5-year and 10-year survival rates were 60%-84.5% and 38.1%-86.2%, respectively.

### CONCLUSIONS:

The detection rate for lung cancer screening using LDCT was significantly higher than using chest X-ray. The use of LDCT in high-risk population is valid for the early diagnosis and therefore can be helpful for early treatment. But given that medical resources are relatively insufficient and that ethical concerns remain (whether it is worthwhile to find out 1% of the population as the patients with lung cancer, while 99% innocents undergoing unnecessary exposure to excess radiation), the rationality of lung cancer screening in the communities using LDCT needs further study.

## Poster 95B A Systematic Study Of Clinical Guidelines On Non-Invasive Prenatal Test: International Experience And Its Wider Implications

### DESCRIPTION:

With a view from the perspective of values and evidence, this study summarized the international experience of non-invasive prenatal test and discussed its implications for developing countries.

### PRESENTING AUTHOR:

Jian Ming, Fudan University, Key Lab of Health Technology Assessment, Ministry of Health, China

### AUTHORS:

Jian Ming

### BACKGROUND AND OBJECTIVES:

Non-invasive prenatal test (NIPT) has been reported to have high sensitivity and specificity in detecting trisomy 21, 18 and 13. And it has attracted much attention due to the early, safe detection for fetal abnormality. However, it also engendered considerable debates of replacement of golden criteria, ethical arrangements and health policy challenges, nevertheless, there is a lack of agreement on the clinical practice of NIPT. This paper aims to summarize the international experience in relation to the clinical guidelines of NIPT and related issues concerning informed consent and genetic counseling, with a view to providing policy recommendations for developing countries that lack of well-established regulatory system in using NIPT.

### METHODS:

Relevant guidelines developed in the period from 2006 to 2015 were identified through systematic searches of two databases (Medline and EMBASE), four guideline websites (National Guideline Clearinghouse, USA; Canadian Medical

Association Infobase: Clinical Practice Guidelines Database; Scottish Intercollegiate Guidelines Network; and New Zealand Guidelines Group, Ministry of Health), and relevant documents from four associations (International Society for Prenatal Diagnosis; American College of Obstetricians and Gynecologists; Society of Obstetricians and Gynaecologists of Canada; and Royal College of Obstetricians and Gynaecologists). These guidelines were examined systematically.

### RESULTS:

Seven guidelines were included in this review. All seven guidelines defined NIPT as an option for specific aneuploidies and advised that test results not be considered diagnostic. NIPT was explicitly recommended for women at high risk of aneuploidy by most guidelines (5/7). In addition, all guidelines emphasized the necessity of informed consent before providing NIPT, as well as the importance of pre-test and post-test genetic counseling. The contents of consent and counseling should include benefits and limitations of the test and the fact that the result was not diagnostic and that CVS or amniocentesis is needed for confirmation.

### CONCLUSIONS:

The implications for countries such as China and other developing countries were discussed and some policy recommendations were put forward. Countries that lack of regulatory system in using NIPT need to carefully determine appropriate NIPT's clinical roles and its indications in early stage, and to effectively integrate NIPT with traditional screening strategies. Regarding informed consent and genetic counseling, it is recommended that training of counselors and doctors be enhanced, that the required contents of genetic counseling be clearly defined, and that informed consent processes be standardized.

### REFERENCES:

[1] Benn P, Borell A, Chiu R et al. Position statement from the Aneuploidy Screening Committee on

behalf of the Board of the International Society for Prenatal Diagnosis [J]. Prenat Diagn 2013, 33(7):622-629.

[2] Committee Opinion No. 545: Noninvasive prenatal testing for fetal aneuploidy [J]. Obstet Gynecol, 2012, 120(6):1532-1534.

[3] Devers PL, Cronister A, Ormond KE, et al. Noninvasive prenatal testing/noninvasive prenatal diagnosis: the position of the National Society of Genetic Counselors [J]. J Genet Couns, 2013, 22(3):291-295.

[4] Gregg AR, Gross SJ, Best RG, et al. ACMG statement on noninvasive prenatal screening for fetal aneuploidy [J]. Genetics in medicine, 2013, 15(5):395-398. [

5] Langlois S, Brock JA, Wilson RD, et al. Current status in non-invasive prenatal detection of Down syndrome, trisomy 18, and trisomy 13 using cell-free DNA in maternal plasma [J]. J Obstet Gynaecol Can, 2013, 35(2):177-183.

[6] Position Statement from the Italian College of Fetal Maternal Medicine: Non-invasive prenatal testing (NIPT) by maternal plasma DNA sequencing [J]. Journal of prenatal medicine, 2013, 7(2):19-20.

[7] Royal College of Obstetricians and Gynaecologists. Non-invasive Prenatal Testing for Chromosomal Abnormality using Maternal Plasma DNA. [EB/OL]. Scientific Impact Paper No.15, March 2014. [https://www.rcog.org.uk/globalassets/documents/guidelines/sip\\_15\\_04032014.pdf](https://www.rcog.org.uk/globalassets/documents/guidelines/sip_15_04032014.pdf).

.....

## Poster 96B Cost Effectiveness Analysis Of Two Nucleotide Antiviral Therapies For Chronic Hepatitis B Patients With Hepatitis Be Antigen-positive In China: Tenofovir Disoproxil Fumarate Vs. Lamivudine

### DESCRIPTION:

In China, chronic hepatitis B (CHB) is prevalent and imposes both heavy disease and economic burden to the whole society, and more than half of CHB are HBeAg-positive, thus local evidence of cost effective therapy for the development of national CHB prevention and control strategy is urgently needed. This study evaluated the cost-effectiveness of the newest available yet costly optimal therapy (tenofovir disoproxil fumarate, TDF) with the most widely used and cheaper suboptimal therapy (lamivudine, LAM).

### PRESENTING AUTHOR:

Yingpeng Qiu, China National Health Development Research Center

### AUTHORS:

Yingpeng Qiu, Xue Li, Wudong Guo, Rui Zhao

### BACKGROUND AND OBJECTIVES:

In China, Chronic hepatitis B (CHB) is prevalent and imposes both heavy disease and economic burden to the whole society. Thus, local evidence of cost-effective therapy in support of a national CHB prevention and control strategy is urgently needed. This study aims to evaluate the cost-effectiveness of the newest available yet costly therapy (Tenofovir Disoproxil Fumarate, TDF) with the most widely used therapy (Lamivudine, LAM).

### METHODS:

A Markov model with 11 states were used to model the life-time (34 years) cost and effectiveness

of a hypothetical 1,000 HBeAg-positive CHB patients, of which 86% were without compensated cirrhosis (CC) (age = 40 years) and 14% with CC (age =51 years). From the perspective of the health system, the total cost of antiviral therapy and the treatment of advanced liver disease, including CC, decompensated cirrhosis (DC) and hepatocellular carcinoma (HCC), were estimated. The relative model parameters were derived from Chinese population studies. Cost and effectiveness were discounted at 3%. One-way sensitivity analysis and probabilistic sensitivity analysis (PSA) were conducted to explore uncertainties.

### RESULTS:

In the base case analysis, compared to LAM, TDF generated more life years (16.1vs13.5) and lower incidence of CC (10.4% vs 25.1%), DC (8.2% vs 33.3%), HCC (13.1%vs18.1%) and death (28.2% vs 84.8%). The ICER (TDF vs LAM) was \$132/QALY. One-way sensitivity analysis revealed that when the current cost of TDF was reduced from\$2,690/year to \$1,930/year or less, it became the dominant regimen. In the PSA, when the threshold of willingness to pay was under one capita China GDP (\$7,485/QALY), TDF was the most cost-effective regimen in 85% of the simulations.

### CONCLUSIONS:

TDF treatment is cost-effective compared to LAM treatment in China. Price reduction and supporting health insurance policies are required to maximize the optimal treatment and make it affordable to CHB patients.

---

## Poster 97B EUnetHTA JA2 WP7 Achievements In Improving Additional Evidence Generation

### DESCRIPTION:

Work package 7 of last EUnetHTA's Joint Action focused on developing and testing a methodological basis for European cooperation

in the field of Additional Evidence Generation (AEG) (generation of further evidence in order to reduce uncertainties identified at the time of an initial health technology assessment). This poster describes the achievements of the three year work on harmonizing AEG recommendations and protocols in Europe.

### PRESENTING AUTHOR:

Irena Guzina, HAS, France

### AUTHORS:

Irena Guzina, François Meyer, EUnetHTA partners involved in JA2 WP7

### BACKGROUND AND OBJECTIVES:

Evidence gaps are often identified at the time of an initial Health Technology Assessment for new technologies. In order to reduce uncertainty, HTA bodies can make recommendations/requests for Additional Evidence Generation (AEG). Improving collaboration among HTA bodies in the field of AEG has been one of EUnetHTA's priorities since 2010. Work package 7 of EUnetHTA's last cooperative project, Joint Action 2, focused on developing and testing a methodological basis for European cooperation in this field. The work was led by HAS (Haute Autorité de Santé, French National Authority for Health), French governmental body with missions in Health Technology Assessment, and Quality of Care. JA2 WP7 objectives: Help HTA doers define more specific research recommendations, that may better serve decision maker and researcher needs, by addressing the following two questions (two EUnetHTA position papers ): i) how to formulate research recommendations ii) how to decide on the appropriate study design; Reduce multiple uncoordinated study requests and favor the collection of more robust data through a definition of a common core study protocol for AEG.

### METHODS:

- Literature review and survey of EUnetHTA partners

- Development of 3 deliverables by EUnetHTA partners (two authoring agencies per deliverable plus reviewers)
- Consultation of stakeholders and key people in the field of AEG (involved in the scoping phase and review of the documents)
- Collaboration with the European Medicines Agency (EMA) and European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)

**RESULTS:**

A survey on AEG practices, performed in 2013 among EUnetHTA partners, confirmed the need to work on structuring and harmonizing AEG recommendations/requests across Europe. The development of the three deliverables was finalized in 2015. The Position paper on research recommendations provided a structured approach for the identification of research gaps arising from HTA reports and for the formulation of research recommendations. The Position paper on study design then provided consideration of various issues around the role of HTA authors in specifying study design to best answer the thus defined research questions. Finally, key elements of a study protocol for AEG have been defined and integrated into the template of a Core protocol for AEG that was then tested in the first pilot of multi-agency AEG recommendation on renal denervation, based on EUnetHTA’s rapid assessment of this technology.

**CONCLUSIONS:**

JA2 WP7 continued EUnetHTA’s work on improving quality and adequacy of Additional Evidence Generation (AEG) by producing two methodological documents aiming to harmonize the formulation of research recommendations, and by performing the first multi-agency pilot of a common AEG recommendation.

.....

.....

## Poster 99B Organizational Readiness In Implementation Of EHR In Two South African Hospitals

**DESCRIPTION:**

Efficient health information management system has been identified by all three spheres of government in South Africa at national, provincial, and local levels. As the country is in the processes of implementation of a National Health Insurance system, it was found to be necessary to conduct a readiness assessment on the current and future of e-Health within organizations.

**PRESENTING AUTHOR:**

Debjani Mueller, CMeRC, South Africa

**AUTHORS:**

Ntombi Mutshekwan, Debjani Mueller

**BACKGROUND AND OBJECTIVES:**

Efficient health Information management system (HIMS) has been identified by all three spheres of government in South Africa at national provincial and local levels. One of the strategic goals of National Department of Health (NDoH) is to develop an efficient health information management system for improved decision making. The importance of e-Health to provide and to improve equitable access to affordable and quality health care has been recognized worldwide as a pathway towards universal health coverage. Many countries have recognized the relevance of HTA and the important role of e-Health to achieve universal health coverage. Usage of quality data generated by Electronic Health Record (EHR) for HTA report production leads to the assessment of comprehensive health benefits of a health technology thus empowering the decision and policy makers with information that is reliable, patient-focused, cost-effective and evidence-based. As South Africa is in the processes of implementation of National Health Insurance

system, it was found to be necessary to conduct a readiness assessment on the current and future of e-Health systems within organizations.

**METHODS:**

Data was collected using a structured questionnaire involving 511 participants in 2 hospitals in the province. The team targeted staff members on both day and night shifts in order to get a more inclusive and representative sample.

**RESULTS:**

The results of the study revealed the following: a) ICT - only 67% had general computer skills and approximately half of them were reported confident with MS office skills. Few of the staff members had skills in specialized programmes b) Software & delayed implementation of clinical module and its integration with other software (interoperability) c) Hardware & limited availability of desktop PC and network points. Furthermore the following issues were identified as possible obstacles for implementation of EHR: (a) Availability of EHR policies; (b) IT staff support (c) Knowledge of IT staff about current software system (d) Adequacy of communication by the hospital executive management (e) Adequacy of communication at provincial level.

**CONCLUSIONS:**

The respondents believed that implementation of EHR would assist in possible reduction of overall cost of health care and possible reduction of waiting time. However, it would require active support of the Provincial and Hospital management. It is necessary to address the above gaps in the system in order to develop a robust HIMS. Using EHR can result in availability of accurate information on a range of participants of a study, a study can be generalized and also involve increased sample size. The widespread implementation and adoption of EHR will provide the opportunity to improve HTA processes.

.....

.....

## Poster 100B Use Of Social Media In US And EU To Study Comparative Treatment Patterns In Multiple Sclerosis

**DESCRIPTION:**

We employed social-intelligence methodology to the study of treatment-switching patterns from/to oral therapies in multiple sclerosis (MS) in European and United States (US) populations. We then compared the social-media populations between the two regions.

**PRESENTING AUTHOR:**

Valery Risson, Novartis, Switzerland

**AUTHORS:**

Valéry Risson, Deepanshu Saini, Ian Bonzani, Alice Huisman, Melvin Olson

**BACKGROUND AND OBJECTIVES:**

Social media is increasingly used by patient seeking information about drugs, but the applicability of social-media analysis to specific questions in outcomes research is largely untested. We employed social-intelligence methodology to the study of treatment-switching patterns from/to oral therapies in multiple sclerosis (MS) in European and United States (US) populations. We then compared the social-media populations between the two regions.

**METHODS:**

A comprehensive listening and analysis process was developed which blends automated listening with filtering and analysis of data by life-sciences qualified analysts and physicians. The population was patients with MS from the US and EU countries. Data sources were Facebook, Twitter, blogs and online forums. The social-media sources were searched for mention of Tecfidera, Aubagio and Gilenya as examples of oral MS treatments.

## RESULTS:

A total of 13,368 extracted data points were relevant to the objectives and included in the analysis. Women, patients aged 30-49 and those diagnosed for >10 years were represented by more data points than other patients. The identified population was highly similar to that identified in MS US social media intelligence research, thus validating the methodology. Treatment switches were most frequent among patients on injectable therapies: 522 data points described patients switching from injectable (mainly BRACE) to oral therapies out of 1052 identified switches. Side effects were the main reason (32%) for switching to oral therapies. Switches away from oral therapies were mostly to non-BRACE injectable therapies in a search for greater efficacy.

## CONCLUSIONS:

This comparative study of switching pattern with MS treatments shows social- intelligence analysis to be a powerful method applicable to outcomes research. The identified EU populations were highly similar to the US populations and comparable to one another. Social intelligence was able to quantify switching patterns and to identify factors behind switching behaviour, which were mostly from injectable to oral therapies, driven by side effects from medication.

---

## Poster 105B Research And Application Of Policy Evaluation In Health Of China - Based On The Literature Review

### DESCRIPTION:

To understand the research progress of policy evaluation theory and methods, explore the research and application of the study in the field of health in China. In practice, evaluation methods have focused on the effects of policies and impact assessment, but policy development, process

evaluation, and application have been limited.

Although certain achievements have been made on health policy evaluation in China, many problems still exist, such as disunion of evaluation norm, and less guidance for practice, etc. The topics of standardized evaluation guidelines or specification are imperative.

### PRESENTING AUTHOR:

Dr. Zhao Rui, China National Health Development Research Center

### AUTHORS:

Rui Zhao, Yanzhun Chen, Yudao Li

### BACKGROUND AND OBJECTIVES:

To understand the research progress of policy evaluation theory and methods, explore the research and application of the study in the field of health in China.

### METHODS:

We retrieved literature and guidelines from China National Knowledge Infrastructure (CNKI) and PubMed databases using 'policy evaluation' as the key word, and searched policy documents in websites of the National Health and Family Planning Commission of China and related government websites from Beijing, Shanghai and Guangzhou.

### RESULTS:

Compared with Western countries, China's policy in the field of health research and evaluation is still in its infancy. Chinese scholars on policy evaluation have less experience, mostly relying on theoretical framework from other countries. There have not been official documents or technical guidelines set up on health policy evaluation. In practice, evaluation methods have focused on the effects of policies and impact assessment; but policy development, process evaluation, and application have been limited. There have been issues on lack of conceptual understanding, vaguely defined evaluation concepts, and improper use of statistical

methods and other issues.

### **CONCLUSIONS:**

Although certain achievements have been made on health policy evaluation in China, there are existing still many problems such as disunion of evaluation norm, and less guidance for practice etc. The topics of standardized evaluation guidelines or specification are imperative.

---

## **Poster 106B** Marginal Differences In Health-Related Quality Of Life Of People With Diabetes In China

### **DESCRIPTION:**

This paper is intended to analyze the health-related quality of life (HRQoL) in diabetes in China, estimate the marginal impact of diabetes (compared to general population) and the impact of diabetes-related comorbidities (for people with diabetes) on HRQoL.

### **PRESENTING AUTHOR:**

Chen Gao, Novo Nordisk (China) Pharmaceuticals Co., Ltd.

### **AUTHORS:**

Haijing Guan, Chen Gao, Gordon G. Liu

### **BACKGROUND AND OBJECTIVES:**

This paper is intended to analyze the health-related quality of life (HRQoL) in diabetes in China, estimate the marginal impact of diabetes (compared to general population), and the impact of diabetes-related comorbidities (for people with diabetes) on HRQoL.

### **METHODS:**

This paper employs the national Urban Resident Basic Medical Insurance (URBMI) Household Panel

Survey data from 2008 to 2011. We describe the health utility and VAS score of people with diabetes and people with diabetes-related comorbidities including hypertension, hyperlipidemia, cardiovascular disease, cerebrovascular disease, cataract. Furthermore, we conduct a set of regression models to estimate the marginal impacts of diabetes and five comorbidities respectively on health utility values and VAS scores, after controlling for individual characteristics and other confounders. Meanwhile, we conduct Probit models to estimate respective marginal impacts to five dimensions in EQ-5D.

