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**Abstract Volume**



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## Workshops

### WS1

#### HTA 101: Introduction to Health Technology Assessment

Clifford Goodman

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**Background:** Introductory short course in HTA that will provide excellent foundation for the HTA 2014 annual meeting. Developed for international participants, including from public and private sector agencies, payers, clinicians, patients, industry, and others. Updated annually, this course has been a popular feature of HTA meetings for many years.

**Requirements/Prerequisites:** For all who are new to HTA or want a "refresher" overview and update with an international perspective.

**Description/Objectives:** HTA concepts, methods, and trends. Time is included for questions and discussion. Emphasizes adapting HTA approaches for all types of health technologies for diverse international settings. Main topics:

1. HTA origins, definitions, purposes, and roles
  - Factors and trends influencing demand for HTA
  - Factors affecting technology overuse, underuse
2. Health technology: types, applications, lifecycle
3. Properties and impacts assessed in HTA
  - Technical performance
  - Health outcomes
  - Quality of life
  - Economic
  - Ethical, legal, and social
4. HTA methods
  - Primary methods (RCTs, registries, surveillance, etc.)
  - Secondary/synthetic methods (systematic reviews, meta-analyses, modeling)
  - Economic analyses (CEA, cost/QALY, budget impact, etc.)
5. Evidence appraisal
  - Individual studies
  - Bodies of evidence
6. Priority setting, moving target problem, rapid reviews
7. Framework for conducting HTA
8. Sources of evidence, expertise, and collaboration (bibliographic databases, international networks/cooperation)
9. Selected topics
  - CER and new forms of data collection
  - Personalized medicine
  - Increased role of patients
  - Impact on innovation
10. Current HTA trends

### WS2

#### A Critical Perspective on Quality of Life and Qualitative Studies in Relation to Patients' Experiences in HTA

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**Background:** Demonstrating the added value of a health technology requires input from a wide range of sources. There is increasing interest in including patients' perspectives in HTA to understand what they value. Some popular mechanisms for hearing 'the patient voice' include use of patient reported outcomes in clinical studies, and submissions from patients in the HTA process. However, these methods are often not sufficiently targeted to identify the key issues that patients can tell us about living with an illness, its burden, and what they would value from a new technology to have a real impact on HTA.

**Requirements/Prerequisites:** There are no prerequisites to attend this workshop.

We request that this be held on 14 June 2014

**Description/Objectives:** This Patient and Citizen involvement in HTA Interest Sub-Group workshop will be introduced with an ethicist's perspective, followed by a former HTA Appraisal Committee Chair outlining the deliberations of an HTA Committee and where patients' experiences could have most impact. Patient value and the patient perspective will be presented in case studies and in discussing how the 'evidence from patient submissions' can be facilitated and strengthened through online guidance for patient organisations.

The types of information these 'personal experiences' provide will be explored and compared with patient-reported outcomes before moving the focus to use of qualitative research to collate 'patient-based evidence' and to explore how synthesis of qualitative research contributes to knowledge production of patient and carer perspectives. The workshop will end with a discussion on how to build collaboration between researchers, patient organisations, HTA and regulatory agencies, and industry to capture the patient perspective in HTA.

### WS3

#### Capacity Building in Agencies for Efficient and Effective HTA

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OSTEBA, Bilbao, Spain

**Background:** HTA yields information to address deficiencies in health systems and to create a wider understanding of the impact of different policy considerations around technology reimbursement and use. The structure of HTA programs varies from country to country according to decision maker needs, and conducting HTA requires specialized skills. Effective decision making can include multiple criteria (medical, economic, ethical, social, legal, cultural, etc.) and require multi-disciplinary teams of experts working together to produce assessments. This workshop explores the multi-disciplinary skills and competencies required to build an efficient and effective HTA team, with a focus on low and middle income settings.

**Requirements/Prerequisites:** There are no prerequisites for this workshop. Participants from different backgrounds and from different levels of health systems (e.g., national, regional, hospital) are encouraged to attend.

**Description/Objectives:** The workshop will discuss competency requirements of HTA agencies and approaches to train staff.

- What background do the professionals involved in HTA have?
- What areas of expertise or subject matter is required for HTA users and does to be part of a multi-disciplinary assessment team?
- What should we, as HTA doers, ask capacity building programs to cover?
- What approaches are being taken by various HTA bodies to provide effective and efficient building capacity programs and what advantages and disadvantages of these?

The workshop will help countries introducing HTA towards UHC and also help guide agencies hiring professionals for professionals wanting to improve their knowledge in using HTA.

This workshop will include presentations from agencies and educational programs followed by small group discussions.

The following additional presenters are to be confirmed:

IECS as a LMIC Country representative

EuroScan, EUnetHTA, and HTAsiaLink

International educational programs:

- Ulysses Program
- SCHARR

## WS4

### Analytical Decision Models for HTA: How to Choose a Distribution for My Probabilistic Sensitivity Analysis? Examples from Mental Health Data

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**Background:** Cost-effectiveness analysis has been increasingly used by decision makers for allocation of health care resources, mainly in the public health system (PHS) perspective. This methodology entails identification, measurement and comparison of costs and outcomes of competing health interventions. The objective is to maximize benefits to society by funding those interventions that generate the best outcomes using available resources. Model's parameters could be extracted from heterogeneous sources with distinct uncertainty grades. Clear understanding of the limitations of these data and knowledge on how to work with these constraints is of fundamental importance in conducting economic evaluation studies.

**Requirements/Prerequisites:** Basis concepts in Epidemiology and Statistics

**Description/Objectives:** The main objective of this course is to discuss how to deal with the uncertainty of data when conducting a sensitivity analysis in cost-effectiveness studies. This practical workshop intends to explore the rationale for choosing different distributions to the variables included in a probabilistic sensitivity analysis. During the course, practical data coming from published studies in mental health will be used, since some issues in psychiatry as the heterogeneity of outcome measures and diagnostic definitions brings an opportunity to discuss challenging topics. The following points will be addressed: a) Review of the main components to conduct a cost-effectiveness study; b) Rationale for modelling and an introduction of decision trees and Markov models; c) Identification of variables to build the models; d) Practical aspects of probabilistic sensitivity

analysis: how to choose distributions for model variables and how to use available data to setting up the parameters of those distributions.

## WS5

### Capacity Building for Information Retrieval for Health Technology Assessments (HTA)

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**Background:** Health care decisions should be based on the best available evidence. To provide decision-makers with an unbiased evidence base, HTA agencies need to have skills in searching and familiarity with the various aspects of information retrieval for HTA. In addition, it is important for agencies to facilitate services, resources, and processes that are needed for information retrieval for HTA. Through this capacity building workshop, the participants will learn about searching for HTA, discuss issues relevant to their own search practices and hear how other HTA organizations organize their services.

**Requirements/Prerequisites:**

- To be held on Saturday June 14th 2014 (in order to avoid collision with the other proposed HTAi IRG full day workshop which has been suggested on Sunday June 15th)
- A workshop room with a projector and Internet access
- Refreshments during the coffee breaks and lunch boxes (if possible)

**Description/Objectives:**

To alert participants to key issues regarding literature searching for HTA, as well as to services, resources and competencies that are needed for information retrieval for HTA.

**Content:** The workshop day will be divided in two sessions:

#### 1. Information retrieval aspects of HTA

This session will focus on important aspects of information retrieval for HTA, such as sources to search, how to design search strategies, reference management, and services that are required.

Mode of delivery: presentations and group discussions.

#### 2. Three case studies

Information specialists from 3 well-established HTA organizations (Canada, Norway and USA) will talk about issues such as how information retrieval activities are organized in their organizations, staff capacity, information retrieval processes, access to resources etc.

Mode of delivery: structured interviews, followed by discussion.

Target audience:

Researchers, administrators and information specialists from newly-established or established HTA organizations, who wish to gain knowledge in information retrieval issues.

## WS6

### Introduction to Ethics in Health Technology Assessment

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**Background:** The relevance of incorporating ethical analysis into an HTA is increasingly acknowledged.

Accordingly, there is a need for experts involved in HTA to learn and to apply methods that can be used to explore potential ethical implications of health care technologies.

This half day introductory course in Ethics in HTA combines lectures, discussions and case study group work. The Faculty who are leading this course is a group of international experts who have contributed substantially over the last several years to methodological developments in this area.

**Requirements/Prerequisites:** This course offers a lively introduction to the role of ethics for Health Technology Assessment (HTA) for those who are familiar with HTA, but who are not that familiar with ethics in HTA.

**Description/Objectives:** The course has been specifically developed for international participants and is based on more recent international achievements in the field. It will emphasize adapting approaches in ethics for all types of health technologies and across international settings. Participants who attend this course will strengthen their understanding and facilitate their participation in ethical assessment in HTA, as well their ability to participate in broader discussions. Most importantly it provides a number of approaches for 'how to' incorporate ethics into an HTA.

After the preconference workshop participants will be able to:

- explain and acknowledge the role of ethical issues in HTA,
- recognize potential ethical issues in HTA and formulate appropriate research questions,
- know and use methodology for analyzing ethical issues,
- know how to critically appraise primary research aimed at identifying ethical implications of health care technologies.
- describe different ways of synthesizing and communicating the results of ethics analyses.

## WS7

### HTA 102: Introduction to Hospital Based Health Technology Assessment (HB-HTA)

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**Background:** The decentralization process occurring in the HTA movement is an emerging phenomenon in many countries. Hospitals and other HCOs are facing an increasing pressure in relation to financial equilibrium and they are more and more interested in rational decision-making processes in order to select and adopt new health technologies (HTs).

The objective of this workshop is to introduce attendants to the principles and practice of Hospital Based HTA.

The main goals for this workshop are:

- 1) to identify the main features of health care organization's management;
- 2) to provide participants with the a general overview of the application of HTA methods and instruments in an health care organizations context (Hospital Based HTA)
- 3) understand how to prepare an hospital based HTA report.

**Requirements/Prerequisites:** During the course some exercise and working group are foreseen. According with the number of participants to the course more than one room or a larger room should required

**Description/Objectives:** First part the workshop introduces principles of management in the health care organisation's context and characteristics of HB-HTA

Then the course, through a deep exercise on a given technology, aim to apply principles of HB-HTA and offer to the students a way to develop their first HB-HTA report. The framework of the exercise is divided in two main steps.

In the first step, after a presentation by the teacher on a specific technology, students answer to a list of question according to their professional background (physicians, economists, engineers...) using a "vertical approach".

In the second step, students will be mixed in manner to have represented in each working group all professional background ("horizontal approach"), each group must prepare an HTA report on the device or drug chosen for the exercise.

At the end of the day each group will present his own conclusion and teacher will guide a discussion.

## WS8

### Evaluating Medical Tests for Coverage Decisions Using the Linked Evidence Approach

Tracy Merlin; Camille Schubert

Adelaide Health Technology Assessment (AHTA), University of Adelaide, Adelaide, Australia

**Background:** A linked evidence approach (LEA) is the synthesis of systematically acquired evidence on the accuracy of a medical test, its impact on clinical decision making and the effectiveness of consequent treatment options. The approach has been used to inform public funding decisions in Australia since 2005.

A decision framework has been developed to apply this approach so that evidence-based information on the safety, effectiveness and cost-effectiveness of new medical tests is provided to the decision-maker in the most efficient way. The framework has also been expanded for use in the evaluation of genetic tests that target or personalise drug therapies.

**Requirements/Prerequisites:** The workshop content assumes that participants have a working knowledge of the technical aspects of undertaking an HTA or have conducted HTAs of therapeutic interventions. However, it is assumed that workshop participants would have no prior experience with the HTA of new medical tests.

**Description/Objectives:** The workshop includes a mix of lectures and hands-on activities to cover both clinical and economic aspects of medical test evaluation. Key content areas include:

1. The HTA of investigative technologies
2. How test effectiveness is measured - overview of direct evidence and linked evidence methods
3. Interpretation and calculation of test accuracy measures
4. Critical appraisal of test accuracy studies
5. Application of a decision framework to determine what evidence is required to properly evaluate a medical test
6. Overview of the expansion of the linked evidence approach to evaluate co-dependent technologies (genetic test/drug therapy) - key clinical and economic modelling concepts

#### References:

- Merlin T, Lehman S, Hiller JE et al. The 'linked evidence approach' to assess medical tests: a critical analysis. *IJTAHC*, July 2013; 29(3):343-350.
- Merlin T, Farah C, Schubert C et al. Assessing personalized medicines in Australia: A national framework for reviewing codependent technologies. *Medical Decision Making*, April 2013; 33(3):333-342.

## WS9

### Implementing Principles and Quality Standards for Patient Engagement in HTA – a Journey Together

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**Background:** Many HTA organisations want to involve patients for the first time or improve the way in which they already involve patients, but the mechanisms for doing this are unclear. The HTAi Interest Sub-Group has been involved in an international research project to develop Values and Quality Standards to support continuous improvement in the journey of patient involvement in HTA. This has involved a literature search, workshops and a Delphi process to achieve consensus. This workshop will identify the facilitators and barriers to implementation of the Standards; and how they can best be used in different contexts and by different organisations.

**Requirements/Prerequisites:** There are no prerequisites for this workshop.

**Description/Objectives:** The workshop will consist of a mix of presentations, two breakout sessions and group discussion. We will present on the scientific background to the project and why we need Values and Quality Standards for patient involvement in HTA. We will outline experiences in different countries and the values of an international patient organisation. The first breakout session will enable facilitated discussion about how the various stakeholders can use the Quality Standards in different contexts. This will be reported back to the participants as a group to allow plenary discussion. The final breakout session will discuss the possible roles for the HTAi Interest Sub-Group for Patient/Citizen Involvement in HTA (PCISG) in increasing awareness of the Values and Quality Standards; and how their implementation by the different stakeholders across the globe can be supported. This workshop will inform the activities of the PCISG.

## WS10

### Optimizing Approaches to Finding the Evidence: Making Information Management More Effective, Efficient and Valuable

Dagmara Chojecki<sup>2</sup> Julie Glanville<sup>3</sup> Ghassan Karam<sup>6</sup> David Kaunelis<sup>1</sup> Carol Lefebvre<sup>4</sup> Monika Mierzwinski-Urban<sup>1</sup> Carolyn Spry<sup>1</sup> Lisa Tjostvold<sup>2</sup> Siw Waffenschmidt<sup>5</sup> Deborah A. Zarin<sup>6</sup>

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**Background:** The Information Resources Group (IRG) advanced skills workshop provides an opportunity for information specialists and others interested in information retrieval to network and discuss important issues in HTA information management and systematic review work. In order to optimize patient-centered care in an era of economic uncertainty, it is essential that scarce resources in HTA evidence-gathering and information retrieval are allocated efficiently and effectively. Continuous change in information retrieval and in the tools available to identify evidence means that information specialists must explore opportunities for efficiencies as they arise. This workshop is an annual exercise in that exploration.

**Requirements/Prerequisites:** o Podium with microphone and tables with 3 chairs for the speakers, microphone for participant questions from the floor

- Up to 40 chairs with attached/separate tables for workshop participants
- Laptop, data projector and internet connection with ready access to IT assistance
- Water for presenters and participants
- Vegetarian options at break (some presenters and participants are vegetarian)

**Description/Objectives:** This interactive workshop examines four aspects of the information retrieval process.

- #1: Clinical trial registers such as clinicaltrials.gov and the WHO ICTRP are widely established. But questions remain: Which trials registers should be searched? Do MEDLINE and other databases still need to be searched? How do we ensure that key trials are not missed? Are there other challenges?
- #2: In this era of economic uncertainty, HTA agencies are under increasing pressure to prove that the work they do has value and impact. Various impact analysis methods will be discussed, including citation/bibliometric analysis, altmetrics and website analytics.
- #3: Adverse events are relevant to patient-centered care. This session analyzes the performance of three CADTH adverse events search filters for MEDLINE and EMBASE.
- #4: Peer review is integral to scientific research. This session presents research results examining the effectiveness of peer review of search strategies on the number and quality of articles retrieved.

## WS12

### Measuring Utility for Health Technology Assessment Using EQ-5D and SF-6D Instruments

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**Background:** The use of preference-based measures of quality of life for health technology assessment has increased exponentially in the last decade. These instruments can generate the QALY (Quality Adjusted Life Years), an outcome measure recommended by several regulatory agencies such as the National Institute for Clinical Excellence (NICE) in the United Kingdom and the Panel on Cost-effectiveness in Health and Medicine of the US Public Health Service. Health-related quality of life (HRQOL) measures suitable for calculating QALYs are those that incorporate preferences into their scoring system, such as the EQ-5D and SF-6D which be presented in this workshop

**Requirements/Prerequisites:** Basic concepts in Health Technology Assessment

**Description/Objectives:** This course aims to introduce essential concepts of Quality of Life for economic evaluation and how to measure this outcome variable, using as examples two widely used instruments the EQ-5D and SF-6D. The following topics will be addressed in the course: a) Basic theoretical elements of Expected Utility; b) Measuring utility in health: basic concepts; c) QALYs as a measure of health utility; d) Generic measures of health status: EQ-5D and SF-6D; e) Preference elicitation methods: Standard Gamble and Time Trade Off; f) Using utilities in health technology assessment: estimation of QALYs; g) Estimations of social preferences using EQ-5D and SF-6D: Study and sample design, MVH Protocol, Instruments, Estimation methods; h) Experience of different countries; i) How to incorporate utility values in cost-effectiveness models



**WS13****Developing a Systematic Approach to Impact Evaluation of Publicly Funded Systems: Examples from Early Awareness and Alert Systems**

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**Background:** Evaluating systems that are funded by public monies is imperative. Early awareness and alert (EAA) systems are a recognised step in health technology assessment, increasingly being funded by governments around the world. Within the EuroScan International Network, evaluation of individual EAA systems is a topic that is frequently deliberated. Evaluations of systems generally fall into three categories: formative – to support the development of activity; evaluation to improve processes; and summative – to assess the final impact. Dimensions to be evaluated include the structure, process, and output. EuroScan is considering developing a tool for a systematic approach to evaluation of EAA systems.

**Requirements/Prerequisites:** Participants will have an interest in the evaluation of systems but no prior knowledge is necessary. The examples presented will focus on EAA systems but may be applicable to other HTA-related systems. Participants will be asked to join in round table discussions and will discuss the strengths, weaknesses, opportunities and threats impact evaluation and the different approaches to measuring impact.

**Description/Objectives:** The objectives of the workshop are to introduce evaluation of systems in general, to share examples of the evaluation of EAA systems and to allow participants time to discuss and work together to consider how the impact of systems can be evaluated in a systematic way. Ideas will contribute to the development of a tool for evaluating EAA systems.

The workshop will involve members of the EuroScan International Network who will present examples of evaluating different aspects of their systems. These will include using the following evaluation tools: analysis of technology usage data (before and after); questionnaires and web-based surveys of end users; bibliometric impact analysis; accuracy of identification and prediction; and timeliness of outputs in relation to launch. Participants will be presented with a framework incorporating proposed measures and tools to aid discussions and work towards developing a practical evaluation approach.

**WS14****Maximising the Value of Comparative Effectiveness Research for Patient Care in an Era of Economic Uncertainty - a Tale from Two Continents**

Thomas D Kenny<sup>1</sup> Joe Selby<sup>2</sup> Hilda Bastian<sup>3</sup> Stijn Tersmette<sup>4</sup> Eleanor Guegan<sup>1</sup>

1. National Institute for Health Research, Southampton, United Kingdom; 2. Patient Centered Outcomes Research Institute (PCORI), Washington, USA; 3. National Institute for Health, Washington, USA; 4. ZonMW, The Hague, Netherlands

**Background:** Never has maximising the value of Comparative Effectiveness Research (CER) been as vital as during the current international financial crisis. CER must offer value to patients and healthcare decision-makers, and provide optimum value-for-money to strengthen healthcare systems. Chalmers and Glasziou outlined sources of avoidable waste in the production and reporting of research<sup>1</sup>, and these

should be applied to CER. Research must be effectively targeted to the most important evidence gaps in healthcare and performed according to quality standards. Evidence-based reports enable healthcare decision-makers to identify the most effective and cost-effective options for patient care.

**Requirements/Prerequisites:** None

**Description/Objectives:** This workshop discusses the key stages of patient-centred CER management; identification & priority-setting, rigorous research performance, involvement of patients & the public, and production of easily accessible and usable reports that are complete and unbiased. Much can be learnt from approaches to the CER management process in different countries, and international communication and collaboration are very beneficial. This workshop brings together representatives from four CER agencies from Europe and the United States of America; the UK National Institute of Health Research Evaluation, Trials and Studies Coordinating Centre (NETSCC), the Netherlands Organisation for Health Research and Development (ZonMW), The US Patient Centered Outcomes Research Institute (PCORI) and the National Institutes of Health (NIH). This workshop will be useful for delegates who are interested in the maximising the use of resources to add value in CER for informing patient care and strengthening healthcare systems.

## Panels

### PN1

#### A Step Forward: Integrating HTA in a Consistent Ecosystem

Marco Marchetti<sup>1</sup> Americo Cicchetti<sup>2</sup> Laura Sampietro Colom<sup>3</sup> Alexandre Barna<sup>4</sup> Risto Roine<sup>5</sup> Debjani Mueller<sup>6</sup> Mitchell Sugarman<sup>7</sup>

1. HTA Unit University Hospital A. Gemelli, Università Cattolica del Sacro Cuore, Rome, Italy; 2. Università Cattolica del Sacro Cuore, Roma, Italy; 3. Health Technology Assessment Unit. Hospital Clinic Barcelona, Barcelona, Spain; 4. AP-HP, Assistance Publique – Hôpitaux de Paris, Paris, France; 5. none, Helsinki, Finland; 6. Charlotte Maxeke Research Consortium, CMeRC HTA unit, Johannesburg, South Africa; 7. Medtronic, Minneapolis, USA

**Background:** Usually Hospital based HTA is considered something different and separated from HTA at macro level. In general the objective of HTA is to contribute to the guide of the health system. This system is an integrated environment, where each different level (national, regional, local) influences each other. In addition at each level there are different stakeholder and many different professionals that play their role within the system. Hospital based HTA could not remain a monad but must be fully integrated in a consistent ecosystem

**Description/Objectives:** The panel aims to present the state of art in the integration of HB-HTA within a more complex system to allow a transversal use of HTA, influencing at the same time all levels (national, regional, local) of the Health Systems.

This panel born from the work of HB-HTA interest sub-group and his reflections on future evolution of the contribute that this HTA level could provide to the Health Systems.

The framework of the panel foresees 6 presentation with experiences and point of view from different country around the world. In particular there will be an introduction to the theme and then 5 presentation on a future possible hospital collaboration in a comprehensive HTA ecosystem and different point of view (research, industries, hospitals and primary care)

### PN2

#### Adaptive Approaches to Licensing, HTA and Use of Technologies in Health Care Systems, Summary of Proceedings from the HTAI Policy Forum

Chris Henshall

University of York, London, United Kingdom

**Background:** Previous Policy Forum discussions have examined ways to make HTA more responsive to the technology lifecycle, and the need for, and possible alignment with, regulatory and other stakeholder processes to ensure that promising treatments get to the patients that need them in a timely manner and that they are safe and (cost) effective. The 2014 Policy Forum meeting discussed opportunities and challenges of adaptive approaches to the introduction of drugs and medical devices involving the use of an evolving evidence base rather than conventional single-point-in-time evaluations as a proposed means to promote patient access to innovation, reduce clinical uncertainty, ensure effectiveness, and improve the health technology development process.

**Description/Objectives:** The 2014 HTAI Policy Forum brought together senior leaders from public and private sector organizations with strategic interest in HTA, members of the HTAI Board, leaders in the regulatory world and other invited experts for a strategic discussion about the emerging concept of adaptive pathways and the implications for various stakeholders, including patients, regulators, HTA/coverage bodies, health systems, clinicians, and industry. This

90-minute panel session will provide an overview of key themes emerging from the discussion, and provide an opportunity for 30 minutes of facilitated audience discussion.

### PN3

#### Decision Rules for Cost-Effectiveness Analysis in Low- and Middle-Income Countries

Rita Faria<sup>1</sup> Paul Revill<sup>1</sup> Aurelio Mejia<sup>2</sup> Pritaporn Kingkaew<sup>3</sup> Thomas Wilkinson<sup>4</sup> Amanda Glassman<sup>5</sup>

1. Centre for Health Economics, York, United Kingdom; 2. Instituto de Evaluación Tecnológica en Salud, Bogota, Colombia; 3. Health Intervention and Technology Assessment Program, Nonthaburi, Thailand; 4. National Institute for Health and Care Excellence, London, United Kingdom; 5. Center for Global Development, Washington, USA

**Background:** Economic evaluation is a tool to guide decisions on how to best use the available resources to improve health. A common rule is to compare the additional costs and health gains of an intervention against a threshold. However, this raises questions about what are the appropriate thresholds in particular contexts and how decisions should relate to the fuller set of choices that policy-makers face. These issues are particularly challenging in low- and middle-income countries (LMICs) for which financial, human and health system constraints are often more severe and for which the availability of information is much more limited.

**Description/Objectives:** This panel will debate the appropriate methods for assessing value for money of healthcare interventions. Paul Revill will critique prevailing methods and present a framework for informing a fuller range of policy decisions in LMICs. Rita Faria will show how to estimate the upper-bound for the threshold using readily available data with application to the Colombian context. Pritaporn Kingkaew will present Thailand's experience on the use of economic evaluation for the selection and price negotiation of medicines. Aurelio Mejia will present the challenges and opportunities faced by Colombia in the incorporation of cost-effectiveness evidence in the decision-making process. Tommy Wilkinson will present how NICE International works with LMICs to help shape health technology assessment to their particular contexts. Amanda Glassman will chair the discussion. Attendees will gain an understanding of the specific challenges and opportunities around making decisions on value for money in LMICs.

### PN4

#### The GRADE/DECIDE Interactive Evidence to Decision (EtD) Framework: a Tool that Can Be Used to Help People Go from HTAs (or Other Evidence Summaries) to Decisions or Recommendations

Gro Jamtvedt<sup>1</sup> Marianne Klemp<sup>1</sup> Shaun Trewweek<sup>2</sup> Sarah Rosenbaum<sup>1</sup>

1. Norwegian Knowledge Centre for the Health Services, Oslo, Norway; 2. Health Services Research Unit, University of Aberdeen, Aberdeen, United Kingdom

**Background:** The EtD framework is a systematic, transparent and flexible approach for going from evidence to decisions (or recommendations) concerning treatment, coverage or policy. It includes: 1) criteria, 2) judgements concerning each criterion, 3) evidence to inform each judgement and 4) conclusions based on an overall judgement across all criteria. The framework helps to ensure that all important factors are considered, enables structured discussions, makes it easier to identify reasons for disagreements, and provides transparency for those affected by a decision. The EtD enables HTA producers to tailor frameworks, reports and interactive resources to help target audiences move from an HTA to a decision.

**Description/Objectives:** DECIDE (Developing and Evaluating Communication Strategies to Support Informed Decisions and Practice Based on Evidence) is a 5-year project funded by the European Commission under the Seventh Framework Programme. DECIDE builds on the work of the GRADE Working Group to develop and evaluate methods for disseminating evidence-based guidelines.

The aim of this panel session is to introduce the DECIDE EtD framework to the HTAi community and to describe/discuss how the framework can facilitate informed, transparent decision making based on information from HTAs. The panel session will include four presentations and an interactive component:

1. Introduction to the EtD framework (Gro Jamtvedt)
2. Examples of use of the EtD framework in HTA and guideline recommendations (Shaun Treweek)
3. Using the EtD framework in making decisions about introducing new technologies in Norwegian hospitals (Marianne Klemp)
4. Developing the interactive EtD (Sarah Rosenbaum)
5. A facilitated, interactive session on using the EtD framework

## PN5

### The Use of Patient Reported Outcomes (PROs) to Assess Treatment Effects in Rare Diseases

Gordon Guyatt<sup>1</sup> Patricia A Miller<sup>1</sup> Deborah Elstein<sup>3</sup> Alric Rütger<sup>2</sup> Durhane Wong-Rieger<sup>4</sup>

1. McMaster University, Hamilton, Canada; 2. Institute for Quality and Efficiency in Health Care, Cologne, Germany; 3. Gaucher Clinic, Shaare Zedek Medical Center, Jerusalem, Israel; 4. Canadian Organization for Rare Disorders, Toronto, Canada

**Background:** A patient reported outcome (PRO) is “any report of the status of a patient’s health condition that comes directly from the patient without interpretation ... by a clinician or anyone else” (USFDA 2009). PROs provide patients’ perspective on treatment benefit and are often the outcomes of most significance to patients (Guyatt 2004).

Rare diseases pose a unique challenge to clinicians and researchers. Due to the low prevalence of rare diseases, establishing the impact of available treatments is difficult. Because many PROs are responsive to modest treatment effects, PROs provide one potential solution to establishing the impact of medical interventions.

**Description/Objectives:** The panel’s objective is to discuss the current body of work on PROs in rare diseases and to identify strategies to develop and implement PRO instruments to help identify treatment options for rare diseases. The value of PROs for health technology assessments (HTAs) and decision-making will be discussed.

0:00 - 0:10: Gordon Guyatt will discuss PRO measurement and use, and introduce the study and panelists.

0:10 - 0:20: Sohail Mulla will describe the findings of a systematic review of PROs in rare diseases.

0:20 - 0:35: Patricia Miller will present the findings of interviews with researchers and HTA experts addressing the incorporation of PROs in clinical research.

0:35 - 0:45: Deborah Elstein will discuss PROs use in clinical practice and research.

0:45 - 0:55: Alrich Ruter will discuss the role of PROs in HTAs.