### **RESULTS:**

1) The mean health utility value and VAS score for people with diabetes (N=2737) are 0.907 and 69.9, those of general sample (N=53594) are 0.959 and 79.8. Econometric analysis shows the marginal effects of diabetes on health utility and VAS scores were -0.031 and -5.996 (P

### **CONCLUSIONS:**

This paper is the first empirical study on the quality of life of people with diabetes in China to estimate the marginal differences in HRQoL of people with diabetes and its comorbidities. Results of this study are valuable for future cost-utility analysis of diabetes in China.

---

## **Poster 107B** Searching For Evidence For Systematic Reviews Of Volume-Outcome Relationships In Peripheral Vascular Surgery.

### **DESCRIPTION:**

When searching for a series of systematic reviews of vascular services, it was not possible to create an a priori search strategy with the aim of identifying all the relevant literature to answer the review questions. An iterative approach to

evidence identification utilising multi-disciplinary working proved to be the most useful and effective approach.

### **PRESENTING AUTHOR:**

Edward Goka, University of Sheffield, United Kingdom

### **AUTHORS:**

Woods Helen Buckley, Phillips Patrick, Poku Edith, Essat Munira, Goka Edward A, Michaels Jonathan, Palfreyman Simon, Paisley Suzy, Kaltenthaler Eva C, Shackley Phil

### **BACKGROUND AND OBJECTIVES:**

This presentation will highlight the importance of iterative searching methods, multi-disciplinary working and the use of collaborative web tools in a recent vascular services research project. It describes the methods used to identify evidence for a series of systematic reviews exploring the relationship between volume and outcome in peripheral vascular surgery. The reviews were an update of a previous review (Michaels et al, 2000). Searching was conducted as one process, with papers subsequently selected for each individual population e.g. carotid artery disease. There were three search iterations for the project. Search one aimed to identify papers for an overview of systematic reviews and was based on the main search strategy of the original review (Michaels et al, 2000); combining terms for vascular conditions and volume of surgery. The second search extended the initial search to identify primary studies and included additional synonyms for surgical procedures. After the results of both searches were examined the team returned to the original review to see if all the included studies had been retrieved. This was to give an indication of where further evidence might lie, rather than to create a search to identify any 'missing' papers.

### **METHODS:**

The consultation of these papers indicated that a new search, focused on specific surgical

procedures and patient outcomes could uncover new evidence. Therefore, keywords from these papers formed the basis for a new search. To improve search sensitivity the Information Specialist invited colleagues to contribute keywords and MeSH. As two experienced clinicians were part of the project team this was a crucial step, facilitated quickly by the use of a shared web document. This search identified 7 of the 29 included studies for the current reviews. Reference, citation and conference searches were undertaken which (to date) also retrieved relevant studies.

### **RESULTS:**

An iterative and multifarious approach to identifying evidence is the most beneficial when the review concepts are not described in a standardised manner. This allows many access points to relevant literature. Multi-disciplinary working is central to supporting this type of non-linear search approach. Using new technology to enable contributions from clinical colleagues facilitates and expedites the process of developing a new search.

### **CONCLUSIONS:**

Multi-disciplinary working within a systematic review team facilitates a more efficient use of time and utilizes technical expertise and subject knowledge at an optimum level. The use of new technology can augment this process. Using a staged approach to identifying evidence alongside commonly used techniques such as citation tracking is a pragmatic approach to this type of review. This approach could be tested alongside data mining methods in order to review effectiveness of retrieving relevant studies and the associated staff time taken to complete these processes.

### **REFERENCES:**

Michaels J, Brazier J, Palfreyman S, Shackley P, Slack R. Cost and outcome implications of the organisation of vascular services. *Health Technol Assess* 2000; 4(11).

## Poster 109B The Methodological Guideline For Therapeutic Medical Devices Of The European Network For Health Technology Assessment (EUnetHTA)

### DESCRIPTION:

We present recommendations for Health Technology Assessment (HTA) of therapeutic medical devices developed within EUnetHTA's Joint Action 2. This Guideline passed a consultation process through HTA Partner organisations, stakeholders and the public

### PRESENTING AUTHOR:

Petra Schnell-Inderst, Austria

### AUTHORS:

Petra Schnell-Inderst, Theresa Hunger, Stefan Sauerland, Matthias Perleth, Naomi Fujita-Rohwerder, Yvonne Zens, Inaki Gutierrez Ibarluzea, Jörg Lauterberg, Uwe Siebert

### BACKGROUND AND OBJECTIVES:

In Joint Action 2 (2012-15) of the European network for Health Technology Assessment (EUnetHTA) six new guidelines ([www.eunetha.eu/eunetha-guidelines](http://www.eunetha.eu/eunetha-guidelines)) were developed. Among them is the methodology guideline on Relative Effectiveness Assessment (REA) of therapeutic medical devices (MD). Health technology assessors are the main target group of these guidelines. The guidelines aim to support assessors to cope with methodological challenges encountered while performing REA of pharmaceutical and other health technologies. Secondary target groups are healthcare decision makers, industry, researchers and other stakeholders. Objectives: The aim of this guideline was to identify those areas where specific HTA methods may be required and to propose best-practice solutions for these problems.

### METHODS:

Guideline development was performed according to a manual that prescribes drafting a concept of the guideline to be reviewed by an extended group of EUnetHTA partners. On the basis of a literature review, the guideline draft group identified issues and methods that are specific or particularly relevant for MD assessment, drawing on the results from a European Union Framework Programme 7 project on medical devices and developed recommendations for performing a systematic review on clinical effectiveness of therapeutic medical devices. Guideline drafts passed through three consultations by EUnetHTA partners, stakeholders and the public.

### RESULTS:

HTA of medical device interventions should generally be done with currently established methods for finding, selecting, analysing, synthesising and interpreting evidence on clinical effectiveness. A need for specific methods mainly derives from the incremental development of MDs and their user and context dependency, and some implications of the physical mode of action. Compared to drugs therapeutic MD interventions are often more complex: The intervention usually consists of several components and procedures and the effects of the intervention are more context and user dependent. In planning and conducting a systematic review this means that in framing the research question more effort is necessary 1) to systematically and clearly define the intervention and its potential variants subgroups and 2) to identify and characterize effect-modifying factors especially proficiency and learning of MD users and providers. If these aspects are transparently characterized, this will help to take them appropriately into account in information retrieval, data extraction and synthesis as well as in assessing the applicability of the review's results. Whether systematic reviews and HTA of clinical effectiveness can contribute to conclusive results for decision making strongly depends on the quality of primary research. Also primary studies have to address the specific challenges that result from the physical

mode of MD action and the often invasive nature of the MD intervention. These challenges include the inability to blind the trial, the strong treatment preferences of patients and care providers, and the effect-modifying influence of MD user proficiency. Several modifications of the common two-armed double blinded RCT design exist, that can be used for therapeutic MD.

#### REFERENCES:

<http://www.eunethta.eu/eunethta-guidelines>

---

## Poster 110B Toward More Pragmatism In HTA: How To Evaluate A Widely Disseminated Health Technology? Assessment Shortening Advantages And Limits. Illustration With PCR For Meningitis And Encephalitis Diagnosis.

#### DESCRIPTION:

We outline two assessments to illustrate a new process to shorten assessment of widely disseminated health technology. We detail how we maintain the relevance and the quality of shortened assessments. We also summarize advantages and limits of this new process.

#### PRESENTING AUTHOR:

Dr. Jean-Charles Lafarge, French National Authority for Health - HAS, France

#### AUTHORS:

Jean-Charles Lafarge, Denis-Jean David, Michèle Morin-Surroca

#### BACKGROUND AND OBJECTIVES:

In France, PCR technology is used in many hospitals for viral meningitis (enteroviruses-EV)

or encephalitis (Herpes simplex virus-HSV, or Varicella zona virus-VZV) diagnosis but those tests are not yet reimbursed by French National Health Insurance. Both PCR are included in most recent viral meningitis and encephalitis guidelines. After a feasibility analysis, we noted the consistency of guidelines. They enlighten the positions of those diagnostic tests in the overall diagnostic strategy. Then, we chose to shorten those assessments outlined in two reports submitted to HAS board for approval.

#### METHODS:

The first approach for EV-PCR in meningitis diagnosis involved critical analysis of guidelines, clinical usefulness and diagnostic performance studies and the views of the stakeholders (practitioners) with a series of interviews. The assessment report was submitted to two HAS boards for approval. The second approach about encephalitis diagnosis and HSV/VZV-PCR was shorter. It was focused on critical analysis of practice guidelines and argued written replies of the stakeholders (practitioners) to extensive questionnaires. The assessment report was only submitted to the main HAS board for approval.

#### RESULTS:

Main HAS board approved both reports, and was in favor of reimbursement by French National Health Insurance of EV-PCR in meningitis, and HSV/VZV-PCR in encephalitis. Neither the practitioners nor French National Health Insurance had objection to HAS's reports conclusions. The reports detailed medical indications of both tests. Both assessments enlightened methodological limits of some guidelines and bias of clinical studies. EV-PCR assessment cannot be shortened due to inconsistency of gold standard mentioned in studies and lack of evidence of clinical usefulness in guidelines. The shorter approach, used for HSV/VZV-PCR assessment in encephalitis, reduced total assessment duration. The short approaches were allowed by the large number of guidelines and the uniformity of the international guideline and stakeholder's views. Short assessment main limits

were: postponed response time which limited the shortening of total assessment duration time, low-quality evidence for diagnostic in guidelines. Most of guidelines are well detailed for treatment of the disease and lack information about disease's diagnosis. Most of the guidelines are based on low-quality evidence (i.e. non observational studies and/or expert opinion). Precise definition of eligible population and clinical usefulness information are often missing in good practice guidelines. Those limits were partially counterbalanced by stakeholder answers/interviews.

### CONCLUSIONS:

Short assessment based on critical analysis of guideline linked with practitioner views for widely used technologies may shorten time line project without reduction assessment quality. Conclusions approvals by different bodies involved in the field (HAS board, Health insurance, practitioners) demonstrate the possibility to conduct short assessment. Practitioner's interviews may be a tool to offset lack of precision of guidelines. Those interviews may be avoided in future assessment if the guidelines are based on better quality evidence and provide more information about diagnosis.

---

## Poster 111B Critical Appraisal Tools: An International Collaboration

### DESCRIPTION:

DIMDI, the German Institute for Medical Documentation and Information, and OSTEBA, the Basque Office for Health Technology Assessment, share a common purpose: supporting information sharing and collaboration in order to promote best practices. The two organizations signed a Memorandum of Understanding to identify the roles and responsibilities of each participant for improved use of Critical Appraisal Tools.

### PRESENTING AUTHOR:

Eva Reviriego, OSTEBA-HTA, Basque Region, Spain

### AUTHORS:

Reviriego Eva, Gutiérrez-Ibarluzea Iñaki, Lopez de Argumedo Marta, Asua José, Dauben Hans-Peter, Frei Svetlana

### BACKGROUND AND OBJECTIVES:

Web for Critical Appraisal is free and its aim is to help out during the assessment of the quality of studies and synthesis of evidence. It is a dynamic web application so it is continually improved in basis of users' proposals and of recent publications' input.

The main objective of this international collaboration is to update and standardize methodology for critical appraisal of scientific evidence, to reduce avoidable variability in the approach and execution of HTA projects. And secondly, the aim is to make explicit and public these methods to improve the transparency and quality of work in HTA.

### METHODS:

To establish methodological development of Critical Appraisal Tools, the specific objectives can be summarized as:

- Continue with national and international collaboration.
- Update Critical Appraisal Tools.

Review of other checklists (STRAD, PRISMA, AMSTAR, CONSORT, STROBE, CHEERS, etc.).

Include other tools like AGREE, or other checklists for cross-sectional or qualitative studies.

Improve some aspects like expert appraisals, search options, user profile, classification of appraisals, and calculators.

- Create the short version of the Application and create user's manual.
- Disseminate the platform.

- Conference presentations, Course: INAHTA webinar, Journal Article, Newsletters.
- Feedback.

Survey to the 6.200 users (data from January 2016).

### RESULTS:

The Critical Appraisal Tools have been recently translated from Spanish into English and German. Laval University on Canada and CONITEC in Brazil are interesting in taking part in this methodological plan making translations into French and Portuguese.

### CONCLUSIONS:

The international collaboration between institutions can take a big boost if the development of these tools for critical appraisal of the scientific evidence continues

## Poster 112B Health-Related Quality Of Life Questionnaires In Lung Cancer Patients Attending A Tertiary Care Hospital

### DESCRIPTION:

Health-related quality of life (HRQoL) is a multi-dimensional concept that includes domains related to physical, mental, emotional, and social functioning. It goes beyond direct measures of population health, life expectancy, and causes of death, and focuses on the impact health status has on quality of life. This abstract gives you an insight into health-related quality of life of lung cancer patients attending a tertiary care hospital.

### PRESENTING AUTHOR:

Dr. Sabin Katpattil, AJ Institute of Dental Sciences, India

### AUTHORS:

Sabin Siddique

### BACKGROUND AND OBJECTIVES:

Lung cancer is usually diagnosed at an advanced stage and survival has not improved in spite of several therapeutic advancements. Since most patients depend on palliative care, it is imperative to evaluate and maintain a satisfactory quality of life in them. Several questionnaires, mostly in western languages, have been used for this purpose.

### METHODS:

A 26-item WHO-Quality of Life questionnaire in local language was used to assess the quality of life in lung cancer patients attending a Tertiary care hospital. This questionnaire comprises four domains-Physical, Psychological, Social and Environmental.

### RESULTS:

A total of 76 patients were evaluated. 66 (86.8%) were males, had a mean age of 55.36 years; presented with cough (82.9%), dyspnoea (72.4%), chest pain (65.8%), and haemoptysis (43.4%). Eight patients (10.5%) had superior venacaval obstruction. The mean duration of symptoms was 5.9 months. 89.5% had Non-Small Cell Cancer (NSCLC). The mean pack-years was 23.7. Most patients had Karnofsky Performance Scale (KPS) of 70 (52.6%). There was no significant correlation of any quality of life domain with age, sex, duration of symptoms, extent of smoking, cough, dyspnoea, chest pain, haemoptysis or haemoglobin. The environmental domain correlated significantly with the serum albumin

### CONCLUSIONS:

Environmental factors influence nutritional status such as albumin levels. The Karnofsky Performance Scale is an important marker of assessing quality of life. It is a simple numerical tool that reliably predicts deteriorating quality of life, particularly the physical and psychological aspects.

## Poster 113B Assistive Technologies For Ageing Populations In Low- And Middle-Income Countries: A Systematic Review

### DESCRIPTION:

A comprehensive review of the current availability of assistive technologies (AT) and existing legislation and initiatives related to the provision and promotion of AT for older adults in low- and middle-income countries. The overall intention is to better understand barriers, facilitators, and implications relating to AT for older adults in low- and middle income countries.

### PRESENTING AUTHOR:

Keshini Marasinghe, University of Waterloo, Canada

### AUTHORS:

Keshini M. Marasinghe, Jostacio M. Lapitan, Alex Ross

### BACKGROUND AND OBJECTIVES:

Despite the benefits derived from the use of assistive technologies (AT), some parts of the world have minimal or no access to AT. In many low and middle-income countries (LMIC), only 5-15% of people who require AT have access to them. Rapid demographic changes will exacerbate this situation as populations over 60 years of age, as well as functional limitations among older populations in LMIC are expected to be higher than in high-income countries in the coming years. Given both these trends, AT are likely to be in high demand and provide many benefits to respond to challenges related to healthy and productive ageing. This review investigated the currently available AT, existing enabling legislation for provision of AT and initiatives that promote AT for older adults in Brazil, Cambodia, Egypt, India, Turkey and Zimbabwe. The objective is to explore in the published literature if currently available AT and existing

legislation related to AT-provision are sufficient to support 'ageing in place' rather than ageing in institutionalised care homes; facilitate better health for older adults, especially in terms of functioning and independence; encourage inclusion and full participation in community activities; and enhance older adults' overall well-being and quality of life.

### METHODS:

Multiple databases were searched for English literature. Three groups of keywords were combined: those relating to AT, ageing population and LMIC selected for this study, namely Brazil, Cambodia, Egypt, India, Turkey and Zimbabwe. These countries are expected to see the most rapid growth in the 65 and above population in the coming years.

### RESULTS:

Results indicate that all countries had AT designed for older adults with existing impairment and disability, but had limited AT that are designed to prevent impairment and disability among older adults who do not currently have any disabilities. All countries have ratified the UN Convention on the Rights of Persons with Disabilities.

### CONCLUSIONS:

The findings conclude that AT for ageing populations have received some attention in LMIC as attested by the limited literature results. Analysis of review findings indicate the need for a comprehensive, integrated health and social system approach to increase the current availability of AT for ageing populations in LMIC. These would entail, yet not be limited to, work on: (1) promoting initiatives for low-cost AT; (2) awareness raising and capacity building on AT; (3) bridging the gap between AT policy and practice; and (4) fostering targeted research on AT.

### REFERENCES:

1) United Nations Department of Economic and Social Affairs. World population prospects:

The 2012 revision. Secondary World population prospects: The 2012 revision 2012. <http://esa.un.org/unpd/wpp/Demographic-Profiles/index.shtm>

2) United Nations. Disability-specific instruments Secondary Disability-specific instruments 2004. <http://www.un.org/esa/socdev/enable/rights/wgrefa3.htm>

3) Wimo A, Prince M. World Alzheimer report 2010, 2010.

4) Hestekin H, O'Driscoll T, Williams JS, et al. Measuring prevalence and risk factors for fall-related injury in older adults in low- and middle-income countries: Results from the who study on global ageing and adult health (sage). Geneva, Switzerland University of Wisconsin/World Health Organization 2013:1-24.

5) Centers for Disease Control and Prevention. Falls in nursing homes. Secondary Falls in nursing homes 2015. <http://www.cdc.gov/HomeandRecreationalSafety/Falls/nursing.html>

6) World Health Organization. Opening the gate for assistive health technology: Shifting the paradigm. Secondary Opening the gate for assistive health technology: Shifting the paradigm 2014. [http://www.aaate.net/sites/default/files/gate\\_concept\\_note\\_for\\_circulation.pdf](http://www.aaate.net/sites/default/files/gate_concept_note_for_circulation.pdf)

7) Connell J, Grealy C, Olver K, et al. Comprehensive scoping study on the use of assistive technology by frail older people living in the community, Canberra, 2008:92.

8) Roelands M, Van Oost P, Depoorter A, et al. A social-cognitive model to predict the use of assistive technologies for mobility and self-care in elderly people. *Gerontologist* 2002;42:39-50.