0:55 - 1:30: Patient representative Durhane Wong-Rieger will discuss her experience with rare diseases and facilitate audience discussion with panelists.

## PN6

### How Do Different HTA Approaches Conceptualize and Measure the Components of “value”?

Steven Pearson<sup>1</sup> Meindert Boysen<sup>2</sup> Bobby Dubois<sup>3</sup> Kim Bailey<sup>4</sup> James Murray<sup>5</sup>

1. Institute for Clinical and Economic Review, Boston, USA; 2. National Institute for Health and Care Excellence, Manchester, United Kingdom; 3. National Pharmaceutical Council, Washington, USA; 4. FamiliesUSA, Washington, USA; 5. Eli Lilly and Company, Indianapolis, USA

**Background:** How HTA organizations conceptualize and measure “value” helps determine the impact of HTA on innovation. In some developed countries there is a single dominant method, such as the incremental cost-effectiveness ratio, that serves as the principal measure of value and the guiding element of coverage decisions. There is no analogous dominant approach to judging value in the United States. This panel will present different approaches to measuring value, compare the dimensions of value considered important by patients, manufacturers, and various HTA organizations, and provide a basis for understanding how HTA methods affect the dynamics of innovation in different healthcare systems.

**Description/Objectives:**

1. Steve Pearson will describe a conceptual framework for payer assessment of value in the US developed by a workgroup involving key insurers, pharmaceutical and device companies, and patient representatives.
2. Meindert Boysen will present NICE’s current approach to valuing innovative products and how it will evolve as part of the UK government’s new pricing agreement with pharmaceutical firms.
3. Jim Murray will present perspectives on value assessment, to include innovation, gained from an Office of Health Economics project documenting an international perspective on approaches to value measurement.
4. Bobby Dubois will present a broad perspective on the different kinds of value considered important to support innovation by the diverse pharma and biotech members of his policy organization.
5. Kim Bailey will comment on the preceding presentations and consider whether the various approaches to measuring value are likely to foster the kind of innovation important to patients and families.

## PN7

### Establishing Early Dialogue between Industry and HTA Agencies: Perspectives of INAHTA Members, NICE and Industry

Brian O’Rourke<sup>1</sup> François Meyer<sup>2</sup> Iñaki Gutiérrez-Ibarluzea<sup>2</sup> Terri O’Grady<sup>1</sup> Nick Crabb<sup>3</sup> Adrian Griffin<sup>4</sup>

1. Canadian Agency for Drugs and Technologies in Health (CADTH), Ottawa, Canada; 2. Basque Office for Health Technology Assessment (Osteba), Vitoria-Gasteiz, Spain; 3. National Institute for Health and Care Excellence (NICE), London, United Kingdom; 4. Johnson & Johnson, , United Kingdom; 5. Haute Autorité de Sante (HAS), Paris, France

**Background:** Early dialogue between manufacturers and HTA agencies on manufacturer development plans for phase III trials is increasingly recognized as beneficial for both groups. Industry has traditionally focused on meeting regulatory requirements but overall success also depends on obtaining reimbursement. Industry now appreciates that early understanding of the needs of HTA agencies related to reimbursement can reduce uncertainty and better position products for success. HTA agencies see the potential to improve the quality of future reimbursement submissions and recommendations through early dialogue. This panel will further awareness, development and

collaboration on early dialogue through discussion of international experiences.

**Description/Objectives:** The objective is to discuss benefits, challenges and issues related to establishing early dialogue. Representatives from three INAHTA organizations will be included: HAS, Osteba and CADTH. HAS is leading a multi-HTA early dialogue pilot, Osteba is discussing formalization of early interactions with stakeholders and collaborating with HAS on aspects of the multi-HTA pilot, and CADTH plans to introduce an advice program. Views from the well-established NICE Scientific Advice and from Industry will also be presented. The panel will address the following:

- Why HTA organizations should establish early dialogue programs
- What is needed for a successful early dialogue program
- How early dialogue programs fit with other aspects of HTA organizations
- Who should participate in early dialogue (focus on payers and patients)
- Issues around bias, confidentiality and conflict of interest
- Collaboration between early dialogue programs globally
- Value of early dialogue pre-product development or post-launch
- Impact of adaptive licensing on early dialogue programs.

## PN8

### Improving the Quality of Decisions Around the Public Funding of New Health Technologies: the Value of Disease-Specific (Reference) Models

Hossein Afzali<sup>1</sup> Jane Kim<sup>2</sup> Erik Dasbach<sup>3</sup> Geert Frederix<sup>4</sup> Natasha Stout<sup>2</sup> Robyn Ward<sup>5</sup>

1. The University of Adelaide, Adelaide, Australia; 2. Harvard School of Public Health, Boston, USA; 3. Merck Research Laboratories, Philadelphia, USA; 4. University of Utrecht, Utrecht, Netherlands; 5. Australian Medical Services Advisory Committee, Canberra, Australia

**Background:** Given that decision analytic models are frequently used to inform public funding decisions, the process of developing such models has attracted increasing attention. While emerging evidence points to the impact of making incorrect structural assumptions on model output, little attention is paid to the assessment of the model structure within the current HTA process. It is highly likely that inappropriate model structures may have been used with consequential impact on the quality of funding decisions. One potential solution to address the above issue is the use of disease-specific (reference) models in submissions to national funding bodies.

**Description/Objectives:** The use of reference models can reduce uncertainty associated with the choice of model structure and hence better informed funding decisions. It will also improve the comparability of funding decisions, as diversity in model structure for a specific disease reduces the comparability of evaluations of competing health technologies. It is acknowledged that the value of reference models is integral to the successful uptake of these models by key stakeholders (e.g. funding bodies and industry).

The main objective of this panel discussion is to allow participants with diverse professional background, expertise and policy experience (i.e. academic, funding bodies, HTA units and industry), to share their perspectives on the values and potential limitations associated with the development and use of reference models. It is expected that the discussion will provide insight into the factors impeding and facilitating the uptake of reference models within the decision-making process.

## PN9

### Integrating Ethics in HTA – Methods and Merits

Bjørn Hofmann<sup>1</sup> Gert Jan van der Wilt<sup>2</sup> Ken Bond<sup>4</sup> Wija Oortwijn<sup>3</sup> Kristin Bakke Lysdahl<sup>1</sup> Dario Sacchini<sup>5</sup> Peitro Refolo<sup>5</sup>

1. University of Oslo, Oslo, Norway; 2. Radboud University Medical Centre, Nijmegen, Netherlands; 3. ECORYS, Rotterdam, Netherlands; 4. Institute for Health Economics, Edmonton, Canada; 5. Università Cattolica del Sacro Cuore, Rome, Italy

**Background:** Ethics has been identified as a key element in health technology assessment (HTA) since its conception in the 1970s. A wide variety of methods for addressing ethical issues in HTA are available. Some of these are specially developed for use in HTA. Despite the constitutive role of ethics in HTA and the fact that many methods are available, ethics is still rarely addressed explicitly in HTA reports. This has prompted attention to why ethics should be integrated in HTA and less to how ethics can be integrated in HTA in a fruitful manner.

**Description/Objectives:** The panel will demonstrate various ways that ethics can be integrated in HTA and to discuss their merits. The objective is to facilitate HTA agencies' assessment of how to integrate ethics in their HTA work. An outline of various ways of integrating ethics in HTA will be illustrated by examples from HTA reports and publications. Various kinds of result based and process based integration will be presented and discussed. Checklist approaches will be compared to focus group approaches. Ethics expert based methods will be compared to HTA expert based schemes.

#### Panel Outline:

Introduction: Integrating ethics in HTA: short background and objective, Lysdahl

Examples of integrating ethics in HTA, Sacchini and Refolo

Integration and decision making – what are the crucial issues? Oortwijn

Integrating ethics in HTA or integrating HTA in ethics? vdWilt

Integration of expertise: HTA versus ethics, Bond

Integrating ethics in HTA – methods and merits, Hofmann

## PN10

### The Value of Patient Involvement in HTA - What are the Means to Reach the Full Potential?

Camilla Palmhøj Nielsen<sup>1</sup> Karen Facey<sup>2</sup> Nancy Davenport-Ennis<sup>3</sup> Kenneth Patterson<sup>4</sup> Moira Howie<sup>5</sup>

1. CFK - Public Health and Quality Improvement, Aarhus C, Denmark; 2. Department of Health Economics and HTA, University of Glasgow, Glasgow, United Kingdom; 3. National Patient Advocate Foundation, Hampton, USA; 4. PACE, Glasgow, United Kingdom; 5. Eli Lilly, Windlesham, Surrey, United Kingdom

**Background:** Patient involvement is a core activity for HTA organisations in order to ensure patient-centred, good quality HTA. However, patient involvement processes and activities need to be developed further with all stakeholders to strengthen the influence it has on policy and decision making. The session will discuss and formulate a position in relation to the value patient involvement in HTA and the ways in which this value is captured and developed to reach its full potential. This position will go on to provide input to the future development of patient involvement activities.

**Description/Objectives:** This panel session includes four presentations followed by discussion with the audience. The opening presentation will give an overview of the current status of patient involvement activities in HTA around the world. The second reflects the patient advocacy perspective, outlining the requirements for HTA organisations to improve PPI how patient organisations can work to improve the value of their contributions to HTA processes. From an HTA or-

ganisation perspective the third presentation will debate how patient involvement activities can be improved to provide added value to HTA processes and the subsequent policy and decision making. The presentation will also discuss the expectations of the patient representatives which take part in HTA processes. The fourth presentation reflects the research perspective; providing commentary on current evidence on the added value of patient involvement and how patient involvement needs to be supported and supplemented with solid research on patient perspectives to provide patient-centred HTA.

## PN11

### Medical Devices: Are Different HTA Approaches Really Needed?

Rod S Taylor<sup>1</sup> Aleksandra Torbica<sup>2</sup> Mirella Marlow<sup>3</sup> Les Levin<sup>4,5</sup> Markus Siebert<sup>6</sup> Oriana Ciani<sup>7</sup>

1. Exeter Clinical Trials Support Network, University of Exeter Medical School, Exeter, United Kingdom; 2. Department for Policy Analysis and Public Management Centre for Research in Health and Social Care Management (CERGAS), Bocconi University, Milan, Italy; 3. Centre for Health Technology Evaluation, National Institute for Clinical and Social Excellence (NICE), London, United Kingdom; 4. Health Quality Ontario & MaRS EXCITE, Toronto, Canada; 5. University of Toronto, Toronto, Canada; 6. EUCOMED CRM Telemonitoring Working Group & Board member of European Health Technology Institute for Socio-Economic Research (EHTI), Brussels, Belgium; 7. University of Exeter Medical School, Exeter, United Kingdom

**Background:** It is well accepted that medical devices differ from other health technologies – in particular, they can change rapidly, clinical outcomes often depend on training and experience of operator, and pricing is more dynamic than drugs. The vast majority of HTA agencies across the globe now actively prioritise the assessment of medical devices. However, interestingly, whilst some agencies appear have kept common structures, processes and methods for devices and drugs assessment, others have evolved innovative evaluative approaches, notably, the Medical Technologies Programme (MTEP) of NICE and the field-based assessments and pre-regulation pragmatic trial programme of Health Quality Ontario.

**Description/Objectives:** The overarching objective of this Panel is to discuss the question of whether different HTA approaches are needed for medical devices.

Four panellists will present and discuss the pros and cons of an HTA agency developing specific structures, processes and methods to handle medical devices (compared to drugs).

- Oriana Ciani: Overview of the findings of an EU funded project survey of HTA agencies approaches to handling of medical devices (*Methods for HTA of medical devices: a European perspective-MedtecHTA*)
- Les Levine: The Health Quality Ontario (MaRS EXCITE) approach to medical device evaluation: field-based evaluation and pre-regulation trials
- Mirella Marlow: The NICE dual approach to medical device evaluation: MTEP and TA programmes
- Markus Seibert: The industry perspective to HTA consideration of medical devices

The panel session will be jointly chaired and discussion facilitated by Aleksandra Torbica (*MedtecHTA Deputy Project Director*) and Rod Taylor (*MedtecHTA WP1 Leader*).

## PN12

### First Experiences with the EUnetHTA Joint Rapid Relative Effectiveness Assessment; the Zostavax Case

Wim Goettsch<sup>1</sup> Finn Borlum Kristensen<sup>3</sup> Po Kam Cheung<sup>1</sup> Lidia Becla<sup>1</sup> Andrea Rappagliosi<sup>2</sup> Ingrid Zechmeister<sup>4</sup>

1. CVZ, Diemen, Netherlands; 2. Sanofi Pasteur MSD, Paris, France; 3. EUnetHTA Secretariat, Copenhagen, Denmark; 4. LBI, Vienna, Austria

**Background:** EUnetHTA JA2 WP5 focuses on testing the collaboration of European partners in the joint production of rapid relative effectiveness assessments (REA). Zostavax for the prevention of herpes zoster and postherpetic neuralgia, was the first of 10 pilots which has been completed in Strand A (pharmaceuticals) in JA2. These pilots aim to support reimbursement decisions at the national/local level and to further improve the collaborative abilities of partners across European borders.

**Description/Objectives:** Nine European HTA organisations from eight countries participated in the production of this pilot. The draft assessment was consulted with Marketing Authorisation Holder, Sanofi Pasteur MSD (MAH) and 32 institutions participating in EUnetHTA JA2 Work Package 5. The pilot was completed in less than five months. Overall, participants reported that process was efficient and transparent and the report was of high quality. The major challenge was a complicated, triple structure of the Model for rapid REA that was used. Data on the experiences of the pilot process was collected at the end of the project through structured surveys.

During this panel session experiences and lessons learned from the production of an international jointly collaborated pilot rapid Relative Effectiveness Assessment (REA) using the HTA Core Model for rapid assessments of pharmaceuticals, will be discussed from different perspectives: the authors, the coordinating office, the users (national HTA agencies) and the MAH.

## PN13

### Introducing the Gates Reference Case

Thomas Wilkinson<sup>1</sup> Damian Walker<sup>2</sup> Peter Neumann<sup>3</sup> Paul Revill<sup>4</sup>

1. NICE International, London, United Kingdom; 2. Bill and Melinda Gates Foundation, Seattle, USA; 3. Tufts University School of Medicine, Boston, USA; 4. Centre for Health Economics, University of York, York, United Kingdom

**Background:** Priority setting decisions in health are unavoidable, and all health priority setting decisions have inevitable consequences in terms of health benefits foregone. Priority setting decisions can be optimised using economic evaluation in a systematic way to ensure decision makers have clarity about both the costs and benefits of different options.

The Bill and Melinda Gates Foundation (BMGF) is a major funder of economic evaluations of health technologies in LMICs. However, to date there has been substantial variation in methodology, quality, and approach when conducting BMGF-funded analyses. Ultimately this limits their usefulness to local policy makers, other stakeholders and BMGF.

**Description/Objectives:** The Gates-RC is a consistent, decision-maker focussed approach to the planning, conduct and reporting of economic evaluations funded by BMGF. The Gates-RC maintains a flexible approach to accommodate different users, technology types and constituencies, however requires some definitive methodological specifications in the base case, such as discount rate of 3% (costs and effects), and DALYs averted as outcome measure.

Tommy Wilkinson will introduce the Gates-RC and provide an overview of current methodological variation in BMGF-funded economic evaluations. Peter Neumann will introduce the cost/DALYs database initiative to extend the repository of economic evaluations. Paul Revill will describe the principle-based approach and the methodological les-

sons for the Gates-RC from the NICE experience in England and Wales. Damian Walker will discuss the future direction for the Gates-RC within the BMGF. Amanda Glassman will chair and introduce her perspective on the opportunities that this unique initiative from a global funder offers the global community.

## PN14

### Strategies for Moving Evidence into Action by Multiple Stakeholders

Daniel Alan Ollendorf<sup>1</sup> Donald Goldmann<sup>2,5,6</sup> Barbra Rabson<sup>3</sup> Wim Goettsch<sup>4</sup>

1. Institute for Clinical and Economic Review, Boston, USA; 2. Institute for Healthcare Improvement, Cambridge, USA; 3. Massachusetts Health Quality Partners, Watertown, USA; 4. College voor Zorgverzekeringen, Diemen, Netherlands; 5. Harvard University Medical School, Boston, USA; 6. Harvard University School of Public Health, Boston, USA

**Background:** Efforts to use evidence on the clinical benefits, potential harms, and cost-effectiveness of tests and treatments to modify clinical practice, increase patient awareness and enhance medical policy have long been hampered by a lack of well-accepted and reproducible pathways for making evidence-based decisions. There is inherent complexity in conveying evidence-based information to patients, clinicians, payers, and policymakers, each of whom has different notions of how such data should be presented. However, there are also differences between organizations serving these stakeholders on how to implement evidence-based findings that may vary by geography, political environment, and other factors.

**Description/Objectives:** This panel discussion will describe multiple efforts to implement evidence-based information that differ by perspective, audience, and location. Specific objectives include: (1) describe each organization's approach toward conveying evidence-based information and translating such evidence into action; (2) document the successes and challenges of each approach; and (3) develop a framework for key considerations that can be reproduced across organizations focused on evidence-based implementation. Presentation topics will include: (1) the similarities and differences in public evidence deliberation and implementation between two distinct regional multi-stakeholder councils; (2) the use of state-based medical societies and hospital associations as a vehicle to disseminate information on best practices to providers; (3) an initiative to disseminate locally-relevant patient and provider education materials based on the American Board of Internal Medicine's "Choosing Wisely" campaign; and (4) the Dutch Health Care Insurance Board's efforts to use evidence-based approaches to manage market entry and reimbursement of new healthcare interventions.

## PN15

### Executing a Global Patient-Centered Research Agenda: Lessons Learned from Establishing PCORI

Marc Boutin<sup>3</sup> Tony Coelho<sup>2</sup> David Grainger<sup>1</sup> Chris Henshall<sup>4</sup> Durhane Wong-Rieger<sup>5</sup>

1. Eli Lilly, Sydney, Australia; 2. Partnership to Improve Patient Care (PIPC), Washington, USA; 3. National Health Council, Washington, USA; 4. Independent Consultant, London, United Kingdom; 5. Consumer Advocacy Network, Toronto, Canada

**Background:** In recent years, there has been an important shift towards healthcare that is centered on patient specific needs and preferences. The Patient-Centered Outcomes Research Institute (PCORI), established by the Affordable Care Act in 2010, is authorized to support research that is focused on "patient needs, outcomes, and preferences." While PCORI's activities and research agenda are still evolving, there is an opportunity to consider early successes and challenges and

to identify learnings from these formational experiences that globally established comparative effectiveness research (CER) and health technology assessment (HTA) entities can leverage in implementing a more patient-centered agenda.

**Description/Objectives:** This panel will engage participants to consider PCORI's formational activities, structure, multi-stakeholder collaboration, transparency, research agenda, governance, and output to date. The session will consist of an overview of PCORI activity, followed by a panel discussion that will collaboratively evaluate which activities could serve as a model for patient-centeredness in the international HTA landscape, as well as those where alternative approaches may be merited. The panelist presentations will include a patient advocacy organization's perspective on the extent to which PCORI's research agenda reflects patient needs, a pharmaceutical manufacturer's insights on PCORI's activities have impacted the product life cycle, and a discussion about how HTA organizations in other countries can leverage early learnings from PCORI.

## PN16

### Early Dialogue with Stakeholders Crucial for Enhancing the Implementation of Innovations. Current Experiences and Future Developments from the Perspective of Early Awareness and Alert Systems

Iñaki Gutierrez-Ibarluzea<sup>1</sup> Marianne Klemp<sup>2</sup> Sue Simpson<sup>3</sup> Hans-Peter Dauben<sup>4</sup> Cedric Jehanno<sup>5</sup> Alexandre Barna<sup>6</sup>

1. Osteba, Basque Office for HTA, Basque Government, Vitoria-Gasteiz, Spain; 2. NOKC, Oslo, Norway; 3. NIHR, Birmingham, United Kingdom; 4. DIMDI, Colonia, Germany; 5. INESSS, Quebec, Canada; 6. CEDIT, Paris, France

**Background:** In order to improve health innovations implementation, timely and high quality relevant advice within the process of integration in a given health care environment is required. HTA as a tool between science, technology development and decision making processes seem to be an ideal platform to moderate the information exchange at all life cycle steps especially in the early phase. To implement a sustainable dialogue process the inclusion of relevant stakeholders is an important step as well as to reduce inefficiencies within the R&D process. Furthermore, technology funds and consistent decision making structures as well as full patient involvement are recommended.

**Description/Objectives:** The panel will describe current activities of the members of EuroScan and some theoretical approaches in addressing early interaction with stakeholders that enhance the activity of technology transfer (TT). These experiences try solving the issue of how systems can be adapted to different forms of TT and which general components of TT should be adapted to conform to HTA's requirements. The panel objectives will be:

- to address the concept of true horizon scanning or constructive technology assessment (CTA)
- to describe processes that aim to improve the communication or non-synergy between TT and HTA including: the role of health professionals and patients in early dialogue/interaction with HTA doers
- To describe current experiences and theoretical approach in early interaction with industry and innovators especially SME, patients and patients' advocacy groups, clinicians and health care providers/ professional organizations or policy makers
- To discuss future initiatives with the audience

**PN17****Coverage with Evidence Development: UK and US Approaches**

Mirella Marlow<sup>2</sup> Louis Jacques<sup>4</sup> Andrew Farb<sup>3</sup> Hannah Patrick<sup>1</sup>

1. IP Programme, NICE, London, United Kingdom; 2. Programme Director – Devices and Diagnostic Systems, London, United Kingdom; 3. US Food and Drug Administration, Baltimore, USA; 4. Centres for Medicare and Medicaid Coverage, Baltimore, USA

**Background:** Knowing what to do when data on the overall clinical benefit, effectiveness or the cost-effectiveness of new medicines or procedures is incomplete or inadequate, is a challenge that confronts virtually all health systems. In February 2009 the Banff Summit brought together international experts from the US, UK, Australia and Canada to identify principles for innovative reimbursement approaches involving the development of “real-world” evidence. Five years on, this panel will explore how the challenge of applying these principles is being met in the US and UK.

**Description/Objectives:** The session objective is to explore how US and UK experiences on “coverage with evidence development” arrangements reflect the “Banff Principles”, which address the need to link the requirements of payers to the design and collection of real-world evidence to reduce uncertainties. Contributions from the US will focus on the US Medicare Coverage with Evidence Development (CED) program, in particular lessons learned during the last decade and thoughts about possible enhancements, as well experience from the Food and Drug Administration. The UK system experience will focus on a new evidence collection initiative (“Commissioning Through Evaluation”) that NICE is leading to address uncertainties and payer resource constraints. Delegates will have the opportunity to debate the balance of benefits between investing in promising treatments at an early stage and waiting until uncertainties are resolved.

**PN18****Nice & Value Based Assessment; Impact on Transferability, Predictability and Utility**

Christopher Paul O'Regan<sup>1</sup> Anne Lee<sup>6</sup> Finn Børlum Kristensen<sup>3</sup> Meindert Boysen<sup>2</sup> Janet Wale<sup>5</sup> Matthew Brougham<sup>4</sup>

1. Merck Sharp & Dohme Ltd, Hoddesdon, United Kingdom; 2. National Institute for Health and Care Excellence, Manchester, United Kingdom; 3. European Network for Health Technology Assessment, Copenhagen, Denmark; 4. Canadian Agency for Drugs and Technologies in Health, Ottawa, Canada; 5. Cochrane Consumer Network, Burwood, Australia; 6. Scottish Medicines Consortium, Glasgow, United Kingdom

**Background:** The National Institute for Health & Care Excellence has been through two years of uncertainty regarding how it appraises new medicines. Initial plans by government were to remove the power of NICE to make recommendations on use of new medicines as well as a drive to change the way NICE valued medicines, all under the heading of ‘Value Based Pricing’. Following protracted negotiations, NICE retains the power to make recommendations, but has had to agree to incorporate other elements of value into its deliberations; ‘Wider Societal Benefits’ and ‘Burden of Illness’. This will change how NICE works and is viewed.

**Description/Objectives:** Meindert Boysen will provide a view from NICE describing the differences that can be expected.

Matthew Brougham will provide a perspective from CCADTH on how transferable NICE recommendations will be under the new system.

Janet Wale will provide a view from the patient/consumer perspective of the relevance of these additional elements of value and what part consumers could play in providing evidence.

Anne Lee will provide a perspective from Scotland, whose HTA agency is determining its own view about, and approach to, incorporation of additional elements of value.

Finn Børlum Kristensen will provide a perspective on how this could affect the drive for harmonisation of HTA in Europe

Chris O'Regan who will provide a perspective from the pharmaceutical industry on how the changes will affect the complexity of submission development as well as whether it will make it more difficult to garner a positive recommendation.

Lively audience participation is anticipated.

**PN19****MCDAs Across the Decision-Making Continuum: Feedback and Reflection from the Field**

Mireille M. Goetghebeur<sup>1,7</sup> Wim Goetsch<sup>2</sup> Alaa Hamed<sup>3</sup> Sitaporn Youngkong<sup>4</sup> François Meyer<sup>5</sup> Janet Martin<sup>6</sup>

1. LA-SER Analytica, Dorval, Canada; 2. College voor Zorgverzekeringen, Diemen, Netherlands; 3. Genzyme Corporation, Cambridge, USA; 4. Health Intervention and Technology Assessment Program (HITAP), Nonthaburi, Thailand; 5. Haute Autorité de Santé, Paris, France; 6. Centre for Medical Evidence, Decision Integrity, and Clinical Impact (MEDICI), University of Western Ontario, London, Canada; 7. University of Montreal, Dept of Health Administration, Montreal, Canada

**Background:** Decisions in healthcare occur across a continuum starting with the developers of an intervention, followed by regulatory authorities, health systems and HTA agencies, clinicians and patients. MCDA may facilitate a systematic approach to healthcare decision-making which can improve the conversation for stakeholders across the continuum. In several regions of the world, reflection on healthcare decisionmaking has been facilitated by identification of criteria and development of pragmatic processes.

**Description/Objectives:** The objective of this panel is to explore experiences and perspectives from the field related to multicriteria approaches across the decision continuum. Experience from the industry on applications of MCDA for decisionmaking on development and data generation will be presented by Alaa Hamed from Genzyme. Perspective and current developments from HTA agencies will be presented by François Meyer from the Haute Autorité de Santé in France, by Wim Goetsch from the Dutch Health Care Insurance Board (CVZ), and by Sitaporn Youngkong from the Health Intervention and Technology Assessment Program (HITAP) in Thailand. Perspectives from the provincial level and experience with multicriteria applications at the hospital-based HTA level will be presented by Janet Martin. A discussion period with the audience will focus on how multicriteria applied at several levels across the continuum of decision-making may enhance pragmatic interaction among stakeholders for efficient development of healthcare interventions and healthcare systems.

**PN20****Scoping as a Means to Systematically Involve Patients and Public in Health Technology Assessment (HTA)**

Gert Jan van der Wilt<sup>1</sup> Louise Brereton<sup>2</sup> James B Chilcott<sup>2</sup> Kristin Bakke Lysdahl<sup>3</sup> Dario Sacchini<sup>4</sup> Kati Mozygemba<sup>5</sup>

1. Radboud University Medical Centre, Nijmegen, Netherlands; 2. School of Health and Related Research (ScHARR), Sheffield, United Kingdom; 3. University of Oslo, Oslo, Norway; 4. Università Cattolica del Sacro Cuore, Rome, Italy; 5. University of Bremen, Bremen, Germany

**Background:** To improve accountability and comprehensiveness, patient and public involvement (PPI) is crucial throughout the various stages of HTA. However, little is known as to how this can be achieved in a systematic, culturally sensitive way. The objective of the session is

to compare different approaches to scoping (the systematic exploration of relevant aspects of a specific problem area from multiple perspectives), within the context of palliative care. Results will be presented that were obtained in the European FP-7 INTEGRATE-HTA project.

**Description/Objectives:** Scoping exercises as a first step in HTA on palliative care were conducted in several European countries. A qualitative approach was adopted in Italy, Germany and the Netherlands. Individual or focus group interviews took place in Italy and Germany. In the Netherlands, patients receiving palliative care took part in semi-structured interviews. Patients and the public were used as research partners in the UK, Norway and Poland. An adapted version of the EUnetHTA core model guided individual or group face-to-face discussions with a total of over thirty patients, carers or representatives of patient organisations. Thematic analysis and conceptual mapping identified key issues.

Both approaches successfully facilitated PPI and each had advantages and disadvantages. Qualitative approaches provided rich data focused on issues identified as important by patients, relatives and professionals. The EUnetHTA core model provided a comprehensive framework for discussions, ensuring that issues pertaining to all domains of the model were identified.

## PN21

### Horizon Scanning: Likely to Stifle or Enhance Adoption of Innovations in Health Care?

Karen Schoelles<sup>1</sup> Elise Berliner<sup>1</sup> Paula Chakravarti<sup>2</sup> Jeff Thompson<sup>3</sup> Hussein Noorani<sup>4</sup>

1. Agency for Healthcare Research and Quality, Rockville, USA; 2. Rutgers School of Public Health, New Brunswick, USA; 3. Mercer, Seattle, USA; 4. Blue Cross Blue Shield Association Technology Evaluation Center, Chicago, USA

**Background:** Some new technologies are adopted widely and later are found not to be as beneficial as originally thought or even harmful, while others are not adopted quickly despite a potential for benefit. Early notice of emerging technologies may lead to a more rational system for adoption of innovations. The AHRQ Horizon Scanning System was developed to provide an inventory of emerging technologies that may impact the health care system, patient outcomes, and costs. The system is currently tracking about 450 emerging technologies and predicts which of the innovations have the highest potential for impact over the next 3 years.

**Description/Objectives:** In this session, we will present an overview of the AHRQ Healthcare Horizon Scanning System. Karen Schoelles will describe the methods used by the system to identify and monitor new technologies and predict the potential for high impact. Hussein Noorani and Jeffrey Thompson will present the perspective from private and public payers on how the horizon scan information may be used to anticipate the diffusion of emerging technologies. Paula Chakravarti will present results of her fellowship research at AHRQ analyzing the trends in health care innovation evident from the potential high impact interventions in AHRQ's horizon scanning system, including the impact of regulatory approval in the US and EU and the correlation of innovation to disease burden. Elise Berliner will moderate the session and lead a discussion with attendees on the methods and results of the system and the implications and possible uses of the outputs.

## PN22

### Innovation and HTA: Paying for Value.... and for Uncertainty?

Reiner Banken<sup>1</sup> Dima Samaha<sup>1</sup> Sarah Garner<sup>2</sup> Wim Goettsch<sup>3</sup> Jens Grueger<sup>4</sup>

1. INESSS, Montréal, Canada; 2. NICE, London, United Kingdom; 3. Health Care Insurance Board - CVZ, Diemen, Netherlands; 4. Hoffman-LaRoche, Basel, Switzerland

**Background:** Patient access to innovative medicines is of central importance for improving patient outcomes. Decision makers and HTA bodies strive to provide access to innovative drugs while respecting health systems' objectives of sustainability, equity, and excellence in the quality of care. The assessment of the value of innovative drugs and its links to reimbursement is of interest to payers worldwide.

Adaptive approaches in regulation and reimbursement are being developed to favour access: progressive licensing, orphan drug frameworks and the rapid development of stratified/personalised medicine are challenging considerably the evidentiary needs and methods of HTA bodies.

**Description/Objectives:** The panel will present three different approaches linking reimbursement to value: the evolution of value-based pricing at NICE in the UK, a deliberative framework for the appraisal of highly promising drugs for coverage at INESSS in Canada and coverage with evidence Development at CVZ in the Netherlands. An industry perspective on these approaches will conclude the panel presentation.

The panel discussion will aim at addressing the following questions: What are the challenges stemming from these adaptive approaches? How are HTA bodies facing these challenges? To what extent is there a willingness for public systems to pay for uncertainty? How do we pay for value with increasing uncertainty? Is there a place for alignment with regulatory agencies and manufacturers in sharing the responsibility of managing these uncertainties?

## PN23

### Challenges in Transferring HTAs from Setting to Setting

Michael Drummond<sup>1</sup> Thomas Wilkinson<sup>2</sup> Andres Pichon-Riviere<sup>3</sup> Sachin Kamal-Bahl<sup>4</sup>

1. University of York, York, United Kingdom; 2. Nice International, London, United Kingdom; 3. IECS, Buenos Aires, Argentina; 4. Merck and Co, Upper Gwynedd, USA

**Background:** The use of health technology assessment (HTA) to make reimbursement and/or coverage decisions for new health technologies is growing in Asia, Central and Eastern Europe and Latin America. However, while an increasing need for HTA is perceived, some jurisdictions lack the resources to conduct local studies. Consequently, decision-makers often need to adapt or interpret studies done elsewhere, often from Europe or North America. The aim of this session is to explore the challenges countries face in interpreting or adapting studies or data from other jurisdictions.

**Description/Objectives:** The following issues will be explored:

- What sources do HTA agencies in emerging nations consult for help?
- What approaches are used to adapt HTAs conducted elsewhere?
- Which elements of data are considered transferable and which not?
- What are the main obstacles to the transfer of HTAs?

Michael Drummond will discuss the findings of a recent survey of HTA agencies in 12 jurisdictions in Asia, Central and Eastern Europe and Latin America, the aim of which was to explore the challenges faced and the practices followed.



Andres Pichon-Riviere will discuss the views of decision makers and HTA researchers in Latin America concerning the transferability of HTAs within and from outside the region.

Sachin Kamal-Bahl will discuss the pros and cons of various approaches to meet the HTA needs of decision-makers in a diverse range of settings from an international technology manufacturer's perspective. Thomas Wilkinson will moderate the panel.

## PN24

### Don't Forget About Ethics! Context-Specific Approaches to Ethical Analysis in Health Technology Assessments

Emelie Heintz<sup>1</sup> Lars Sandman<sup>2</sup> Sigrid Droste<sup>3</sup> Iñaki Gutierrez Ibarluzea<sup>4</sup> Clémence Thebaut<sup>5</sup> Bjørn Hofmann<sup>6,7</sup>

1. Swedish Council on Health Technology Assessment (SBU), Stockholm, Sweden; 2. University of Borås, Borås, Sweden; 3. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG), Köln, Germany; 4. Osasun Teknologien Ebaluazioaren Zerbitzua (OSTEBA), Vitoria-Gasteiz, Spain; 5. Haute Autorité de Santé (HAS), Saint-Denis La Plaine Cedex, France; 6. University College of Gjøvik, Gjøvik, Norway; 7. University of Oslo, Oslo, Norway

**Background:** In order to achieve Health technology assessment's (HTA) aim of providing decision-support concerning health technologies, information about ethical implications is an essential input. However, in today's HTA practice, ethical implications are not always considered. To assure that ethical aspects are being covered in the assessment and that the ethical analyses respond to relevant questions, a systematic approach has been seen to be fruitful. However, in order to respond to the needs of the multifaceted landscape of HTA-agencies with different objectives, procedures, and resources, this systematic ethical approach needs to be adapted to each agency's specific context.

**Description/Objectives:** The objective of this session is to present different sets of ethical criteria and questions that are currently in use in HTA organizations and to discuss advantages and disadvantages of using these sets or questions. The panel session will offer examples on how to structure the work with ethical analysis in HTA and how to develop a set of criteria or questions that would fit into each country's organizational context.

Five examples from HTA organizations in Sweden (SBU), Germany (IQWiG), Basque Country (Spain, OSTEBA), France (HAS), and Norway (NOKCHS) will be presented. These organizations have developed different sets of criteria or question lists that have been adapted to their respective context and will share their experiences, addressing barriers and facilitators related to the implementation and use of these lists. The advantages and disadvantages pointed out will be discussed with the participants of the panel session.

Moderators: Bjørn Hofmann, Emelie Heintz

## PN25

### Coverage with Evidence Development (CED) for Non-Drug Interventions - Promises and Truths

Christopher Henshall<sup>1</sup> Urs Bruegger<sup>1</sup> Matthias Perleth<sup>3</sup> Les Levin<sup>4</sup> Louis Jacques<sup>5</sup> Robyn Ward<sup>6</sup>

1. Zurich University of Applied Sciences, Winterthur, Switzerland; 2. Independent Consultant, London, United Kingdom; 3. Gemeinsamer Bundesausschuss, Berlin, Germany; 4. Health Quality Ontario, Toronto, Canada; 5. CMS, Washington, USA; 6. MSAC, Canberra, Australia

**Background:** Coverage with Evidence Development (CED) is seen by some policy makers and HTA experts as the optimal approach in situations where a promising new health technology has not yet been able to sufficiently demonstrate value for money. Much of the recent activity and discussion of CED has focused on drugs, but the concept was

initially developed and applied to non-drug interventions and several countries around the world now have significant CED programmes for non-drug interventions running. Can the real-life experience of CED for non-drug interventions keep up with the promises? What are the experiences, the challenges and the lessons learned?

**Description/Objectives:** The panel session will start with a brief introduction on CED (5 minutes). Then five speakers from different regions around the world present CED programmes and discuss their significance as well their strengths and weaknesses (maximum 10 minutes each). The session will end with a moderated discussion between the panelists and the audience. The speakers are

1. Chris Henshall: Chair and brief introduction (5 Min)
2. Urs Bruegger: Europe overview and Switzerland (10 Min)
3. Matthias Perleth: Germany (10 Min)
4. Les Levin: Ontario (10 Min)
5. Louis Jacques: USA (10 Min)
6. Robyn Ward: Australia (10 Min)
7. discussion (30 Min)

The Objectives of the session are:

- To demonstrate how a promising tool (CED) is working in practice in different settings and cultures
- To compare different CED approaches
- To show possible shortcomings and ways how to overcome them

## PN26

### Developing Relative Effectiveness Estimates for Medicines in Development: a Shared Framework Based on Collaboration Across Stakeholders. Insights from the IMI GetReal Consortium

Sarah Garner<sup>2</sup> Mike Chambers<sup>1</sup>

1. GlaxoSmithKline, Middlesex, United Kingdom; 2. National Institute for Health and Care Excellence (NICE), London, United Kingdom

**Background:** There is limited guidance on how to incorporate different study designs (including studies generating early 'real world' data) into development programmes to best meet decision makers' needs over time.

A decision-making framework based on collaboration across regulatory and reimbursement/HTA agencies and pharma R&D will ensure a common understanding of challenges and best practice in developing and evaluating evidence of relative effectiveness (eg. assessment and adjustment for bias, innovative study designs, evidence synthesis and predictive modelling).

The framework will support improved estimates of relative effectiveness and timely decision-making by regulatory and reimbursement agencies and improve the efficiency of medicine development.

**Description/Objectives:** The panel session will begin with a brief description of the current challenges in developing and evaluating evidence of relative effectiveness. This will be presented from the following different perspectives:

- a. Reimbursement / HTA (S.Garner / M.Pavlovic)
- b. Regulatory (F.Cerreta)
- c. Pharmaceutical industry (M.Chambers)

Historical examples and scenarios as well as insights from the work undertaken to date by the GetReal consortium will be used to illustrate the discussion. An overview of philosophy, structure, key objectives and achievements to date of the GetReal consortium will then be presented and the extent that decision making could benefit from elements of a shared framework will be discussed from each of these perspectives. The discussion will focus on the opportunities and potential value of better incorporating real world data into medicine development programmes.

**PN27****A New Reality for New Technologies Assessed by HTA Bodies and Implication for Patient Access: Presentation of the Case of Renal Denervation Therapy**

[Chris Henshall](#)<sup>1</sup> [Matthieu Couche](#)<sup>2</sup> [Tove Ringerike](#)<sup>3</sup> [Inaki Gutierrez](#)<sup>4</sup>  
[Brendan Kearney](#)<sup>5</sup> [Sebastian Gaiser](#)<sup>6</sup>

1. University of York, London, United Kingdom; 2. Covidien, Zurich, Switzerland; 3. Nasjonalt kunnskapssenter for helsetjenesten, Oslo, Norway; 4. Osteba, Bilbao, Spain; 5. Queensland Department of Health, Brisbane, Australia; 6. St Jude Medical, Zaventem, Belgium

**Background:** Health Technology Assessment (HTA) is a routine practice for drugs and is rapidly developing in the field of medical devices. The medical devices industry needs to increasingly consider HTA expectations in addition to CE mark requirements in order to ensure patient access of their products. Healthcare payers make decisions on the appropriate use and reimbursement of new technologies. Renal Denervation therapy (RDN) is a breakthrough therapy that received a lot of attention from HTAs since its launch in 2011 and is therefore a good example to show the increasing importance of HTA evaluations in the medical device sector.

**Description/Objectives:** Description

Chris Henshall – introduction

Matthieu Couche - summary of RDN and industry perspective on collaboration and HTA approaches in Europe and Australia/New Zealand (10 minutes)

Tove Ringerike - EUnetHTA work on RDN (10 minutes)

Inaki Gutierrez - National and regional perspective on RDN (10 minutes)

Brendan Kearney – Approaches to RDN in Australia and New Zealand (10 minutes)

Sebastian Gaiser - Reflections on RDN in the USA (10 minutes)

Audience discussion - 30 minutes

Objectives:

Promote understanding of how manufacturers, HTA agencies and health systems are approaching RDN.

Discuss the key learnings from RDN for the launch and assessment of other innovative technologies in jurisdictions around the world, and consider recommendations for the future development, launch and assessment of such technologies.

Promote understanding and discussion of industry, HTA agency, health system and other key stakeholder perspectives on these issues with the aim of improving the development, launch and assessment of innovative device technologies.

**PN28****“Same, Same But Different!”: HTA in and for Hospitals**

[Claudia Wild](#)

Ludwig Boltzmann Institute for HTA, Vienna, Austria

**Background:** Hospitals are the main entry point for new, but not always innovative health technologies. At times good-value innovative health technologies never reach clinical practice, though, while other health technologies with no significant added value actually do. This highlights the importance of HTA for decision support in hospitals. Further networking and exchanges are needed. The panel can be a good starting point.

**Description/Objectives:** Objectives: to support the exchange of global experiences with local, national and supranational models of good practice and to contribute to further networking.

5 presentations from 3 different continents (Europe: Spain, Denmark, Austria, Italy; New Zealand/Australia; Canada) and different perspec-

tives (local, national, supranational) and roles (policy/regulation, local decision support, supranational cooperation).

Laura Sampietro (Europe, Spain): AdHopHTA – overview, building an ecosystem.

Stephen Munn (Australia, New Zealand): Policy advice provided from hospital-based HTA: 8 years experience.

Claudia Wild (Europe, Austria): National (Austria) and supranational (EUnetHTA) HTA for hospitals.

Janet Martin (Canada): Evidence in Context: Hospital-Based HTA adds Significantly to Arms-Length HTA in Canada.

Kristian Kidholm (Europe, Denmark) and Marco Marchetti (Europe, Italy): Information needs of hospitals managers: conclusions from 51 interviews of hospital managers from 9 EU countries.

**PN29****Accessing Unpublished Evidence – Issues Around Trials Registers and Regulatory Agency Data**

[Julie Glanville](#)<sup>6</sup> [Carol Lefebvre](#)<sup>1,5</sup> [Beate Wieseler](#)<sup>2</sup> [Tom Jefferson](#)<sup>3</sup> [Deborah Zarin](#)<sup>4</sup>

1. Lefebvre Associates Ltd, Oxford, United Kingdom; 2. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne, Germany; 3. Cochrane Acute Respiratory Infections Group, Rome, Italy; 4. ClinicalTrials.gov, US National Library of Medicine, Bethesda, USA; 5. Cochrane Information Retrieval Methods Group, Oxford, United Kingdom; 6. York Health Economics Consortium Ltd, University of York, York, United Kingdom

**Background:** A very successful and well-attended panel session was held at HTAI in Bilbao (2012), addressing issues around accessing unpublished evidence. In this panel session we seek to provide an update on this fast-moving and complex issue. HTA aims to consider all relevant evidence when assessing new technologies and there is increasing recognition that trial results should be made publicly available. There is, however, increasing concern about disclosure of trials results.

**Description/Objectives:** This panel will explore clinical trials and trials results registers and some of the challenges of identifying trials and their results via registers and other sources such as regulatory agencies. We shall address the development of trials and trials results registers and some of the influences to register trials prospectively; the relevance of unpublished studies for HTA, impact of trial registries on the evidence base and how to achieve a more complete evidence base; the challenges faced by the Cochrane Acute Respiratory Infections Review Group in identifying unregistered / unpublished trials of Tamiflu and other treatments for influenza; the role of major registers such as ClinicalTrials.gov and issues around compliance; and a regulatory agency perspective.

**PN31****Using HTA in China: From Strengthening Patient-centered Care to Enhancing Health System Performance**

[Yingyao Chen](#)<sup>1</sup> [Di Xue](#)<sup>1</sup> [Hengjin Dong](#)<sup>2</sup> [Lizheng Shi](#)<sup>3</sup> [Raymond Pong](#)<sup>4</sup>

1. National Key Lab of Health Technology Assessment, School of Public Health, Fudan University, Shanghai, China; 2. Research Centre for Health Policy, School of Public Health, Medical college of Zhejiang University, Hangzhou, China; 3. School of Public Health and Tropical Medicine, Tulane University, New Orleans, USA; 4. Centre for Rural and Northern Health Research and Northern Ontario School of Medicine, Laurentian University, Sudbury, Canada

**Background:** There are many challenges in improving the HTA use and uncertainties about its impact on health systems strengthening in China. Although some HTA evidence has been used to inform policy decisions (e.g., adoption of assisted human reproductive technology, gamma knife technology, and prenatal screening) in China, use of

HTA in the policy-making processes and in guiding patient-centered clinical practices is neither formally developed nor widespread.

**Description/Objectives:** The objective of this panel is to describe the development of China's HTA research, present future perspective of patient-centeredness in HTA applications for health systems strengthening and explore the determinants on knowledge translation from HTA evidence to health policy-making. By qualitative and quantitative analysis, we hope to clearly describe the current status of HTA evidence utilization in China, quality of care, and economic evaluation implication for policy making, especially from the future perspective of patient-centeredness. For characteristics of individual actors (e.g., HTA researchers, decision-makers, providers, and patients or their representatives) and organizations (e.g., policy-making agencies, universities, research institutes, professional associations, and industries) often facilitate or impede HTA utilization in strengthening healthcare systems, qualitative and quantitative analysis will be also applied to better understand what factors are most influential in promoting HTA approaches, and how they interact with the process of policy-making. Taken together, we will propose policy recommendations to foster better utilization of patient engagement and involvement in HTA applications in strengthening the patient-centered healthcare systems.

### PN32

#### Quality Standards for Patient Involvement in HTA

Karen Facey<sup>1</sup> Moira Howie<sup>2</sup> Eric Low<sup>3</sup> Newell E McElwee<sup>4</sup> Brian O'Rourke<sup>5</sup> Kin Ping Tsang<sup>6</sup>

1. University of Glasgow, Drymen, United Kingdom; 2. Eli Lilly and Company, Surrey, United Kingdom; 3. Myeloma UK, Edinburgh, United Kingdom; 4. Merck, North Wales, USA; 5. Canadian Agency for Drugs and Technologies in Health, Ottawa, Canada; 6. International Alliance of Patients' Organizations, Hong Kong, Hong Kong

**Background:** There is a growing desire to involve patients in HTA, but guidance is needed about how this can be achieved. A starting point is to agree and promote best practice for patient involvement in different HTA systems and political contexts. To determine what best practice is, international research has been undertaken in collaboration with the HTAi Interest Sub-Group for Patient/Citizen Involvement in HTA to develop Values and Quality Standards for patient involvement in HTA.

This panel session will outline how the Values and Quality Standards have been developed and discuss how they may be used in practice.

**Description/Objectives:** A rapid review was undertaken of principles for HTA, principles for patient involvement in health services research and principles for public participation in policy. This was presented to an expert workshop and a Nominal Group Technique was used to elicit draft principles for patient involvement in HTA. This led to 44 possible principles.

After further expert review, these were developed into

Values: legitimacy, equity, mutual respect and unique knowledge;  
Standards for overarching requirements: policy, budget, contact person, education;

Standards for process: communication, advance notice, appropriate information, use of input, feedback, clear reporting.

These Values and Standards have been issued widely among international networks for consultation and development via a 3-round Delphi process.

This panel will present an overview of the development of the final Values and Quality Standards for patient involvement in HTA. Panellists will discuss how they can be used to help develop patient-centred HTA.

### SY1

#### Is HTA for Oncology Medicines Working (Well Enough)? How Can it Be Improved?

David L Grainger<sup>1</sup> James Murray<sup>1</sup> Jeff Allen<sup>2</sup> Robyn Ward<sup>3,4</sup> Eric Lowe<sup>5</sup> Laura Sampietro-Colom<sup>6</sup> Erin Huntingdon<sup>7</sup>

1. Eli Lilly & Company, Sydney, Australia; 2. Friends of Cancer Research, Washington, USA; 3. University of New South Wales, Canberra, Australia; 4. Lowy Cancer Research Centre, Sydney, Australia; 5. Myeloma UK, Edinburgh, UK; 6. Hospital Clinic Barcelona, Barcelona, Spain; 7. Eli Lilly & Company,

**Background:** Oncology medicines are often highly innovative in terms of action and in many cases, association with genetic markers. They are also often high cost and for both these reasons are frequently the subjects of technology assessment processes, often as a pre-requisite for reimbursement or coverage decisions. At times, they come to market with limited evidence of overall effectiveness and value, in part because of small trial sizes and accelerated development and regulatory processes. These factors often combine to result in protracted technology assessment processes, delays to reimbursement or rejections of coverage.

**Objectives/Description:** The session will begin with a brief presentation by David Grainger of data from several sources, illustrating some of the challenges of generating and assessing evidence of effectiveness and value in this area. These data will include:

# Observations on variations in HTA outcomes in regard to oncology treatments across a range of agencies, delays to reimbursement and the role of uncertainty in HTA of oncology products.

# Observations on the expansion of the "value footprint" of an oncology product following the initial market authorization.

# Observations on real-world effectiveness of oncology treatments and the heterogeneity of oncology patients.

This introduction will be followed by brief presentations from the other panelists, giving their perspective on the contemporary issues associated with HTA for oncology treatments. The panel will provide a range of perspectives (regional, health system and stakeholder).

The moderator will then lead a discussion on the issues including Q&A with the audience.

**Moderator:** Jeff Allen, Friends of Cancer Research (Friends), a cancer research think tank and advocacy organization based in Washington, DC.

#### Panelists:

Australia:

Professor Robyn Ward, Clinical Associate Dean and Head of the Prince of Wales Clinical School, University of New South Wales, and also Head of the Adult Cancer Program at the Lowy Cancer Research Centre, Sydney, Australia and Chair of the Medicare Services Advisory Committee. UK / Patient:

Eric Lowe, CEO of Myeloma UK. Amongst a very busy portfolio of projects, Eric's recent achievements have included establishing a national Myeloma Early Phase Clinical Trial Network and a myeloma genetics and drug development research program. Eric has also ensured that myeloma patients in the UK have been able to access novel treatments through advocating solution-oriented approaches to the way drugs are made available on the NHS.

Europe / Hospital HTA:

Dr Laura Sampietro-Colom, Deputy Director of Innovation and Head of the Health Technology Assessment (HTA) Unit at the Hospital Clinic of Barcelona, a high-tech hospital and a reference for health care, research and medical training in Spain.

Industry:

Erin Huntingdon, Vice-President, International Corporate Affairs and Global Pricing, Reimbursement and Access, Eli Lilly and Company  
David Grainger, Senior Director, Global Public Policy, Eli Lilly and Company

## Oral Presentations

### OR1.1

#### Economics Determinants of Physical Activity Participation of Women in Brazil and the Implications for Obesity

Giacomo Balbinotto<sup>1</sup> Marcia Regina Godoy<sup>2</sup> Angelica Massuquetti<sup>2</sup>

1. UFRGS/PPGE E UFRGS/IATS, Porto Alegre, Brazil; 2. UNISINOS - Economics, São Leopoldo, Brazil

**Background:** More than 50% of Brazilian population is obese or overweight and sedentary. The determinants of individual participation in physical activity are not well understood.

**Objectives:** The objective of this research is to use a time allocation framework to explore how economic and demographic factors influence participation in physical activity of women between 20 and 40 years, the South and Northeast regions of Brazil.

**Methods:** We used data from the Brazilian Household Survey (Pesquisa Nacional de Amostra de Domicílios) of 2008, with survey 391.000 observations for men and women in Brazil.

Our sample size is 21.971 observations for women between 20 and 40 years old.

The analysis examines frequency of participation in physical activity using a probit model.

**Results:** On average, 28% of women interviewed practiced some physical activity, but as there is a positive relationship between income and practice of physical exercise, the percentage of practitioners varies from 11% to 72% depending on the household per capita income and schooling.

The women with lower schooling and lower individual and family income do less likelihood of participation in physical activity.

Women with dependent children under five years-olds tend to participate in lower weekly levels of physical activity.

The women with high education level, despite have more time total occupied, does more physical activity.

Our results from logit regressions showed that the main factor that affect the physical activity participation are schooling, income and to have children under five. The impact of schooling and income is positive.

**Conclusions:** The results confirm that women with more years of education invest more in health by doing physical activity and buying more health insurance than the sedentary women.

In terms of policy, the results suggest that policy should focus on the promotion of family friendly exercise programs and facilities especially for working women.

### OR1.2

#### Cost Evaluation of a CPAP Funded Policy for the Treatment of Obstructive Sleep Apnea in Quebec

Eric Potvin; Michel Lebrun

Institut national d'excellence en santé et en services sociaux, Quebec, Canada

**Background:** Obstructive sleep apnea (OSA) is characterized by frequent breathing pauses due to the partial or complete upper airway collapse. Untreated OSA is associated with cardiovascular morbidity, cognitive and mood disorders, and driver and worker safety. The recognition of the economic burden of OSA pressed decision makers to address the budgetary impact of covering the gold standard treatment: continuous positive airway pressure (CPAP).

**Objectives:** To review the existing policies set forth by Canadian and international jurisdictions concerning CPAP coverage and to evaluate the costs of covering the CPAP treatment by Quebec's public payer.

**Methods:** Information from government web sites, official documents, and contact agents were reviewed and summarized. For cost analysis, scenarios with variable covering rates and material features were generated according to demographic and diagnostic data, medical experience, and patient needs.

**Results:** Two covering frameworks were identified: one with full public coverage (diagnosis, CPAP device, and follow-ups) and one with a partially-public covered treatment in which the CPAP is provided and set up by private respiratory dealers. Currently, patients spend an average of \$1,720 per 5 years for CPAP devices and an additional \$300 per year for consumables. Taking to account that most patients indicated for CPAP will refuse it (31 %) or abandon it (15 %), around 60 000 individuals annually would ask for a public support to purchase CPAP (1/3) or the consumables (2/3). Considering a 100 % public coverage for full CPAP therapy (initiation and maintenance), INESSS evaluates a total annual cost of 41 M\$ for 2014 and growing to 46 M\$ for 2018.

**Conclusions:** Policy makers addressing the coverage of the highly cost-effective CPAP for OSA should be aware of the growing prevalence and the direct health costs driven by untreated disease. Our study shows the major common characteristics present in existing policies can be applied in Quebec.

### OR1.3

#### Bortezomib Improves Effectiveness of Treatment of Multiple Myeloma with Considerable Budget Impact

Agnes Männik<sup>1</sup> Katrin Lutsar<sup>1</sup> Raul-Allan Kiiwet<sup>1</sup> Ain Kaare<sup>2</sup>

1. University of Tartu, Tartu, Estonia; 2. Tartu University Hospital, Tartu, Estonia

**Background:** Studies have shown that new medicines (bortezomib, thalidomide and lenalidomide) increase the effectiveness of multiple myeloma treatment. However, due to budgetary restrictions the use of bortezomib in Estonia is reimbursed only as third line option in patients, whose previous therapies have failed.

**Objectives:** To compare costs and clinical effectiveness of using bortezomib in different treatment strategies and to evaluate the respective budget impact in order to advise reimbursement decisions.

**Methods:** The incidence of multiple myeloma was obtained from Estonian Cancer Registry. Information about the effectiveness and safety of medicines used to treat multiple myeloma was obtained from scientific literature. The cost of different treatment strategies were calculated according to current wholesale prices and expected frequency of use.

**Results:** There are up to 20 new cases of multiple myeloma in Estonia annually, which are eligible for autologous stem-cell transplantation. By switching bortezomib from third line to first line treatment in these patients, the total health gain could be up to 12 progression-free life years with additional costs of €420,080 (€21,004 per patient). If bortezomib would be used as first line treatment in all multiple myeloma patients, the cost of one progression-free life year gained would be €107,993 and if used as first line treatment only in patients eligible for autologous stem-cell transplantation, the cost of one additional progression-free year would be €72,885.

**Conclusions:** Based on the analysis conducted, recommendations were given to government to change the reimbursement criteria of multiple myeloma. Since 2014 bortezomib is reimbursed in Estonia as first-line treatment for patients eligible for autologous stem-cell transplantation and as second line treatment for transplantation ineligible patients.

## OR1.4

### Use of HTA in Developing Public Policies for Effective Illicit Drug Prevention Programs

Marina Gonçalves de Freitas; Júlia Souza Vidal

Brazilian Ministry of Health, Brasília, Brazil

**Background:** The epidemic crack usage is complex, and an effective prevention is the best treatment available. Prevention programs already exist in Brazil, however, the numbers of crack users are alarming. Thus, the lack of monitoring/evaluation of these programs' effectiveness was identified as a problem.

**Objectives:** To propose the creation of information/monitoring/evaluation systems as an option for addressing the crack problem using scientific evidence. To identify potential barriers to implementing these systems, analyzing the evidence to overcome the obstacles.

**Methods:** The SUPPORT tools were used, according to the EVIPNet methodology. The search for evidence was performed in the databases: Health Systems Evidence, Health Evidence, The Campbell Collaboration, Health Services Research Queries; and manually.

**Results:** The literature about experiences in monitoring/evaluation of the prevention programs effectiveness in the mental health area is scarce. The selected study (Ortiz et al., 1979) reports the drug system information (IRSD) experience in Mexico. Two transverse assessments were carried out throughout the year, with data collected using a survey answered by illicit drugs users. The identified implementation barriers of this information system were: "non-recognition of the monitoring importance by users", "lack of training by the health professionals to interview drug users", "the need of validating the IRSD instrument to the Brazilian reality", among others. Further evidence were searched in the literature looking for ways to overcome barriers to the creation of these systems, such as "professional training", "suitable environment" and "good relationship between practitioners and patients".

**Conclusions:** The ISRD instrument can serve as an evaluation model to crack prevention programs. The literature reports barriers, but offers solutions that should be considered when implementing this type of system in Brazil. The application of EVIPNet methodology is an example of the usefulness of HTA principles in health policy-making, expanding the universe of hard technologies and innovating health management.