9) Mann WC, Ottenbacher KJ, Fraas L, et al. Effectiveness of assistive technology and environmental interventions in maintaining independence and reducing home care costs for the frail elderly & a randomized controlled trial. *Arch Fam Med* 1999;8:210-17.

10) Heywood F, Turner L. Better outcomes, lower costs & implications for health and social care budgets of investment in housing adaptations, improvements and equipment: a review of the evidence. In: Department of Work and Pensions, ed. Office for Disability Issues, 2007.

11) Scott VJ, Dukeshire S, Gallagher EM, et al. A best practices guide for the prevention of falls among seniors living in the community. Ottawa: Ontario Minister of Public Works and Government Services Canada, 2001.

12) McConatha D, McConatha J, Dermigny R. The use of interactive computer services to enhance the quality of life for long-term care residents. *Gerontologist* 1994;34: 553-6.

13) Evans N, Orpwood R, Adlam T, et al. Evaluation of an enabling smart flat for people with dementia. *J Demen Care* 2007;15:33-6.

14) Chase CA, Mann K, Wasek S, et al. Systematic review of the effect of home modification and fall prevention programs on falls and the performance of community-dwelling older adults. *Am J Occup Ther* 2012;66:284-91.

15) World Health Organization. Assistive devices/technologies: what world health organization is doing. Secondary Assistive devices/technologies: what world health organization is doing 2014. <http://www.who.int/disabilities/technology/activities/en/>

16) World Health Organization. Ageing and life course. Secondary Ageing and life course 2012. <http://www.who.int/ageing/about/facts/en/>

17) de Oliveira Assis L, Tirado MGA, de Melo Pertence AE, et al. Evaluation of cognitive technologies in geriatric rehabilitation: a case study pilot project. Wiley Inter Science, 2009.

18) da Cruz DMC, Emmel MLG. Associations among occupational roles, independence, assistive technology, and purchasing power of individuals with physical disabilities. *Rev Latino-Am Enfermagem* 2013;21:484-91.

- 19) Mann WC, de Mello MAF. Assistive technology use by the elderly in Brazil and the United States. *Top Geriatr Rehabil* 2010;26:62-9.
- 20) Production of low cost assistive technology. Proceedings of the Fifth International Conference on Management of Emergent Digital EcoSystems. Luxembourg, Luxembourg:
- 21) Jones HE, Reed RA, House SJ. Water supply and sanitation access and use by physically disabled people. Leicestershire, United Kingdom: Loughborough University, 2003.
- 22) Salah O, Ramadan AA, Sessa S, et al. Systematic approach for design a low-cost mobility assistive device for elderly people. *Int J Med Health, Pharm Biomed Eng* 2011;5:36-41.
- 23) Jefferds AN, Beyene NM, Upadhyay N, et al. Current state of mobility technology provision in less-resourced countries. *Phys Med Rehabil Clin N Am* 2010;21:221-42.
- 24) Kumar P, Dixit U, Goyal VC. Assistive and enabling technology needs of elderly people in India: issues and initial results. 2009.
- 25) Biswas P, Langdon PM. A survey on technology exposure and range of abilities of elderly and disabled users in India. *LNCS*, 2013:23-31.
- 26) Manogna S, Vaishnavi S, Geethanjali B. Head movement based assist system for physically challenged. 2010 4th International Conference on Bioinformatics and Biomedical Engineering (iCBBE) Chengdu IEEE Advancing Technology for Humanity, 2009:1-4.
- 27) Shore SL. Use of an economical wheelchair in India and Peru: impact on health and function. *Med Sci Monit* 2008;14:PH71-79.
- 28) Shore S, Juillerat S. The impact of a low cost wheelchair on the quality of life of the disabled in the developing world. *Med Sci Monit* 2012;18:CR533 - 42.
- 29) Zipfel E, Cooper RA, Pearlman J, et al. New design and development of a manual wheelchair for India. *Disabil Rehabil* 2007;29:949-62.
- 30) Bengisu M. Assistive technologies for visually impaired individuals in Turkey. *Off J RESNA* 2010;22:163-71.
- 31) ?im?ek TT, Yümin ET, Sertel M, et al. Assistive device usage in elderly people and evaluation of mobility level. *Top Geriatr Rehabil* 2012;28:190-4.
- 32) Asuman O, Ucsular FD. Effectiveness of a wheelchair skills training programme for community-living users of manual wheelchairs in turkey: a randomized controlled trial. *Clin Rehabil* 2011;25:416 -24.
- 33) Eide AH, Nhiwathiwa S, Muderredzi J, et al. Living conditions among people with activity limitations in Zimbabwe. A representative regional survey. Oslo, Norway, 2003:136.
- 34) Department of Human Rights Recidency. First national report of the federative republic of Brazil on fulfillment of the provisions of the convention on the rights of disabled persons. Brazil, 2008-2010.
- 35) da Silva L, Inacio L. Decree 5296 of 2 december 2004. Secondary Decree 5296 of 2 december 2004 2004. [http://www.planalto.gov.br/ccivil\\_03/\\_Ato2004-2006/2004/Decreto/D5296.htm](http://www.planalto.gov.br/ccivil_03/_Ato2004-2006/2004/Decreto/D5296.htm)
- 36) Institute for Applied Research. The rights and the social reality of people with disabilities in Brazil, Germany, France, Romania, South Korea, and Tanzania with a supplementary country survey performed in the Netherlands. Secondary the rights and the social reality of people with disabilities in Brazil, Germany, France, Romania, South Korea, and Tanzania with a supplementary country survey performed in the Netherlands 2011. [http://www.diakoniewuerttemberg.de/fileadmin/Medien/Pdf/Ver\\_IntDiakoniekongress-UebersichtsstudieEngl.pdf](http://www.diakoniewuerttemberg.de/fileadmin/Medien/Pdf/Ver_IntDiakoniekongress-UebersichtsstudieEngl.pdf)
- 37) Kingdom of Cambodia. The 5th Asian & Japan high level officials meeting on caring societies Secondary The 5th Asian & Japan high level officials

meeting on caring societies 2007. [http://www.mhlw.go.jp/bunya/kokusaigyomu/asean/asean/kokusai/siryoudl/h19\\_cambodia1.pdf](http://www.mhlw.go.jp/bunya/kokusaigyomu/asean/asean/kokusai/siryoudl/h19_cambodia1.pdf)

38) United Nations. Convention on the rights of persons with disabilities. Secondary Convention on the rights of persons with disabilities 2006. <http://www.un.org/esa/socdev/enable/rights/convtexte.htm>

39) Thomas P. Poverty reduction and development in Cambodia: enabling disabled people to play a role. Secondary poverty reduction and development in Cambodia: enabling disabled people to play a role 2005. [http://r4d.dfid.gov.uk/PDF/Outputs/Disability/PolicyProject\\_cambodia.pdf](http://r4d.dfid.gov.uk/PDF/Outputs/Disability/PolicyProject_cambodia.pdf)

40) Ministry of Social Justice and Empowerment Government of India. National policy for persons with disabilities. In: Department of Social Justice and Empowerment and Department of Disability Affairs, ed. New Delhi: India Government of India, 2006.

41) Ministry of Law Justice and Company Affairs. The persons with disabilities (equal opportunities, protection of rights and full participation) act, 1995. Secondary The persons with disabilities (equal opportunities, protection of rights and full participation) act, 1995 1996. <http://socialjustice.nic.in/pwdact1995.php>

42) Government of India Ministry of Social Justice and Empowerment. Scheme of assistance to disabled persons for purchase, fitting of aids/appliances (adip scheme). In: Department of Social Justice and Empowerment and Department of Disability Affairs, ed. New Delhi, India: Government of India, 2005.

43) Giri M, Sabharwal MM, Gangadharan KR, et al. National policy for senior citizens. 2011.

44) The Republic of Turkey. Agenda item: value added tax. <http://socialjustice.nic.in/pdf/dnpsc.pdf>. Secondary Agenda item: value added tax 2006. [http://www.gib.gov.tr/fileadmin/mevzuat/uluslararası\\_mevzuat/cerceve\\_anlasmalari/Ayrintili\\_](http://www.gib.gov.tr/fileadmin/mevzuat/uluslararası_mevzuat/cerceve_anlasmalari/Ayrintili_)

[Tarama/VAT.pdf](#)

45) European Blind Union. Six dots foundation for the blinds project. Secondary Six dots foundation for the blinds project 2008. [http://6nokta.org.tr/eski/en\\_index.html](http://6nokta.org.tr/eski/en_index.html)

46) Disabled and Elderly Services. Social assistance and solidarity law. Secondary Social assistance and solidarity law. <http://www.eyh.gov.tr/html/8262/2.41>

47) The Permanent Mission of the Republic of Zimbabwe. Permanent mission to the United Nations and other international organizations at Geneva. Geneva, 2011.

48) Hamza S, Manar M, Shereen M, et al. Assistive technologies for ageing populations. In: Lapitan JM, Marasinghe KM, eds. Egypt: Ain Shams University, 2014.

49) The Canadian Trade Commissioner Service. Export, innovate, invest the Canadian trade commissioner service. Secondary Export, innovate, invest the Canadian trade commissioner service 2013. <http://www.tradecommissioner.gc.ca/eng/document.jsp?did=146364&cid=723&oid=136#2.2>.

50) Japan International Cooperation Agency. Country profile on disability kingdom of Cambodia. Secondary country profile on disability Kingdom of Cambodia 2002. [http://siteresources.worldbank.org/DISABILITY/Resources/Regions/East-Asia-Pacific/JICA\\_Cambodia.pdf](http://siteresources.worldbank.org/DISABILITY/Resources/Regions/East-Asia-Pacific/JICA_Cambodia.pdf)

51) ICRC Resource Centre. Cambodia: ICRC action continues after 30 years of presence. Secondary Cambodia: ICRC action continues after 30 years of presence 2009. <http://www.icrc.org/eng/resources/documents/update/update-cambodia-111209.htm>

52) World Health Organization. The UN standard rules on the equalization of opportunities for persons with disabilities: ngo responses to the implementation of the United Nations standard rules on medical care, rehabilitation, support services and personnel training, 2002.

53) Rao SGN. Artificial limbs manufacturing corporation of India ISO 9001-2008. Geneva, Switzerland: ALIMCO, 2014.

54) United Nations (UN). Production and distribution of assistive devices for people with disabilities. Madras, India: United Nations, 1995.

55) Science for Equity Empowerment & Development Division (SEED). Call for R & D and technology development proposals. Secondary call for R & D and technology development proposals 2010. [http://www.dst.gov.in/whats\\_new/whats\\_new10/tie\\_proposal.pdf](http://www.dst.gov.in/whats_new/whats_new10/tie_proposal.pdf)

56) World Health Organization. The UN standard rules on the equalization of opportunities for persons with disabilities: government responses to the implementation of the United Nations standard rules on medical care, rehabilitation, support services and personnel training. WHO/DAR/011-01-8. Geneva, Switzerland: United Nations, 2001.

57) World Health Organization. Survey of needs for assistive and medical devices for older people in six countries of the WHO western pacific region: China, Japan, Malaysia, the Philippines, the Republic of Korea and Vietnam. Geneva, 2014.

58) The World Bank. World report on disability. Geneva, Switzerland: World Health Organization, 2011.

59) da Silva L, Inacio L. Presidency of the republic, civil cabinet, subchefia for legal affairs. Secondary Presidency of the republic, civil cabinet, subchefia for legal affairs 2004. [http://www.planalto.gov.br/ccivil\\_03/\\_Ato2004-2006/2004/Decreto/D5296.htm](http://www.planalto.gov.br/ccivil_03/_Ato2004-2006/2004/Decreto/D5296.htm)

60) Hui-Ching Y. Elderly people's use of and attitudes towards assistive devices.

61) Handicap International Middle East Regional Office. Taking a step forward, views from stakeholders on disability policies and services in Egypt, Jordan and Lebanon. Jordan: Handicap International, 2006.

62) Stevens JA, Thomas K, Teh L, et al. Unintentional fall injuries associated with walkers and canes in older adults treated in U.S. emergency departments. J Am Geriatr Soc 2009;57:1464-9

---

## Poster 115B Scientific Literature Monitoring Of Brazilian Emergency Services

### DESCRIPTION:

A scientific literature monitoring of Brazilian emergency services was conducted to identify public health situation, analysis of outcomes in health, trends, and impact of public policies.

### PRESENTING AUTHOR:

Tatiana Yonekura, Hospital do Coração, Brazil

### AUTHORS:

Tatiana Yonekura, Jeane Roza Quintans, Mayla Youko Kato, Cesar Roberto Braga Macedo, Armando De Negri Filho

### BACKGROUND AND OBJECTIVES:

Health care in emergency services is a relevant issue, due to the high demand for assistance in Brazil. Scientific literature monitoring is an instrument that facilitates information access, which allows the identification of the public health situation, analysis of outcomes in health, trends, impact of public policies and encouragement of the production of specific studies. The aim was to develop a scientific literature monitoring strategy of Brazilian emergency services.

### METHODS:

A scientific literature monitoring of Brazilian emergency services was conducted. A search strategy with controlled vocabulary thesaurus was constructed to capture the Brazilian scientific studies of the health care in emergency services in the following databases: LILACS, PubMed, SciELO,

BDENF, CINAHL, Fiebulletin and Google Scholar. Inclusion criteria were: studies with focus on emergency services, conducted in Brazil, written in Portuguese, English or Spanish, at any time and methodology. Data were stored in a database with the following variables of each study: year, magazine, area of magazine, title, author, State, County, Link of study, summary, source, population study and category. Two reviewers performed the search, data description and critical analysis.

### RESULTS:

The search resulted in the identification of 2261 citations, from which 772 studies clearly addressed the topic and were included after critical analysis. The scientific production increased in last decades (two studies were published during the decade of the 70's and 332 during the last decade - 2000-2009). The main topics discussed were: patient socio-demographic characteristics and identification of main reasons to search medical assistance (accident, violence, trauma, pain, asthma and stress). A most studies had conducted in metropolitan areas services and was produced by the nursing field.

### CONCLUSIONS:

Scientific literature monitoring of Brazilian emergency services was an important systematic dissemination of information and research recommendation. The instrument is able to support new studies and also to benefit the management of the Brazilian emergency services.

---

## Poster 116B Situation Analysis Of Implementation Of HTA In Kazakhstan

### DESCRIPTION:

The use of HTA tools is gaining in popularity in Kazakhstan. Kazakhstan already has informal guidelines in place and is now considered a "mature" market in terms of HTA adoption. For

Kazakhstan, the need for real-world evidence in itself brings another set of challenges. Despite the obvious challenges, some would argue that the time for HTA has arrived in Kazakhstan.

### PRESENTING AUTHOR:

Dr. Alexander Kostyuk, Kazakh Agency for Health Technology Assessment, Kazakhstan

### AUTHORS:

Alexander Kostyuk, Amangaly Akanov, Talgat Nurgozhin

### BACKGROUND AND OBJECTIVES:

Increasing life expectancy in Kazakhstan is giving rise to the greater burden associated with ageing populations, while governments struggle to balance growing costs with a need to expand healthcare provision to all. At the heart of any cost-containment strategy is a set of tools, ranging from complex risk-sharing schemes and health technology assessment (HTA) through to more simplistic mechanisms, such as prescribing controls and mandatory price cuts. Analysis of cost-management trends in Kazakhstan, relative with international experience, suggests a leaning towards less complex approaches. At the same time, there is growing appreciation that cost containment can only be effective when implemented in a systematic manner. Hence, the use of HTA tools is gaining in popularity in Kazakhstan. Kazakhstan already have informal guidelines in place and are now considered «mature» markets in terms of HTA adoption. The are provided situation analysis of implementation of HTA in Kazakhstan. We used a holistic approach, because the success of HTA, will be contingent on a number of factors, including technical expertise, availability of local data, stakeholder education and last, but not least, transparency of decision making.

### METHODS:

Lack of technical expertise among the regional and national health authorities is a key challenge for moving the agenda forward. The effective

working of an HTA process relies heavily on local data, be they clinical data in the local population, or healthcare resource use and cost data which will be used to evaluate the cost effectiveness of different treatment options relative to the current standard of care. Hence, the growing demand for real-world evidence (RWE) to support HTA submissions. For Kazakhstan, the need for RWE in itself brings another set of challenges.

**RESULTS:**

Local databases are scarce; even when they exist they tend not to be readily available. They are invariably limited in scope, restricted to a particular locality or condition, or provide only a sub set of relevant information. This reality reflects the relatively early stage of HTA programs in Kazakhstan; however, it will have to change in the future, with greater investment in databases and generation of RWE evidence fast becoming a priority. Any HTA process that is implemented will need to be transparent in its decision making and influence.

**CONCLUSIONS:**

When the sweeping price cuts announced on a regular basis by payer are added into the mix, the industry could be forgiven for weighing up the benefits and risks of complying with the process. Despite the obvious challenges, some would argue that the time for HTA has arrived in Kazakhstan. Implemented correctly, it can play a role in the future of the region, not only as a key component of cost containment but also as a pivotal enabler for the efficient use of resources, as governments look to provide broader access to affordable healthcare for all.

.....

## Poster 118B Pharmaceutical Review Of Mongolia

**DESCRIPTION:**

The government involvement in the pharmaceutical sector was decreased sharply after Mongol Em Impex Concern was privatized in 2007, which was formerly a state-owned company. Since then, the sector has had positive and negative impacts. The free market pharmaceutical system has increased the abundance of medication countrywide, it is still difficult for people to choose high quality drugs. The differing prices and a weakly controlled non-prescription drugs market can lead to abuse of pharmaceuticals, self-medication and negative impacts of treatment of patients.

**PRESENTING AUTHOR:**

Maitsetseg Badarch, Public Health Institution, Mongolia

**AUTHORS:**

Maitsetseg Badarch, Undarmaa Purev Mainbayar Badarch

**BACKGROUND AND OBJECTIVES:**

Mongolia is a country with a huge territory and small population. Currently, 66.4% of the total three million people live in urban areas. In Ulaanbaatar the city there are many crowded pharmacies located just within a distance of 400-500 meters of each other. According to the report of the Ministry of Health and Sport, a total of 1496 pharmacies, 32 drug manufacturers, 160 drug distribution entities, 46 biology active drug distributes, and 61 medical instrument distributor companies are operating in the country. It is estimated that 1611 pharmacists and 1840 technicians are working in the sector. The government involvement in the pharmaceutical sector was decreased sharply after Mongol Em Impex Concern was privatized in 2007, which was formerly a state-owned company. Since then, the sector has had positive and negative impacts.