## OR1.5

### Offering Relevant Services for High Burden Conditions: What is the Economic Evidence?

David Paul Lindhard-Tordrup; Roberto Bertolini

World Health Organisation, Bruxelles, Belgium

**Background:** Since the 2008 credit crisis, the financial sustainability of many European health systems has come under pressure. Policy makers must increasingly balance finance with access to care. From the patient perspective, economic evidence may be more important than ever since efficient purchasing of services and commodities could become a prerequisite for maintaining broad and equitable health service coverage. In many contexts, economic evidence is explicitly taken into account through Health Technology Assessment (HTA), which reviews the cost-effectiveness of novel health technologies, however ensuring that additional spending is cost-effective contributes only marginally to the overall cost-effectiveness of a health system. Thus, health economic evidence can be an important driver of decision making at many organisational levels, and efficient overall management of conditions responsible for a high burden of disease is likely to become a prerequisite for the continued funding of health services more broadly.

**Objectives:** The present work is part of a wider project, where we aim to outline a future research agenda for the EU on health economic

evaluation, based on both gaps in the available evidence and the application of health economic studies in practice through case studies in selected countries. Here we present an overview of the state of health economic evidence for a selection of high burden conditions in the European Union, with the objective of highlighting cases where the health economic evidence required to efficiently manage these conditions is lacking.

**Methods:** We undertake a systematic assessment of current and recent research projects in the EU, United States and Canada, as well as published reviews on the health economics of the 10 conditions, which are: ischaemic heart disease, low back pain, stroke, depression, lung cancer, falls, chronic obstructive pulmonary disorder, diabetes, neck pain and other musculoskeletal problems.

**Results:** Results cannot be disseminated at this point due to organisational policies

**Conclusions:** n/a

## OR1.6

### Economics of Diabetes Mellitus: Theory and Evidence for Brazilian Data - 2008

Ramon Wiest<sup>1</sup> Giacommo Balbinotto<sup>1</sup> Paulo de Andrade Jacinto<sup>2</sup>

1. Universidade Federal do Rio Grande do Sul - UFRGS, Porto Alegre, Brazil; 2. Pontifícia Universidade Católica do Rio Grande do Sul - PUCRS, Porto Alegre, Brazil

**Background:** Diabetes Mellitus (DM) is characterized by the high level of blood glucose. It causes triggers poor wound healing, heart attack, stroke, kidney failure, vision problems and amputation of limbs. Ministry of Health data estimated that in Brazil in 2010 had about 10 million DM cases, being the fourth main cause of death in the country. WHO data estimated that the prevalence of DM in Brazil is 10.2% of the population, about 20 million people.

**Objectives:** From the human capital approach - Grossman (1972), and the classical theory of labor supply, the objective of this paper is measure the earnings losses of Brazilian workers due to DM in 2008.

**Methods:** The hypothesis is that the health status interferes in three distinct mechanisms: (i) the decision to participate in the labor market - measured through a probit model, (ii) the amount of hours worked and (iii) the productivity/earnings per hour - measured using the two-stage Heckman model. Each model is estimated separately for individuals with and without disease to capture the counterfactual effect.

**Results:** DM reduces the probability of participating in the labor market by 0,86% for men and 0,52% for women. Considering comorbidities, the reduction is 7,06% for men and 6,44% for women. There is no impact of DM on productivity for both genders and in hours worked for men, however there is a loss of 6.11% in labor hours for women. Considering comorbidities, there is no loss of productivity and hours for men, but there is a loss of 8.20% in productivity and 20.37% in hours worked for women.

**Conclusions:** DM generates significant losses in income of Brazilian workers, especially in relation to their participation in the labor market. The results indicate that public policies should be directed to the prevention of disease, since the development of comorbidities amplifies the effect of losses.

## OR2.1

### The Diagnostic Value of Fluor-18-deoxyglucose(18F-FDG) PET or PET/CT for Hepatocellular carcinoma: a Systematic Review and Meta-analysis

Jinkyung Park; Gihyeon Seo; Hyesook Ahn; Kumhee Choi; Gyungsook Roh

Health Insurance Review & Assessment Service, Seoul, Korea

**Background:** Health Insurance Review and Assessment Service (HIRA) is a statutory public corporation in Korea (South). HIRA promotes the increase in patient safety and quality in medical treatment by advocating evidence-based reimbursement criteria. In Korea, positron emission tomography(PET, PET/CT) is limited to 18F-FDG, and the reimbursement for use with certain cancers has been set since 2006.

**Objectives:** The aim of this study is to assess the clinical effectiveness(diagnostic value) of 18F-FDG PET(PET/CT) on Hepatocellular Carcinoma(HCC) based upon systematic review of published studies.

**Methods:** We searched the international databases of OVID-MEDLINE, EMBASE, Cochrane library and 4 domestic databases. Two assessors independently selected and excluded studies. Moreover, using QUADAS 2(quality assessment tool for diagnostic studies), risk of bias assessment of selected studies and data extraction were conducted. We estimated pooled sensitivities, specificities, likelihood ratio(LR), diagnostic odds ratio(DOR) and summary receiver operating characteristic(SROC) curves by meta-analysis with a bivariate model.

**Results:** Fifteen eligible studies were identified evaluating 18F-FDG PET(PET/CT) on HCC. The pooled estimates of sensitivity, specificity, LR+, LR-, and DOR of 18F-FDG PET/CT for clinical staging of HCC were 78%(95%CI 69-84%), 97%(88-99%), 26.11(6.30-108.26), 0.23(0.17-0.32), and 112.96(29.12-470.50). The pooled estimates of positive predictive value(PPV) and negative predictive value(NPV) were 82.1-94.4% and 63.9-86.7%, and the area under the SROC curve was 0.87(0.84-0.90).

The pooled estimates of sensitivity, specificity, LR+, LR-, and DOR of 18F-FDG PET/CT for recurrence evaluating of HCC were 84%(62-95%), 85%(46-98%), 5.74(1.14-28.93), 0.18(0.07-0.50), and 31.55(4.13-240.88). The pooled estimates of PPV and NPV were 86.7-98.7% and 59.5-94.6%, and the area under the SROC curve was 0.92(0.89-0.94).

**Conclusions:** Based on the results of this study(systematic review), 18F-FDG PET/CT was useful in clinical staging and recurrence evaluating on HCC. Words, 18F-FDG PET/CT provides useful information in ruling-in extrahepatic metastases of HCC and ruling-out recurrence of HCC. The results of this study will be reflected the committee of reimbursement decision about 18F-FDG PET(PET/CT).

## OR2.2

### Robotically-Assisted Coronary Artery Bypass Grafting (CABG) Surgery: a Systematic Review and Meta-Analysis

Anna Maria Buehler<sup>1</sup> Cleusa Pinheiro Ferri<sup>2</sup> Jefferson Gomes Fernandes<sup>1</sup> Tiago Veiga Pereira<sup>1</sup>

1. German Hospital Oswaldo Cruz, Institute of Education and Health Sciences, Health Technology Assessment Unit, São Paulo, Brazil; 2. German Hospital Oswaldo Cruz, São Paulo, Brazil

**Background:** The Da Vinci robotic-assisted surgical system has been used for minimally invasive CABG surgeries. However, it remains uncertain if this technology offers benefits compared to traditional surgical procedures.

**Objectives:** To conduct a systematic review and meta-analysis of the current literature on the efficacy and safety of robotically assisted CABG compared to non-robotic procedures (i.e. median sternotomy and thoracotomy).

**Methods:** Literature searches were performed in MEDLINE, Embase and Lilacs databases (from inception to 1/03/2013). The search strategy was constructed using the controlled vocabulary from each database and sensitizing by free text words. Two independent investigators evaluated study eligibility and extracted the data. Outcomes investigated were: proportion of extubated patients, operative time, intensive care unit (ICU) stay and hospitalization, odds for stroke, atrial fibrillation and mortality. Results were pooled using a random-effects model. Statistical heterogeneity was quantified by the I<sup>2</sup> index. The risk of bias was assessed using adapted domains of the Cochrane's risk bias tool, whereas the quality of the evidence was evaluated by the GRADE system.

**Results:** Our searches resulted in 563 references, from which three studies met the inclusion criteria. None was randomized. All studies had a high risk of biases. Compared to non-robotic surgical modalities, CABG surgeries were associated with more frequent extubations (odds ratio (OR): 3.55; 95% CI:1.17,10.83; I<sup>2</sup>=68.1%), a shorter hospital stay (mean difference (MD): -2.21 days; 95% CI:-3.23,-1.18; I<sup>2</sup>=62.2%), a shorter ICU stay (MD: -28.72 hours; 95% CI:-34.29,-23.15, I<sup>2</sup>=0.0%) and a lower odds for atrial fibrillation (OR: 0.60; 95% CI 0.43,0.90, I<sup>2</sup>=0.0%). There were no differences for the odds of stroke and mortality. Surgery time was increased by 99.9 minutes (95% CI=73.1,126.8, I<sup>2</sup>=87.8%).

**Conclusions:** Despite robotic-assisted CABG appears to be promising, the current evidence is not enough to strongly recommend the technology. Adequate randomized controlled trials are necessary.

## OR2.3

### Self-Sampling Devices in HPV-Based Cervical Cancer Screenin: a Systematic Review to Assess the Effect on Participation

Paolo Giorgi Rossi; Annamaria Pezzarossi; Working Group Method to increase participation

AUSL Reggio Emilia, Reggio Emilia, Italy

**Background:** The major barrier to cervical cancer screening effectiveness is still non-participation. HPV-DNA test has been proven effective as a primary screening test. This molecular test can be performed on self-collected samples, with sensitivity not-inferior, but lower specificity, than that of clinically collected cytology. These facts suggested that the use of self-sampling devices to increase participation in screening programmes in underscreened women was justified.

**Objectives:** We present the results of a systematic review on the effect self-sampling on screening participation.

**Methods:** Population: underscreened women or non-responders to screening program invitation aged 25 to 64; Intervention: mailing self-sampling device; Control: standard or enhanced recall for Pap-test at clinic; Outcome: participation; Study design: RCT.

A PubMed search was done until 31/7/2013. Abstracts to conferences and grey literature were searched.

**Results:** We found 9 studies, randomising 98072 women. Direct home mailing of the device had higher participation than standard or enhanced recall to perform Pap test at the clinic (pooled Relative Risk=2.9 95% confidence interval: 1.6-5.2). All the studies observed a positive effect but the magnitude was extremely heterogeneous (RR range 1.2 – 9.1; I<sup>2</sup>=99%).

A further study compared the participation in a population in Mexico that had never been invited before. Participation to self-sampling was lower compared to Pap-test (RR=0.85, IC95%: 0.84-0.86), but the difference was due to the women "not found at home" to whom, according to protocol, the device was not mailed.

**Conclusions:** Self-sampling devices are effective in increasing participation among non-responders. Context-specific logistical, behavioural, and cultural conditions can strongly modify the effectiveness.

## OR2.4

### Cost-Effectiveness of Dipeptidyl Peptidase-4 Inhibitors for Type 2 Diabetes: a Systematic Review

Jinsong Geng<sup>1,3</sup> Yingyao Chen<sup>1</sup> Yiwei Mao<sup>1</sup> Peng Zhang<sup>1</sup> Lizheng Shi<sup>2</sup>

1. National Key Lab of Health Technology Assessment, School of Public Health, Fudan University, Shanghai, China; 2. Department of Health Systems Management, School of Public Health and Tropical Medicine, Tulane University, New Orleans, USA; 3. Medical School of Nantong University, Nantong, China

**Background:** Type 2 diabetes (T2DM) is one of key risk factors for cardiovascular disease and mortality. Dipeptidyl peptidase-4 (DPP-4) inhibitors are a new class of anti-diabetic drugs.

**Objectives:** To assess the cost-effectiveness of DPP-4 inhibitors for the treatment of T2DM by a systematic review.

**Methods:** MEDLINE, EMBASE, NHS Economic Evaluation Database, Web of Science and EconLit were searched on November 2013. Studies assessing the cost-effectiveness of DPP-4 inhibitors for T2DM were eligible for inclusion. Two reviewers independently evaluated the quality of included studies by using criteria listed in 'Consensus on Health Economic Criteria'. Characteristics, results and conclusions of included studies were extracted and analyzed.

**Results:** Eleven studies were included in the review, all of which used economic modeling to conduct the cost-effective analysis. Seven studies were funded by pharmaceutical companies. Participants in the included studies were T2DM not well controlled by metformin alone. Seven studies suggested that saxagliptin, when added to metformin, was a cost-effective treatment alternative for T2DM. The comparison used in these studies were sulfonylurea plus metformin, thiazolidinedione plus metformin, or insulin plus metformin. One study showed that adding sitagliptin to metformin was cost-effective compared with adding thiazolidinedione or sulfonylurea to metformin. One study indicated that DPP-4 inhibitors (sitagliptin, vildagliptin), which had lower cost at present, might be more cost-effectiveness than thiazolidinedione. One study found that treatment strategy based on DPP-4 inhibitors as second-line therapy with sulfonylureas as a third-line therapy add-on provided the most cost-effective strategy. However, another study suggested that treatment with DPP-4 inhibitors or thiazolidinediones had unfavorable cost-effectiveness estimates compared with sulfonylureas.

**Conclusions:** In patients with T2DM who do not achieve the glycemic targets with metformin alone, DPP-4 inhibitors are likely to represent a cost-effective option. However, high quality cost-effectiveness analysis with no conflict of interests is still needed. (PROSPERO: CRD42013003354)

## OR2.5

### Systematic Review of Economic Evaluation of Prenatal Screening for Down's Syndrome

Yuan Huang<sup>1</sup> Yingyao Chen<sup>1</sup> Jinsong Geng<sup>1</sup> Bosheng Wu<sup>1</sup> Lizheng Shi<sup>2</sup>

1. Fudan University, Shanghai, China; 2. Tulane University, New Orleans, USA

**Background:** Down's syndrome is a common birth defect caused by autosomal disorders, which leads to the lifespan disability. It can pose huge burden on the patients and their families, and cause high use of health care services. Since there has no effective curative treatment for Down's syndrome, the prenatal screening is a common and effective way to detect Down's syndrome. There are several prenatal screening methods for Down's syndrome.

**Objectives:** To review the cost-effectiveness studies of prenatal screening for Down's syndrome and to identify the most cost-effective screening program.

**Methods:** The literatures about economic evaluation of prenatal screening of Down's syndrome were retrieved, and the quality of the

literatures included was evaluated using the consolidated health economic evaluation reporting standards. 4 English medical research databases (Cochrane library, Pubmed, Embase and NHS Economic Evaluation Database) and 2 major Chinese databases, including China Biology Medicine disc and Wanfang Database, were used.

**Results:** Of the 15 studies included in the analysis, 5 were from the U.S.A., 1 from the U.K., 4 from Canada, and 4 from China. The quality of the studies included was moderate. All the quality evaluated scores were above 14 of 24 full scores, and the highest score was 21 with two studies included. 11 kinds of prenatal screening methods were involved in the 15 studies, while each study had its own concerns. Almost all of the studies had referred to combination of serum screening and chromosome analysis in different gestation periods, which further formed the comprehensive methods, such as integrated screening, sequential screening and contingent screening. In the studies, methods of prenatal screening were dominant compared with no screening. While comparing with single-screening methods, such as serum screening only or maternal age only, comprehensive screening methods were dominant.

**Conclusions:** The prenatal intervention of Down's syndrome was cost-effective, especially for the comprehensive screening methods.

## OR2.6

### Urea for the Management of the Syndrome of Inappropriate Secretion of ADH: a Systematic Review

Oriol Solà-Morales; Maribel Riera

HITT, Barcelona, Spain

**Background:** Urea has been proposed for the treatment of hyponatremia linked to the Syndrome of inappropriate secretion of ADH (SIADH).

**Objectives:** To review the evidence for the treatment of SIADH with urea

**Methods:** Systematic review of experimental trials and grading according to SIGN

**Results:** no clinical trials were found. The 5 analysed studies show methodological limitations and are prone to biases

**Conclusions:** there is no evidence on the efficacy of Urea for the treatment of hyponatremia following SIADH

## OR3.1

### A Novel Integrated Rapid Access to Assessment and Treatment Model of Care Using Fibroscan for Patients with Chronic Virus Hepatitis in Queensland, Australia

Hong Ju<sup>1</sup> Kaye Hewson<sup>2</sup>

1. University of Queensland, Brisbane, Australia; 2. Queensland Department of Health, Brisbane, Australia

**Background:** Liver fibrosis/cirrhosis is the main cause of morbidity and mortality in patients with chronic virus hepatitis. The current gold standard to diagnose liver fibrosis prior to initiating antiviral therapy, liver biopsy (LB), is an invasive procedure performed by limited number of hepatologists. This results in a long waiting time (> 6 months) from the first clinic visit to initiation of therapy in a high proportion of patients in Queensland.

**Objectives:** To avoid risks and costs associated with LB and improve access to treatment and surveillance of patients with chronic virus hepatitis.

**Methods:** A new model of care using Fibroscan, a non-invasive method to assess liver stiffness, to screen and triage patients with chronic virus hepatitis was piloted in two public hospitals in Queensland. Based on FibroScan results, patients with no/mild fibrosis and severe

fibrosis/cirrhosis were not offered LB, potentially reducing LB waiting list, enabling rapid access to treatment and ongoing monitoring. Time interval between FibroScan and initiation of therapy, total number of appointments until commencement of therapy, and the related costs were compared to historical cohorts receiving conventional management with LB.

**Results:** Data from a 3-month feasibility study from one hospital revealed that the new model of care had lower costs ( $n=27$ , median AU\$2,716) and shorter time to treatment (median 194 days) than for LB ( $n=13$ , median AU\$5,005, 420 days;  $p<0.01$ ). Differences were due to the lower costs of FibroScan test and the consults between first medical review and establishment of a treatment plan.

**Conclusions:** Early experience and preliminary data suggests FibroScan used as part of a new model of care is potentially cost saving in the short-term and reduces waiting times. This approach has potential to improve the efficiency with which patients with chronic virus hepatitis are managed in public health systems.

### OR3.2

#### Health Technology Assessment of Pulse Wave Velocity and Ankle Brachial Index: Reimbursed by the Health Insurance in Shanghai or Waiting for Further Evidence?

Yiwei Mao<sup>1</sup> Yingyao Chen<sup>1</sup> Raymond Pong<sup>2</sup>

1. Fudan University, Shanghai, China; 2. Laurentian University, Sudbury, Canada

**Background:** Pulse wave velocity (PWV) and ankle brachial index (ABI) are non-traumatic methods that can be used to diagnose arteriosclerosis, peripheral arterial and other diseases. These two diagnostic techniques are widely used in some parts of China, but they are not covered by health insurance plans.

**Objectives:** To collect safety, effectiveness, and economic information pertaining to PWV and ABI, assess current evidence supporting the use of PWV and ABI, and make recommendations on whether the Shanghai Employee Health Insurance Scheme should cover them.

**Methods:** Systematic review and meta-analysis were conducted on pertinent articles retrieved from Medline, Cochrane, Embase, Ovid, China National Knowledge Infrastructure and other databases.

**Results:** There were five PWV-related articles and eight ABI-related articles. The studies showed that both PWV and ABI were safe. Since the specificities of the two diagnostic techniques were high and sensitivities were low, they were deemed to be more effective among high-risk populations, such as smokers over age 50 and individuals with other cardiovascular risk factors. The cost per visit is about US \$20. The percentage of people with at least one cardiovascular risk factor in China is 73.4% according to an epidemiological survey, and the size of the age-50-or-over population in Shanghai was about 7 million. Thus, we estimate the costs of the two techniques applied in high-risk populations are over \$100 million annually. It seems that it is beyond the Shanghai government's financial capability to cover the costs, particularly in light of the rapidly aging population. But since PWV and ABI are very effective among specific groups, the government should consider reimbursing part of the costs.

**Conclusions:** This study suggests that PWV and ABI can be used for screening or diagnosing individuals aged 50 or over with at least one cardiovascular risk factor. However, the Shanghai Health Insurance Scheme should only provide partial reimbursement.

### OR3.3

#### Promoting Patient's Medication Safety Through SMS Media Campaigns, the Aids Support Organization (TASO) Uganda, Experience

Justine Negesa; Jonathan Wangisi

The AIDS Support Organisation (TASO), Kampala, Uganda

**Background:** Unsafe medication/unsafe use of medication: public health challenge in Uganda. Patients are harmed/ loose lives. challenges: lack of adherence, self medication, quality/safety of medicine, adverse drug reaction (ADRs), High consumption of substandard and counterfeit medications, seeking alternative health care, low literacy levels, leaky supply chains, weak regulatory capacity; medicines dispensed without prescription, sale of drugs in market places and buses, pharmacists diagnosing, prescribing and treating, inadequate/ ill trained personnel to handle and control drug safety. TASO provides health services to 96,000 people living with HIV/ AIDS (68,584 on antiretroviral therapy). 5% of patients referred for hospital admission; unsafe use of medication, contribute to patient morbidity, account for most frequent reasons for treatment modifications and interruptions. Pharmacovigilance systems performance, 2011 report; increasing access to newly introduced essential medicines; greater need to monitor and promote their safety and effectiveness

**Objectives:** Raise patient's awareness to ensure that they receive safe medicines and know how to use them correctly/safely. Empower patients, consumers, healthcare professionals to promote patient medication safety & patient centered healthcare.

**Methods:** Conducted meetings; patient's organizations, National drug authority, consumers, community leaders, health workers to design medication safety messages. Recorded patients/health consumer's mobile phone numbers, multi-angle message delivery & in themes; posted mobile phone personalized medicine reminders, caller tunes, SMS, voice messages, Multiple answer interactive quiz questions, radio adverts; spots, jingles and dramas; targeting patients groups; people living with HIV, tuberculosis, malaria, cancer, sick cell, diabetes, Caller centre enabled follow ups.

**Results:** Patient's under TASO care are empowered and are essential tools for improving safe use of medicines, reduces hospital referrals, Mobile phone promote public health information including disease management, sexual health promotion, health education, medicine adherence, quick recovery of patients

**Conclusions:** Patient access to appropriate medicine information, appropriate transcribing and verification of medication improves health practice, facilitates quick recovery, enhances adherence and reduces adverse drug reaction

### OR3.4

#### Assessment of the Fast Track Surgery for Kazakhstan

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**Background:** In recent years, Kazakhstan's healthcare experiences global changes, whereupon our medicine is becoming increasingly competitive. With the aim of improving the efficiency of the healthcare, its system of organization, management and financing were reformed. Impressive progress has been made in transplantation, microsurgery, neurosurgery, cardiac surgery and other medical fields. The introduction of advanced technology enabled for Kazakhstan's medicine achieve the quality level of healthcare of developed countries in the world which conduct such as unique technologies transplant artificial left ventricle, the donor liver, etc.

**Objectives:** Health System Modernization involves the transfer of technology from countries near and far abroad, followed by their introduction into medical practice. Multidisciplinary surgical service



of Kazakhstan is positioned as a platform for the introduction of the world's highest technology in the field of surgery.

**Methods:** The literature review of the efficacy and safety «Fast track surgery» were conducted on the database of the Cochrane Library, a database of bibliographic review on the effectiveness of medical intervention (Database of Abstracts from Reviews of Effectiveness - DARE) and database reviews of health technology assessment (Health Technology Assessment - HTA).

**Results:** The search for effective treatments for surgical patients contributed to the emergence of a new concept - «Fast track surgery». Clinical trials of using the FTS program yielded enough data about decreasing the number of complications and reducing length of hospitalization compared with the conventional post-surgical care, with condition of keeping a clear and coherent interdisciplinary cooperation among the different specialists: surgeons, anesthesiologists, nurses, physiotherapists, doctors, general practitioners and specialists for rehabilitation.

**Conclusions:** Results from clinical studies underscore the depth and complexity of the processes taking place at different levels of care for these patients, therefore it is necessary to conduct further clinical studies to provide higher levels of evidence.

### OR3.5

#### Patient Safety Climate in Secondary General Public Hospitals in Shanghai

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**Background:** Increase of disease complexity and advance in health technology in patient care has increased risks of medical error in hospitals. Like high risk industries, such as aviation, nuclear energy and shipping, health care industries try to predict patient safety, using term of "safety culture". The components of safety culture include management behaviors, safety systems, and employee perceptions of safety. With the reform of public hospitals in China, many efforts has been made to improve patient safety in public hospitals.

**Objectives:** To describe workforce perceptions of patient safety climate in public hospitals in Shanghai, China and to determine whether perception of patient safety climate varies across workers in different types of jobs.

**Methods:** A modified Patient Safety Climate Survey in Healthcare Organization had been developed to assess patient safety climate in Chinese hospitals. The survey of employees of 6 secondary general public hospitals in Shanghai was conducted during 2013. We used the percentage of "problematic responses" (PPRs) to measure the level of safety climate, and compared the PPRs among employees with different job types, using the  $\chi^2$  tests and multivariate models.

**Results:** Perceptions of patient safety climate were relatively positive among hospital employees, but the highest PPRs were in the scales of "fear of blame" and "fear of shame". Hospital managers perceived a more positive patient safety climate overall than other types of personnel.

**Conclusions:** The two dimensions of "fear of shame" and "fear of blame" may be the most important barriers to improvement of patient safety in Chinese hospitals. Managers in Chinese hospitals should be aware of the impact of Chinese culture, mechanism of pay for performance, and employee workloads on patient safety climate.

### OR3.6

#### Implementing Community Based Support for People with Severe Mental Illness – Experiences from Denmark

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**Background:** Community based mental health also includes activities by volunteers, such as the so-called 'community families' who offer people with severe mental health problems regular contact with private families. The present study analyses experiences with a country-wide project in Denmark, which introduced 'community families' in seven local authorities between 2006 and 2011. The focus is on patients' experiences with 'community families'.

**Objectives:** The objective is from the patient's perspective to gain insight into and understanding of the project. This paper focuses on issues related to patients' motivation for and experiences with participation in the project.

**Methods:** The analysis draws on qualitative interviews with patients participating in as well as patients who previous had participated in the project. Data was collected during the entire project period.

The analysis is a sub-project of a research project which investigates the qualitative/quantitative effects of the project.

**Results:** Predominantly the motivation was a desire of establishing a relationship to adults outside the psychiatric system and of acquiring an oasis from the system. However "the longing" for was typical mixed with anxiety about and concern for that the relationship would go wrong.

The motivations were mirrored in the experiences. Positive input with someone who did care about you without discussing "plans for treatment" and "mental illness" was the leading experience. Added to this many patients faced challenges which often were overcome due to the desire of keeping the relationship. Worry of being odd and of missing the "family" were also central issues.

**Conclusions:** Central in the discussion is the issue of the involvement of professional staff in a service like this "outside the system".

To facilitate a successful 'community families'-relationship it seems crucial that the professional staff is involved when the match patient-family is done and is accessible when needed to resolve a challenge or to assist in finalizing a relationship.

### OR4.1

#### Modern Dressings and Skin Grafting in the Management of Diabetic Foot Ulcers in Cipto Mangunkusumo Hospital Jakarta Indonesia

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**Background:** Diabetic foot ulcer is the most common chronic complication in diabetic patients. In 2012, there were 3,794 diabetic patients hospitalized in Cipto Mangunkusumo Hospital (CMH) which 31.4% of them experienced diabetic foot ulcers and gangrenes. The use of modern dressing was expected could improve healing rate of wound, but will contribute high cost. After wound care with dressings, the decision for skin grafting or primary healing must be carefully considered.

**Objectives:** To develop the local recommendation for the management of diabetic foot ulcers in CMH for the use of modern dressing and skin grafting.

**Methods:** We searched databases in MEDLINE, Cochrane Library, Ebscohost for meta-analysis and randomised controlled trial (RCT) studies of Diabetes Mellitus Type 1 or 2 with foot ulcers. We excluded all non-Indonesian nor non-English articles.

**Results:** Meta-analysis of two studies comparing hydrocolloid with conventional dressing found no statistically significant difference in the number of ulcers healed (RR 1.01; 95% CI 0.74 – 1.38). Two meta-analyses of three studies and one RCT comparing hydrogel with conventional dressing found significantly greater healing in hydrogel group (RR 1.84; 95% CI 1.30 – 2.61). Three studies also showed adverse events in hydrogel group was lesser than those in conventional (RR 0.6; 95% CI 0.38 – 0.95). More studies are needed to confirm the cost effectiveness of modern to conventional dressing. No comparison of skin graft and primary healing was found in the literature search.

**Conclusions:** Some evidence suggested hydrogel are more superior compared to conventional dressing, however there were concerns regarding risk of biases in the original studies. Recently, there is no sufficient evidence indicated hydrocolloid and hydrogel are more cost-effective compared to conventional dressing. Some evidence also showed there is no difference in healing effects between hydrocolloid and conventional. No evidence was found on the comparison between skin graft and primary healing.

#### OR4.2

##### Assessing the Effectiveness of Electronic Documentation in Australian Nursing Homes

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**Background:** Information technology offers promise for improving the efficiency of residential aged care, a major area of health services. However, its adoption in Australian nursing homes has been limited. In part, this reflects uncertainty on the effectiveness of IT in a workforce that has limited experience in the use of computers.

**Objectives:** To obtain information, in collaboration with five aged care organisations, on the implementation, use and benefits of electronic documentation in nursing homes

**Methods:** A mixed methods approach including qualitative interviews with staff in nine nursing homes; audits of admission and assessment forms, care plans, and the quality of paper and electronic records; and a work sampling study following implementation of electronic documentation. Feedback was obtained from the collaborating aged care organisations.

**Results:** Benefits from electronic systems perceived by caregivers included improvements in documentation efficiency and better communication between residents and staff. However, electronic systems had poorer scores than paper records for use of succinct language and factual statements.

Caregivers tended to use the electronic systems rather than oral communication, but maintaining this change was a challenge. It may take over a year for nursing staff to completely integrate an electronic documentation system in their daily work. Entry of some data into a computer was considered to be inefficient when compared with carers' paper-based procedures.

Collaborating organisations reported that this research facilitated their transition from paper to electronic records, providing understanding of success indicators, and of areas for improvement.

**Conclusions:** The usefulness of electronic documentation systems in nursing homes was confirmed, with some caveats. Achievement of sustainable benefits requires continuous training and support of

caregivers. Account must be taken of staff competencies, and the compatibility of available electronic systems with established practices.

#### OR4.3

##### Health Technology Assessment (HTA) in a Community Hospital: Lessons from the Learning Curve

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**Background:** Decisions in health technologies (HTs) uptake are taken in both High-Tech and Community Hospitals. However HTA activities in the latter are scarcely established.

**Objectives:** To present the experience from the set up and first steps of a HTA Committee in a community hospital through a case-study on the assessment of video Head Impulse Test (vHIT), a new technology for Vertiginous Syndromes and Other disorders of vestibular system (ICD-9-M code: 386).

**Methods:** A multidisciplinary HTA Committee was set up. Perception on the role of HTA in hospital before and after the first assessment and relative importance of the assessment criteria were collected among members of the Committee. The latter were compared with the weights given by professionals in a close High-Tech hospital. The vHIT was assessed using the mini-HTA tool.

**Results:** Hospital based HTA (HB-HTA) was perceived initially as a cost-containment tool. Perceptions were positively changed after the first assessment. The assessment took longer than expected, several reasons were identified dealing with HTA process (e.g. lack of HTA knowledge among clinicians, lack of skills in some HTA areas) and the technology itself (e.g. heterogeneous evidence). Weights given to assessment criteria do not differ from those given by clinicians at High-Tech hospital.

**Conclusions:** Understanding of the role of HB-HTA in a hospital is acquired through hands-on. Decisions on technology uptake are mainly driven by the same criteria as in high-tech centers. The long learning curve points out the need of a route-map to make more efficient the implementation of HB-HTA activities in a hospital.

#### OR4.4

##### Health Technology Assessment of Rehabilitation Hospital: a Review

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**Background:** The role of rehabilitation centers in the service industry has grown considerably in the two past decades due to medical advances improved health status, and increased longevity has led to increased elderly in the society.

**Objectives:** This study aims to assess the rehabilitation hospital in terms of effectiveness, cost effectiveness and the process of services organizing.

**Methods:** The Cochrane library, CRD (Centre for Reviews and Dissemination), Scopus, and Google scholar were searched until June 2012. The studies compared types of rehabilitation centers for the treatment of patients with motor or perception disability with other common rehabilitation methods in terms of functional outcomes,

Barthel index, QALY and cost per QALY, were included. Results were analyzed using qualitative method.

**Results:** The fifteen articles were included, for inpatient centers, early rehabilitation led to the rapid acquisition of functional abilities than outpatient centers (1.55 vs. 0.50). The Barthel index scores in patients with inpatient rehabilitation ( $42 \pm 29$  points) were more than outpatient rehabilitation ( $26 \pm 23$  points) ( $P < 0.050$ ). In term of cost-effectiveness of heart diseases, the adjusted cost difference between outpatient and inpatient rehabilitation was about -2895 Euro ( $P = 0.102$ ); adjusted effect difference was about 0.018 QALY (Quality-adjusted life year) in favor of outpatients rehabilitation, too.

**Conclusions:** Considering to the potential performance of rehabilitation services and outpatient clinics in day clinics, the establishment of rehabilitation hospitals was not recommended. Therefore, it is proposed to provide services to disabled patients in "rehabilitation units" established in specialized hospitals.

#### OR4.5

##### Early Results of AdHopHTA and Potential Contribution to Development of HTA in Turkey

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**Background:** AdHopHTA (Adopting Hospital Based Health Technology Assessment in EU) is a European Union project started in 1st september 2012 for a 36 month period. Ten partners take part in the project from 9 countries; Spain, Denmark, Switzerland, Turkey, Italy, Finland, Estonia, Austria, Norway. The project aims at strengthening the use and impact of quality HTA results in hospital settings, making available pragmatic knowledge and tools to boost adoption of hospital based HTA initiatives. Turkey has established its first national HTA unit and first hospitalbased HTA unit in 2012.

**Objectives:** We aim to present early results from the AdHopHTA project regarding the arm run in Turkey and would like to discuss how the project has the potential to contribute further development of HTA in the country.

**Methods:** We have run interviews with several hospital CEOs and clinical directors for the project. We also interviewed heads of HTA units. This has been an opportunity to hear their views and opinions on HTA. The results were qualitatively analysed.

**Results:** The interviews done for the project have revealed that there is a great interest for HTA by the clinical directors and CEOs of the hospitals, although the awareness, especially on hospital based HTA, is limited. We observed that they would like to develop their technical skills and learn more of HTA. CEOs have the most important role in current decisionmaking process. The heads of units wanted a well-established collaboration between national and hospital levels, but there is no formal collaboration as of today. The interviewees were interested in the project and emphasized they would like to receive the final toolkit.

**Conclusions:** The developments in HTA field recently in the country is promising and AdHopHTA seems to be a good opportunity to further support development of HTA in Turkey.

#### OR4.6

##### Bridging Hospital-Based and Regional/National HTA in Norway

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**Background:** To strengthen patient safety in Norwegian hospitals, a system for introducing new health technologies in hospitals has been established. In this system, HTA will be a tool to support prioritisation and decision-making, both at the hospital level, regional level and national level. An interaction between the different levels of HTA-activities is a prerequisite for the well-functioning of the system.

The present abstract is part of the EU-funded project "Adopting hospital-based health technology assessment in EU" (AdHopHTA).

**Objectives:** To describe the interactions between the hospital-based and regional/national HTA-activities in Norway.

**Methods:** This case study is, to a large extent, based on the results from an extensive national consensus process preparing the establishment of the new system for introduction of new health technologies in Norway.

**Results:** Norway has chosen a model that formally regulates the interaction between hospital-based HTA and HTA-activities at the national level. Clear criteria exist for when hospitals should interact with the regional and national levels after the completion of a mini-HTA. Likewise, the national HTA-agency in Norway, the Norwegian Knowledge Centre for the Health Services (NOKC), has a responsibility to assist and provide advice to HTA-activities at the hospital level.

Completed hospital-based HTAs (mini-HTAs) are published in an open-access national database, primarily to secure transparency in the process and avoid duplication of work. If uncertainty regarding clinical effectiveness or safety still exists after the completion of a mini-HTA, a more comprehensive evaluation of the technology in question may be performed at the national level.

**Conclusions:** In order to maximise the HTA-resources in the new system, it is required that the HTA-activities between the different levels are well regulated. In this way, hospital-based and regional/national HTA-activities may take advantage of each other. The formalization of the interaction between different levels of HTA in the new system will facilitate the interaction between levels.

#### OR5.2

##### Nadroparin in the Treatment of Patients with Pulmonary Embolism (PE)

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**Background:** PE is a cardiovascular urgency, with a complex diagnosis and early death. It has a wide clinical spectrum and is a clinical condition of high morbidity and mortality caused by blockage of the pulmonary artery by a thrombus that originates and evolves in venous territory. Thus, undiagnosed or untreated thromboembolic episodes predisposes to recurrence. Drug treatment includes the use of anticoagulants and thrombolytics.

**Objectives:** To evaluate the efficacy and safety of nadroparin (an anticoagulant agent) to EP, especially regarding to: PE recurrence, thromboembolic events and side effects.

**Methods:** A systematic search was conducted in 5 databases aiming to retrieve the best scientific evidence available. A request to INAHTA members was also done in order to know if they have made any HTA on this subject. The selected studies were evaluated according to Brazilian Ministry of Health's Rapid Review Guideline (3rd edition) criteria.

**Results:** Two studies were selected – 1 Randomized Clinical Trial (RCT) and 1 prospective cohort. The first one compared 3 dosages of nadroparin to unfractionated heparin (UFH) in 101 patients for 14 days. It evaluated the evolution of pulmonary vascular obstruction in half of the population before and after the treatment (80 day  $\pm$  1) and there wasn't statistical difference between nadroparin and UFH. The second one did the analysis of PE ambulatorial treatment with nadroparin and vitamin K antagonist in 297 patients for 3 months. During this period, 6 patients had recurrent venous thromboembolism, 2 had a major bleeding event and 3 died. Furthermore, 16 HTA agencies have answered our request and none have made any HTA on the subject.

**Conclusions:** The studies show incipient data, which outcomes analysis for an infinitesimal follow-up period that doesn't allow inferences for a longer period. So, up until now, there is no strong scientific evidence concerning nadroparin for EP treatment.

### OR5.3

#### Clinical Effectiveness of Art Therapy in People with Non-Psychotic Mental Health Disorders: Health Technology Assessment for the National Institute for Health Research, UK

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**Background:** Mental health problems account for almost half of all ill health in people under 65. The majority are non-psychotic (e.g., depression, anxiety, and phobias). For some people, art therapies may provide more profound and long-lasting healing than more standard forms of treatment, possibly because they provide an alternative means of expression and release from trauma.

**Objectives:** We aimed to systematically review the relative clinical efficacy of art therapy for people with non-psychotic mental disorders and to identify areas worthy of further research.

**Methods:** Comprehensive searches of databases including Medline, Embase and Cochrane were undertaken. Supplementary searches, grey literature sources and hand searching of key journals were also conducted.

Inclusion criteria were randomised controlled trials of art therapy in patients with or without a mental health diagnosis. Exclusion criteria included psychotic patients and patients without mental health symptoms. Outcomes of interest were psychological symptoms and quality of life.

**Results:** Of the 10270 records retrieved, fourteen studies were included into the review. Study populations included adults and children with: depression; cancer; HIV/AIDS; sickle cell disease; PTSD; dementia; asthma. Due to the scarcity of data in each condition as well as heterogeneity of clinical profiles and outcomes measures, meta-analysis was not possible. Art therapy was reported to have significant positive effects in outcome measures in 9 studies. Comparators were: treatment as usual; CBT; psychodynamic psychotherapy; regular programme activities; simple calculations; art & craft activities; garden walking; educational support and viewing a video tape. Four studies reported improvement from baseline but no significant difference whilst one study reported outcomes were worse in the art therapy group. The quality of included trials was poor to moderate.

**Conclusions:** Evidence from high quality trials of art therapy in non-psychotic populations are required to determine the relative benefits of art therapy in pre-specified populations versus other interventions, including no active treatment.

### OR5.4

#### Eculizumab (Soliris®) for the Paroxysmal Nocturnal Haemoglobinuria: a Rapid Review

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**Background:** The Paroxysmal Nocturnal Haemoglobinuria (PNH) is a rare disease characterized by cell hemolysis. The most common signs and symptoms are anemia, fatigue, haemoglobinuria, abdominal pain, erectile dysfunction and thrombosis. Eculizumab is a biological drug, classified as monoclonal antibodies which binds with high affinity to Complement System C5 protein, inhibiting the cleavage of C5 to C5a and C5b, and therefore hemolysis. In Brazil, the product is not registered in the National Health Surveillance Agency (ANVISA) and its demand is mainly by legal queries. The estimated annual cost of treatment per patient in Brazil is \$ 472,379,39.

**Objectives:** To assess whether the use of eculizumab is safe and effective for treatment of patients with PNH.

**Methods:** A broad search was performed in September 2013 in Medline (Pubmed), Embase, CRD, The Cochrane Library and Brazilian Network for Health Technology Assessment database (SISREBRATS). In addition, consultation was carried out by e-mail to members of the International Network of Agencies for Health Technology Assessment.

**Results:** Nine studies were selected: one randomized clinical trial (RCT) and eight uncontrolled intervention studies. In addition, it was included two results of official documents, one from the FDA and other from the Scotland NHS, and five HTA. Studies results were favorable to the use of eculizumab mostly for the outcome of reducing hemolysis and anemia, besides the extension studies showing probable reduction of thromboembolic events. However, the available studies have important methodological limitations that compromise the results reliability and the quality of evidence. The recommendations of international agencies were unfavorable to the use of eculizumab.

**Conclusions:** It was evident the lack of studies with improved methodological quality to answer the research question. To evaluate a possible superiority of treatment with eculizumab in patients with PNH randomized controlled studies are needed with good methodological quality, including randomization, blinding, control group, subgroup analysis and appropriate follow-up.

### OR5.5

#### Equal Access to Treatment in Elderly Patients with Acute Myocardial Infarction: a Case Study in a Shanghai Hospital

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**Background:** Under the background of new medical reform of China, basic medical security system has been carried out since 2011 in Shanghai. It is necessary to explore the equal access to treatment in elderly patients with acute myocardial infarction.

**Objectives:** To investigate social and insurance equality in access to treatment for those patients with acute myocardial infarction in Shanghai between 2007 and 2012.

**Methods:** A retrospective cohort study was conducted within the large teaching tertiary hospital. All patients over 65 years old with a hospital stay for acute myocardial infarction were eligible for the study, in total 994 persons. The Hospital Discharge Register during six years was used to define the study population. The patients were divided into four groups according reimbursement (A:0, B:70%~79%, C:80%~89%, D:90%~). Length of stay (LOS), inpatient costs, surgery costs and in-hospital mortality were examined. Chi-

square test and ANOVA were used to estimate the effect of socio-economic and insurance status for the treatment of percutaneous coronary intervention (PCI).

**Results:** There was significant difference in the mean of LOS (A:11.07days, B:10.65days, C:13.41days, D:14.77days), mean of total inpatient costs (A:39454.12 CNY, B:54650.22 CNY, C:47354.25 CNY, D:23651.48 CNY), mean of surgery costs(A:16714.22 CNY, B:31506.45 CNY, C:25581.28 CNY, D:6698.87CNY) and in-hospital mortality(A:9.00%, B:4.82%,C:5.81%,D:25.43%). LOS and in-hospital mortality in the highest reimbursement group were the highest. However, total inpatient cost and surgery cost were higher in the middle groups than the lower and highest groups and the line were U type.

**Conclusions:** A strong association was found between insurance status and the treatment quantity and quality in patients receiving PCI surgery within AMI patients. The finding suggests that there are insurance and socio-economic inequalities in access to cardiac procedures in Shanghai. Further studies are needed to determine the factors to the inequalities of the provided treatment.

## OR5.6

### A Comparative Study of Semiautomated Defibrillators for In-Hospital Early Defibrillation

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**Background:** Semiautomated external defibrillators (AEDs) should be considered as a means to facilitate in-hospital early defibrillation (IHED) in areas where advanced life support rescuers are not readily available.

**Objectives:** In this study, we aimed to develop a checklist and a measurement protocol to evaluate and compare AEDs by assessing factors that may affect IHED.

**Methods:** A clinical and technical comparison of six AEDs was performed. Technical specifications were analyzed, while an emergency team evaluated ergonomics and appropriateness for IHED at Bambino Gesù Children's Hospital. A measurement protocol was implemented, which aimed to assess the ability of defibrillators to recognize shockable and non-shockable rhythms, accuracy of delivered energy, and charging time.

**Results:** Designs of AEDs differed in several features which influence their appropriateness for IHED. Some units showed poor ergonomics and instructions/feedback for cardiopulmonary resuscitation. Differences between defibrillators in recognizing shockable and non-shockable rhythms emerged for polymorphic ventricular tachycardia waveforms and when the frequency and amplitude of input signals varied. Tests for accuracy revealed poor performances at low and high impedance levels for most AEDs. Notably, differences greater than 20 s were found in the time from power-on to "ready for discharge".

**Conclusions:** The approach we employed to assess AEDs allowed us to evaluate their appropriateness with respect to the organizational context, to measure their parameters, and to compare models. Results showed that ergonomics and/or performances (timing and accuracy) could be improved in each device.

## OR6.1

### Web 2.0 Utilization in Health Technology Assessment Agencies of Euroscan

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**Background:** The emergence of Web 2.0 and its tools as a mean of mass communication requires further analysis on its utility and real implementation in HTA.

**Objectives:** To analyse the perceptions on the utility and real utilization of the Web 2.0 and its tools by the members of EuroScan International Network.

**Methods:** A questionnaire tested and validated by Spanish HTA agencies was distributed among the representative members of the different organizations conforming EuroScan (n=18). It included degree of knowledge, the acting role on the net and the possible impact of Web 2.0 in HTA.

**Results:** The response rate was 83% (15 out of 18). The knowledge around Web 2.0 and its tools was widespread among the respondents. Regarding its use, no significant differences were encountered on internal use, external production or consumption.

In terms of acting role of respondents, we observed three predominant profiles: 83% act as viewers of other's contents, 67% as content creators and 50% as participants, just expressing their opinions.

The Web 2.0 applications are considered increasingly important in HTA context and their impact and leading use in HTA mainly relates to products' dissemination.

Regarding the impact of Web 2.0 to contact interest groups, they highlighted the role of these tools to better communicate with health manufacturers, professional associations and patients.

The outmost used tools were webalerts and social networks (83%), mainly Facebook and LinkedIn. Other mentioned applications were RSS (67%), wiki (58%) and, surveys and document sharing (50%).

**Conclusions:** The utilization of Web 2.0 is mentioned to be an easy way to improve knowledge transfer. Moreover, according to previous and current analysis, Web 2.0 can be used as a mean of dissemination of the HTA products. Once again, the impact of these tools in real practice should be tested and analysed on the basis of defined metrics.

## OR6.2

### Does HTA Affect Decisions and Clinical Practice - Case Studies from SBU

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**Background:** Health Technology Assessment (HTA) has the ultimate objective to give a basis for more evidence-based healthcare and a more efficient use of scarce resources. The question is whether HTA reports and systematic reviews have impact on health care.

**Objectives:** The aim is to analyse if it is likely that SBU (the Swedish Council on Health Technology Assessment)-reports have influenced changes in clinical practise, guidelines or research priorities in Sweden.

**Methods:** SBU has attempted to measure the impact of its reports on clinical practise by conducting surveys or register-based follow-ups before and after the presentation of its conclusions. Based on a theoretical model and 26 case studies we analyse changes in trends and the likelihood that changes have been influenced by HTA-reports.

**Results:** The follow-up shows varied, but in many cases substantial changes in clinical practise. The reports are from a wide variety of diagnostic and treatment methods, e.g. surgical treatment for severe obesity, mild head injury and home blood pressure monitoring. In many other cases, HTA has been the primary source for clinical guidelines developed by the National Board of Health and Welfare or professional

societies. It is also obvious from this review that research has been initiated as a result of the knowledge gaps identified by SBU.

**Conclusions:** Many interrelated forces change practise, but all the presented cases, commonly with direct and substantial changes after publication of HTA reports, indicate the importance of HTA. The conclusion is that HTA contributes to a more effective health care in Sweden.

## OR6.5

### Evaluating Implementation Strategies – Modelling the Link Between Information and Implementation Dynamics Using Data Obtained from Elicitation of Expert Opinions

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**Background:** With health technology uptake considered low in many countries, there has been recent discussion on evaluating implementation strategies that help reach more patients who may benefit. The relationship of further research evidence and implementation has been of particular interest for the use in expected value of information and implementation analyses. However, it remains unclear how this relationship can be described and data obtained. One added modelling complexity lies in the dynamic nature of implementation.

**Objectives:** To propose methods for identifying drivers of implementation, estimating future implementation and quantifying the effects of further research on implementation for a new pre-term birth screening technology.

**Methods:** Drivers of implementation were identified through qualitative interviews with stakeholders. We selected an implementation dynamics model after having conducted a review of existing models. We performed elicitation of expert opinions using the Sheffield Elicitation Framework (SHELF) to generate estimates of future implementation and to quantify the effect of the main implementation drivers identified.

**Results:** Further evidence was found to have the greatest impact on future implementation, specifically research on a) the predictability of the screening technology and b) improved pre-term birth outcomes when screening was combined with treatment. The model of new product growth developed by Bass was chosen to predict implementation dynamics. We found that availability of more evidence had a positive effect on future implementation with both types of research, but more significantly so with type b) evidence. Given more evidence, implementation was predicted not only to reach a higher level but also to exhibit a more rapid growth.

**Conclusions:** We have proposed approaches to identifying key drivers of implementation and to quantifying implementation dynamics. These methods are easily transferrable to other technologies and may enable researchers to evaluate implementation strategies, to inform expected value of information and implementation analyses and may support decision-makers in setting research priorities.

## OR7.1

### Korean Cost-effectiveness Threshold Revisited - Asian Collaborative Study

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**Background:** Though cost-effectiveness threshold is an important standard for assessing economic efficiency of health technologies, studies on Korean threshold is rare.

**Objectives:** To compare the threshold estimated in the previous NECA study and the Asian collaborative study and to suggest a rational threshold for Korea

**Methods:** A survey of Willingness-to-pay (WTP) questionnaire based on EQ-5D scenarios (mild, moderate, severe) and End-of-Life (EOF) scenarios was developed in 2012 to measure a threshold value in four Asian countries - Japan, Korea, Malaysia, Thailand. The Korean survey was performed among the Korean adults aged between 20 and 60 with quota on gender, age group, and regional population. Prevention scenarios are added in Korean WTP survey. The format of WTP elicitation was designed as Double Bounded Dichotomous Choice (DBDC) questions along with an open question were used to elicit WTPs. Number of respondents was 1,932, almost doubled from the previous study. The main analysis of threshold value was based on the final open-ended questions but DBDC analyses, Nonparametric Turnbull Estimation (NTE), Interval Data Model (IDM), Bivariate Probit Model (BPM), Random effect Probit Model (RPM), were added for sensitivity analysis purpose.

**Results:** After excluding those respondents answered zero WTP for all scenarios (protesters; N=25), 1,907 respondents were used in the analysis. The average WTP for EQ-5D scenarios were 20.5 million KRW, 30.7 million KRW, 40.3 million KRW for mild, moderate, severe case scenarios. Those of EOF scenarios were 29.7 million KRW to 32.4 million KRW. The grand average of all five types of scenarios (threshold value) was 30.5 million KRW, which is about 1.5 times higher than the 2010 study. The difference may be resulted by differences in method for WTP elicitation: quota on regional population and scenario differences.

**Conclusions:** New threshold value estimated in Korea is a little higher than 1 GDP level, which is similar to other countries.

## OR7.2

### Audit of Adherence to Health Technology Assessment Guidance for New Procedures with an Uncertain Evidence Base

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**Background:** New procedures are often used in health services before the evidence for their safety or efficacy is clear. In the UK, the National Institute for Health and Care Excellence (NICE) normally specifies, as one of its recommendations that written information about the procedure and its uncertainties should be provided to all patients.

**Objectives:** To audit whether NICE recommendations about consent are followed for new procedures when evidence on their safety and/or efficacy is inadequate.

**Methods:** Collaboration with surgical trainees in hospitals throughout the UK to discover whether specified procedures were being done; whether written patient information was available; what it contained; and (by questionnaire) what obstacles specialists perceived in providing information.

**Results:** Responses were received from 31 hospitals. Written patient information was available in 27 of 35 instances where procedures were being done. Inclusion of written information about specific risks highlighted in NICE guidance was variable. Specialists cited time constraints (16), logistic difficulties (15), lack of available information packages (10) and local resistance (6) as obstacles to providing information.

**Conclusions:** Written information (supplementing verbal explanation) should be part of high quality care, especially when procedures are new and aspects of their safety or efficacy are uncertain. Despite

NICE recommendations, provision of information is inconsistent and specialists perceive a variety of obstacles. Improvement is needed including more effective publicity of recommendations; better local policies in hospitals; and culture change among both specialists and trainees to ensure that adequate information is available to patients.

### OR7.3

#### Differences and Similarities of Models for the Identification of Ineffective Interventions: Deriving Good Practice Recommendations Based on International Experiences

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**Background:** Decision makers are facing rising health care costs all over the world. Many interventions currently in use have never been systematically assessed regarding effectiveness, cost-effectiveness and safety. Active identification of ineffective interventions is thus gaining importance to facilitate the best possible use of limited resources and to provide effective and safe care for patients.

**Objectives:** To identify differences and similarities of models for the identification of ineffective interventions and to derive recommendations for their implementation based on good practice examples.

**Methods:** A systematic literature review was conducted in addition to a handsearch on HTA-websites. Models were included and analysed according to predefined criteria. To gain additional information, international experts were consulted via a half-standardised questionnaire.

**Results:** 8 already implemented models for the identification of ineffective interventions were identified, mostly additionally including prioritisation and assessment of identified interventions. Similarities concern objectives, stakeholder involvement, choice of target groups, information sources (person- and literature-based), identification criteria (effectiveness, costs and benefit) and prioritisation criteria. Outputs – largely HTA reports or lists – are mainly disseminated passively via internet.

Government initiated models stand opposed to models that have been brought up by either practitioners or individual institutions – both approaches do have benefits when it comes to the implementation of recommendations either as binding guidelines or as non-binding information for physicians and other stakeholders. One model has a remarkably broader dissemination strategy than the others and thereby enhances the reachability of stakeholders considerably.

**Conclusions:** More similarities than differences were identified. However, several challenges, derived from international experiences, concern the models' dependency on evidence, an absence of definitions and lacking acceptance by physicians as the most important target group. Admittedly, for a sustainable implementation of identification processes and formulated recommendations the increase of acceptance is crucial. Currently, there is not enough data to appraise the impact of the models analysed.

### OR7.4

#### Impact of Essential Health Benefit Benchmark Plans on Patient Choice and Health Outcomes: Analysis of CMS 2014 Plans for Top Five States

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**Background:** Beginning in 2014, the Affordable Care Act requires new health plans to cover essential health benefits (EHB), including pharmaceutical products, according to the state level benchmark plans.

**Objectives:** The objectives of this analysis were to understand state level variations in design of plans, access to drugs and likely impact on patient choice and health outcomes.

**Methods:** The benchmark plans for top five states, i.e., FL, IL, NY, TX and CA, covering ~116 million lives, were obtained from CMS. For each plan the categories, classes and number of covered drugs was collected and pooled into one database. Analysis was conducted at the entire population level, state-level and for top classes of drugs. The comments from patient groups were reviewed to understand the impact of EHB on patient choice and health outcomes.

**Results:** The benchmark plans for top five states provide coverage of 4215 drugs belonging to 158 classes as defined by USP. While four states FL, IL, NY and TX had similar number of covered drugs (Median of 892 drugs), CA had significantly lower number of covered drugs, 28% less than other four states. On average, 10% of the drugs were in the class called "No USP Class", highlighting the limitation of CMS designated USP classification system for the new plans. In CA, FL, IL, NY and TX there were 18, 7, 8, 11 and 8 classes, respectively for which only 1 was covered. For CA, top 8 classes were identified for which patients had 75% lower choice than other States, these include indications such as Anti-Diabetics and Pain medications.

**Conclusions:** Review of new benchmark plans shows some states can have significantly lower patient choice of therapies. There is a need for new policy measures to ensure that all patients have equal access to new treatments.

### OR7.5

#### Health Technology Assessment (HTA) in Switzerland: The "SwissHTA" Multi-Stakeholder Consensus

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**Background:** Health Technology Assessment (HTA) initiatives in Switzerland have been fragmented and impaired by blurred boundaries between assessments and appraisals as well as by methodological issues.

**Objectives:** To use a transparent and inclusive process ("SwissHTA") to develop a multi-stakeholder consensus on the future implementation of official HTAs in Switzerland.

**Methods:** Santésuisse (the national association of sick funds) and Interpharma (representing the interests of the Swiss research-based pharmaceutical industry) invited national stakeholders to participate in SwissHTA. The process was led by a project team, with membership from santésuisse, Interpharma, the Swiss federal government (BAG), the Swiss Medical Association (FMH), and the Swiss Academy of Medical Sciences (SAMW). After seven retreats of the project team and three workshops, which were supported by a scientific steering committee, the team reached a consensus that was endorsed by the participating organizations.

**Results:** SwissHTA issued a consensus statement supplemented by six "implementation papers", recommending a broad technology focus (covering both new and existing ones by specific processes following a common set of core principles) and defined opportunities for stakeholder involvement. Primary evaluation criteria should be driven by the social pre-ferences of the Swiss population, constrained by a prior normative commitment in line with the rights-based legal tradition of Switzerland. The full range of health-related benefits should be evaluated. Assessment of clinical evidence should take into account the level of evidence that can reasonably be expected in a given context, rating the degree of confidence in outcomes in relation to the relevance and the magnitude of the effects observed. Economic viability should be evaluated based on budgetary impact and social

cost-benefit ratios. SwissHTA rejects the idea of using cost per QALY benchmarks as a measure of value for money.

**Conclusions:** SwissHTA illustrates the possibility of a broad-based stakeholder consensus on HTA and offers well-defined evolutionary options.

## OR7.6

### Equity Considerations Among HTA Agencies – Current Practice and Ways Forward

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**Background:** Equity is one of the founding principles in most health care systems, while addressing health inequities remains high on the health policy agenda. Financial constraints entail both an increased risk of propagating or initiating inequities and a more pronounced need to employ evidence-based approaches for decision-making at health system level. It is therefore both important and timely to explore how equity is addressed in current HTA practice.

**Objectives:** To explore the practices of a broad range of HTA agencies towards addressing issues of equity in relation to different population groups, identify exemplary practices and common concerns and offer insights for future considerations.

**Methods:** From an initial comprehensive pool of agencies those for which both methodological guides and HTA reports were publicly available were selected. Information was extracted on issues ranging from a general commitment to fairness to specific measures targeting both procedural and outcome-related elements.

**Results:** The methodological guides and a total of 98 reports from 19 agencies were analyzed. While 9 agencies mentioned equity among their principles, this was not necessarily reflected in their outlined methodological approach. Specific equity-related measures, most notably regarding appropriate information sources and/or subgroup analyses were mentioned in 10 cases. Stakeholder involvement (44%) and the explicit consideration of specific population groups (29%) were the most commonly reported approaches in included HTA reports. The nature and extent of equity-related information varied based on agency role and type of technology.