## METHODS:

Meta analyzes done including statistical of Health sector-2014, literature review and legal aspects of pharmaceutical sector.

## RESULTS:

Pharmaceuticals with potentially dangerous effects are available only by prescription. Recently, the Professional Inspection Agency conducted an inspection for 62 pharmacies and drug manufacturers. Of these 62, 20% was evaluated as high risk and the findings show that 71% of pharmacies have been providing prescription drugs without prescription or by invalid prescription. It also found that 42.3% of the total antibiotics sold have been without prescription. To analyze prescription, 40.2% was standard prescription and 59.8% was non-standard prescription by doctors. Moreover, it is evidenced that a 13% of the total medicine has not met related standards. The main reason for this shortcoming was related to customer behavior, whereby they go directly to the pharmacy rather than seeing doctors. Also, doctors and pharmacists do not thoroughly explain the side effects to the patients and often without prescription. Approximately 6-7 different kinds of medicines are prescribed per patient in patient service. A limited number of drug inspection professionals and weak capacity of drug laboratories also affects the situation negatively. Pharmaceutical prices are not strictly controlled in Mongolia. It depends on quality, manufacturers' pricing and importing companies. Prices can differ between neighboring pharmacies subject to the owner's decision on the profitability and cost-recovery. Factory-gate prices of pharmaceuticals in Mongolia are lower than other Asian counties on average. Prices of imported medicines are relatively high.

## CONCLUSIONS:

The free market pharmaceutical system has increased the abundance of medication countrywide, it is still difficult for people to choose high quality drugs. The differing prices and a weakly controlled non-prescription drugs market can lead to abuse of pharmaceuticals and self-medication.

Therefore, there is a need to improve regulatory frameworks and law enforcement, and to enhance awareness against the abuse of pharmaceuticals.

## REFERENCES:

Statistical of Pharmaceutical sector-2014

---

## Poster 120B Multi-Indication Pricing: Pros, Cons, And Applicability To The UK

### DESCRIPTION:

Multi-indication pricing (MIP) involves setting different prices for medicines for each approved indication. MIP could ensure medicines are appropriately priced according to value per indication. We explored (i) attractiveness of MIP as a potential solution to the challenge of providing optimal pricing and reimbursement to multi-indication drugs and (ii) feasibility of implementing MIP in the UK.

### PRESENTING AUTHOR:

Dr. Jorge Mestre-Ferrandiz

### AUTHORS:

Jorge Mestre-Ferrandiz, Adrian Towse, Renato Dellamano, Michele Pistollato

### BACKGROUND AND OBJECTIVES:

Many medicines currently available, and many more in pharmaceutical industry pipelines, are likely to be effective in multiple indications. More than 50 per cent of major cancer medicines marketed in 2014 were for multiple indications. By 2020, this share is estimated at 75 per cent. Value is likely to be different across these indications. If prices paid for on-patent medicines are to reflect their value then multi-indication medicines should have different prices across indications, reflecting the different values. Yet current pricing and reimbursement systems are not equipped to handle this. There

tends to be one single (uniform) price across all indications. As a result, price and clinical value will rarely match up across multiple indications. Multi-Indication Pricing (MIP) involves setting different prices for medicines for each approved indication. MIP could ensure medicines are appropriately priced according to value per indication. We explored (i) attractiveness of MIP as a potential solution to challenge of providing optimal pricing and reimbursement to multi-indication drugs and (ii) feasibility of implementing MIP in the UK.

#### **METHODS:**

(1) desk research on MIP and modelled its effects versus uniform/flat pricing (i.e. same price across all indications); (2) Workshop with health care system stakeholders to discuss pros and cons of MIP and practicalities of implementing it in the UK

#### **RESULTS:**

Workshop agreed that relative prices should reflect relative value, but prices should not exceed value, and thus MIP might be a way forward. However, two operational challenges remain: 1) Whether NHS can handle MIP-schemes involving variable net selling prices by indication, requiring monitoring of volume usage per patient per indication, and undertake any financial reconciliation ex post to ensure correct funds flow across necessary stakeholders. 2) Data availability: are there data sets which allow such monitoring of usage, and is the necessary data being generated routinely or requiring ad hoc intervention? There is a UK collaboration to pilot the feasibility of MIP in the UK setting, based on UK NHS's own Systemic Anti-Cancer Therapy (SACT) dataset

#### **CONCLUSIONS:**

Handling pricing for drugs with multiple indications within the same disease area & including different potential lines of treatment and/or combination regimens & is challenging, and will increasingly be so. A necessary condition for implementation of MIP-type schemes is the potential to track specific utilisation of the drug in different indications,

regimens and patient sub-populations. The UK collaboration referred above suggests this is achievable

---

## **Poster 121B** The Road Map For HTA Development In Kazakhstan: For Well Informed Health-Care Decisions

#### **DESCRIPTION:**

The road map for HTA development in Kazakhstan will give a powerful impetus to the further spread of effective science-based medical technology into clinical practice. Regional HTA agencies and national clinical practice guidelines (CPG) developers in Kazakhstan in post carriage period would produce relevant, reliable, transparent, and up-to-date evidence synthesis and recommendations, avoiding unnecessary duplication on regional and national levels, making their work accessible to decision makers, and engaging stakeholders.

#### **PRESENTING AUTHOR:**

Ainura Sassykova, Republican Center for Health Development, Kazakhstan

#### **AUTHORS:**

Temirkhan Kulkhan, Ainura Sassykova, Nagima Issatayeva

#### **BACKGROUND AND OBJECTIVES:**

Despite significant investments during last years in clinico- and pharmaco-economic evaluation, as part of a formulary listing or reimbursement submission, too much research is wasted and too many decisions are still not well informed. The objective was to invent the long-term strategy for the HTA development in the Republic of Kazakhstan.

**METHODS:**

We conducted a survey of HTA terms in 6 countries (Kazakhstan, Turkey, Tajikistan, Kyrgyzstan, Uzbekistan, and Montenegro). Informal stakeholder interviews within the framework of first Eurasian Forum of HTA were used to supplement lacking information.

**RESULTS:**

Rising affordability and accessibility of the healthcare services have been considered as the most important policy issues in Kazakhstan. In light of this fact The Republican Center for Health Development is devising The Road Map of HTA Development in the Republic of Kazakhstan in 2016-2020. Healthcare professionals and managers who are responsible for seeking reliable information and learning sufficient skills to use evidence-based resources to provide optimum patient care should promote hospital based HTA on the regional level and support HTA research and CPG development in clinics. There is growing recognition of the need for local efforts that go beyond sharing the evidence. Hospital based HTA should be accountable to their patients, governments, and third party payers.

**CONCLUSIONS:**

The Road Map for HTA Development in Kazakhstan will give a powerful impetus to the further spread of effective science-based medical technology into clinical practice. Regional HTA Agencies and National CPG developers in Kazakhstan in post carriage period would produce relevant, reliable, transparent, and up-to-date evidence synthesis and recommendations, avoiding unnecessary duplication on regional and national levels, making thier Works accessible to decision makers, and engaging stakeholders.

**REFERENCES:**

Republican Center for Health Development, Astana, Republic of Kazakhstan

.....

.....

**Poster 122B Social Media: A New Tool For Collecting Effectiveness Data?**

**DESCRIPTION:**

Real world data could be used to assess relative effectiveness, in addition to RCTs that are traditionally used. This explorative review showed that social media may be a potential source of real world data and could potentially contribute to relative effectiveness assessment in oncology, especially on aspects such as side effects, treatment switching, adherence behaviour, and quality of life.

**PRESENTING AUTHOR:**

Wim Goettsch, National Health Care Institute, Netherlands

**AUTHORS:**

Rachel Kalf, Amr Makady, Renske ten Ham, K. Meijboom, Wim Goettsch

**BACKGROUND AND OBJECTIVES:**

In the context of rising healthcare costs, limited budgets, and upcoming innovative yet expensive medications, the need for robust relative effectiveness assessments (REA) is becoming increasingly important. Conventionally randomized clinical trails (RCTs) are used for REA. Although RCTs provide robust measures for efficacy, they may not be suitable for assessing relative effectiveness. In addition to RCTs, researchers can resort to real world data (RWD) for REA. Social media provide a potential new source of RWD. The aim of this explorative review is to assess if, and how, health data generated via social media could contribute to relative effectiveness assessment.

**METHODS:**

We conducted a review to identify examples in oncology research where social media was used as a mode to collect health data. Scientific literature

was identified by searching PubMed, and by assessing citations and key journals (such as drug safety and journal of medical internet research). Reports from grey literature were identified through websites of online patient networks, online research platforms, and other relevant organizations. Two reviewers independently screened studies for eligibility and extracted data. A descriptive qualitative analysis was performed.

**RESULTS:**

Initially 794 articles were identified. Study inclusion criteria were met by 28 articles based on title and abstract, and by 5 based on the full article. All, but one, of the included articles focused on identifying side effects to cancer treatments by using either forums or Twitter. One article assessed the feasibility of disseminating a quality of life survey via a Facebook support group. Several strengths of using health data generated via social media were identified, such as the efficient collection of patient experiences, the recruitment of a small sample of patients spread over a relatively wide geographic area, and identification of new or unlabelled side effects. Limitations of using social media to generate health data included validating authenticity of posters, information bias, and selection bias. According to the included articles, social media could provide insights on patients' perspectives relating to side effects, treatment switching, adherence behaviour and quality of life.

**CONCLUSIONS:**

Social media may provide a potential source of RWD for REA in oncology, particularly on aspects such as treatment side effects, adherence, and quality of life. This potential has not yet been fully realised due to limitations that accompany social media-generated health data. However, the degree of usefulness of such data for relative effectiveness should be further explored.

.....

.....

## Poster 123B Health Technology Assessment Of Femtosecond Laser: A New Frontier In Cataract Surgery

**DESCRIPTION:**

The article describes the assessment of the femtosecond laser-assisted cataract surgery compared to conventional cataract surgery.

**PRESENTING AUTHOR:**

Giorgia Tedesco, Bambino Gesu' Children's Hospital, Italy

**AUTHORS:**

Giorgia Tedesco, Francesco C. Faggiano, Luca Buzzonetti, Giuseppe Di Pinto, Sergio Petroni, Giuseppe Chessa, Matteo Ritrovato

**BACKGROUND AND OBJECTIVES:**

Cataract extraction has become the prevailing and safest procedure used to treat cataract with significant advances in visual outcomes, even in children and adolescents. The aim of this study is to describe the application of Decision-oriented HTA (viz., a new implementation of the EUnetHTA CoreModel©, integrating the Multicriteria Decision-Making Analysis by using the Analytic Hierarchy Process) to assess the femtosecond laser-assisted cataract surgery (FLACS) compared to conventional cataract surgery (CCS).

**METHODS:**

This article reviews the spectrum of evidence regarding the feasibility, safety, technical and organizational features, costs and economic factors of FLACS compared to CCS, by using doHTA methodology. The information is summarized in a hierarchical decision tree by means of Key Performance Indicators (KPI), subsequently weighted through pairwise comparisons. For each pair of elements in the pairwise comparison, a verbal judgment by professionals involved in the

assessment was gathered, and then converted in the numerical ratings. Lastly, FLACS and CCS were ranked against lowest indicators of decision tree. A global score was determined delivering a consequent ranking between the alternatives.

## RESULTS:

According to the professionals judgments, 'safety' along with 'clinical effectiveness' make up almost 60% of the whole evaluation, while the weights associated to 'costs and economic evaluation' dimension was 14.63%, followed by 'technical characteristics of technology' (14.28%) and 'organizational aspects' (10.51%) domains. FLACS seems to overcome CCS with several important developments such as increased precision of anterior capsulotomy, reduced ultrasound power requirement during phacoemulsification, decreased collateral tissue damage, increased accuracy in surgical results as well as better visual outcomes. Notwithstanding such clinical improvements, FLACS is more expensive than its comparator; the relative costs were also analyzed in the cost-minimization analysis.

## CONCLUSIONS:

The Hospital's Top Management has decided to fully consider the doHTA evaluation, thus taking into account the promising aspects of FLACS pertaining to the safety, efficacy and technical. Indeed, although FLACS had the highest purchase price, its safety, clinical and technical features led FLACS to be the preferred alternative. Moreover, due to the peculiar features of doHTA (i.e. the quantitative integration of different aspects of the assessment and their synthetic representation), the Top Management has provided a timely response between both alternatives: the implementation of FLACS seems to be attainable.

## REFERENCES:

1. Donaldson KE, Braga-Mele R, Cabot F, et al. ASCRS Refractive Cataract Surgery Subcommittee. Femtosecond laser-assisted cataract surgery. *J Cataract Refract Surg.* 2013;39(11):1753-63.

2. Dick HB, Schultz T. Femtosecond laser-assisted cataract surgery in infants. *J Cataract Refract Surg.* 2013;39:665-8.

3. Ritrovato M, Faggiano FC, Tedesco G, Derrico P. Decision-Oriented Health Technology Assessment: one step forward in supporting the decision making process in hospitals. *Value in Health. Value Health.* 2015;18(4):505-11.

4. Radaelli G, Lettieri E, Masella C, et al. Implementation of EUnetHTA Core Model in Lombardia: the VTS framework. *Int J Technol Assess Health Care* 2014;30:105-12.

5. Saaty TL. *The Analytic Hierarchy Process.* New York: McGraw-Hill, 1980. 6. Saaty TL. Decision making with the analytic hierarchy process. *Int J Serv Sci* 2008;1:83-98.

7. Abell RG, Kerr NM, Vote BJ. Femtosecond laser-assisted cataract surgery compared with conventional cataract surgery. *Clin Experiment Ophthalmol.* 2013;41(5):455-62.

8. Abell RG, Allen PL, Vote BJ. Anterior chamber flare after femtosecond laser-assisted cataract surgery. *J Cataract Refract Surg.* 2013;39(9):1321-6.

9. Abell RG, Vote BJ. Cost-effectiveness of femtosecond laser-assisted cataract surgery versus phacoemulsification cataract surgery *Ophthalmology.* 2014;121(1):10-6.

10. Nagy ZZ. New technology update: femtosecond laser in cataract surgery. *Clin Ophthalmol.* 2014;8:1157-67. 11. Abell RG, Davies PE, Phelan D, et al. Anterior capsulotomy integrity after femtosecond laser-assisted cataract surgery. *Ophthalmology.* 2014;121(1):17-24.

## Poster 124B Extending Provincial Health Coverage To Include Eye Examinations For Diabetic Retinopathy By Optometrists: Economic Evidence From Prince Edward Island, Canada

### DESCRIPTION:

Diabetic retinopathy, eye examination, cost-utility analysis, optometric services, provincial health insurance, Prince Edward Island, Canada

### PRESENTING AUTHOR:

Dr. Kednapa Thavorn, Ottawa Hospital Research Institute, Canada

### AUTHORS:

Kednapa Thavorn, Sasha, van Katwyk, Graham, E Trope, Richard, Wedge, Sherif, El-Defrawy, John, Flanagan, Yvonne, Buys, Yaping Jin

### BACKGROUND AND OBJECTIVES:

Diabetic retinopathy (DR) is one of the leading causes of vision loss and blindness in Canada and is expected to rise with the increasing rate of diabetes. Eye examination plays an important role in early detection as it can prevent progressive vision loss. Prince Edward Island (PEI), one of eastern Canada's maritime provinces, does not offer government-insured optometric services for residents with diabetes of any age, which may lead to lower rates of DR detection and higher rates of vision loss. This study assessed whether expanding provincial health coverage to include eye examination for DR by optometrists is cost-effective from the perspective of the PEI health.

### METHODS:

We built a decision tree to determine incremental costs and effects of extended coverage for examination for DR by ophthalmologists (currently

covered under PEI health) to optometrists. We used a Markov chain to model a natural history of disease progression according to currently reported eye examination rates, transition probabilities across non-DR patients, background DR, pre-proliferative DR, blind, and death. We created two interacting Markov chains for patients aged 45 to 64 and patients 65 and above as these two groups have different rates of DR progression and examination. A series of sensitivity analyses were performed.

### RESULTS:

Our findings to date showed that extending health coverage to eye examination by optometrists for diabetic patients is cost-effective, yielding an incremental cost-effectiveness ratio of \$853.69 per quality-adjusted life year (QALY) gained. We are currently performing one-way and probabilistic sensitivity analyses. We are also conducting scenario analyses, varying capacity to screen and treat according to different supply and demand assumptions.

### CONCLUSIONS:

Our study highlights that extending government coverage to include examination for diabetes retinopathy offered greater benefits with higher costs. Based on a common threshold of \$50,000/QALY, government-insured diabetic retinopathy screening by optometrists was cost-effective.

---

## Poster 125B Study On Process Of China's Essential Medicine System Based On Smith-Model

### DESCRIPTION:

In this study, the Smith-Model of policy implementation was used to analyze the process of China's Essential Medicine System (NEMS). As a ceiling effect policy, there do exist some limitations in China's NEMS. It limits the drug use in primary medical institutions. Effective measures should be taken to optimize the NEMS.

**PRESENTING AUTHOR:**

Zhongming Chen, Weifang Medical University, China

**AUTHORS:**

Zhongming Chen, Wenqiang Yin, Jifei Zheng, Haiyi Jia, Xuedan Cui, Shiliang Hu, Jinwei Hu

**BACKGROUND AND OBJECTIVES:**

The overpriced medicine and rapid growth of medical costs are common and serious problems of China. In the interest of safeguarding basic pharmaceuticals and lighten the economic burden on patients, National Health and Family Planning Commission of China have implemented the National Essential Medicine System (NEMS) in 2009. In this study, the Smith-Model of policy implementation was used to analyze process of the NEMS.

**METHODS:**

A cross-sectional study was performed in Shandong Province in the context of the NEMS. A random sampling method was adopted for investigating primary hospital doctors, managers and residents were conducted in five cities which were representative of different socioeconomic status (SES). From the each five cities, three counties were selected according to the SES. Then three towns for each county and two or three villages per town were selected randomly. In addition, several respondents and pharmaceutical manufacturers' administrators were interviewed. Then the Smith-Model of policy implementation was used to analyze process of the NEMS from four aspects.

**RESULTS:**

As a ceiling effect policy, there do exist some limitations in China's NEMS. It limits the drug use in primary medical institutions. For implementation institutions of policy, executive force and executive strength, they vary with different regions, and it is difficult to coordinate with different institutions

of policy implementation. As a result, working enthusiasm and medical service capacity of doctors in primary medical institutions have been influenced by it, and most of them are against this policy. Few residents are benefit from the NEMS. Policy escapism is an ordinary phenomenon for pharmaceutical manufacturers in implementing policy.