**Conclusions:** While varying legal contexts and institutional principles can lead to different interpretations of equity at the decision point, a combination of process and outcome-related practices already in place could contribute to more equity-sensitive evaluations, especially in conjunction with enhanced dissemination of existing methodological tools. Networking initiatives, such as an Equity Interest Sub-Group, could play an important role in this direction.

## OR8.1

### Narrative Reviews - One Way of Putting Patients and Relatives in the Centre

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**Background:** Finding literature on the perspectives of patients with gynaecologic and lung cancer and their relatives is difficult. Evidence of this specific group was paramount as part of a larger project focusing on rehabilitation interventions addressing the needs and perspectives of the patient and the relative. Having sparse amount of literature on a topic made it difficult to conduct a systematic review in that it tends to be more quantitative in orientation. Therefore a narrative review was chosen to generate and present the available evidence.

**Objectives:** The purpose of this presentation is to discuss the narrative review as a viable way of producing valuable evidence on the needs and perspectives of patients and the relatives in relation to HTAs.

**Methods:** A narrative review was conducted. This specific kind of review summarises, explains and interprets qualitative evidence on a selected topic. The review process was structured according to typical scholarly articles with attention to the search and review process in order to counteract perceived criticism of being less systematic and explicit than other approaches.

**Results:** The evidence produced in this narrative review contributed with valuable insight into the target population. The narrative review process proved to be a suitable and viable way of producing qualitative evidence when available literature on a topic is sparse. This challenge is often present in HTAs.

**Conclusions:** Narrative reviews can be an appropriate way of getting the patients' and the relative's needs and perspectives into the centre of HTAs, health policy papers and clinical guidelines.

## OR8.2

### Types of Outcomes (Intermediate/Disease-Oriented Vs. Patient-Oriented) Used in Guideline Development by Various Guideline-Making Bodies Around the World

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**Background:** The U.S. Institute of Medicine has established standards for the development of trustworthy clinical practice guidelines that recommend determining of the balance of benefits and harms of a test or intervention. Various types of outcomes are used to assess benefits in guideline development.

**Objectives:** To improve the quality of guidelines based on the world-wide experience in policy making, we explored how various types of outcomes have been and should be used in guideline development among different countries.

**Methods:** We compared guideline development methods from various guideline-making bodies as follows;

- 1) Is it possible to make a strong recommendation based on intermediate outcomes alone? If so, how should the link between intermediate and patient-oriented outcomes is established?
- 2) After making the decision regarding the recommendation based on intermediate evidence, what should we do next?
- 3) How should we measure net benefits, if the measures for benefits and harms are different types of outcomes? Is there any consensus regarding the ideal threshold of net benefit for making a strong recommendation?
- 4) What are the limitations of relying exclusively on patient-oriented outcomes in the development of guidelines?

**Results:** Patient-oriented outcomes were always used for guideline development, but it included intermediate and final outcomes in various types of topics. Intermediate outcomes were often used to make recommendation, but basic rule was not determined. If intermediate outcomes were used, the results which were based on the studies conducted in their own countries were considered as priority matter. Although both benefit and harms were always considered in guideline development process, measuring net benefits could not be unified. Modeling approach and number need to screen has been used in several guidelines.

**Conclusions:** To improve quality of guideline, we have to learn and learn guideline development method from various guideline-making bodies.



### OR8.3

#### Coalition Building Towards Effective Patient Entered Health Care

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**Background:** A model of partnership exhibited by Patient Organizations, through their expertise and experience while dealing with key healthcare stakeholders results into a multiple knowledge for contributing and strengthening patient centered health care and healthcare systems. Patient organizations are empowered and enabled to communicate with a strong unified voice on shared agendas and issues that affect their constituent patient. Also brings together patient groups so as to build and empower them into an active network. Both Communicable and Non communicable diseases such as, are included.

**Objectives:** Patient organizations representing multiple disease areas in form an alliance to promote patient entered healthcare. This is an initiative aimed at diversifying the IAPO strategy of 'strengthening the patients' voice in Africa' and contribute to the global patients' voice; ensuring it accurately reflects the diverse needs and experiences of patients globally and that it is well communicated. It promotes meaningful involvement and engagement of patients and other key stakeholders to improve quality health service delivery, create awareness and bring out the plight of patients in Uganda for inclusion in decision making, as well as promote patient safety for quality improvement in health care

**Methods:** Alliance of Patient Groups engages with various healthcare and professionals institutions to discuss access and availability of health care as the best strategy for improving health care. Monitoring of health service delivery, health literacy and education, organizing public events are formulated and agreed upon.

**Results:** 10 patient groups are able to reach over 20,000 patients with health information on different diseases enabling them to demand for quality and adequate health services.

**Conclusions:** Patient engagement at all levels of healthcare decision-making leads to effective healthcare policies and systems. to meet the needs of patients. Efforts are galvanized towards patient-centered healthcare as it brings together patients with common issues and concerns, to make their collective voice stronger.

### OR8.4

#### Patients Matter: Engaging Patients as Collaborators to Improve Osteoarthritis (OA) Care in Alberta

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**Background:** We targeted two areas in health care reform: 1) Building capacity of patients to engage confidently in meaningful dialogue with clinicians and decision makers, and 2) Bringing positive change to relationships and the readiness for patient engagement uptake within the targeted organizations.

**Objectives:** To develop and test a new model of capacity building and engagement with the Bone and Joint Health Strategic Clinical Network (BJSCN), as the first organization where patient engagement researchers (PERs) could be deployed and engaged in decision making in a meaningful way.

**Methods:** We applied research methods previously shown to increase the involvement of seniors in research. The intervention was an innovative model of patient engagement – patient engagement research (PER). PERs are citizens with chronic conditions trained (120 classroom hours plus research internship) to design and conduct health research, using qualitative inquiry methods. Outcomes were

monitored and evaluated using Outcome Mapping and grounded theory data analysis. Project trainees and collaborators were observed throughout, using semi-structured interviews, surveys, focus groups, and project documentation review. Evaluation focused on outcomes of the training intervention, and uptake of patient engagement.

**Results:** The project graduated 21 PERS patient engagement researchers. Five original PER research studies were developed and completed by PERs as part of their internship, and will be published. The BJSCN is using this research to inform health policy strategy for improving arthritis care. Eight PERs have joined several Strategic Clinical Networks. The first cohort of trained PERs has been established and recognized as a valuable resource. An original inquiry-based curriculum has been designed, tested, and will be implemented as a University course beginning 2014.

**Conclusions:** This research innovation signifies a dramatic shift to include patients as legitimate partners in health care reform. In just two years it has become an incubator of new research partnerships with patients and decision makers.

### OR8.5

#### Electronic Personal Health Records in Canada: Priority Issues for Implementation

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**Background:** In Canada, health system managers, decision-makers, and researchers currently have a high interest in the implementation and use of the electronic personal health record (ePHR) given the various benefits that are associated with it. The ePHR could have an important impact on the efficiency and effectiveness of patient care, as well as on the provider-patient relationship. However, we still have insufficient scientific evidence about the benefits of ePHR and their potential implications for health care systems.

**Objectives:** To explore priority issues of key stakeholders associated with the implementation of ePHR in Canada.

**Methods:** We conducted 30 semi-structured interviews (26 individual and 3 with two participants each) between October 7 and November 27, 2013. The 32 participants represented five stakeholder groups (patients, healthcare professionals, policy-makers, information technology specialists and ePHR administrators), and 13 organisations from 7 Canadian provinces. Based on interview content and from a scoping review on PHR, we identified priority themes.

**Results:** 13 priority themes were identified: health information access and sharing; awareness of ePHR; costs for the health system; cultural change; efficiency; literacy; healthcare professional support; monitoring; patient and healthcare professional communication; security, privacy and confidentiality; self-management; targeted population; and users' perspectives. Some themes were common to all stakeholder groups: access and sharing information, security, privacy and confidentiality and users' perspectives. Other themes were emphasized by specific groups. For example, self-management was highlighted by patients, ePHR administrators and information technology specialists. Concerns about security and confidentiality were expressed by patients, healthcare professionals and information technology specialists.

**Conclusions:** These themes will be shared during an online consultation and a workshop with stakeholder groups in order to prioritize policy issues that need to be addressed to guide the implementation of ePHR in Canada.

## OR8.6

### How to Put Patients in the Centre when Developing Clinical Practice Guidelines (CPG)?

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**Background:** In Argentina, CPG are considered a valuable instrument to assist both professionals and patients in making informed decisions. Values, expectations and experience of target population should be part of the CPG development process. In this sense, we developed a specific method for including patients in the process.

**Objectives:** To discuss the process of including patients in the development of the obesity CPG and present our experience in making patient-centered recommendations.

**Methods:** Patient participation was included in a variety of ways during the development process: 1) Inclusion of high quality guidelines in which patient participation had been considered, as a resource for our guideline. 2) Inference of patient acceptability of recommendations by applying the GRADE method. 3) A workshop for patients in which they developed a patient decision aid tool. 4) Using of the Guideline Implementability Appraisal (GLIA) instrument to evaluate the CPG characteristics that predict potential challenges to effective implementation. 5) Access for the general population to the preliminary version through open websites.

**Results:** The CPG presented 45 recommendations, characterized by collaborative patient involvement. Patients were included as equal partners, contributing to the scoping, evidence synthesis, writing and reviewing of recommendations. The final clinical practice guideline is presented in different formats: complete version, short version, algorithms, patient decision aids and implementation strategies that address identified barriers.

**Conclusions:** Patient participation in CPG is at a developing stage in Argentina but it's taking up speed. Consideration to patient opinions and values can help to overcome potential barriers to guideline implementation. Taking into account their views and opinions can facilitate CPG dissemination and acceptance.

## OR9.1

### Access to Medicines, the High Cost of the Universal Health System: The Case of Pegylated Interferon

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**Background:** This is a descriptive study of access to the drug pegylated interferon, used to treat hepatitis C, in relation to the high cost of medication, free distribution and universal access established by the Unified Health System (SUS) in Brazil. The study was conducted in Bahia, from 2004 to 2010 and is part of the doctoral thesis of the first author.

**Objectives:** To analyze access to the drug pegylated interferon with a focus on public policy and drug spending.

**Methods:** N/A

**Results:** The state has successfully regulated costs in the highly complex pharmaceutical market using the following actions: 1 - Creation of the Executive Group of the Health Industrial Complex (GECIS) in 2008. 2 - Centralization of the acquisition of high-cost drugs by the Ministry of Health, characterizing it as a monopsony purchaser (in 2005 an ampoule cost R \$ 1,702.91 and R \$ 507.88 in 2010 reais).

3 - Creation of an institutional agreement between Brazil and Cuba for technology transfer and production of pegylated interferon by FIOCRUZ. Operational technical issues were the principal barrier to access to medicines.

A lack of diagnostic confirmation by liver biopsy prevented the start of drug treatment. The difficulty for SUS users, was that they had to wait up to 18 months for a liver biopsy, highlighting the inequity in the system.

The judicialization of access to drugs has impacted the public budget (34 cases in 2006 to 112 in 2007). Government action to resolve this issue included an alignment between federal, state and municipal administrations and centralization at the University Hospital.

**Conclusions:** To ensure access to medicines for chronic use, it is necessary to treat all the elements that impact on access to both free and high cost medicines.

## OR9.2

### Dealing with Uncertainty and High Prices of New Medicines: a Comparative Analysis of the Use of Managed Entry Agreements in Belgium, England, the Netherlands and Sweden

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**Background:** Managed entry agreements (MEAs) are a set of instruments used to alleviate the impact of uncertainty and high prices when introducing new medicines.

**Objectives:** This study analyses MEA implementation in four European countries.

**Methods:** Using publicly available data from HTA agencies and survey data from the European Medicines Information Network, a database of MEAs implemented between 2003 and 2012 was developed. A review of governance structures around MEAs was also undertaken.

**Results:** Over time there has been a steady growth in the number of MEAs implemented, with the highest number of MEAs in the Netherlands in 2012. The number of new MEAs introduced each year followed a different pattern. In Belgium and England it increased over time, while it decreased in the Netherlands and followed an up-and-down trend in Sweden.

We identified 110 unique drug-indications with a MEA across the four countries. Only 19 (17%) of these were part of a MEA in two or more countries, of which 10 (9%) used at least one common MEA.

England uses mainly discounts and free doses to influence one single variable, namely price. In the Netherlands, coverage with evidence development (CED) is extensively used to modulate effectiveness by generating real-life data on the medicine's effectiveness and use. Sweden has a strong focus on addressing uncertainty relating to cost-effectiveness, which is achieved by implementing CED complemented by monitoring use and compliance with restrictions through registries. Belgium uses a combination of the above.

**Conclusions:** Despite similar reasons being cited for MEA implementation, only in a minority of cases have countries implemented a MEA for the same drug-indication; even when they do, a different MEA is often implemented. This raises the question as to what drives such variations. More research is needed to understand whether e.g. risk-perception and/or notion of what constitutes a high price differ between these countries.

### OR9.3

#### HTA and Orphan Drugs: to What Extent Do Disease and Treatment Characteristics Influence HTA-Based Recommendations, and Could These Indicate Whether Orphan Drugs Have a “Special Status”?

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**Background:** HTA relies on evidence-based approaches and economic evaluation to determine the incremental benefits and costs of treatment alternatives, and is commonly used to support drug coverage decisions. Routine HTA methods may not adequately capture all the important considerations of a treatment's value and the impact of the condition on the patient. This study aims to explore the influence of these broader aspects by focusing on reimbursement decisions in a sample of orphan drugs.

**Objectives:** Objectives were two-fold: to identify and compare the extent to which disease and treatment characteristics, defined as “other considerations”, influence the HTA decision-making process in four countries; and on this basis, explore whether orphan drugs have a “special status”.

**Methods:** Countries included were England, Scotland, Sweden, and France. Ten drug-indication pairs with EMA orphan designation and all appraised by NICE were selected. Publicly available HTA reports were coded using thematic analysis to systematically identify and compare all other considerations accounted for during the assessment.

**Results:** In total, 120 different other considerations were identified and grouped into 15 subcategories based on the information provided. The most commonly identified related to nature of the disease and its burden on the patient, and considerations based on rarity, unmet need and treatment innovativeness. Of the 15 subcategories, 6 included aspects that were not captured in explicit quantifiable terms within the quoted incremental cost-effectiveness ratios (ICERs). The remaining 5 categories included aspects that were partly captured within the ICERs. Sub-categories were analysed separately to determine whether they apply only to orphan drugs.

**Conclusions:** Considerable variation was seen in the application of other considerations suggesting a need for further research to support a more consistent and transparent approach. A number of these other considerations may also favour orphan drugs, furthering the debate around whether orphan drugs deserve special status.

### OR9.4

#### Consideration for Rare Diseases in Drug Reimbursement Decision-Making

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**Background:** Reimbursement processes have been implemented to inform which therapies should be funded in light of scarce health-care resources. However, the applicability of standard processes to drugs for rare diseases is heavily debated. As a result of the small patient populations affected by rare diseases, coupled with a limited understanding of the natural history of these conditions and the high cost of these treatments, it is argued that drugs for rare diseases may not meet the evidentiary standards routinely applied when making resource allocation decisions.

**Objectives:** This study identified current reimbursement processes for prescription pharmaceuticals both within Canada and internationally, with the objective of assessing how drugs for rare diseases are considered within existing processes.

**Methods:** Using the G20 countries as a sampling frame, a review of published and grey literature was conducted to identify the reimbursement processes used in 28 countries, and in Canadian provinces/territories. A search for peer-reviewed publications was conducted using Medline, Scopus, CINHAL, EconLit and PsychInfo. The grey literature search included websites of health technology assessment agencies and government agencies.

**Results:** Drugs for rare diseases are considering uniquely for reimbursement within three Canadian provinces and seven countries. While some jurisdictions have created specialized procedures for the evaluation of drugs for rare diseases, other jurisdictions require a unique evidence base within their existing decision-making processes when considering reimbursement for these same drugs. Jurisdictions also vary to the extent by which the criteria applied for decision making are altered for drugs with rare diseases.

**Conclusions:** This review identifies approaches for making resource allocation decisions for drugs; explicitly considering funding decisions related to drugs for rare diseases. An understanding of the evidence base applied when making resource allocation decisions may help inform the development of more standardized approaches for the reimbursement of drugs for rare diseases.

### OR9.5

#### Do Drug Product Changes Have an Impact on Hospital Treatment? a First Health Technology Assessment

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**Background:** Drug product changes occur in hospitals for different reasons: improved efficacy or tolerance of a drug, reduced costs, new pharmaceutical innovations or drug shortage.

**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.

Key words: Drug product changes, process model, process costs,, HTA,, drug shortage

**OR9.6****A Conceptual and Methodological Framework for Value Assessment of Medical Technologies Using Multiple Criteria Decision Analysis**

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**Background:** Most value assessment (VA) approaches for medical technologies examine only a partial dimension of societal value mainly relating to scientific elements of their therapeutic aspect, possibly in relation to cost. Many important factors relating to social value are not adequately reflected.

**Objectives:** A new conceptual and methodological framework for assessing value is needed that takes into account a wider set of criteria, based on an explicit definition of value for medical technologies.

**Methods:** The paper builds on literature to analyse the current practices, processes, and policies of VA, including the criteria for measuring value in a number of EU countries. Using decision analysis principles it explores the use of Multiple Criteria Decision Analysis (MCDA) as an alternative framework.

**Results:** Value parameters considered include burden of illness, therapeutic and safety, innovation, socioeconomic, evidence uncertainty, efficiency and equity groups of criteria. Not all criteria are examined across all countries, and if they are this can be on an implicit and non-systematic manner. The main limitations of current VA systems include the absence of an explicit value-for-money definition, the incomplete and subjective nature of valuation criteria, and decision heterogeneity. An MCDA value tree with criteria hierarchies was constructed ensuring that criteria are essential, understandable, operational, non-redundant, concise and preferential independent. Following the description of the main MCDA modelling techniques, we propose the application of a value function method, involving direct (and possibly indirect) scoring, swing weighting, and an additive linear aggregation approach because of its simplicity, practicality, and relevance to the HTA context.

**Conclusions:** MCDA is a promising alternative approach for use within HTA due to its robustness in terms of the multiplicity of criteria that can be incorporated, its flexibility in terms of differential weights that can be applied, its comprehensiveness in terms of expanded stakeholder involvement (including patients and public), and transparency across all stages.

**OR10.1****Attitudes Toward Ethical Dilemmas in Genetic Testing Among Medical Students in China**

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**Background:** As a novel technology, genetic testing brings both medical progress and evolving ethical dilemmas. For medical students who are the main force of future healthcare, knowledge of handling ethical principles is of vital importance.

**Objectives:** To analyze medical students' attitudes toward dilemmas in genetic testing, the survey was carried out among medical students who had graduated in 2012 and 2013, in one medical college of Shanghai in China. A total of 347 valid questionnaires were collected.

**Methods:** Five Scenarios were designed in the questionnaire, among which three involved prenatal diagnosis decision-making, and two about psychologically sensitive information disclosure, reflecting ethical dilemmas among autonomy, non-maleficence and justice. And students were asked to select corresponding options. Logistic Regression was used to analyze what factors may influence medical students' selections, including demographic variables (i.e. age, sex, education

level, specialty), access to genetic testing, degrees of familiarity with genetic testing.

**Results:** Medical students' options concerning three prenatal diagnosis scenarios were mainly distributed over the peak frequency from 64.93% to 84.35%, favor of telling patients potential risks and related information but no suggestions or decisions for them. While attitudes towards two psychologically sensitive information disclosure cases distributes as homogeneous, with none higher than 50%, the highest were 45.51% and 35.07% separately, both represented patient confidentiality. Logistic regression showed that in five scenarios, female tended to respect autonomy of the pregnant and protect confidentiality for patients ( $P < 0.05$ ), while access to genetic testing only influenced cases of psychologically sensitive information, showing those who had acquired genetic knowledge chose non-maleficence for the vulnerable ( $P < 0.05$ ).

**Conclusions:** Faced with ethical dilemma in genetic testing, most medical students can't well balance the principles of autonomy, non-maleficence and justice, which further urges extensive and in-depth ethical education with this new technology. Thereby, strengthening education and innovating ethics teaching methods should be emphasized.

**OR10.2****Valuable Tools for Patients in the Treatment of Type 1 Diabetes? when Treatment Satisfaction Matters**Sophie Söderholm Werkö<sup>1,3</sup> Emelie Heintz<sup>1,2</sup> Stella Jacobson<sup>1,3</sup>

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**Background:** Continuous subcutaneous insulin infusion (CSII) is used by approximately 20% of adults and 50% of children with Type 1 diabetes in Sweden. The equivalent figures for long-term use of continuous glucose monitoring (CGM) are a few percent of adults and 3-16% of children.

**Objectives:** To present the available evidence on effects of CSII, CGM and sensor-augmented pump (SAP) compared to multiple daily injections (MDI) with mealtime insulin analogues and self-monitored blood glucose (SMBG), based on a systematic review on adults and children with diabetes.

**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. GRADE was used in grading the strength of evidence. Annual costs were calculated based on previous literature, information from the producers and expert opinions. Ethical aspects were also considered.

**Results:** We identified many knowledge gaps in all patient groups for most primary outcomes such as mortality, morbidity and quality of life. Treatment satisfaction was reported higher with CGM for children and much higher with SAP for both children and adults, but the scientific evidence is insufficient for CSII. The increased annual treatment costs per patient was €1 260 for CSII vs. MDI, €3 133 for CGM vs. SMBG and €4 347€ for SAP vs. MDI and SMBG.

**Conclusions:** More and better research is needed.

CGM demonstrates higher treatment satisfaction especially when using SAP. Being satisfied with the treatment can be assumed to be important to get a better control of blood glucose. Studies indicate an improvement in the surrogate marker HbA1c, which may be associated with improved prognosis.

Individual assessment therefore needs to consider both the higher costs associated with CSII, CGM and SAP as well as the possible short and long-term benefits of a well-functioning treatment of diabetes.

### OR10.3

#### Use of Patient-Reported Outcomes Among Patients with Rare Lysosomal Storage Diseases: a Systematic Survey of the Literature

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**Background:** Patient-reported outcomes (PROs) are reports of a patient's health condition that come directly from the patient without interpretation of the patient's response by anyone else. PROs are often crucial in determining the benefits of new health technologies. Confidence in PRO results requires the use of instruments with established validity and responsiveness (i.e., sensitivity to change). Disease-specific instruments are often more responsive than generic instruments.

**Objectives:** To explore the use of PROs in peer-reviewed literature involving patients with rare lysosomal storage diseases (LSDs), including Fabry, Gaucher, Mucopolysaccharidoses Types I and II, Niemann-Pick (Type B), and Pompe Diseases.

**Methods:** We systematically searched eight databases for experimental and non-experimental studies, or articles that report the development of PROs for LSDs. Pairs of trained reviewers independently screened potentially eligible articles and subsequently conducted data extraction on the eligible studies.

**Results:** Our search yielded 2028 articles; 996 underwent full text screening. Of the 141 articles that met our eligibility criteria and underwent data extraction, the majority involved patients with Fabry Disease (n=74). The SF-36 was the most frequently utilized PRO (48 articles). The EuroQol was used in 17 articles and health utility measures in 3. Pain, the most common symptom examined, was measured using the Brief Pain Inventory in 29 articles. Only 3 studies addressed the development and testing of condition-specific PROs in our target populations. There were 32 articles in which investigators used their own researcher-developed PROs without psychometric testing.

**Conclusions:** The majority of researchers have relied on generic instruments to evaluate quality of life and symptoms in patients with rare LSDs. Investigators are wise to consider the use of condition-specific instruments in addition, but the use of an unvalidated instrument is problematic. Additional research to develop and investigate the psychometric properties of PROs used in studies with patients with LSDs appears warranted.

### OR10.4

#### How Essential Hypertensive Patients Assess Different Endpoints of Their Treatment? an Elicitation of Patients' Preferences by Analytic Hierarchy Process (AHP)

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**Background:** Patient-relevant endpoints play a more important role in HTA. Furthermore there is a need not only to quantify the effects but also to prioritize the endpoints according to patients' preferences.

**Objectives:** To investigate how patients prioritize treatment endpoints for the assessment of interventions in anti-hypertensive therapy.

**Methods:** The AHP study included a feasibility test and interviews of 26 hypertensive patients for the complement of a specific questionnaire. In these questionnaires patients at different general practitioners' offices in Northern Bavaria (Germany) rated their preferences with

respect to the importance of different endpoints of hypertension treatment (mortality, myocardial infarction, stroke, heart failure, and subdivided side effects) by a pairwise comparison of individual endpoints. AHP, a Multi-criteria decision analysis (MCDA) method using matrix algebra was used to generate relative weights for each endpoint. The robustness of the AHP results was checked by calculation of the respective consistency. Additionally the EQ-5D VAS was applied to stratify the patients into subgroups.

**Results:** The AHP yielded the following results (weight, CI95%): Stroke (0,320, 0,232-0,345), Mortality (0,297, 0,249-0,434), Myocardial Infarction (0,202, 0,133-0,211), Heart Failure (0,119, 0,083-0,172), and Side effects (0,062, 0,040-0,095), subdivided in Dyspnea, Pain, Edemas, and Cough. The robustness overall inconsistency reached a consistency ratio of 0.1 and did not exceed the respective limit. On an individual level inconsistency exceeded the limits in almost half of the cases, with age, duration of therapy, and VAS utility being statistical significant explaining variables for inconsistency in a respective calculated logistic regression model ( $R^2=0,477$ ).

**Conclusions:** AHP can be used in HTA to obtain patients' preferences for treatment endpoints. Stroke was weighted higher than mortality by the patients. Preference elicitation could provide important information at various stages of HTA and challenge opinions on the importance of treatment aspects or endpoints. Furthermore it offers a sound method for the incorporation of patients' preferences in HTA.

### OR10.5

#### Patient Reported Outcomes Monitoring (PROM) for Cardiac Ablative Techniques

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**Background:** Patient Reported Outcomes (PRO) Measurements have been used in clinical trials and economic evaluations. Some instruments have also been developed to assist health professionals in the audit of care for individual patients. Collection of PROs is particularly important for procedures such as ablative techniques for cardiac arrhythmias which are performed primarily for the amelioration of specific symptoms. In this context, assessment of effectiveness of the interventions requires the development of validated tools for recording of PRO.

**Objectives:** To assess the validity and reliability of a new tool for PROMs collection in a UK population undergoing cardiac ablation for the treatment of symptoms related to arrhythmias.

**Methods:** Pilot project to assess a new cardiac ablation PROM tool comprised of three individual questionnaires (short arrhythmia specific questionnaire (SASQ), Patient Perception of Arrhythmia Questionnaire (PPAQ) and EQ-5D-5L). Invitations to take part were sent by an independent organisation to 800 patients registered by 3 hospitals on the UK national cardiac audit database as having undergone arrhythmia ablation.

**Results:** The final response rate was 73.8% (n=791) following a single reminder letter to all initial non-responders. Cronbach's  $\alpha$  statistic for both the severity score (0.81 preop - 0.85 postop) and impact score (0.81 preop - 0.87 postop) demonstrated good reliability. As part of validity testing, severity and impact scores showed significant inverse correlations with the generic EQ-5D-5L Utility index and EQ-5D-VAS scores (Pearson's correlation coefficients ranging from -0.35 to -0.67). In a subgroup (n=161), for which clinical follow up information was available, the mean change in the severity score was -8.71 (SD 6.36) in the clinically improved group versus -6.24 (SD 4.38) the non-improved group, respectively ( $p=0.007$ ).

**Conclusions:** In a retrospective pilot test, the PROM tool for cardiac ablation patients performed well. Improvements have subsequently been made and the tool is now being tested prospectively.

## OR10.6

### Patient Preferences: Understanding Risk-Benefit Trade-Offs of Genomic Testing in Chemotherapy Decisions for Breast Cancer Patients

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**Background:** Gene expression profiling (GEP) of tumours informs baseline risk prediction, potentially affecting decisions about adjuvant chemotherapy for women with early breast cancer (BrCa), of whom only 15% will experience a recurrence. Limited evidence exists on the clinical utility of GEP in chemotherapy treatment decisions.

**Objectives:** We aimed to measure the value of GEP testing information in chemotherapy treatment decisions for early BrCa patients using a stated preferences study measuring risk-benefit trade-offs.

**Methods:** Based on literature review and findings from our qualitative research (focus groups, interviews with BrCa patients and medical oncologists), we developed a discrete choice experiment survey (DCE) and administered it via an internet panel to three groups: patients with a history of BrCa (N=300), women from the general population (N=1004), and medical oncologists (N=50) across Canada. The DCE included 12 choice tasks with 5 attributes and 3 scenario profiles considering orthogonality, D-efficiency and level balance. Preferences were analyzed using conditional logit and hierarchical Bayes and evaluated for goodness-of-fit. We conducted scenario analyses for alternative combinations of attribute levels to predict respondent preference for chemotherapy.

**Results:** Respondents were middle-age (mean 50 years), middle income (\$20,000-\$79,999; 45%, n=612) and highly educated (at least some post-secondary; 67%, n=916). Most (>75%) respondents know someone who had chemotherapy for cancer, but only <10% know someone who had GEP testing. Across the three groups, the two most important attributes in chemotherapy treatment decisions were GEP test score indicating likely benefit from chemotherapy and doctor's estimate of risk of cancer returning (based on clinical algorithms), followed by likelihood of permanent side effects, trust in cancer treatment doctor, and likelihood of temporary side effects.