**CONCLUSIONS:**

Measures should be taken to optimize the NEMS. Firstly, doctors should not be limited to using essential medicines, and they have autonomous right in rational medication. The relevant supervision mechanism should be built to promote the implementation of the NEMS, for instance, the communication and coordination mechanism among implementation institutions of policy, supervision and feedback system of the public bidding for drug procurement, and strengthen the purpose driven inspection. Meanwhile, comprehensive supporting policies should be formulated to mesh with the NEMS, such as health insurance policy, the equality of essential public health and the rational functional orientation of primary hospital.

.....  
**Poster 126B Activities Of Center Of Health Technology Assessment In Hospital In Brazil: An Experience Report**

**DESCRIPTION:**

Center of health technology assessment in hospital in Brazil: an experience report.

**PRESENTING AUTHOR:**

Silvana Molina Lima, Botucatu Medical School - Unesp, Brazil

**AUTHORS:**

Silvana Molina Lima, Meline Kron, Marcelo Lima,

Ana Claudia Molina, Denise Zornoff, Henrique Soares, Emilio, Curcelli

**BACKGROUND AND OBJECTIVES:**

The Health Technology Assessment (HTA) is a process that evaluates and regulates the use of technologies in health, offering technical information based on the best scientific evidence and contributing to decisions on health. The study aimed to report the experience of Center of Health Technology Assessment in Clinical Hospital of Botucatu Medical School (NATS-HCFMB) in the year 2015.

**METHODS:**

The NATS-HCFMB was created in January 2010. In 2015, the NATS-HCFMB accomplished HTA activities by internal and external hospital demands.

**RESULTS:**

In the year of 2015, the NATS-HCFMB accomplished: Meeting of HTA Committee, HTA for Hospital and Health Ministry, HTA instructional material, HTA bulletins, HTA Courses for internal public and external public and lectures for the undergraduate and postgraduate.

**CONCLUSIONS:**

The NATS contributes to the dissemination and knowledge of the activities developed in HTA in our institution and in Brazil as well for the managers decision of health services.

**REFERENCES:**

Brasil. Ministério da Saúde. Avaliação de Tecnologias em Saúde Ferramentas para a Gestão do SUS. 2009. Acesso disponível em: [http://bvsmis.saude.gov.br/bvs/publicacoes/avaliacao\\_tecnologias\\_saude\\_ferramentas\\_gestao.pdf](http://bvsmis.saude.gov.br/bvs/publicacoes/avaliacao_tecnologias_saude_ferramentas_gestao.pdf)

## Poster 127B Efficacy And Safety Of Beta Interferon-1A-30 G For Multiple Sclerosis: A Systematic Review

**DESCRIPTION:**

Beta interferon-1A-30µg is a candidate for disinvestment in Brazil. This systematic review showed that beta interferon-1A-30µg is less effective than the other beta interferons provided by the Unified Health System. On the other hand it presents better safety and adherence profiles. A well designed observational study is needed to conclude whether or not the safety and therapy adherence advantages translate into good effectiveness results in Brazil.

**PRESENTING AUTHOR:**

Augusto Afonso Guerra Junior, SUS Collaborating Centre for Technology Assessment and Excellence in Health, Brazil

**AUTHORS:**

Gustavo Leal, Isabela Diniz, Isabella Godói, Marina Garcia, Livia Lemos, Francisco Acurcio, Augusto Afonso Guerra Junior

**BACKGROUND AND OBJECTIVES:**

Multiple sclerosis (MS) is characterized by demyelination and inflammation of the white matter causing neurological and motor disorders. Beta interferons (BIFN) are anti-inflammatory cytokines produced by genetic engineering techniques (1-5) used in prevention of new outbreaks of MS. Recently, in Brazil, a network meta-analysis commissioned by the National Commission for Health Technology Incorporation (CONITEC) showed that BIFN-1a-30µg (intramuscular, once/week) is less effective than INF-1a-22/44µg (subcutaneous, 3x/week) and BIFN-1b-250µg (subcutaneous, every 48h), and comparable to placebo in the number of relapse-free patients after two years of treatment. With this study CONITEC preliminarily recommended the

disinvestment in BIFN-1a-30µg and sent the matter for public consultation. 5,000 people contributed mainly patients, family members or caregivers, requesting the maintenance of public founding of BIFN-1a-30µg. To aid in the subject we conducted a systematic review of efficacy.

## **METHODS:**

A systematic review was performed using the Cochrane handbook. We searched the Medline (via Pubmed), The Cochrane Library (via Bireme), Lilacs and the Centre for Reviews Dissemination (CRD). Two independent reviewers (GL, ID) performed the selection of potential papers in three phases (i.e. titles, abstracts and whole texts). A third reviewer (IG) analyzed the dissimilar results. Randomized Controlled Trials (RCT) and observational studies, comparing the use of BIFN-1a-30µg with BIFN or placebo were included. The quality of evidence and strength of recommendation were assessed using the GRADE system, for RCTs, and Newcastle-Ottawa Scale, for observational studies (6-8).

## **RESULTS:**

We included six RCT and seven observational studies comparing BIFN-1a-30µg to other BIFN (BINF-1a-22/44µg BIFN-1b-250µg) or to placebo in MS treatment, whose quality ranged from moderate to low. BIFN-1a-30µg safety profile was better when compared with other BIFN (liver, blood disorders, skin reactions, flu-like symptoms), but it showed worse results of efficacy and effectiveness when compared to other BIFN with respect to relapse rates, EDSS and brain lesions outcomes. BIFN-1a-30µg was more effective than placebo. Two cross-sectional studies showed better adherence results with BIFN-1a-30µg than with INF-1a-22/44µg and BIFN-1b-250µg.

## **CONCLUSIONS:**

BIFN-1a-30µg less effective than the other BIFN provided by the Brazilian public health system, however it presented better safety and adherence profiles. These results emphasize the need for a well-designed observational study to conclude

whether or not this safety and therapy adherence advantages translate in good effectiveness results in Brazil. If BIFN-1a-30µg shows worst results, than CONITEC will be able to take an informed decision regarding this drug (restriction of use or full withdrawal) and will have clear evidence to convince health professionals, patients and politicians.

## **REFERENCES:**

1. BRASIL. Portaria nº 391 - Protocolo Clínico e Diretrizes Terapêuticas de Esclerose Múltipla. Ministério da Saúde. Brasília. 2015. Disponível em: . Acesso em 11 de novembro de 2015.
2. MILO, Ron; KAHANA, Esther. Multiple sclerosis: Geoeidemiology, genetics and the environment. *Autoimmunity Reviews*, [S.l.], v. 9, n. 5, p.387-394, mar. 2010. Elsevier BV. DOI: 10.1016/j.autrev.2009.11.010.
3. MCDONALD WI, COMPSTON A, EDAN G, et al. Recommended diagnostic criteria for multiple sclerosis: guidelines from the International Panel on the diagnosis of multiple sclerosis. *Ann Neurol* 2001; 50(1):121-27.
4. OLIVEIRA, E.M.L. & SOUZA, N.A. - Esclerose Múltipla. *Rev. Neurociências* 6(3): 114-118, 1998. Disponível em: .
5. DAUMER, Martin et al. Prognosis of the individual course of disease: the elements of time, heterogeneity and precision. *Journal of The Neurological Sciences*, [s.l.], v. 287, p.50-55, dez. 2009.
6. Higgins J, Green S. *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0: The Cochrane Collaboration; 2011. Available from: [www.cochrane-handbook.org](http://www.cochrane-handbook.org).
7. Guyatt G, Oxman A, Kunz R, Falck-Ytter Y, Vist G, Liberati A, et al. GRADE: going from evidence to recommendations. *British Medical Journal*. 2008;336:1049-51.
8. Guyatt G, Oxman A, Vist G, Kunz R, Falck-Ytter

Y, Alonso-Coello P, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *British Medical Journal*. 2008;336:924-6.

---

## Poster 128B Study On Relative Price Of Current Traditional Medical Service Items In Shanghai - Based On A Standard Value Model

### DESCRIPTION:

This abstract is mainly concerned with health service price setting. A new standard value model was constructed and used for comparing with current prices. We found that current prices are unreasonable and should adjust step by step.

### PRESENTING AUTHOR:

Haiyin Wang, Shanghai Medical Information Center, China

### AUTHORS:

Wang Hai-yin, Chen Min-xing, JIN Chun-lin, WANG We, Gong li, Zhang Xiao-xi

### BACKGROUND AND OBJECTIVES:

Introduction: China payment model is predominantly Fee-for-service nowadays, which has been hotly debated for its unreasonable price standard, especially low price for traditional medical items. Price setting is basically based on experts' opinions and other politics' consideration, a standard price model that can guide the evidence-based policy making was not found. China health ministry published new price specification in 2012 (national 2012 version), which put forward some price making indices. There was no research reported based on these value indices. Our research hypothesis is that national 2012 version is reasonable and can be used for price making

combined with Shanghai location. This study goal is to grasp the current price level of Shanghai medical service items, Create a standard value model to calculate service schedule true value, and to compare and screen the unreasonable items between them so as to provide the basis for price set and adjustment.

### METHODS:

National 2012 version and Shanghai current price version was compared with expert consulting method, which include tradition medicine doctors and price regulators. The same items were selected for calculation and comparison. A standard value model was constructed with two main component: labor value and expense value. While labor value is designed with three factors-time, complexity and risk, and labor value parameters were fixed based on Shanghai salary reform plan. Expense value was mainly include direct cost using activity-based costing method implemented in five city hospitals. Current price and standard value was compared directly and relatively with ratio indices, and schedule that need to give priority to adjust were selected. Policy recommendations were put forward.

### RESULTS:

A total of 143 was basically matched and compared. 115 items current price was lower than standard value both in secondary and tertiary hospitals, which were mainly as acupuncture, Chinese medicine, orthopedics and other anorectal diseases stuffs. 2 items were higher than standard value, accounted for 1 percent. The standard value was average of 3.4 times the current price. High degree of deviation was shown in the proportion ratio, the difference was statistically significant ( $t=6.275$ ,  $P$

### CONCLUSIONS:

The Shanghai current price level of Chinese medicine service schedule was generally low, the price relationship was unreasonable, and it is recommended to adjust step by step taking into account the price adjustment space, health

insurance balance , medical institutions running and patients' burden.

---

## Poster 129B What Is The Problem In China's Medical Care Resources Allocation: Some Evidence From Data Envelopment Analysis (DEA)

### DESCRIPTION:

In China, the resources in hospitals cannot meet the demands, though the resources are abundant; some primary institutions lying idle, though the resources are in shortage. We used the data envelopment analysis to confirm whether the working efficiency leading to this phenomenon. As a result, maybe the patient's medical care choices, rather than the working efficiency leads to the phenomenon.

### PRESENTING AUTHOR:

Hao Zhang, Zhejiang University, China

### AUTHORS:

Hao Zhang, Lin Gao, Yuhang Zeng, Xuemei Zheng, Shuyan Gu

### BACKGROUND AND OBJECTIVES:

The healthcare delivery system of China is hospital centered, there are excessive resources in hospitals while the resources in primary medical care institutions are in shortage. However, there is a contrary phenomenon in medical care utilization: it seems the resources in hospitals cannot meet the demands of the patients yet, since the patients complain about the difficult access to hospital services; while, the recourses in primary medical care institutions seems excessive, since there are some of the primary institutions lying idle. How does this phenomenon happen? We want to confirm whether the difference in working

efficiency of different medical care institutions leading to this phenomenon, and provide suggestion for decision-makers on evidence.

### METHODS:

We used the data envelopment analysis (DEA) to calculate the working efficiency of the hospitals and primary health institutions respectively in 2003, 2008 and 2013. We collected the data of medical care resources as the input data, and the data of medical care utilizations as the output data. The medical care resources indicators we used are human resources and beds. The utilization indicators we used are outpatient, inpatient and family medical care services, since the hierarchical diagnosis and treatment procedure has not been operated in China yet, both the hospitals and primary medical care institutions provide these services.

### RESULTS:

The technical efficiency form CRS DEA (CRSTE), the technical efficiency form VRS DEA (VRSTE) and scale efficiency (SCALE) of hospitals are 0.78, 0.846, 0.928 in 2003, are 0.907, 0.93, 0.975 in 2008, and are 0.936, 0.956, 0.979 in 2013. The CRSTE, VRSTE and SCALE of primary medical care institution are 0.655, 0.731, 0.908 in 2003, are 0.638, 0.783, 0.884 in 2008, are 0.898, 0.939, 0.957 in 2013. It indicates that, the working efficiencies are high in hospitals; however, the efficiencies are respectively low in primary medical care institutions.

### CONCLUSIONS:

The working efficiencies in hospital system are rather high, though the resources are redundant. This indicates that the hospitals system provides more services than its reasonable output, and the medical care demands are higher than needs. The working efficiencies in primary medical care system are relatively low, though the resources are in shortage. This indicates that the primary medical care system provides less services than its reasonable output, the medical care demands are lower than needs. It can be deduced that

maybe the patient's medical care choices leads to the unsatisfied hospital demands and the wasted primary medical care resources.

## REFERENCES:

1. Anand S, Fan V Y, Zhang J, et al. China's human resources for health: quantity, quality, and distribution. *The Lancet*, 2008, 372(9651): 1774-1781.
2. World Health Organization. *The world health report 2000: health systems: improving performance*. World Health Organization; 2000.
3. Yip W, Hsiao W, Chen W, Hu S, Ma J, Maynard A. The Chinese health system at a crossroads. *Health Affairs*. 2008; 27(2): 460-468.
4. Zhao T. Workload of primary care physicians in rural China: evidences from three provinces. *Economic Review*. 2014; 1: 12-24.
5. Tang S, Meng Q, Chen L, Bekedam H, Evan T, Whitehead M. Tackling the challenges to health equity in China. *The Lancet*. 2008. 372(9468): 1493-1501.
6. Hollingsworth B. Non-parametric and parametric applications measuring efficiency in health care. *Health care management science*, 2003, 6(4): 203-218.
7. Kao C, Hwang S N. Efficiency decomposition in two-stage data envelopment analysis: An application to non-life insurance companies in Taiwan. *European Journal of Operational Research*, 2008, 185(1): 418-429.
8. Jacobs R. Alternative methods to examine hospital efficiency: data envelopment analysis and stochastic frontier analysis. *Health Care Management Science*, 2001, 4(2): 103-115.
9. Braveman P, Gruskin S. Defining equity in health. *Journal of epidemiology and community health*, 2003, 57(4): 254-258.
10. Yun H, Jie S, Anli J. Nursing shortage in China: State, causes, and strategy. *Nursing outlook*, 2010,

58(3): 122-128.

11. Wang H, Xu T, Xu J. Factors contributing to high costs and inequality in China's health care system. *JAMA*, 2007, 298(16): 1928-1930.
12. Akin J S, Dow W H, Lance P M, et al. Changes in access to health care in China, 1989-1997. *Health Policy and Planning*, 2005, 20(2): 80-89.
13. Ministry of Health. *China's health statistics yearbook 2014*. Beijing: China Statistics Press; 2014.
14. Ministry of Health. *China's health statistics yearbook 2009*. Beijing: China Statistics Press; 2009.
15. Ministry of Health. *China's health statistics yearbook 2004*. Beijing: China Statistics Press; 2004.

---

## Poster 130B Omitting Routine Chest Radiograph (X-ray) In Routine Medical Examination (RME) In Malaysia: Potential Cost Saving

### DESCRIPTION:

Chest radiograph (X-ray) has become an integral part of RME which are conducted either in the public hospitals and public health clinics or private healthcare facilities. With more than 250,000 chest X-rays performed as part of RME in public health clinics annually, the cost is substantial. Hence, impact of omitting chest X-ray in RME would result in estimated annual saving of RM 4.8 million to the government.

### PRESENTING AUTHOR:

Dr. Junainah Sabirin, MaHTAS, Medical Development Division, Ministry of Health, Malaysia

## **AUTHORS:**

Junainah Sabirin, Roza Sarimin, Ku Nurhasni Ku Ab Rahim, Noridah Mohd Saleh, Ali Ngatman

## **BACKGROUND AND OBJECTIVES:**

In Malaysia, routine medical examination (RME) are carried out as a requirement before employment in the public and private sector, entry into tertiary educational institutions or admittance to residential schools, and for employees above 40 years old. Chest radiograph (X-ray) has become an integral part of this RME which are conducted either in the public hospitals and public health clinics or private healthcare facilities. However, three HTA and Mini-HTA reports conducted by Malaysian Health Technology Assessment Section (MaHTAS) in 2002 and 2009 recommended that chest X-ray should not be performed routinely but to be justified by history and clinical examination.<sup>1,2,3</sup> Based on the reports, the Family Health Development Division, Ministry of Health (MOH), initiated discussions with the Public Services Department and Ministry of Higher Education advocating the omission of routine chest X-ray in RME and had received positive response. Since substantial number of chest X-rays are being conducted as part of RME in public health clinics annually, we aim to estimate the potential cost saving by omitting chest X-ray from the RME in the public health clinics in Malaysia.

## **METHODS:**

Data on the number of X-rays performed in the public health clinics in Malaysia for 2014 were reviewed.<sup>4</sup> The number of chest X-rays performed as part of routine medical examinations was extrapolated based on a study conducted in one of the public health clinic in Malaysia in 2010 whereby 63% chest X-rays were produced as part of RME.<sup>5</sup> The estimated cost saving was calculated based on the cost of producing a single posterior-anterior view chest X-ray in one public health clinic (from the viewpoint of the provider) from the same study and was adjusted to the cost of year 2014 as RM 17.545

## **RESULTS:**

A total of 790,416 X-rays were performed in public health clinics in Malaysia in 2014, whereby about 55% (434,728) were chest X-rays based on statistics from nine public health clinics in Pulau Pinang. Of these, about 273,878 chest X-rays were produced as part of RME. The estimated cost for chest X-rays performed in public health clinics in Malaysia as part of RME in 2014 was RM 4,803,831.35.

## **CONCLUSIONS:**

With more than 250,000 chest X-rays performed as part of RME in public health clinics annually, the cost is substantial. Hence, impact of omitting chest X-ray in RME would result in estimated annual saving of RM 4.8 million to the government. However, this study has its own limitation as the cost of one chest X-ray and the frequency of chest X-ray for RME were based on estimation from a single public health clinic in Malaysia.

## **REFERENCES:**

1. Thayapparam T, Sathyamoorthy P, Subramani V et al. Routine Chest Radiographs in Routine Medical Examinations. Health Technology Assessment Report. Health Technology Assessment Unit, Medical Development Division, Ministry of Health.2002. MOH/P/PAK/53.02(TR)
2. Routine Medical Examination. Technology Review Report. Health Technology Assessment Unit, Medical Development Division, Ministry of Health.2002
3. Zalina A, Junainah S. Routine Medical Examination - An Update. Technology Review Report. Health Technology Assessment Section, Medical Development Division, Ministry of Health.019/2009
4. X-Ray Examination 2011 to 2014. Family Health Development Division, Ministry of Health.2015
5. Izamin I, Mohd Rizal AM. Chest X-ray as an essential part of routine medical examination: Is it necessary?. Med J Malaysia.2012;67(6):606-609

---

## Poster 131B Pilot Study Of Establishing A Horizon Scanning System In China

### DESCRIPTION:

In China, the government faces the need to improve the level of decision-making. Establishing a horizon scanning system (HSS) can support decision-makers with information about new health technologies prior to their adoption and introduction. This study aimed to identify existing best practices and effective methods for health technology horizon scanning and collect the needs and recommendations for the proposed HSS in China from potential users. Trial running of the pilot HSS system in China and collect user feedback to improve the system.

### PRESENTING AUTHOR:

Dr. Zhiyuan Xia, Fudan University, China

### AUTHORS:

Zhiyuan Xia

### BACKGROUND AND OBJECTIVES:

Background: In China the government faces the need to improve the level of decision-making. Establishing a horizon scanning system(HSS) can support decision-makers with information about new health technologies prior to their adoption and introduction. Objectives: This study aimed to identify existing best practices and effective methods for health technology horizon scanning and collect the needs and recommendations for the proposed HSS in China from potential users. Trial running of the pilot HSS system in China and collect the users' feedback to improve the system.

### METHODS:

A comprehensive search for literature and a targeted search of web sites of the HSS

organizations were performed to identify existing horizon scanning methods. 20 potential users including national and regional level policy makers, health insurance administrators, hospital administrators, clinical experts and HTA researchers, were invited to participate the face to face interview to collect their needs and recommendations. A pilot HSS in China was established, a trial running of the system was carried out and produced 5 new health technologies alerts. The alerts were sent to 20 decision makers to get their feedback to improve the system.

### RESULTS:

Most of formally established HSSs in the world are members of EuroScan and they share common functions and structures defined by EuroScan, all HSSs aim to 'identify, filter and prioritize new and emerging health technologies to assess or predict their impact'. However, it is necessary to adjust the common stages to the needs of the individual HSS. The interview results showed that potential users thought HSS would be helpful for their decision making. It was important to emphasize the information sources from clinical experts and current horizon scanning databases. The feedback results showed that the HSS need work with decision makers closer to produce evidences to meet their demands.

### CONCLUSIONS:

We could establish a HSS in China by adapting the international experience and localizing it according to the needs of Chinese health system. It was necessary to introduce the concept of HSS in China in the first step. According to the limiting resources, information from clinical experts and current horizon scanning databases were important, and work with decision makers closely will help to improve the value of the outputs.

## Poster 132B Systematic Review Of Restrictive Transfusion Thresholds In Major Orthopedic Surgery

### DESCRIPTION:

Meta-analysis of published RCTs comparing liberal and restrictive transfusion thresholds in hip fracture or joint replacement surgery found no outcomes for which results were significantly better with liberal thresholds. Restrictive transfusion thresholds reduced the number of patients receiving transfusions and the average number of units transfused, while reducing the risk of infection.

### PRESENTING AUTHOR:

Matthew Mitchell, University of Pennsylvania Health System, United States

### AUTHORS:

Matthew D. Mitchell, Joel S. Betesh, Samir Mehta, Craig A. Umscheid

### BACKGROUND AND OBJECTIVES:

Red blood cell transfusions are often initiated in patients undergoing major orthopedic surgery where there is expected blood loss or when patients experience post-operative blood loss. Clinicians are questioning whether it is safe to use stricter thresholds for giving these transfusions because there are significant risks associated with transfusion, including hemolytic and non-hemolytic adverse reactions and transfusion-related infection.

### METHODS:

Systematic search of Medline, EMBASE, Cochrane databases, and Transfusion Evidence Library for randomized controlled trials comparing different transfusion thresholds in patients undergoing major orthopedic surgery; followed by random-effects meta-analysis using Cochrane methods. Studies compared restrictive transfusion thresholds (typically 8 g/dl) with liberal thresholds (typically 10

g/dl).

### RESULTS:

Searches yielded a total of 579 references. After title and abstract screening and full-text review, we ultimately included 9 RCTs in the analysis. Five of the trials (totaling 2,079 patients) studied hip fracture patients, and four (1,137 patients) studied elective hip and/or knee replacement patients. Restrictive transfusion thresholds reduced the number of patients transfused by about half and reduced transfusions by about 1 unit per patient. There was substantial heterogeneity in those results however, so estimates of the size of the effect are uncertain. There was a modest decrease in infections in the patients managed with restrictive thresholds (OR 0.71, 95% CI 0.56-0.91). No significant difference was found for other outcomes including mortality, overall adverse events, bleeding, VTE, delirium, and 30-day readmission rate (see table). There were no apparent differences in results between the trials with hip fracture patients and the trials with joint replacement patients.

### CONCLUSIONS:

Lowering the threshold for considering transfusion from 10 g/dl to 8 g/dl reduces utilization of transfusions in elective total joint arthroplasty and emergent hip fracture patients and reduces infection rates while not adversely affecting other outcomes.

## Poster 133B Survey On Patient Safety Climate In Public Hospitals In China: Psychometric Properties Of The Chinese Version Of The Patient Safety Climate In Healthcare Organizations Survey

### DESCRIPTION:

Patient safety climate has been recognized as a core determinant for improving safety in hospitals. This study aimed to adapt the Patient Safety Climate in Healthcare Organizations survey (PSCHO) linguistically to the Chinese context and test aspects of its validity and reliability. The study also describe workforce perceptions of patient safety climate in public hospitals in China.

### PRESENTING AUTHOR:

Minqi Lee, Fudan University,China

### AUTHORS:

Minqi Lee

### BACKGROUND AND OBJECTIVES:

Patient safety climate has been recognized as a core determinant for improving safety in hospitals. The U.S. Patient Safety Climate in Healthcare Organizations survey (PSCHO) was specifically developed to assess workforce perceptions of patient safety culture. For this study of patient safety climate in China, the PSCHO is linguistically adapted to the Chinese context, with the aim of testing aspects of its validity and reliability and describing workforce perceptions of patient safety climate in public hospitals in China.

### METHODS:

4176 employees in 54 public general hospitals in three provinces located in the eastern, central and western regions in China were surveyed from March to September 2015. The response rate is

87.86% and the effective response rate is 86.70%. Reliability is assessed by Cronbach's  $\alpha$  coefficient and validity is analyzed by confirmatory factor analysis. The percentage of 'problematic responses' (PPRs) was used to measure patient safety climate, and the PPRs were compared among regions, using chi-square tests.

### RESULTS:

11 scales had high internal consistency(Cronbach's alpha coefficient ranging from 0.77 to 0.95).The scale of 'Fear of blame' had lower Cronbach's  $\alpha$  coefficient (0.64), slightly lower than the criterion. Confirmatory factor analysis showed good fit indexes for the Chinese version of the PSCHO(Standardized Root Mean Square Residual (SRMR)=0.0481,Root mean square error of approximation(RMSEA)=0.0563,Bentler's comparative fit index=0.9137,Bentler&Bonett's normed fit index=0.9077,Non-normed fit index=0.9082,Goodness of fit index(GFI)=0.8531,Adjusted GFI(AGFI)=0.8365). For hospital workers in the eastern region, the whole scale had the lowest PPRs(10.26%), whereas in the central and western regions the whole scale had a higher PPRs(11.98% and 11.96% respectively).

### CONCLUSIONS:

The Chinese version of the PSCHO is potentially useful to measure workforce perceptions of the patient safety climate in China. Hospital workers in the eastern region in China perceived a more positive patient safety climate overall than those in the central and western regions.

### REFERENCES:

- [1] IAEA S S N. 75-INSAG-4.(1986). Summary Report on the Post-Accident Review Meeting on the Chernobyl Accident[J]. Vienna: International Atomic Energy Agency.
- [2] IAEA S S N. 75-INSAG-4.(1991). Safety culture[J]. Vienna: International Atomic Energy Agency.
- [3] Cooper Ph D M D. Towards a model of safety culture[J]. Safety Science, 2000, 36(2): 111-136.

- [4] Cox S, Cox T. The structure of employee attitudes to safety: a European example[J]. *Work & Stress*, 1991, 5(2): 93-106.
- [5] Mearns K, Flin R, Gordon R, et al. Measuring safety climate on offshore installations[J]. *Work & Stress*, 1998, 12(3): 238-254.
- [6] Helmreich R L, Merritt A R L. Culture at work in aviation and medicine: National, organizational and professional influences[M]. 2001.
- [7] Grote G, Künzler C. Diagnosis of safety culture in safety management audits[J]. *Safety Science*, 2000, 34(1): 131-150.
- [8] Geller E S. Ten Principles for achieving a total safety culture[J]. *Professional Safety*, 1994, 39(9): 18-24.
- [9] Lee T, Harrison K. Assessing safety culture in nuclear power stations[J]. *Safety Science*, 2000, 34(1): 61-97.
- [10] Gill G K. Perception of safety, safety violation and improvement of safety in aviation: findings of a pilot study[J]. *Journal of Air Transportation*, 2004, 9(3).
- [11] 蒋庆其. 电网企业安全文化建设[J]. *电力安全技术*, 2004, 10: 003.
- [12] 马华维. 企业安全文化的实证研究——对一国有大型电力公司企业安全文化的调查与分析[J]. *管理世界*, 2001, 3: 56-61.
- [13] 常西坤, 黄冬梅, 温兴林. 基于安全文化的煤矿安全管理探讨[J]. *中国煤炭*, 2006, 9: 66-67.
- [14] Singer S J, Gaba D M, Geppert J J, et al. The culture of safety: results of an organization-wide survey in 15 California hospitals[J]. *Quality and safety in health care*, 2003, 12(2): 112-118.
- [15] 韩光曙. 医院的安全文化与医疗安全[J]. *中华医院管理杂志*, 2004, 20(3): 129-131.
- [16] 谭琳玲, 李亚洁, 李洪亮, 等. 构建医院安全文化保障病人安全[J]. *护理研究*, 2006, 20(4): 856-859.
- [17] 杨人懿, 杨平勋, 赵先柱. 医院安全文化发展概要[J]. *西南国防医药*, 2012, 7: 053.
- [18] 汪丽杰. 关于构建医院安全文化的探索[C]//疗养康复发展的机遇与挑战——中国康复医学会第 21 届疗养康复学术会议论文汇编. 2010.
- [19] 卫生部. 医院管理评价指南 (2008 年版)[J]. *中国护理管理*, 2008, 8(7): 6-11.
- [20] 张云平. 浅谈新形势下的医院安全文化建设[J]. *中医药管理杂志*, 2008, 16(10): 786-787.
- [21] 张晶. 医院安全文化建设之实践与体会[J]. *中国医药导报 ISTIC*, 2007, 4(35).
- [22] 韩军. 浅谈医院安全文化建设[J]. *医院院长论坛*, 2008, 5(6): 48-50.
- [23] 刘正卫. 新时期医院安全文化构建的策略[J]. *中国职工教育*, 2013 (10).
- [24] Weaver S J, Lubomksi L H, Wilson R F, et al. Promoting a Culture of Safety as a Patient Safety Strategy A Systematic Review[J]. *Annals of internal medicine*, 2013, 158(5\_Part\_2): 369-374.
- [25] 张翔, 薛军, 龚勋. 病人安全文化构建的哲学审视[J]. *中国医院管理*, 2010 (007): 54-55.
- [26] 张雷, 沈桂英, 李小玲. JCI 标准在构建医院护理安全文化中的应用[J]. *海军医学杂志*, 2012, 33(3): 207-209.
- [27] Braithwaite J, Westbrook M T, Travaglia J F, et al. Cultural and associated enablers of, and barriers to, adverse incident reporting[J]. *Quality and Safety in Health Care*, 2010, 19(3): 229-233.
- [28] Singer S, Lin S, Falwell A, et al. Relationship of safety climate and safety performance in hospitals[J]. *Health services research*, 2009, 44(2p1): 399-421.
- [29] Mardon R E, Khanna K, Sorra J, et al. Exploring relationships between hospital patient safety culture and adverse events[J]. *Journal of patient safety*, 2010, 6(4): 226-232.



## Poster 134B Effectiveness Of Prophylaxis With Palivizumab In A Brazilian Real-World Setting

### DESCRIPTION:

The purpose of this study is to evaluate whether PWP was associated with decrease of hospitalisation and emergency admission rates in a real-world setting. A prospective cohort was performed in a tertiary institution including infants born prematurely (< 32 weeks gestational age) between may/2011 - dec/2012. Patients were followed up until their complete one year old. From 87 infants included, 36 (41.5%) received PWP and complete prophylaxis was achieved in 30,6% of patients. Hospitalisation or emergency admission rates due to RSV or for any other cause were not decreased by prophylaxis with palivizumab. Moreover, we observed a low proportion of complete prophylaxis with palivizumab in this cohort, which was not associated to mother's age and education, or season of birth.

### PRESENTING AUTHOR:

Dr. Leila Moreira, Universidade Federal do Rio Grande Sul, Brazil

### AUTHORS:

Maria Angélica P. Ferreira, Larissa Prujá, Camila Chiodi, Luiza Grazziotin, Rita Silveira, Leila B. Moreira

### BACKGROUND AND OBJECTIVES:

Respiratory syncytial virus (RSV) is the leading cause of lower respiratory tract infection (LRTI) in hospitalised infants, particularly in those who are premature.<sup>1</sup> Palivizumab is designed to provide passive immunity against RSV and it has demonstrated to reduce the risk of hospitalisation in high-risk children.<sup>2</sup> Prophylaxis with palivizumab (PWP) for high risk children was recently adopted as a public health policy in Brazil, however its clinical effectiveness in brazilian setting remained unknown. Therefore, the purpose of this study

is to evaluate whether PWP was associated with decrease of hospitalisation and emergency admission rates in a real-world setting.

### METHODS:

A prospective cohort was performed in a tertiary institution including infants born prematurely (< 32 weeks gestational age) between may/2011 - dec/2012. Patients were followed up until their complete one year old. Brazilian public guidelines defined palivizumab prophylaxis season in our region from May to September. Collected data included number of palivizumab doses, complete prophylaxis (1 dose per month within prophylaxis season until complete 1 year old), Pediatric Intensive care unit admission and mechanic ventilation rate. To measure outcomes we used hazard ratio (HR) adjusting for tabagism, maternal education, gestational age and mother's age using Cox regression analysis.

### RESULTS:

From 87 infants included, 36 (41.5%) received PWP. Patients received an average of 2 palivizumab doses (range: 1-5) and complete prophylaxis was achieved in 30,6% of patients. We found no statistical significant association between PWP and hospitalisation for any cause (HR=1.89; p=0.15), due to RSV (HR:0.28; p=0.32), emergency admission for any cause (HR:1.82; p=0.09) and due to RSV (HR=3.09; p=0.08). Also no association was found even considering only patients who received complete prophylaxis (HR=1.65; p=0.43 and HR=0.93; p=0.90 for hospitalization and emergency admission, respectively). Only three patients required ICU admission (1 received PWP) and no patient required mechanical ventilation.

### CONCLUSIONS:

In this study, hospitalisation or emergency admission rates due to RSV or for any other cause were not decreased by prophylaxis with palivizumab. Moreover, we observed a low proportion of complete prophylaxis with palivizumab in this cohort, which was not

associated to mother's age and education, or season of birth (data not shown). Further studies are necessary to elucidate the palivizumab role in this population.

#### REFERENCES:

<sup>1</sup> Bawage SS, Tiwari PM, Pillai S, Dennis V, Singh SR. Recent Advances in Diagnosis, Prevention, and Treatment of Human Respiratory Syncytial Virus. *Advances in Virology*. 2013;2013:595768. doi:10.1155/2013/595768.

<sup>2</sup> Wegzyn C, Toh LK, Notario G, et al. Safety and Effectiveness of Palivizumab in Children at High Risk of Serious Disease Due to Respiratory Syncytial Virus Infection: A Systematic Review. *Infectious Diseases and Therapy*. 2014;3(2):133-158. doi:10.1007/s40121-014-0046-6.

---

## Poster 135B 'Pink Pill': Does It Add To Non-Pharmacological Treatment Of Hypoactive Sexual Desire Disorder?

#### DESCRIPTION:

This systematic review evaluated the efficacy and safety of flibanserin, the first drug approved for hypoactive sexual desire treatment in premenopausal women. Flibanserin 100 mg at bedtime was more effective than placebo. In controlled environments its safety profile was satisfactory. We did not find any study comparing flibanserin to non-pharmacological strategies & thus it is unknown if it adds to the treatment.

#### PRESENTING AUTHOR:

Augusto Afonso Guerra Junior, SUS Collaborating Centre for Technology Assessment and Excellence in Health, Brazil

#### AUTHORS:

Isabella Godói, Renata Nascimento, Lívia Lemos,

Francisco Acurcio, Augusto Guerra

#### BACKGROUND AND OBJECTIVES:

Female sexual response, differently of what is usually seen in men, doesn't happen in a fixed and inert way of desire, arousal, orgasm and resolution. Female sexual dysfunction (FSD) is characterized as a multifactorial problem possibly related to factors such as physiological status, comorbidities and substance abuse. The hypoactive sexual desire disorder (HSDD) stands out among the most common FSD. Despite being an important clinical condition affecting a high number of women, it is still a poorly understood problem. It is mainly treated with non-pharmacological strategies, but its high impact on quality of life emphasizes the need for pharmacology advances to aid in the treatment (1-6). Flibanserin was firstly developed for depression treatment, but was considered ineffective and, despite evidence showing possible good results for HSDD, Boehringer Ingelheim decided to discontinue its development (October/2013). On August/2015 Sprout Pharmaceuticals licensed flibanserin for HSDD in premenopausal women in the USA. (1-3). This study evaluated the efficacy and safety of flibanserin for hypoactive sexual desire treatment.