**Conclusions:** GEP testing is highly valued and strongly influences chemotherapy treatment decisions in all three groups. These findings provide preliminary evidence supporting the clinical utility of GEP in BrCa treatment decisions.

## OR11.1

### Engaging Relevant Publics in the HTA Process: Results from a Qualitative Policy Analysis to Inform the Development of a Comprehensive Public Engagement Approach

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**Background:** Engaging patients and citizens has been a priority for international HTA organizations for over a decade yet progress on this front has been minimal and ad-hoc.

**Objectives:** We explored the 'policy problem' of how to engage relevant 'publics' in the evidence-based but value-laden arena of health technology assessment (HTA) and its related policy decisions. A qualitative policy analysis was undertaken in Ontario, Canada to inform the development of recommendations for a comprehensive public engagement (PE) approach for Ontario's HTA process.

**Methods:** Findings were drawn from three data sources: (1) a website review of 53 international HTA agencies to identify state-of-the-art PE strategies and documented experiences; (2) a synthesis of published and grey literature reviews, empirical studies and conceptual analyses; and (3) in-depth interviews with staff and advisory committee members responsible for producing Ontario's HTA recommendations about perceived opportunities for, barriers to and influences on public engagement.

**Results:** Website review results reinforced findings from the evidence synthesis, which highlighted poorly documented PE activity within HTA organizations, emphases on different publics and approaches to their involvement (e.g., direct representation of patients and user groups on boards and committees vs. more passive approaches such as seeking "public comment" on draft documents). Varied and conflicting interpretations and rationales for PE emerged as a dominant theme in the interview data and explain differing views about how to proceed on this front. The evolving nature of Ontario's HTA work from single technology reviews to 'mega analyses' adds further complexity to sorting out the who, when and how of PE.

**Conclusions:** Despite the expectations for public engagement to take hold within HTA organizations, there are considerable institutional and ideational challenges to achieving this goal. Critical reflection on these challenges will be necessary as Ontario and international HTA decision makers consider the development of comprehensive PE efforts for their organizations.

## OR11.2

### Patient and Public Involvement in Health Technology Assessment: Experiences from the World and Propositions for Its Increase in Brazil

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**Background:** Although Health Technology Assessment (HTA) should primarily consider the social, ethical, and legal impacts associated with technologies, other basic attributes (efficacy, effectiveness, safety, and cost) end up taking precedence over the previous ones.

However, with the increasing emphasis on the engagement of patients as full partners in caring for their own health, there is a need to establish effective means for their involvement in the decision-making process. Patient and public involvement in HTA is crucial and needs to be implemented.

In Brazil, community participation is one of the guidelines of the Brazilian Public Health System (SUS) present in the Federal Constitution. It is also one of the principles outlined in Laws 8,080/1990 and 8,142/1990, which provide for community participation in the SUS. In 2011, Law 12,401 was enacted, officializing the participation of civil society in the process of incorporating technologies in the health system.

**Objectives:** The aim of this study is to explore the challenges in both national and international contexts for involvement of the various perspective of society (patients, caregivers, and health professionals) in the process of assessment and incorporation of health technologies.

**Methods:** An integrative method was adopted, consisting of literature review and analysis of documents and official records from the Brazilian Ministry of Health.

**Results:** The results indicate that international involvement experiences are developing rapidly, especially in the UK and Canada. While legal instruments for involving citizens in health and technology

incorporation policies exist in Brazil, their practical implementation is still incipient. The main challenges identified both in the national and international scopes are those relating to cultural aspects.

**Conclusions:** Based on the results, it was possible to identify proposals for improving the mechanisms of societal involvement in the processes of assessment and incorporation of technologies in the SUS, like training and education, better use of social media, public hearings.

### OR11.3

#### Involving Healthcare Service Users in Developing Information Material to Present HTA Report and Recommendations

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**Background:** We conducted a multipronged research project that involved healthcare service users in the assessment of alternatives measures to seclusion and restraint in short-term psychiatric wards and long-term care facilities. The last phase of this project was to involve service user representatives in the communication of HTA findings and recommendations.

**Objectives:** To involve mental health services users' representatives in developing information material to increase the dissemination of HTA reports and recommendations to service users.

**Methods:** We held a focus group with representatives of mental health community groups to explore how HTA findings could be communicated to service users. We asked about the potential use of information, the proposed audience, the intended context of use and the specific content to disseminate. A first version of the material was produced and revised by user representatives and HTA producers. A final version was produced following their comments.

**Results:** Six participants took part in the focus group and another was consulted by telephone. Participants agreed that HTA reports might interest them, but given its content, should be directed primarily to leaders of community mental health groups. In a form of leaflets, this material could present the main findings and recommendations in order to inform about gaps and what should be done in the healthcare system to support the use of alternatives to restraint and seclusion. This could ensure that patients are aware of the findings and recommendations and can understand the basis for subsequent decisions.

**Conclusions:** It is possible to involve services user representatives in the HTA dissemination process. In a context where communications of HTA findings is considered as a key area and where community groups could support HTA agencies, it could be relevant to see if the involvement of services user representatives favours users' ownership of HTA results.

### OR11.4

#### Integrating Patients' Perspectives, Context, and Implementation in the Assessment of Complex Health Technologies

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**Background:** The rise in chronic diseases in ageing populations has led to the development of increasingly complex technologies. Current Health technology assessment (HTA) methods do not sufficiently take into account the diversity in patient characteristics and patient preferences, as well as context and implementation issues. A strategy is needed to integrate all these aspects into a comprehensive assessment.

**Objectives:** This EU-funded project aims at developing concepts and methods for a comprehensive, patient-centered, and integrated assessment of complex technologies.

**Methods:** Palliative care has been chosen as a case study as it is a highly complex health technology that deals with heterogeneous patients' conditions, needs and objectives. Stakeholder advisory panels (SAPs) were established in 6 European countries to ensure public and patient involvement (PPI) that informs the scope, research questions and outcomes. Logic models and a framework are used to conceptualize the intervention in its context. Literature searches, quantitative and qualitative methods are employed to assess effectiveness as well as ethical, socio-cultural, economic, and legal issues.

**Results:** Interim results suggest SAPs are instrumental for including the patients' perspective in the assessment of complex technologies. Logic models have rarely been used in HTA but are helpful in understanding sources of complexity in the intervention and its implementation, in (un)desired outcomes and in the interactions between intervention and context. The integration of patients' perspectives with medical, economic, ethical, socio-cultural, and legal issues needs to be undertaken from the outset of the HTA, not at the end.

**Conclusions:** For the assessment of complex technologies HTA-methodology needs to be adapted at all stages. The patients' perspective can be obtained through stakeholder panels. An integrated perspective will improve the relevance of the assessment for all stakeholders, including patients.

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### OR11.5

#### Patient and Public Involvement in Agenda Setting and Prioritization of HTA and Systematic Reviews: the Norwegian Experience

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**Background:** HTAi Interest Subgroup on Patient and Citizen Involvement develops values and quality standards for patient involvement in the HTA process. Patients perspectives are increasingly incorporated in the assessment and dissemination stage of HTA/systematic reviews but not frequently in the identification and prioritization process. Our

knowledge center runs a yearly open, transparent and inclusive process for suggestions and prioritization of HTA/systematic reviews. The output of this process counts for more than half of our 30-40 reports published each year.

**Objectives:** To investigate the impact of inviting patients and citizens to suggest topics and research question for assessment and contribute to prioritization of HTA and systematic reviews through a two years period.

**Methods:** During the spring of 2012 and 2013 we invited stakeholders, including patients and citizens in Norway to suggest questions for national HTA/systematic reviews. Various canals were used, such as written and verbal invitations and newsletters. Suggestions were submitted by filling in an online form containing background information, justification for topic, PICO etc. All suggestions were published online. A reference group of 20 stakeholders, including four patient/consumer representatives provided major input to the prioritization through a scoring system and a whole day meeting.

**Results:** From a total of 80 and 67 suggestions for HTA/systematic reviews in 2012 and 2013 respectively, three and six were submitted by patient organizations/representatives or citizens. The questions were within the area of cancer, rheumatology, multiple sclerosis, dementia, whip lash and HIV. During the prioritization process one out of three suggestions was taken forward as an HTA in 2012, whereas in 2013 all six topics addressed by patient representatives will be taken forward by an HTA or systematic review.

**Conclusions:** Patients and citizens can contribute successfully with other stakeholders in setting the agenda and prioritization of HTA. In 2012 and 2013 seven suggestions from patients or patient organizations were prioritized.

## OR11.6

### GRIPP 2: Developing Consensus on the Reporting of Patient and Public Involvement for HTA

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**Background:** Patient and public involvement (PPI) in research has expanded over the last decade and become an important part of HTA, helping enhance the relevance, appropriateness and quality of HTA. However, reporting of PPI in papers is poor and there is an important need to enhance its quality and transparency, in order to develop a stronger PPI evidence base (Staniszewska et al 2011).

**Objectives:** To develop GRIPP 2, a checklist that provides guidance on key information papers must report in order to provide an appropriate description of PPI in a. studies where PPI is the main focus, b. studies where PPI is secondary aim.

**Methods:** This study followed the EQUATOR guidance on developing high quality checklists (Moher et al 2010) utilising the original GRIPP checklist (Staniszewska et al 2011) to develop GRIPP 2 using a Delphi process. This consensus-based process is drawing together key experts and stakeholders to identify, debate and agree on the key items for inclusion in GRIPP 2, underpinned by updated systematic review evidence (Brett et al 2011, Mockford et al 2009).

**Results:** The original GRIPP checklist identified key areas of poor reporting in the field of PPI that need enhancement. GRIPP 2 offers comprehensive consensus-based guidance for papers whose primary focus is PPI and a core set of items for papers where PPI is a secondary focus, such as clinical trials. Recommendations focus on clear reporting of definitions, context, process, methods, impacts, outcomes, and measurement.

**Conclusions:** GRIPP 2 provides the first international evidence-based, consensus informed EQUATOR guidance for reporting patient and public involvement in HTA. GRIPP 2 will contribute to the development

of a stronger PPI evidence base, generated through better reporting. It will enable a clearer evaluation of what PPI works, for whom, why and in what context in HTA.

## OR12.1

### Towards an Embedded Role for Patients and Caregivers in the Life Cycle of Orphan Therapies

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**Background:** In many countries, patients and families affected by rare diseases are keen to become more actively engaged in the development, regulation, reimbursement, and use of orphan drugs, collectively known as their 'lifecycle'. While formal opportunities for patient input exist in Canada, they are primarily limited to the 'reimbursement' stage, and comprise patient submissions to the centralized drug review process.

**Objectives:** To identify ways for patients and caregivers to contribute meaningfully throughout the lifecycle of orphan drugs

**Methods:** An inventory of possible roles for patients/caregivers in each stage of a drug's lifecycle was first created through a systematic review of relevant published and unpublished studies. Nine facilitated small-group workshops were then held with patients/caregivers from across Canada who had been convened by the Canadian Organization for Rare Disorders. Prior to the workshops, participants attended plenary sessions, which provided an overview of proposed policy frameworks adopting a life-cycle approach, international initiatives for encouraging timely and equitable access to orphan drugs, and key challenges limiting efforts to optimize patient outcomes within a sustainable healthcare system. During the workshops, participants were asked to consider where and how they could be involved in each stage to ensure that evidence accumulated throughout the lifecycle reflected what mattered to them. All discussions were digitally recorded, transcribed and analyzed using content analysis.

**Results:** Patients identified 5 points at which they could play important roles: 1) Collection of natural history information to support R&D, 2) Identification of outcome measures for clinical trials, 3) Weighing of benefits against harms, 4) Acceptability of conditions of managed entry schemes, and 5) Informing discussions around the value proposition during reimbursement and appeal processes.

**Conclusions:** Patients appear willing to take on roles that span the technology lifecycle. Discussions with industry, trialists, clinicians, and payers are now needed to assess feasibility.

## OR12.2

### Multi-Stakeholder Partnership as a Tool of Citizens' Empowerment to Build a Participatory HTA Model in Italy

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**Background:** In 2011 Cittadinanzattiva (Active Citizenship) and SIHTA (Italian Society of HTA) signed an agreement for the promotion of a summer school for civic leaders in HTA, which was also supported



by Italian Agency for Regional Healthcare (Agenas). The agreement focused on:

- the need to support HTA as a tool of government qualified public spending in a context of resources reduction,
- the absence in Italy of the citizens' involvement in HTA,
- the lack of civic leadership aware and sufficiently informed.

In 2013 partners numbers was increased, involving FIASO (Italian federation of health authorities and hospitals).

The school program was coordinated by a Steering and Scientific Committee expressed by the founding partners plus Fiaso (2013).

**Objectives:** The overall aim was to encourage the implementation of an Italian model of citizens' involvement in all stages and levels of HTA, investing in leaders of civic organizations by training them through a path defined by all the above actors.

**Methods:** The initiative was inspired by

- HTA Patient Academy, London School of Economics
- Report "Implementation of the European Patients' Charter Rights"
- Documents of the sub-group "Patients and citizens involvement", HTAi
- NICE documents (Patient and by public involvement program)
- Guideline "Understanding HTA", Health Equality Europe

**Results:** - 50 civic leaders, representative of patients and civic associations in all Italian regions (HTA community).

- Development of Operational Guidelines addressed to civic and patients organizations HTA. OG come from a down-up process.
- Website for the "community".

**Conclusions:** HTA in Italy is no longer the exclusive domain of economists, administrators, clinicians, but also of the public (patients, families,...): it may be the future of patient involvement decisions in health care. Fifty new "civic" leader, trained by the HTA Summer School, are ready to make the voice of citizens and patients to be heard in HTA.

### OR12.3

#### Patients, Empowerment and HTA

Helle Ploug Hansen

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**Background:** In the past, patients' perspectives and patient-centered approaches have often been considered anecdotal or biased. Today there is an increased interest in patient-focused HTAs, empowerment and participatory approaches.

**Objectives:** This presentation focus on an ongoing study of patient-centered and participatory approaches to engage patients and citizen in HTA aiming at understanding and critically discuss how patient-focused HTAs can be generated.

**Methods:** The data set consists of HTA-reports, scientific articles, conference presentations, where patient-centered and participatory approaches have been described. Based on theories from the social sciences about 'power, conduct and discipline' concepts as empowerment, patient and citizen perspectives and involvement have been explored.

**Results:** First it is noticeable that the concept patient, citizen and other related terms are often used without explicit reflections from the researchers, HTA-professionals etc. about the meaning of the concepts. Secondly, it is very often taken for granted that education of patients/citizen is a positive endeavor and thirdly, the patient/citizen involvement is seldom discussed in relation to for instance gender perspectives, age, education or other social and cultural determinants.

**Conclusions:** It is important that researchers and stakeholders involved in HTA explicitly relate to patient-centered and participatory

approaches from a reflective and critical perspective. This is an important prerequisite for the production of evidence based practice.

### OR12.4

#### Patient and Public Involvement (Ppi) and Engagement in Early Awareness and Alert (Eaa) Activities in England

Kathryn Miles; Alison Cook; Claire Packer

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**Background:** The NIHR Horizon Scanning Centre (HSC) 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.

**Objectives:** The HSC aimed to investigate the potential benefits of increasing patient and public involvement (PPI) and engagement in early awareness and alert (EAA) activities, and to identify areas of work where we can build and strengthen mutually advantageous relationships.

**Methods:** In August 2012 we undertook a search to identify literature documenting PPI in EAA activities. We networked with experts and key academics in England to identify good practice and discuss implementation in a range of organisations.

**Results:** We found no literature on the use of PPI in EAA activities. With input from the experts consulted, we developed a PPI strategy and identified areas for initial piloting of methods. We are implementing this strategy and are:

- Involved in the provision of information on key developments in the pipeline in a topic area (inherited eye disorders) identified by a patient-clinician priority setting partnership (PSP),
- Asking for feedback and comments from a patient group on topics identified as potentially of interest in one of our horizon scanning in-depth reviews (urinary and faecal incontinence),
- Increasing the targeting of our outputs to specific patient groups by Twitter. Between 30th May 2013 and 8th January 2014, 39 patient groups have been targeted with information about our published outputs, with 6 patient groups tweeted more than once, and
- Investigating the practicality of recruiting a patient group to explore and reflect on the accessibility and signposting of our current website.

**Conclusions:** We are in the early stages of the implementation of our PPI strategy and will need to reflect on the implementation process and potential benefits.

### OR12.5

#### Developing MEET – Innovative Training About HTA for Patient Leaders

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**Background:** Patients are seeking more engagement in HTA processes and agencies are responding to this. However, there is a need for more training about HTA for patients to understand how they get involved and add value. Eli Lilly has responded to this by developing training using scientific sources with facilitator and patient feedback.

**Objectives:** This presentation will outline the development of training initiatives for patient leaders to build their understanding of medicines development, regulation and HTA.

**Methods:** An interactive one-day workshop was developed using a PhRMA five-part video about medicines' discovery, development and regulatory evaluation and material prepared by HTA and communica-

tions experts. A detailed facilitator guide, slide set and Learning Journal for participants were produced to ensure consistency of quality of training and a national HTA expert provides local context.

**Results:** Medicine Evaluation Educational Training (MEET) was piloted as a one-day face-to-face workshop in English. After inclusion of feedback from participants, it was translated into Italian, German, French and Czech to allow workshops in local countries. It has also been adapted for the USA and Asia/Pacific. This local delivery encourages discussion of issues, experiences and opportunities among participants and the national expert. Feedback from the workshops indicated a major improvement in knowledge after the workshop and a commitment to clear actions to take forward in participant's local organisations.

An e-learning tool (eMEET) has been developed from the workshop that uses presenters, patient stories, infographics and interactive exercises to explain the complex issues underlying HTA. eMEET will be launched in March 2014 and made freely available on the HTAi website

**Conclusions:** To put patients at the centre of HTA we need to equip them to understand how they can add most value to regulatory and HTA decision makers. The MEET tools will help this through a variety of learning techniques

## OR12.6

### Strengthening Public Engagement for HTA Decision Making in Ontario: Results from a Stakeholder Dialogue

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**Background:** Ontario has been on the leading edge of experimentation with public and patient engagement initiatives in the Canadian HTA arena. These initiatives have yielded useful input to HTA decision making in Ontario; however, addressing the more comprehensive task of sorting out which publics to involve, through what methods, and at which juncture in the HTA process has been an elusive goal to date.

**Objectives:** We explore, through a one-day stakeholder dialogue, the problem of, and proposed solutions for, engaging relevant publics in the evidence-based but value-laden arena of health technology assessment (HTA). Dialogue results will be used to inform the development of recommendations for a comprehensive public engagement (PE) approach for Ontario's HTA process.

**Methods:** A one-day stakeholder dialogue will be convened in early May with a diverse group of approximately twenty participants, including government officials, HTA community leaders, patients, citizens and national and international PE and HTA researchers. The dialogue will be informed by a pre-circulated evidence brief which mobilizes global and local research evidence about the problem and proposed solutions related to engaging publics in HTA processes. Dialogue participants will share their views and experiences about the problem, critically review elements of a comprehensive approach for addressing the problem, and reflect on implementation considerations.

**Results:** A thematic summary of the dialogue will be shared which focuses on unique understandings of the problem, insights about viable solutions and key implementation considerations. Particular emphasis will be given to themes relevant to the international HTA context.

**Conclusions:** This stakeholder dialogue provides a unique opportunity to comprehensively explore the challenges related to engaging relevant publics in the HTA process and potential strategies for moving this field forward.

## OR13.1

### Challenges to the Systematic Review of Sexual Health Interventions for People with Severe Mental Illness

Eva Kaltenthaler; Abdullah Pandor; Ruth Wong

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**Background:** People with severe mental illnesses (SMI), such as schizophrenia and bipolar disorder, may be more likely to engage in high-risk sexual behaviour putting them at risk of worse sexual health outcomes than the general population. Sexual health promotion interventions for people with SMI could lead to a reduction in risky sexual behaviour.

**Objectives:** To identify methodological issues affecting the evaluation of effectiveness of sexual health interventions for people with SMI compared with usual care.

**Methods:** Standard systematic review methods including narrative synthesis were used to identify areas of discrepancy between the trials.

**Results:** Thirteen controlled studies were included in the review. Due to the large between study variability and mixed results, there was insufficient evidence to fully support or reject the identified sexual health interventions for people with SMI. Several issues were identified that affected the generalizability of the results. These included variations in how SMI was defined across studies and how a diagnosis of SMI was made; the use of a range of recruitment methods; lack of reporting of co-morbidities and medications; little detail provided in the description of the beneficial components of sexual health risk reduction interventions; short follow-up periods used in the studies and wide variation in study populations. In addition, changes in health promotion activities (particularly technologically-based) over the past 20 years made it difficult to compare studies from different time periods.

**Conclusions:** Addressing some of the issues identified in this research in future trials of sexual health promotion interventions for people with SMI will help to bridge the gap between efficacy and effectiveness research. Taking these factors into account will assist health care professionals in determining whether or not the study results are generalizable to their patient populations.

## OR13.2

### Effectiveness of Treatments for Multiple Chemical Sensitivity: Systematic Review

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**Background:** Multiple chemical sensitivity (MCS) is a chronic condition with symptoms that recur reproducibly in multiple organ systems in response to low levels of exposure and to multiple unrelated chemicals and which improve or are resolved when incitants are removed. Symptoms occur in the central nervous system and at least one symptom in another organ system; they last at least 6 months and cause significant lifestyle or functional impairments. Although the condition has been described since the 1990s, there is little knowledge of effective treatments.

**Objectives:** To identify treatments or preventive measures for MCS and evaluate their effectiveness.

**Methods:** A systematic literature review on the effectiveness of any treatment for multiple chemical sensitivity was done. The search was performed by an information specialist and two researchers independently selected relevant articles for full-text evaluation using jointly agreed exclusion criteria. Full-text articles were evaluated for quality and results. We accepted HTA reports, systematic reviews, meta-analyses, clinical trials, case-control studies and cohort studies. We excluded

studies on sick building syndrome, studies without control groups and that had not measured objective outcomes.

**Results:** We identified two HTA reports and two other reviews on MCS, and outside the studies referred to in these, we identified one controlled nonrandomized study, one cohort study and one randomized pilot study. The outcome measures varied from study to study and results were not always reported clearly. Cognitive psychotherapies may have an effect on MCS but larger studies are needed.

**Conclusions:** Treatments for multiple chemical sensitivity have been little studied. Suitable outcome measures for this condition have been difficult to define. Large, well-designed studies on the effectiveness of especially various forms of psychotherapy are needed.

### OR13.3

#### Systematic Review and Meta Analysis of Ultrasonography versus HVPG for Portal Hypertension

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**Background:** The measurement of the hepatic venous pressure gradient (HVPG) has been accepted as the gold standard for assessing the degree of PH. However, this method is limited by its invasiveness. Many investigators using non-invasive Doppler US. However, previous studies on the usefulness of Doppler US for assessing PH have suggested conflicting results.

**Objectives:** This systematic review aimed to identify the clinical usefulness of non-invasive Doppler US for assessing PH in patients with cirrhosis.

**Methods:** Through Ovid MEDLINE(1948–), EMBASE(1947–), and the Cochrane Library(–2013), the literature searched. Key words were used 'liver cirrhosis mp. AND portal hypertension mp. AND ultrasonography mp. AND hepatic venous pressure gradient mp.'

RoB was used the QUADAS-II.

**Results:** A total of 313 studies were searched. 14 studies were finally selected. All papers included 827 patients. The average age of the patients was 53.2±9.6 years. The average value of HVPG was 16.36±5.3 mmHg. Less than 10% of each list had literatures evaluated as "high" for bias risk.

Because of there was a significant heterogeneity, different cut off value, we could not perform a meta-analysis. Therefore, we were carried out only a descriptive analysis of outcome variables.

9 studies evaluated the correlation between HVPG and PVV. The range of portal venous velocity was from 10.2 cm/s to 23.5 cm/s. but only in 4 studies were a significant correlation detected. 4 studies evaluated the correlation between HVPG and portal venous flow. The range of portal venous flow was from 325 mL/min to 773 mL/min, but only 1 showed a statistically significant correlation.

**Conclusions:** Our review indicated that measurable parameters of HV had a high accuracy for detection of portal hypertension. HV is promising and worthy to translate into clinical practice in detecting significant PH that it is a reliable and non-invasive procedure.

### OR13.4

#### A Systematic Review of Sexual Health Risk Reduction Interventions for People with Severe Mental Illness

Abdullah Pandor; Eva Kaltenthaler; Ruth Wong

University of Sheffield, Sheffield, United Kingdom

**Background:** Despite variability in sexual activity among people with severe mental illness (SMI), high-risk sexual behaviour (e.g. unprotected intercourse, multiple partners, sex trade and illicit drug use) is

common. Sexual health reduction interventions (such as educational and behavioural interventions, motivational exercises, counselling and service delivery), developed and implemented for people with SMI, may improve participants' knowledge, attitudes, beliefs or behavioural practices (including assertiveness skills) and could lead to a reduction in risky sexual behaviour.

**Objectives:** A systematic review was undertaken to evaluate the effectiveness of sexual health reduction interventions for people with SMI and their applicability to the UK.

**Methods:** Thirteen electronic databases (including MEDLINE, EMBASE and PsycINFO) were searched to December 2012, and supplemented by hand-searching relevant articles and contacting experts. All controlled trials (randomised or non-randomised) comparing the effectiveness of sexual health reduction interventions with usual care for individuals living in the community with SMI were included. Outcomes included a range of biological, behavioural and proxy endpoints.

**Results:** Thirteen controlled trials (all from the USA) were included. Although there was no clear evidence that sexual health improvement interventions reduce the total number of sex partners, incidence of unprotected intercourse or improved behavioural intentions in sexual risk behaviour, positive effects were observed in condom use, condom protected intercourse and on measures of HIV knowledge, attitudes to condom use and behavioural practices. However, the robustness of these findings is low due to the large between study variability, small sample sizes and low-to-moderate quality of included studies.

**Conclusions:** There is insufficient evidence at present to fully support or reject the identified sexual health risk reduction interventions for people with SMI. Given the serious consequences of high-risk sexual behaviours, there is an urgent need for well-designed UK based trials, as well as training and support for staff implementing sexual health interventions.

### OR13.5

#### Value of Education Program for Children with Asthma: a Systematic Review and Meta-Analysis

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**Background:** For education program to be active, an appropriate governmental funding is required. However, the budget and medical insurance fee for nursing is usually lacking.

**Objectives:** The purpose of this study was to estimate insurance reimbursement decrease rate using meta analysis to assess the effect size of education program for asthmatic children.

**Methods:** Literatures were selected from 8 domestic databases and the international databases such as Ovid-MEDLINE and EMBASE. The outcome variables include; emergency room visit rate, hospitalization rate, inhalant prescription days, pulmonary function, days of limited activity, and quality of life, etc. A total of 1,903 literatures were identified, they were filtered according to the inclusion/exclusion criteria and 26 studies were selected in the final analysis. RevMan5.0 was used for meta-analysis.

**Results:** The variables related with direct medical expense are decreased a number of ER visit/patient (32%), days of ER visit (0.3 days), days of hospitalization (0.01 days), days of inhalant prescription (0.22 days), and number of inhalant prescribed patient (18%) when they had education on asthma. Direct medical expense savings was calculated by applying the Health Insurance Data for 2009 of patients under the age of 18 with asthma or status asthmaticus. In result, out of the annual sum of emergency room fee of 542,315,090 approximately 173,540,829, out of the annual sum of emergency demanded payment of 1,618,362,478 approximately 490,917,705, out of the annual sum of hospitalization fee of 19,264,706,870 approximately 490,917,705, out of the annual sum of inhalant prescription fee of 983,183,553 approximately 154,436,998 and 176,973,040 can be

saved according to the decrease of ER patients, ER visits, days of hospitalization, days of prescription, and number of patients, respectively.

**Conclusions:** the 2.9 billion. This is 2.2% of annual medical expenses (129 billion) for asthmatic children in Korea.

### OR13.6

#### Use of Autologous Fat Grafting for Reconstruction Post-Mastectomy and Breast Conserving Surgery: a Systematic Review and Meta-Analysis of Oncological Outcomes

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**Background:** There is growing interest in the potential use of autologous fat grafting (AFG) for the purposes of breast reconstruction. However, concerns have been raised regarding the techniques clinical effectiveness, safety and interference with screening mammography.

**Objectives:** The primary objective was to determine the oncological, clinical, aesthetic and functional, patient reported, process and radiological outcomes of AFG.

**Methods:** A protocol was published a priori. All studies investigating AFG for women undergoing reconstruction post mastectomy or breast conserving surgery for treatment of breast cancer were considered. We assessed six domains; Oncological, clinical, aesthetic/functional, patient reported, process and radiological. Electronic databases were searched to June 2013; additional grey literature searches were also performed. Two independent reviewers assessed eligibility of articles for inclusion and performed data extraction.

**Results:** 31 studies were included in this review (3,521 patients). Current studies show a high degree of patient and surgeon satisfaction at medium term follow up of 14.8 months with an average of 1.9 sessions. Fat necrosis is the commonest reported complication at 4.4% (the majority were Grade I Clavien-Dindo and managed conservatively). Other harms include the anxiety caused by the need for further radiological investigation through interval mammograms (11.5%) and the need for biopsy (2.5%) to exclude malignancy. The weighted mean recurrence rate was 4.4% at a median of 18.3 months. Random effects Meta-analysis showed no significant difference ( $p=0.10$ ).

**Conclusions:** AFG is a potentially useful tool within the armamentarium of those performing breast reconstruction. The need for long-term clinical and radiological follow-up of these patients has been underscored by this review. Further research, ideally through high quality RCTs, is necessary to demonstrate long-term oncological ramifications, especially for those with in-situ disease. Research is also needed to assess the potential for total breast reconstruction using AFG.