#### METHODS:

A systematic review was performed using the Cochrane handbook. A search was performed in Medline (via Pubmed), The Cochrane Library (via Bireme), LILACS and the Centre for Reviews Dissemination (CRD). Two independent reviewers (IG, RN) performed the selection of potential papers in three phases (i.e. titles, abstracts and whole texts). A third reviewer (LL) analyzed the dissimilar results. Randomized controlled trials (RCT) comparing flibanserin to other therapies or placebo for HSDD treatment in premenopausal women were eligible. The quality of evidence and strength of recommendation were assessed using the GRADE system (7-9).

## RESULTS:

Five RCT were included comparing flibanserin to placebo in HSDD treatment, whose quality ranged from moderate to low. All RCT included women in premenopausal, over 18 years, and in all studies women were not exposed to other type of treatment. Most studies showed superior clinical efficacy of flibanserin compared with placebo, using parameters of satisfying sexual events, FSFI desire domain score, FSFI total score, FSDS-R (Item 13) and total score. The administration of 100 mg flibanserin once daily at bedtime seems to be more effective. The main adverse events identified were somnolence, dizziness, nausea, fatigue and headache.

## CONCLUSIONS:

Flibanserin 100 mg/day can be considered effective for the pharmacological treatment of HSDD in premenopausal women when compared to placebo. Flibanserin safety profile in controlled/ experimental environments was satisfactory. It is noteworthy that it is unknown if it adds to the non-pharmacological strategies. Potential drug interactions with other drugs and alcohol can cause serious adverse events which emphasize the importance of pharmacovigilance and training of health professionals involved in prescribing and dispensing flibanserin.

## REFERENCES:

1. Fisher H, Aron A, Brown LL. Romantic love: an fMRI study of a neural mechanism for mate choice. *J Comp Neurol*; 2005. v. 493, p. 58-62.
2. Kaplan D. Female sexual dysfunction: diagnosis and treatment in 2002. *Patient Care*; 2002. v. 36, p. 15-24.
3. American Psychiatric Association DSM-IV. Manual de Diagnóstico e Estatística das Perturbações Mentais. 4ª ed. Lisboa. Climepsi Editores; 1996. p. 505-24.
4. Lara LAS et al. Abordagem das disfunções sexuais femininas. *Rev. Bras. Ginecol. Obstet*; 2008. v. 30,

n. 6, p. 312-321.

5. Boehringer Ingelheim. Briefing document, Flibanserin Tablet, NDA22-526. Reproductive Health Drugs Advisory Committee Meeting. 2010. Available at:.

6. Gellad WF, Flynn KE, Alexander GC. Evaluation of Flibanserin & Science and Advocacy at the FDA. *JAMA*; 2015. v. 314, p.869-870.

7. Higgins J, Green S. *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0: The Cochrane Collaboration*; 2011. Available from: [www.cochrane-handbook.org](http://www.cochrane-handbook.org).

8. Guyatt G, Oxman A, Kunz R, Falck-Ytter Y, Vist G, Liberati A, et al. GRADE: going from evidence to recommendations. *British Medical Journal*. 2008;336:1049-51.

9. Guyatt G, Oxman A, Vist G, Kunz R, Falck-Ytter Y, Alonso-Coello P, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *British Medical Journal*. 2008;336:924-6.

---

## Poster 136B HTA Capacity Building And Institutionalization: The Case Of Bulgaria

### DESCRIPTION:

In the context of exponentially growing number of health technologies and increasing health needs of the population, the Ministry of Health in Bulgaria executed the first decisive step for the implementation of transparent, robust, and evidence-based methods of HTA by adopting a new legislative act - Ordinance No. 9 from December 11, 2015 - determining the conditions and procedures for health technologies assessment. Despite the political consensus, the HTA capacity building in Bulgaria is in its very early stage. The successful institutionalization of HTA structure, especially in a small country, requires

healthcare policy reforms explicitly supported by all stakeholders.

**PRESENTING AUTHOR:**

Ralitsa Raycheva, Medical University Plovdiv, Bulgaria

**AUTHORS:**

Ralitsa Raycheva, Rumen Stefanov

**BACKGROUND AND OBJECTIVES:**

In the context of exponentially growing number of health technologies and increasing health needs of the population, the Ministry of Health in Bulgaria execute the first decisive step for the implementation of transparent, robust and evidence-based methods of HTA by adopting new legislative act - Ordinance No. 9 from December 11, 2015 determining the conditions and procedures for health technologies assessment. The international survey on HTA was designed to gain information about the present status of HTA activities; to examine its institutional contexts and the kind of application of its principles, logic, methods and tools; and to design a theoretical framework for capacity building and institutionalization of HTA practices. As a result in order to satisfy the specific Bulgarian settings a flexible framework for HTA was rendered.

**METHODS:**

The method used was international Web-based survey of HTA organizations with diversified profile, collated by merging the information from various sources. During 2013 - 2015 an extensive survey of HTA activities was conducted among 386 organizations in 83 countries, including 11 international organizations. Data were obtained by semi-structured questionnaire, which contained 102 questions incorporated in six different panels, one specific section and two information segments with a total of 71 multiple choice and 31 open questions.

**RESULTS:**

Based on the results of the survey a dynamic interactive model for capacity building and institutionalization of HTA structure was established. Regarding the model Bulgarian settings need improvement in all three dimensions of the model - micro, macro and mezzo - and their corresponding internal levels. Although the newly adopted Ordinance outlines the frameworks of HTA process, there are a lot of significant gaps that have to be properly addressed & lack of strategy for financial support of the agency, underdeveloped international cooperation, lack of approach for active stakeholder involvement, lack of sufficient number of well-trained Bulgarian experts or strategy for recruiting advisors or consultants.

**CONCLUSIONS:**

Despite the political consensus the HTA capacity building in Bulgaria is in its very early stage. The successful institutionalization of HTA structure, especially in a small country, requires healthcare policy reforms explicitly supported by all stakeholders.

.....  
**Poster 137B Medical Devices:  
From Licensing To Coverage.  
Highlights From Argentina,  
Brazil, Colombia, And Mexico**

**DESCRIPTION:**

The objective of this study is to assess, describe, and compare the requirements and pathways of medical devices from licensing to coverage in four Latin American countries (LAC) health systems. The processes for licensing and reimbursement in these Latin American countries are formally similar to that of drugs, without taking into account the particularities of medical devices.

**PRESENTING AUTHOR:**

Sebastián García Martí, IECS, Argentina

## **AUTHORS:**

Rey-Ares Lucila, Hernández-Vásquez Akram, Garay Ulises, Pichon Riviere Andres, García Martí Sebastián, Galardono Ramiro, Cabra Hermilo, Augustovski Federico

## **BACKGROUND AND OBJECTIVES:**

Medical devices have become important in world's health systems due to rising costs and risks of use. The wide availability of devices for use in a wide spectrum of health problems is a challenge for decision makers who must prioritize the selection and acquisition taking into account various priorities such as disease burden and availability of resources. Objectives: To assess, describe and compare the requirements and pathways of medical devices from licensing to coverage in four Latin American countries (LAC) health systems.

## **METHODS:**

We conducted a literature search (February 2015) on Pubmed, Lilacs and Value in Health Regional Issues journal. We also searched specific websites of Health Technology Assessment (HTA) and regulatory agencies, ministries of health and health agencies; and performed generic Internet search. We included all publications describing aspects related to regulation, coverage, and HTA and Economic Evaluation (EE) guidelines, specifically reviewing device specific content. We additionally interviewed key informants from included countries to gather complementary information.

## **RESULTS:**

We included 74 publications out of the retrieved 2369. The licensing process is similar in the four countries, as well as to the rest of the world. The decision-making process for the inclusion of a new device in benefits packages in the four countries is not formally different than that used for drugs. Although there are some differences between the four countries, in general Brazil, Colombia and Mexico had a similar explicit process informed by HTA and EE, with different degree of involvement of different stakeholders. A unique characteristic

of medical devices is that health systems (with the exception of Mexico) focus coverage on procedures -including a medical device- without specification of the brand or model, and for that reason they may reimburse different devices for the same procedure without making explicit one by one device evaluation.

## **CONCLUSIONS:**

The process for licensing and reimbursement in these Latin American countries are formally similar to that of drugs, without taking into account the particularities of medical devices. They also allow the adoption of medical devices without a comprehensive assessment, and in some cases without even being evaluated.

---

## **Poster 138B Dynamic Interactive Model For Capacity Building And Institutionalization Of An HTA Structure**

### **DESCRIPTION:**

Based on an international survey held 2014-2015, we propose a dynamic interactive model for capacity building and institutionalization of HTA structure. The model is not a static framework or strict step-by-step algorithm for HTA capacity building, but on the contrary is a dynamic framework that integrates the three interrelated macro, meso, and micro levels. The implementation of iterative and recursive processes in the model enables synchronization, harmonization, and the overall balance of the HTA activities and meets the needs of all three levels.

### **PRESENTING AUTHOR:**

Ralitsa Raycheva, Medical University Plovdiv, Bulgaria

### **AUTHORS:**

Ralitsa Raycheva, Rumen Stefanov

## **BACKGROUND AND OBJECTIVES:**

Globally, the exponential evolution of multidisciplinary methodology for health technology assessment, results in capacity building of formal HTA bodies. Although, the main purpose is the same, the institutionalization of these structures has to be harmonized with the national and local settings in which they are located and work in order to address the specifics of decision making processes, legal and socio-cultural norms.

Objectives: The international survey on HTA was designed to gain information about the present status of HTA activities; to examine its institutional contexts and the kind of application of its principles, logic, methods and tools; and to design a theoretical framework for capacity building and institutionalization of HTA practices.

## **METHODS:**

The method used was international Web-based survey of HTA organizations with diversified profile, collated by merging the information from various sources. During 2013 - 2015 an extensive survey of HTA activities was conducted among 386 organizations in 83 countries, including 11 international organizations. Data were obtained by semi-structured questionnaire, which contained 102 questions incorporated in six different panels, one specific section and two information segments with a total of 71 multiple choice and 31 open questions.

## **RESULTS:**

A total number of 161 questionnaires from 39 countries on 6 continents were received representing a 41.70% response rate. Based on the analyses of the results, a dynamic interactive model for capacity building and institutionalization of HTA structure was designed. The model includes three interrelated levels 1) macro, meso and micro level. Macro environment - exogenous for the organization 2) includes economic, political, legal, socio-cultural, physical and institutional dimensions. Meso environment 3) transition zone

between the macro and micro environment - includes stakeholders, external to the organization experts and consultants and international relations and cooperation. Specific to this environment, within the context of HTA structure, is the ability to pass its representatives between macro and micro levels, depending on the role they need to perform at a given time of the assessment. Micro level, the endogenous setting of the organization, includes management hierarchy, priority setting process, human resources, training and staff expertise, shared values, dissemination and impact.

## **CONCLUSIONS:**

The model we propose is not a static framework or strict step-by-step algorithm for HTA capacity building, but on the contrary is a dynamic framework that integrates the three interrelated macro, meso and micro levels. The implementation of iterative and recursive processes in the model enables synchronization, harmonization and the overall balance of the HTA activities and meets the needs of all three levels.

---

## **Poster 139B Waiting Time In CT And MRI Scan Services In China**

### **DESCRIPTION:**

With the expansion of basic medical insurance schemes and socio-economic status improvement, the supply of CT and MRI services gradually do not meet the demand from patients, thus causing long waiting time especially in some general hospitals. So this study will focus on patients' waiting time for using CT and MRI scan services in China.

### **PRESENTING AUTHOR:**

Zude Guo, School of Public Health, Fudan University, China

### **AUTHORS:**

Jinsong Geng, Bosheng Wu, Hao Yu, Yingyao Chen

## BACKGROUND AND OBJECTIVES:

Although high technology medical equipment, such as CT and MRI, has become widely used in Chinese hospitals over the past decade, few studies have examined patients' waiting time for using the equipment. This study aims to fill the gap in the literature.

## METHODS:

This study applied a multi-stage sampling method. First, 12 tertiary hospitals were selected from six provinces that are located in East, Middle, and West China. Second, all the CT scans and MRI scans received by the patient in the study hospitals in one entire month (i.e., August 2014, which is the month right before the field study), were selected. The study sample included 39,609 CT scans and 16,321 MRI scans. Waiting time is defined as the period between the time of a doctor's prescribing a CT/MRI scan order and the time of a patient's receiving the ordered scan. For statistical analysis, both parametric and nonparametric (e.g., Wilcoxon signed-rank test) methods were applied.

## RESULTS:

The median time that patients had to wait for CT scans was about 2.4 hours, while the median waiting time for MRI scans was 20.1 hours. Inpatients had much longer waiting time than outpatients (CT 9.2h vs. 1.4h, MRI 24.1h vs. 11.4h). From the Wilcoxon signed-rank test, we found a significant variation in waiting time for both CT and MRI between patient types (outpatient vs. inpatient), geographical regions (east, middle, west), and city levels (provincial capital vs. noncapital).

## CONCLUSIONS:

There is a significant variation in waiting time for CT and MRI scan services across regions and cities in China. Such a variation needs to be considered in the ongoing health care reform in China, especially in the current revision of the certificate of need policy for allocating high technology medical equipment across Chinese provinces and cities.

---

## Poster 140B A New HTA System For Japan - Simulating Potential Effects On Drug Prices

### DESCRIPTION:

Japanese authorities announced the plan to introduce a HTA system in 2016. We argue that it is not clear that a new HTA system would reduce public health care expenditure in Japan, because drug prices in Japan are already tightly regulated. This assertion is confirmed by a simulation using a hepatitis C drug as an example.

### PRESENTING AUTHOR:

Dr. Joerg Mahlich, Janssen KK & University of Duesseldorf, Germany

### AUTHORS:

Jörg Mahlich, Bruno Rossi, Yoichi Sasatani, Isao Kamae

### BACKGROUND AND OBJECTIVES:

Japanese authorities announced the plan to introduce a HTA system in 2016. We aim at assessing the potential impact of such a policy on drug prices.

### METHODS:

Taking the antiviral drug Simeprevir (Olysio®, Sovriad®) as an example, we compare the current Japanese price with hypothetical prices that would result if an UK (cost-utility) or German (efficiency frontier) style HTA assessment would be in place.

### RESULTS:

Depending on the comparator and the approach employed and if HTA was used as a basis for price setting, Simeprevir prices would be up to four times higher than under the current Japanese pricing scheme.

## CONCLUSIONS:

Although the analysis is based on only one drug, it cannot be taken as granted that a new HTA system would reduce public health care expenditure in Japan.

---

## Poster 141B Involving The Public In The Development Of An Horizon Scanning Website: Experiences From Two Focus Groups.

### DESCRIPTION:

Involving the public in research and healthcare decision making is becoming the norm. Since 2012, the National Institute for Health Research Horizon Scanning Research and Intelligence Centre (NIHR HSRIC) has explored different ways to do this in their early awareness and alert (EAA) activities. This session will describe the experiences of using focus groups with the public to make the HSRIC's website more accessible and informative for the public.

### PRESENTING AUTHOR:

Kathryn Miles, NIHR HSRIC University of Birmingham, United Kingdom

### AUTHORS:

K Miles, A Cook, M Mohamed

### BACKGROUND AND OBJECTIVES:

The NIHR Horizon Scanning Research and Intelligence Centre (HSRIC) aims to supply timely information to UK research commissioners and NHS policy makers in England on emerging health technologies that may have a significant impact on patients or the provision of health services.

Since 2012 HSRIC has aimed to investigate the potential benefits of increasing patient and public involvement and engagement (PPIE) in early

awareness and alert (EAA) activities, and to identify areas of work where we can build and strengthen mutually advantageous relationships.

The HSRIC website is a key way that patients are able to engage with the work of the Centre and potentially become involved in what we do. To maximise these activities, two focus groups were held, 19 months apart, with members of the public to reflect on the accessibility, usability and signposting of certain aspects of the website.

### METHODS:

In April 2014 and November 2015 focus groups were held at the HSRIC's offices at the University of Birmingham, UK. For both focus groups participants were recruited from pre-existing local groups (a research project's PPI group and volunteers from a local University hospital). Both sessions focused on the 'suggest a topic' page and the website's search facility. The sessions involved participants using the live website, facilitator lead discussion and recording participants views on a flip chart. The second session considered the implemented changes from the previous session, also looking at the newly developed 'for the public' information page.

### RESULTS:

In 2014 and 2015 there were 3 and 8 attendees respectively. In 2014 comments on the 'Suggest a topic' page included a wish for a dynamic opening paragraph and indication of who gets the form on submission. Changes were made and in 2015 the group had no substantive comments on this page. The 2014 group commented that the search facility needed a help facility and the results needed to be presented more clearly. Both were introduced and the 2015 group were content with this, but made additional comments. The 2015 group made numerous comments on the 'for the public' page.

### CONCLUSIONS:

Working with members of the public provided important insights on the usability of the HSRIC's

website. Comparison will be drawn between these two focus groups and key findings, learning and limitations will be discussed.

---

## Poster 142B Can Lack Of Clinical Utility Be Used As A Reason For Disinvestment Of Investigative Tests?

### DESCRIPTION:

This presentation will cover examples of when disinvestment decisions have been made, based on the lack of clinical utility (health benefit) of an investigative test, rather than inferior accuracy. The importance of a linked evidence approach for disinvestment as well as investment will be discussed.

### PRESENTING AUTHOR:

Skye Newton, Adelaide Health Technology Assessment, School of Public Health, The University of Adelaide, Australia

### AUTHORS:

Jacqueline Parsons, Skye Newton, Tracy Merlin

### BACKGROUND AND OBJECTIVES:

The field of HTA has progressively been acknowledging that decisions regarding the effectiveness of an investigative test, should consider not only the accuracy of the test, but how that information is used, and the downstream health consequences of both true and false results, after the subsequent management changes. If direct evidence, following patients from testing to health outcomes, is not available, these individual steps of accuracy and clinical utility can be assessed, using a 'linked evidence approach'. Within the reimbursement sphere, the use of linked evidence is growing. Currently, however, there are no known examples of the linked evidence approach being used for disinvestment, or removal

of reimbursement. This review will attempt to provide an overview of current methodology, and trial the assessment of clinical utility, for investigative tests reimbursed in Australia.

### METHODS:

A search of published literature and a survey of HTA groups and reimbursement agencies websites will be performed, to try and identify cases of disinvestment decisions being made regarding investigative tests, and whether anything other than accuracy was assessed. Some case studies will then be performed, assessing whether evidence regarding treatment effectiveness has changed for any of the investigative tests that the Australian Medical Services Advisory Committee have recommended for reimbursement in the last 15 years, and discussing possible implications.

### RESULTS:

Results will be presented at HTAi 2016. If no existing case studies of disinvestment due to lack of clinical efficacy are identified, examples of investigative tests that may be eligible for disinvestment due to lack of clinical efficacy, identified through the United States and Australian Choosing Wisely initiatives will be discussed.

### CONCLUSIONS:

Methodology surrounding disinvestment is developing, and the use of a linked evidence approach should be considered as part of this growing field.

---

## Poster 143B A Proposal To Improve Quality Indicators Assessment Of Managed Health Care In Health Insurance In Brazil.

### DESCRIPTION:

This study aims to review the current health care quality indicators used by the Brazilian Regulatory Agency and to propose quality indicators, especially focused on process and results, that improve managed health care assessment in Health Insurance in Brazil. Specific population groups and a few lines of care according to the Brazilian morbidity and mortality profiles should restructure this monitoring.

### PRESENTING AUTHOR:

Dr. Gisele Alexandre, UFF - Universidade Federal Fluminense, Brazil

### AUTHORS:

Aluísio Silva Junior, Marcia Alves, Gisele Alexandre

### BACKGROUND AND OBJECTIVES:

The health care quality provided by private health plans in Brazil is currently evaluated by a series of different indicators without any possibility of assessment by beneficiaries specific characteristics. Knowing in advance that disease process occurs differently in individuals, it has been recommended that health care data should be evaluated and monitored, at least by gender, by age or lifecycle, by region of the country and also by health condition. This study aims to review the current health care quality indicators used by the Brazilian Regulatory Agency and to propose quality indicators, especially focused on process and results, that improve managed health care assessment in Health Insurance in Brazil. Specific population groups and a few lines of care according to the Brazilian morbidity and mortality profiles should restructure this monitoring.

### METHODS:

This study analyzed national and international experiences focused on health care quality monitoring indicators of the Brazilian Ministry of Health (DATASUS); The Oswald Cruz Foundation (PROADESS); the Health Ministry Performance Index (IDSUS); The National Health Service (NHS); The National Committee for Quality Assurance (NCQA) and The Center for Disease Control and Prevention (CDC). In addition, searches were conducted in PubMed and BIREME databases between May and August 2015 in order to seek the best available evidence on this topic. After a critical review of the documents, there were suggested some indicators to improve the health care quality assessment in Health Insurance.

### RESULTS:

The critically review suggests that the quality monitoring indicators should contemplate both lines of care, as diabetes, câncer, hypertension, obesity, pregnancy, and life cycles, as infants, adolescentes, adults and elderly, for medical and dental care. It should be take into account that these indicators construction are directly related to the quality of the information that is obtained regarding to the consultation, hospital admission, examination, gender and age of the operator's beneficiaries in the period studied. It is recommended to approach the setting of indicators used by the Brazilian Regulatory Agency to Brazilian own experiences, as well as the international ones.

### CONCLUSIONS:

The indicators proposed to monitor health care quality provided by private health plans should reflect the best experiences studied, approaching the set of indicators used by the Brazilian Regulatory Agency to those used by NHS; NCQA; IDSUS; DATASUS and PROADESS. In these experiences, all indicators used are analyzed by gender, lifecycle, health condition and health region, although they are not grouped in this way. This proposal should contribute to the improvement of Operators Qualification Program

through the better assessment of managed health care in Health Insurance.

## REFERENCES:

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ). National Healthcare Quality Report,. p. 79-82., 2005

BRASIL. Índice de Desempenho do SUS. Disponível em: <http://idsus.saude.gov.br/apresentacao.html>.

COMISSÃO EUROPEIA. Disponível em [http://ec.europa.eu/health/indicators/echi/list/index\\_en.htm](http://ec.europa.eu/health/indicators/echi/list/index_en.htm).

DONABEDIAN. The quality of Care: how Can It be Assessed? In: Journal of American Medical Association. EUA, vol. 260 nº 12, p.1743-1748, 1988.

FUNDAÇÃO OSWALDO CRUZ. Avaliação do Desempenho do Sistema de Saúde. Disponível em <http://www.proadess.icict.fiocruz.br/index.php?pag=princ>.

HEALTH INDICATORS WAREHOUSE. Disponível em: <http://www.healthindicators.gov/>.

INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES & IOM. Committee on Quality of Health Care in América. Crossing the Quality Chasm: a new health system for the 21st century, 2001 [www.iom.edu/.../media/Files/Report%20Files/2001/Crossing-the-Quality Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf](http://www.iom.edu/.../media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf)

JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS - JCAHO. The Measurement Mandate & on the Road Performance Improvement in Health Care. Chicago IL, Department of Publications, 1993. 53p.

NATIONAL COMMITTEE FOR QUALITY ASSURANCE. Disponível em: <http://www.ncqa.org/HEDISQualityMeasurement.aspx>.

NATIONAL HEALTH SERVICE. Disponível em <http://www.nhs.uk/NHSEngland/thenhs/about/Pages/overview.aspx>.

PROADESS, 20015. FIOCRUZ, disponível em <http://www.proadess.icict.fiocruz.br/index.php?pag=matp>

---

## Poster 144B Quality Monitoring Program Of Service Providers In Health Insurance In Brazil

### DESCRIPTION:

Quality Evaluation System for Health Insurance covers the domains: security; effectiveness; efficiency; equity of care; access and patient centeredness. This study reviewed domains indicators to restructure the Quality Monitoring Program of Service Providers in Health Insurance in order to increase its assessment capacity, availability of information to enable the choice of providers by operators and beneficiaries of health insurance companies.

### PRESENTING AUTHOR:

Dr. Gisele Alexandre, UFF - Universidade Federal Fluminense, Brazil

### AUTHORS:

Aluísio Silva Junior, Ricardo Lima, Marcia Alves, Gisele Alexandre

### BACKGROUND AND OBJECTIVES:

Systems that evaluate the quality of service providers in the health insurance must be based on valid information that allows results comparability. Indicators may be used to disseminate quality of care information, both to beneficiaries, in order to increase their ability to choose, as to providers, aiming at the promotion of improvement strategies performance and also to operators of health care private plans, focused on the improvement of health care quality in providers network. The domains evaluated were based on the axes of the Quality Evaluation System for Health Insurance: security; effectiveness; efficiency; equity of care;

access and patient centeredness. This study aims to contribute, through critical review of its indicators to restructure the Monitoring Quality Program of Service Providers in Health Insurance in order to increase its assessment capacity, information availability to enable the choice of providers by operators and beneficiaries of health insurance companies.

## **METHODS:**

This study reviewed the best evidence available for the definition of quality care indicators in PubMed and BIREME databases and analyzed national and international experiences in the evaluation of service providers. The domains evaluated were: security; effectiveness; efficiency; equity of care; access and patient centeredness. The experiences and indicators studied were from the Brazil Ministry of Health; The Performance Index Unified Health System; the DATASUS indicators; experiences of the Oswaldo Cruz Foundation; the European Commission on Public Health, the National Health Service, the National Committee for Quality Assurance and the Center for Disease Control and Prevention.

## **RESULTS:**

There was a confluence in the experiences for three areas related to health services and care provision: Effectiveness, Safety and Patient Experience. As used in others experiences, the Effectiveness domain was strengthened as a potential response to indicators used to evaluate structural and results aspects of health interventions, and the domains Access and Equity of Care were incorporated to it. These changes and the Patient Centeredness could point trends in patient perception in terms of solving their problems. These indicators offer information to fulfill the main goal of the Quality System and the interface between actors of health insurance.

## **CONCLUSIONS:**

By analyzing the national and international experiences, we regrouped the 3 domains'

indicators towards the main objective, which is to provide healthcare quality information that: enhances better choices by beneficiaries, aids operators in investing in more effective care networks, and enhances health providers processes and performances. It is expected that this proposal favors the Monitoring Quality Program of Service Providers in Health Insurance in Brazil and contributes to the improvement of the Regulatory Agency. More studies need to evaluate these indicators capacity to reflect valid information.

## **REFERENCES:**

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ). National Healthcare Quality Report., p. 79-82., 2005

BRASIL. Índice de Desempenho do SUS. Disponível em: <http://idsus.saude.gov.br/apresentacao.html>. Acesso em 01 de agosto de 2015.

COMISSÃO EUROPEIA. Disponível em [http://ec.europa.eu/health/indicators/echi/list/index\\_en.htm](http://ec.europa.eu/health/indicators/echi/list/index_en.htm). Acesso em 01 de agosto de 2015.

DONABEDIAN. The quality of Care: how Can It be Assessed? In: Journal of American Medical Association. EUA, vol. 260 nº 12, p.1743-1748, 1988.

FUNDAÇÃO OSWALDO CRUZ. Avaliação do Desempenho do Sistema de Saúde. Disponível em <http://www.proadess.icict.fiocruz.br/index.php?pag=princ>. Acesso em 01 de agosto de 2015.

HEALTH INDICATORS WAREHOUSE. Disponível em: <http://www.healthindicators.gov/>. Acesso em 01 de agosto de 2015.

INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES & IOM. Committee on Quality of Health Care in América. Crossing the Quality Chasm: a new health system for the 21st century, 2001 [www.iom.edu/.../media/Files/Report%20Files/2001/Crossing-the-Quality Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf](http://www.iom.edu/.../media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf)

JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS - JCAHO. The

Measurement Mandate - on the Road Performance Improvement in Health Care. Chicago IL, Department of Publications, 1993. 53p.

NASCIMENTO-SILVA, V.M; SILVA JUNIOR, A.G; PINHEIRO, R. O caráter formativo da avaliação e a integralidade: reflexões teóricas. In: PINHEIRO, R.; SILVA JUNIOR, A.G. (orgs.). Por uma Sociedade Cuidadora. Rio de Janeiro: CEPESC-IMS-UERJ/ ABRASCO, 2010. p. 307- 316.

NATIONAL COMMITTEE FOR QUALITY ASSURANCE. Disponível em: <http://www.ncqa.org/HEDISQualityMeasurement.aspx> . Acesso em 01 de agosto de 2015.

NATIONAL HEALTH SERVICE. Disponível em <http://www.nhs.uk/NHSEngland/thenhs/about/Pages/overview.aspx>. Acesso em 01 de agosto de 2015.

PINHEIRO, R; SILVA JUNIOR, A.G.; MATTOS, R.A; (org.). Atenção Básica e Integralidade: contribuições para estudos de práticas avaliativas em saúde. Rio de Janeiro: Cepesc, 2008. p.215-224.

PROADESS, 20015. FIOCRUZ, disponível em <http://www.proadess.icict.fiocruz.br/index.php?pag=matp>

SANTOS-FILHO, S B. Perspectivas da avaliação na Política Nacional de Humanização em Saúde: aspectos conceituais e metodológicos. Ciênc. saúde coletiva.v.12(4) 2007:999-1010.”

---

## Poster 146B How Asia-Pacific Patients Perceive Impact Of UHC And HTA On Orphan Drug Access

### DESCRIPTION:

Rare disease associations that are well organized perceive they can influence service and coverage issues, but mostly through (external) advocacy

rather than (internal) roles within the policy-making processes. However, most rare disease patient groups have little engagement with policy makers on universal health coverage (UHC) and HTA.

### PRESENTING AUTHOR:

Dr. Durhane Wong-Rieger, Institute for Optimizing Health Outcomes, Canada

### AUTHORS:

Durhane Wong-Rieger, William Claxton, John Forman, Ramiah Muthyala, Lea Prujean, Yukiko Nishimura, Kevin Huang Rufang, Prasanna Kumar Shirol

### BACKGROUND AND OBJECTIVES:

While all patients in Asian countries, especially those in low-and-middle income countries (LMIC), welcome the introduction of universal health coverage (UHC), rare disease patients may wonder how, or if, they will be included. Moreover, per recommendations of WHO, as HTA is introduced to attempt ‘cost-effective’ allocation of health resources, including medicines, these patients may justifiably be concerned that the process will preclude orphan drugs among ‘essential medicines.’ Worldwide, rare disease patient organizations have formed not only to advocate for development of orphan drugs but also to obtain access to clinical trials and effective therapies. The purpose of this research was to determine how rare disease patients in Asia-Pacific countries perceive the potential impact of UHC and HTA on orphan drug access.

### METHODS:

The Asia-Pacific Alliance of Rare Disease Patient Organizations (APARDO) surveyed representatives for their knowledge of (the implementation of) UHC and HTA in each of their respective countries as well as their perceptions of the (potential) impact on access to rare disease drugs. The survey was conducted via Survey Monkey and sent to the patient group representatives with a request for further distribution to potentially knowledgeable

members. Countries represented by the groups surveyed were: Singapore, China, Malaysia, Taiwan, Japan, India, Hong Kong, Philippines, Australia, and New Zealand. Findings were analyzed by country and summarized across the region.

**RESULTS:**

Preliminary results indicate that patient representatives are somewhat knowledgeable about their country's implementation and plans for UHC but have less knowledge about the implementation and/or plans for formal HTA to address resource allocation. All representatives perceive rare diseases as under-serviced relative to more common diseases, regardless of the healthcare services in place, although the degree of disparity varies across countries. Some countries have rare disease programs (national and/or local) but most do not have orphan drug policies (or practices). Perceptions of impact of UHC and HTA for access to orphan drugs were neutral to negative.

**CONCLUSIONS:**

These results suggest that rare disease patients do not perceive UHC as necessarily inclusive of their needs and, for the most part, the introduction of HTA as not supporting access to therapies. Rare disease associations that are well organized perceive they can influence service and coverage issues but mostly through (external) advocacy rather than (internal) roles within the policy-making processes. However, most rare disease patient groups have little engagement with policy makers on UHC and HTA, and these are important gaps going forward in the region.

.....

## Poster 147B Including The Poor In Indonesia's National Health Insurance In West Java Province: A Stakeholder Analysis.

**DESCRIPTION:**

In January 2014, Indonesia introduced their National Health Insurance scheme which aims to cover every Indonesian by the year 2019. To improve targeting of the poor, creating a single regional center of expertise that bypasses the RT is perceived as a feasible option and can help form one shared perception between government bodies, allows monitoring, and is more straightforward.

**PRESENTING AUTHOR:**

Maarten Jansen, Radboud University Medical Center, Netherlands

**AUTHORS:**

Maarten Jansen

**BACKGROUND AND OBJECTIVES:**

In January 2014, Indonesia introduced their National Health Insurance scheme called Jaminan Kesehatan Nasional which aims to cover every Indonesian by the year 2019. Targeting of previous programs was sub-optimal. This qualitative study evaluates the targeting process used to exempt the poor in the West Java province of Indonesia from paying premiums, identifies barriers to optimal targeting, and provides policy advice to improve targeting.

**METHODS:**

Semi-structured qualitative interviews were conducted with 20 stakeholders involved in targeting the poor within West Java province. Interviews asked about steps from the analytical framework for interventions targeting the poor in low and middle income countries. Subsequently,

interviews were transcribed, coded, triangulated, and summarized.

## RESULTS:

The analysis revealed communication and coordination among different government bodies is weak or lacking. Furthermore, mistargeting still remains everyday practice in the field due to a lack of monitoring and updates to the national database of poor people, called the PBI database. At the same time, the local neighborhood representative, called the RT, functions as an unmonitored gatekeeper to local programs. In addition, the referral process used by local programs, the so-called SKTM process, is perceived as being too difficult, driving poor people to use the cheap level 3 payment scheme of the National Health Insurance program instead of receiving free membership.

## CONCLUSIONS:

To improve targeting of the real poor, creating a single regional center of expertise that bypasses the RT is perceived to be a feasible option and can serve as a breeding ground for the formation of one shared perception between government bodies, allows monitoring, is more straightforward and should be provided with the authority to withdraw cards if needed. Results from this study should be considered when evaluating targeting in different provinces and low- and middle income countries. A study limitation is the potential selection bias of stakeholders and possible underrepresentation of relevant stakeholders from rural areas within the province.

---

## Poster 150B Budget Impact Of Long-Acting Insulin Analogues In Brazil

### DESCRIPTION:

A budget impact analysis of long-acting insulin analogues compared to NPH in the perspective

of Brazilian public health system. We applied an innovative method to approximate the model to reality, the bargaining power of centralized purchases from Ministry of Health. The results were favorable and lower than previous estimates used by Ministry to deny the coverage of these insulins.

### PRESENTING AUTHOR:

Fernanda Laranjeira, University of Brasília, Lab of Evidence-based Health Research and Scientific Communication, Brazil

### AUTHORS:

Fernanda Laranjeira, Everton Nunes da Silva, Maurício G. Pereira

### BACKGROUND AND OBJECTIVES:

Type 1 diabetes (T1D) affects 0.35% of Brazilian population. Human insulins currently available in the public health system are not able to guarantee appropriate treatment for all T1D patients. In 2014, the Ministry of Health of Brazil denied the coverage of insulin analogues based on huge budget impact. Our aim is to estimate the incremental budget impact of long-acting insulin analogues (LAIA) for T1D patients in the Brazilian public health system compared to the current scenario with NPH insulin.

### METHODS:

We carried out a budget impact analysis of LAIA compared to NPH insulin. Target population was estimated: 11.6 million diabetic adults x 5% T1D plus 31100 children and 10845 adolescents. Incidence was 10.4/100,000 children per year and mortality 23.15/1000 adults per year. Mean insulin dose was obtained from trials. For NPH prices, we considered last purchase of Ministry of Health. We calculated the bargaining power dividing NPH's average regulated price by the Ministry's last purchase price. We applied 50% of bargaining power to LAIA's regulated price. Market share was 50%-80% in five years. Uni and multivariate sensitivity analysis were performed.

## RESULTS:

The incremental budget impact of LAIA in Brazil was U\$71.4 million in the first year, considering 50% target population, reaching U\$108 million in the fifth year, with 80% target population. In five years of analysis, the total incremental budget impact was U\$470 million. The sensitivity analysis showed that the prevalence of T1D and LAIA's price are the main factors affecting the budget impact. Regarding the LAIA's price, under the assumption that Ministry of Health would obtain the same discount, the incremental budget impact would fall substantially, corresponding to a reduction of more than 35.7% (U\$470 million vs. U\$167.5 million).

## CONCLUSIONS:

Ministry of Health's budget impact estimates used to deny the insulin analogues were 32% higher than our analysis. We believe that our estimates turn budget impact closer to the willingness to pay value of Ministry of Health. The application of "bargaining power" proved to be the trump card of this study, with the use of more realistic profiles of resource utilization. Centralized purchasing reveals itself as the way to an affordable coverage.

.....



#HTAiTokyo2016

HTAi: International Society  
for the Promotion of Health  
Technology Assessment

[HTAi.org](http://HTAi.org)