### OR14.1

#### Rocking the Boat: Social Media's Impact on Producers and Users of HTA

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**Background:** Love it or hate it, social media has gained a legitimate place in health care as a medium for real-time discussion of the day's issues. More and more, clinicians are using social media to share sources of credible evidence and researchers are using it to collabor-

ate. Advocacy groups are training supporters in the art of using social media campaigns to lobby for access and reporters are using it to find both patient and expert sources. Over the past two years CADTH has effectively harnessed social media to disseminate our HTA work beyond traditional audiences, promote the value of HTA to a diverse group of stakeholders, and enhance our knowledge translation and mobilization efforts.

**Objectives:** Supporting evidence-informed decision-making by producing and brokering HTAs is central to CADTH's mandate. By taking advantage of cost-effective tools such as Twitter, LinkedIn, and others, CADTH is using social media to support organizational objectives, including improved communications, transparency, patient engagement, dissemination, and knowledge mobilization.

**Methods:** N/A

**Results:** Since launching our social media efforts in 2012, CADTH has become one of the few HTA organizations that has a defined a strategy and regularly communicates with users on our social media platforms. By closely monitoring outcomes, we have consistently seen increased engagement from key audiences, including other HTA producers, pharmacists, physicians, professional societies, and patient groups. By interacting with HTA users online, we have quickly identified trends, responded to customer needs, disseminated evidence in a highly targeted manner, and enhanced connections between our Liaison and Knowledge Mobilization programs.

**Conclusions:** HTA producers shouldn't underestimate the ability of social media to reshape the way HTA is accessed and understood by decision makers at all levels of the health system. CADTH has successfully used this technology to decrease barriers to HTA, expand our network, and increase interaction among our stakeholders.

### OR14.2

#### Do are the Economists Working with HTA in Brazil?

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**Background:** Several studies have examined the scientific production in health technology assessment (HTA) and pharmacoeconomics in Brazil of researchers in various areas of knowledge. However, specific data about the Brazilian economists in HTA are scarce.

**Objectives:** To describe the demographic characteristics and academic production of Brazilian economists whose areas of expertise focus on HTA.

**Methods:** The data was obtained on Lattes curriculum vitae platform of The National Council for Scientific and Technological Development (CNPq), which is an agency linked to the Ministry of Science and Technology of Brazil. In the search strategy we used the key words: "pharmacoeconomics" and "health technology assessment". We conducted the search in December 2013 in way independent and blinded. We analyzed all profile and their scientific production. The exclusion criteria were: non PhD; do not have any scientific production or participation in research project about HTA. We analyzed all profiles of researchers in the applied human sciences area. We analyzed the main characteristics of these researchers analyzing the variables: gender, institutional affiliation, time of completion of doctorate and researchers' scientific production over the past ten years.

**Results:** There are in Brazil 26.658 researchers of applied human sciences area and 5.025 researchers in economics. We identified 13 researchers working in HTA. There was a predominance of females (8). In terms of geographic distribution they are spread in 6 States and 8 universities. Six researchers received their the doctoral degree until 2000. Five researchers have post-doctoral training or professorship habilitation. Most published papers are in international journals. By coauthorship we identified two collaboration networks.

**Conclusions:** An important finding that emerges from our analysis is low number of researchers of economics area working with HTA in Brazil. Further studies addressing some issues like collaborative efforts, and main obstacles to economists in HTA might contribute to our better understanding of this area of research

#### OR14.4

##### Characterization of the Interaction Between Hospital-Based HTA Programs and HTA Activities at National and Regional Levels in AdHopHTA-Partner Countries

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**Background:** Interaction (i.e. any type of coordination or collaboration) of HTA-activities at the various levels of a health care system is likely to contribute to more efficient and tailored decision-making processes when considering uptake of new health technologies in the health service. Therefore, as part of the EU-funded project AdHopHTA (Adopting Hospital Based Health Technology Assessment in EU), a survey to study these interactions has been performed.

**Objectives:** To investigate interactions of HTA-activities across the national/regional level and the hospital level within different European countries.

**Methods:** A survey was conducted in all nine AdHopHTA-partner countries, i.e. Spain, Austria, Switzerland, Finland, Estonia, Turkey, Italy, Denmark and Norway. The AdHopHTA-coordinator in each country interviewed two to four persons, who were either working with or familiar with HTA and/or hospital-based HTA. The coordinator chose interviewees working at different levels: i.e. both national/regional level and hospital level when possible.

**Results:** In total, 24 persons were included in the survey. Most countries reported existing ongoing interaction between the national/regional level and the hospital level. However, the way the interaction of HTA-activities was put into practice varied a great deal between the AdHopHTA-partner countries, and in many cases even within the individual countries. This is probably due to the fact that the interactions in most countries and regions are not formally established. Interestingly, despite these differences, most respondents considered the interaction of HTA-activities between the national/regional level and the hospital level as very useful.

**Conclusions:** We found that in most AdHopHTA-partner countries, interactions between hospital-based and national/regional HTA-activities are informal and often scarce. The majority of HTA-experts and hospital leaders still consider such interactions to be beneficial and would prefer the collaboration to be formalized.

#### OR14.5

##### Medical Equipment Management Qualification in Brazilian Healthcare Networks

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**Background:** The QUALISUS-Network is cooperation project between the Brazilian Ministry of Health and the World Bank that contributes within the Brazilian Public Health System (SUS), for healthcare and health management qualification, through the setting of regional healthcare networks. One of its approaches is the systemic intervention of training and medical equipment management quality improvement in these networks.

**Objectives:** To diagnose and to qualify medical technologies' management, focusing on the medical equipment management for techni-

cians belonging to around 300 selected healthcare institutions spread all over the country.

**Methods:** An electronic survey was developed to verify whether there is a medical equipment management process in the selected healthcare establishments and if these establishments use Health Technology Assessment (HTA) in the management process. Besides filling the surveys, site visits were carried out to collect the evidence reported previously. The collected information will be compiled and processed in order to guide the training development that will be provided to about 1000 people in its initial phase by an educational institution with expertise in Clinical Engineering in Brazil.

**Results:** Even though around 50% of the answered surveys bring an affirmative response for the use of HTA within the management process, the site visits showed a lack of knowledge regarding the standardization of HTA methods and weak technical capacity for developing its methods within the healthcare establishment.

**Conclusions:** The survey findings were able to highlight the performance of medical equipment management; to confirm the need of a nationwide training for the healthcare establishment's technical teams; as well as to increase the dissemination of HTA methods. Willing to improve the safety, quality, productivity and rationalization of investments within the country, the project aims to strengthen the medical equipment management capacity in Brazil in a decentralized way.

#### OR14.6

##### The Incorporation of New Technologies in Brazil: the Advances of CONITEC in the Last Two Years

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**Background:** In 2011 was created the National Committee of Health Technology Incorporation - CONITEC, which established new rules for the incorporation of technology in Brazil and extinguished the previous Commission, called CITEC. The CONITEC's law requires the presentation of studies of efficacy, safety, economic evaluation and budget impact analysis of new technology.

**Objectives:** This study aims to compare the incorporation of new health technologies before and after the law that created the CONITEC.

**Methods:** Retrospective descriptive study, based on information from database of CITEC (period 2006-2011) and CONITEC (period 2012-2013).

**Results:** In CITEC 340 technologies were demanded. However 44% were not evaluated; 57% of the technologies evaluated were incorporated, 37% were not incorporated and 6% were excluded from the list of technologies SUS. In CONITEC 294 technologies were demanded, 122 were being evaluated and 25% were not evaluated because they were not in accordance with the criteria for analysis; 52.5% of the technologies evaluated were incorporated, 35.2% were not incorporated and 12.3% were excluded. There were 90% assessed during the established deadline. In both cases the most of them were medicines technologies.

**Conclusions:** In just two years, the CONITEC has evaluated almost 90% of the total evaluated by CITEC (in six years). It is important to emphasize that the annual average of CONITEC is 60 technologies evaluated per year, double the annual average of CITEC. The technologies incorporated average of CONITEC is 32 per year, almost double than CITEC. The performance of CONITEC contributed heavily to expand the access of Brazilian patients to new treatments while maintaining the sustainability of the public health system.

**OR15.1****Exploring Psychometric Properties of the Sf-6d, a Preference-Based Health-Related Quality of Life Measure, in the Context of Spinal Cord Injury**

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**Background:** With progress in clinical and rehabilitative care, life expectancy for individuals living with spinal cord injury (SCI) has increased substantially. As survival has improved and more individuals are living longer with SCI, health-related quality of life (HRQoL) has become an important outcome measure in this clinical context. In order to measure HRQoL, validated instruments are required. The validity of the SF-6D, a preference-based measure of HRQoL, is not well explored in the context of SCI.

**Objectives:** The aim of this analysis was to assess appropriate measurement properties of the SF-6D in a sample of individuals living with SCI.

**Methods:** Longitudinal data from the Rick Hansen Spinal Cord Injury Registry (RHSCIR) were used. Responses of the 36-item Short-Form Health Survey (SF-36v2) were transformed into SF-6D utility scores. We investigated practicality, floor and ceiling effects, and responsiveness to change. Responsiveness to change was explored using three different anchors that reflected changes in self-reported health, functional independence, and life satisfaction. Discriminative validity was assessed by ten a priori defined hypotheses, with a distinction made between 'strong' and 'weak' hypotheses.

**Results:** Three hundred and fifty-eight individuals with SCI were included in this analysis. Practicality was deemed acceptable based on a completion rate of 94%. The SF-6D showed low responsiveness to detect important health changes over time and differences in responsiveness were found between individuals with paraplegia and tetraplegia. All five strong hypotheses and three weak hypotheses were confirmed.

**Conclusions:** The SF-6D demonstrated good practicality and discriminative validity in this sample. The failure to detect self-reported and clinically important health changes requires further consideration. Comparative performance of the SF-6D (i.e., how the SF-6D performs against other preference-based measures) is unknown in the SCI context and requires further research.

**OR15.2****Selection and Review of Evidence for Cost-Effectiveness Models Within HTA**

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**Background:** Health technology assessments (HTA) typically require the development of a cost-effectiveness model which necessitates the selection and review of other types of information beyond costs and clinical effectiveness evidence in order to populate the model parameters. The way in which this evidence is used can have a fundamental impact on the results of the model and ultimately the decision outcome. Little procedural guidance exists in this area.

**Objectives:** To explore appropriate methods for the selection and review of evidence to inform models.

**Methods:** Methods A series of focus groups were held with HTA experts including systematic reviewers, information specialists and health economic modellers in order to explore these issues. Framework analysis was used to analyse the qualitative data elicited during the focus groups and key themes were identified. Draft recommendations were developed and shared with all participants for comment and revised accordingly.

**Results:** Seven key themes related to the selection and review of model parameters were identified from the focus groups and these formed the basis of the recommendations. The recommendations included the consideration of both quality and relevance when selecting information and the use of rapid reviewing methods. The need for transparency in the reporting of review methods was emphasised including reporting of choices for evidence sources and description of the limitations of chosen methods. It was suggested that additional attention should be given to the reporting of parameters deemed to be more important to the model or where the preferred decision regarding the choice of evidence is equivocal. Hierarchies of evidence were considered to be useful for selecting model parameter estimates.

**Conclusions:** It is intended that these recommendations will help to ensure a more systematic, transparent and reproducible process for the selection and review of model parameters within HTA.

**OR15.3****Production of Economic Opinions on Drugs and Medical Devices in France: Challenges and Issues**

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**Background:** Cost-effectiveness assessment is required in France since October 3rd 2013, for innovative drugs and medical devices which reimbursement could have high financial consequences on health expenditures. The evaluation report produced by the pharmaceutical firm has to be examined within 90 days by the French National Authority for Health (HAS) which produces an economic opinion. This opinion is transmitted to the French Health Product Economic Committee (CEPS) to support the price negotiation.

**Objectives:** The aim of this study is to give an overview of the first economic assessment reports and opinions of the HAS, and to highlight the main challenges for this new activity.

**Methods:** From October 2012 to October 2013, HAS had the opportunity to assess, on a non-mandatory basis, the cost-effectiveness reports already produced by the firms. The present study is based on an analysis of these opinions and on a description of the process implemented by the HAS to satisfy this new regulatory requirement.

**Results:** Economic evaluations reports were submitted for seven medicines and two medical devices. The following lessons can be drawn from these first assessments:

- All studies were cost-utility model-based studies,
- The choice of comparators and utility measures were the first sources of methodological limitations,
- As shown by sensitivity analysis, uncertainty around the ICER still remained high,
- In the absence of cost-effectiveness threshold in France, HAS had to define an original way to present a straightforward opinion to the decision maker.

**Conclusions:** The activity of non-mandatory cost-effectiveness evaluations gave to the HAS the opportunity to prove the feasibility of the process within 90 days and to identify future works to be initiated. The need for updating the methodological guideline has been raised in

order to precise requirements. Social sciences issues have also been identified, thoughts about methodology to highlight such issues are initiated in the HAS.

## OR15.4

### Using Equivalent Income Concept in Blood Pressure Lowering Drugs Assessment: How to Include Inequality Aversion in Cost/Benefit Analysis?

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**Background:** Whether it is possible to ground health technology assessment on egalitarian social justice theory is an ongoing debate.

**Objectives:** This study aims to contribute to answer this question by proposing a concrete application of the “equivalent income” approach that has been developed by M. Fleurbaey and that aims to include inequality aversion in cost/benefit analyses. The objective is to prove its feasibility in the context of public decision making. For this first application case, we focus on the economic assessment of antihypertensive treatments for patients with essential hypertension.

**Methods:** The method is based on the comparison of three social welfare functions associated with three strategies: no antihypertensive treatments in primary prevention (A), ACE inhibitors/ ACE inhibitors-diuretics/tritherapy (B) and calcium antagonists/calcium antagonists-ACE inhibitors/ tritherapy (C). An extensive assessment of their consequences on health, income and equivalent income within the French population has been produced. We measure the impact of strategies A, B and C on individuals’ health (cardiovascular events and mortality prevention), careers and income (out-of-pocket expenses and increase or decrease of taxes). Two data set are used: a survey focused on equivalent incomes on a representative sample of the French population (n=3331) and a cost-effectiveness model produced by the French National Authority for Health. The social welfare function that dominates the two others at the horizon of ten years is considered as being welfare improving.

**Results:** Efficiency of strategy A, B and C depend on the time horizon. On one year time horizon, placebo is more efficient. However from the third year on, placebo is not efficient anymore and the strategy (B and C) that dominate the two others depends on the degree of inequality aversion which is chosen (0, 1, 2 or 3).

**Conclusions:** Feasibility of equivalent income approach in health technology assessment has been proved.

## OR15.5

### Examining Exclusion Criteria in National Health State Valuation Studies: a Systematic Review

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**Background:** Several national valuation studies have been conducted to capture societal preferences for the sets of health states that comprise different preference-based health-related quality of life (HRQoL) measures. In such studies, participants have to complete valuation tasks of varying complexity (e.g. time trade-off (TTO), standard gamble (SG), and/or visual analogue scale (VAS) exercises) but often valuation

data are excluded from the subsequent modelling procedure based on pre-defined criteria.

**Objectives:** To provide a systematic examination of exclusion criteria used in national valuation studies.

**Methods:** A comprehensive search, including a bibliographic database, websites, and reference lists was undertaken. National valuation studies using VAS, TTO, or SG for the purpose of developing a scoring algorithm for a generic preference-based HRQoL measure were included. Data extraction focused on the adopted exclusion criteria, the context of justification, as well as the number and the socio-demographic characteristics of excluded respondents.

**Results:** 71 valuation studies were identified for the EQ-5D (-3L and -5L), SF-6D (SF-12 and SF-36), HUI (-2 and -3), AQoL (-4D, -6D, -7D, and -8D), 15D, and QWB-SA. Besides logical inconsistencies, respondents were often excluded if they valued fewer than three health states or if they valued all health states the same. Numerous other exclusion criteria were identified with varying degrees of justification. While some exclusion criteria were based on the assumption that respondents did not understand the task, others were attributable to the applied scoring model. The number of excluded respondents ranged from 0% to 65.1%. Excluded respondents tended to be older, less educated, and less healthy.

**Conclusions:** Considerable variation was observed in exclusion criteria adopted in the identified valuation studies. The trade-off inherent in this topic is between accuracy and generalizability of the data. Much attention has been given to logical inconsistencies but more consideration is needed of the effect of other exclusion criteria on valuation sets.

## OR15.6

### Brazilian Methods for Data Quality Control during National EQ5D-3L Valuation. Results from QALYBrasil Project

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**Background:** EQ-5D is a widely used multiattribute questionnaire to generate utilities.

**Objectives:** To describe the fieldwork methodology and the data quality control measures adopted to assure data quality.

**Methods:** The whole set of 243 states was elicited. Each respondent ranked and valued a set of 9 health states - 6 randomized; 3 fix (11111; 33333; Death), using the TTO technic, in face-to-face interview. The recruitment and data collection were conducted by an outsourced fieldwork research agency (OA). All the interviewers were submitted to a 3-day intensive training provided by a team of experienced academic researchers (AR). The first stage of data quality control process took place in the OA headquarters, where the supervisors checked the questionnaires for missing data. Then the questionnaires were scanned and sent to AR team, the second stage of data quality control, that consisted in evaluate any data inconsistency and queries reporting. After receiving all answers for the queries, the questionnaire could be clear for data entry or the same set of health states ought to be reapplied to another subject. A spread sheet, created by the AR to support quality control, was filled with data about all the questionnaires.

**Results:** A total of 71 interviewers worked in the field, under the supervision of 4 regional field-supervisors. The fieldwork lasted 6 months, with a mean of 31 questionnaires per day.

All interviewers performance were scrutinized for systematic errors or response patterns (e.g. always the same order in the ranking and VAS). The most common error was data transcription and transcribes the wrong number in the VAS by the subject.

**Conclusions:** The quality control procedures adopted on this study showed to be feasible and reliable. The spreadsheet developed by the AR team revealed to be a useful tool, and can be potentially applied in other similar studies

## OR16.1

### The Impact of Hospital Based Reports on Medical Devices of Unità Di Valutazione Delle Tecnologie (UVT)

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**Background:** The HTA Unit (UVT) of "A. Gemelli" University hospital is involved in the evaluation of new technologies from 2001, including Medical Devices (MDs), according his Mission. It carries out a hospital-based report on each request arising from Departments to provide a recommendation with the purpose of advice the hospital in difficult resource allocation decisions.

**Objectives:** The present report aims to review the impact of the recommendations on MDs introduction expressed in the first 165 reports in terms of policy and economic impact.

**Methods:** Starting from the analysis of the data we provide a revision of the level of acceptance of the report recommendation's from policy point of view and the "saving" of hospital resources from economic point of view. Each report includes: a rapid review on effectiveness and safety on the MD, issues related to regulation, alternatives of market, economic and organizational impacts.

**Results:** From September 2006 UVT produced 165 reports on MDs. On the basis of the information retrieved in each report we provide to the decision maker (a commission) a recommendation on MD introduction or not. In terms of type of recommendation we express 51 Recommendations of introduction, 20 of Denial, 94 of limitation in use. The level of acceptance of the recommendations and subsequent incorporation into hospital policy is around 80%. The average annual quantifiable savings has been € 438.000 on an average of €847.000 of total expenditure required per year. Moreover, main thing, the activity increased the quality of care and efficiency of the process of resource allocation.

**Conclusions:** We relate the influence of the HTA on the policy decisions of our institution by determining whether institutional policy is consistent with the recommendations of our reports. We observed good result justified by the combination of several factors: Timeliness, end users and other relevant stakeholders' involvement, method's robustness and transparency.

## OR16.2

### Hospital-Based HTA: Current Evidence and Challenges

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**Background:** While Health Technology Assessment (HTA) is often done at a national or international level, many regions and hospitals consider that it makes sense to move the assessment closer to the

point of care, where the costs, impacts and benefits can be directly assessed.

**Objectives:** We reviewed studies examining the effects of HTA at a local/hospital level while identifying strengths, weaknesses, barriers to implementation and opinions of stakeholders on the system's effectiveness.

**Methods:** We carried out a systematic review of published literature to explore the impact of local/hospital-based HTA at different levels: management (Have HTA recommendations been accepted and initiated by managers?); financial (What expenses and savings are related to HTA activities and their recommendations?); and clinical (What is the acceptability and adoption of HTA by healthcare professionals and patients?). This synthesis also identifies barriers and benefits to the adoption of local/hospital-based HTA, as well as the conditions for the success of local/hospital HTA.

**Results:** We identified different models for performing HTA at the local/hospital level: ambassador model, mini-HTA, internal committee, and HTA unit. Each model corresponds to specific needs and structures and has strengths and limitations. Reports available from various local experiences show positive impacts related to local/hospital-based HTA on hospital decisions and budgets, as well as positive perceptions from managers and clinicians.

**Conclusions:** This knowledge synthesis shows that local/hospital-based HTA may have important impacts on decision-making. It is difficult to evaluate the real impacts of local HTA at the different levels of health care given the relatively small number of evaluations with quantitative data and the lack of clear comparators. Further research is necessary to explore the conditions under which local/hospital-based HTA results and recommendations can impact hospital policies, clinical decisions and quality of care, and optimize the use of scarce resources.

## OR16.3

### Is There a Match Between Hospital-Based HTA Practices and Best Practices in HTA? A Literature Review

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**Background:** Several initiatives have explored best practices in undertaking and reporting HTA at national/regional level (general HTA) with no clear examination of them from the hospital perspective (HB-HTA). While some already established best practice criteria could be applied to HB-HTA, the contextual differences in hospital will probably lead to idiosyncratic criteria.

**Objectives:** Available HB-HTA practices were identified and matched to HTA best practices at national/regional level, through an analysis of similarities and differences. This work is performed under the EU project AdHopHTA, which aims to build a framework of guiding principles for best practices in HB-HTA.

**Methods:** A literature review has been conducted by searching Medline (Pubmed), Trip Database, results from multinational HTA projects (grey literature) and others. Identified information has been organized following the structure of an adaptation of the EFQM model. Then a ranking of the most cited EFQM key elements, supported by identified practices, was developed in order to assess the potential match and identify similarities and differences.

**Results:** 52 studies were included from 774 identified. For several EFQM key elements we found a match between most cited national/regional HTA and HB-HTA practices: e.g. "Identification and engagement of all stakeholders" (first and second rank, respectively); "Conduction of HTA with the appropriate methods, tools and competency" (both third rank). Occurrence of mismatch was dominating. Not supported key elements were also identified ("customers' results", "society results").



**Conclusions:** Mismatch on key elements points out the need for a development of specific HB-HTA principles for best practices, which reflects the contextual characteristics of HTA at hospital level. Examples of match can point out basic or “core” best practices principles that have to guide any HTA organization at any health care level (macro-meso-micro).

## OR16.4

### Systematic Review of the Informational Needs of Hospital Managers on Investments in Health Technologies

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**Background:** Hospitals are often the main entry level for health technologies. HTA can support the adoption of health technologies at hospitals, thus it is crucial to ensure that HTA-products are aligned with the needs and expectations of its end-users. However, not much is known about the informational needs of hospital managers when deciding whether or not to invest in health technologies.

**Objectives:** To analyse both the informational needs of hospital managers before making decisions on health technology investments, and the relative importance they assign to these informations.

This review is part of the European research project AdHopHTA, which aims to strengthen the use and impact of HTA in hospitals.

**Methods:** A systematic review of empirical studies published in English or Danish from 2000-2012 was carried out. Assessment of the literature was performed by two reviewers independent of each other. The identified informational needs were assessed with regard to their consistency with the 9 domains of EUnetHTAs Core Model.

**Results:** 2.689 articles were identified and assessed. The review process resulted in a total of 14 relevant studies containing 74 unique criteria that hospital managers find relevant. In addition to criteria covered by the domains of the Core Model other criteria dealing with political and strategic aspects were identified.

Clinical, economic and political/strategic aspects were mentioned most frequently in the literature, and the importance of clinical and economic aspects were confirmed in 3 studies of relative importance assigned by hospital managers. Legal, social and ethical aspects were rarely considered most important.

#### Conclusions:

- Hospital managers are able to describe their informational needs.
- All decision-making criteria are not of equal importance for decision-makers.
- There is not perfect consistency between the domains of EUnetHTAs Core Model and hospital managers need for information. Hospital managers also seek information on political and strategic aspects not covered by the model.

## OR16.5

### Reimbursement Policies, Hospital Features and Innovation in Healthcare. the Case of Transcatheter Aortic Valve Implantation in Italy

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**Background:** Transcatheter aortic valve implantation (TAVI) use in high-risk and inoperable patients with symptomatic severe aortic stenosis is supported by increasing empirical evidence. Many factors influence its introduction into healthcare systems.

**Objectives:** We investigated the adoption and diffusion of TAVI since its introduction into the Italian market in 2007, and we identified the potential drivers of uptake and diffusion at hospital and regional levels.

**Methods:** Our sample consisted of all Italian hospitals that adopted TAVI since its introduction in 2007. We estimated correlation coefficients between the number of TAVIs and variables at the regional level. Last, we run several regressions to estimate the determinants of TAVI adoption in 2012 and the variation of its diffusion between 2011 and 2012.

**Results:** In total, 7,261 patients underwent TAVI in Italy between 2007 and 2012. At the regional level, TAVI is strongly positively correlated with DRG-based funding mechanisms. At the hospital level, tariff-funded hospitals perform a higher number of procedures than capitation-funded ones but difference is not statistically significant. The regression analysis shows that none of the control variables at the hospital level significantly explains the level of TAVI adoption in 2012, except for the presence of a regional BBP which significantly reduces TAVI adoption. The incremental TAVI adoption between 2011 and 2012 is not significantly explained by hospital-level covariates, while it is significantly correlated with geographic area and regional health expenditure per capita.

**Conclusions:** The diffusion of TAVI in Italy is characterised by great variability. Major drivers of TAVI adoption and diffusion seem to be hospital type, ownership and reimbursement schemes. Our findings suggest that – although relevant – reimbursement policies are not the major driver of new technologies’ adoption and that other variables would need to be further investigated (e.g., the role of referring clinicians) to better interpret wide variability of TAVI diffusion.

## OR16.6

### A Systematic Approach to Define a Framework for Best Practices in Hospital Based Health Technology Assessment

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**Background:** In the search of best practices in HB-HTA, a business excellence framework (EFQM) with a proven record in the health sector, has been applied. However there was a need to check on relevance and practical recommendations to build a tool for managerial improvements and the transfer of best practices to other settings. The

latter is a major objective of the AdHopHTA project funded under EU FP7 in order to strengthen the use and impact of HB-HTA initiatives.

**Objectives:** To design a framework for best practices of the HB-HTA function.

**Methods:** The EFQM model was adapted to the HB-HTA function through a literature review and an iterative process: application to AdHopHTA partner's settings and a focus group discussion. Consensus on the items of the framework was explored through a Delphi survey among renowned global HTA and HB-HTA experts. Finally, a maturity model was applied to check on relevance of framework items for different deployment steps.

**Results:** The adaptation of the EFQM led to the identification of a preliminary set of 42 key elements relevant as best practices for HB-HTA. The Delphi survey showed a strong consensus on the importance of these elements demonstrating the adequacy of the proposed framework. We also gained further knowledge on maturity steps of the HB-HTA function, which will help its deployment. Additional views on important concepts, such as patient involvement, were also identified.

**Conclusions:** The adequacy of the EFQM has been confirmed by global HTA and HB-HTA experts as a good tool to identify best practices for conducting HTA at the hospital level. Moreover, the systematic elaboration of the framework complemented with the application of a maturity model allowed additional insights to guide the development of a toolkit for the establishment or improvement of a HB-HTA function.

### OR17.1

#### Serendipitous Disinvestment: Horizon Scanning for Disinvestment Opportunities

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**Background:** Disinvestment of ineffective, inefficient or harmful clinical practices and technologies is increasingly important to health systems, presenting opportunities to enhance quality of care, improve patient safety whilst at the same time resulting in health system savings.

Research and debate has centred on identifying a method for disinvestment. In Australia, the Comprehensive Management Framework systematically reviews existing Medicare Benefits Schedule items to ensure value for money and improve health outcomes for patients. In a process akin to an HTA, safety, clinical effectiveness and cost-effectiveness evidence is reviewed in addition to significant stakeholder engagement. With limited healthcare resources, these reviews may be considered time consuming and expensive. Elshaug et al attempted to develop a strategy to enable the identification of low-value clinical services via an "environmental scan" of the literature. Although this project identified 156 potentially ineffective services, it again was time-consuming and resource dependent.

**Objectives:** HealthPACT, the Australian horizon scanning (HS) committee, provides jurisdictions with evidence-based advice on emerging health technologies, assisting in the decision-making process for the prioritisation of health investments at a jurisdictional level. Recently the focus of these assessments has been on technologies that may impact on hospital waiting lists and shorter patient stays.

HS proactively identifies new healthcare technologies but may serendipitously identify disinvestment opportunities. In the past 12-months, HealthPACT's HS has identified potential targets for disinvestment, including the routine replacement of IV catheters, the placement of vena cava filters, use of antibiotics instead of appendectomy and catheter ablation for atrial fibrillation.

**Methods:** N/A

**Results:** HS assessments are rapid and consider the latest, best quality evidence, ensuring timely advice to jurisdictions using few resources. This presentation will discuss the results of these HS disinvestment assessments, their impact on jurisdictions and concerns they raise for stakeholders.

**Conclusions:** HealthPACT view these assessments as the beginning of much needed conversations around clinical practice.

### OR17.3

#### Action Proposals for Obsolete Medical Devices - Disinvestment in the Brazilian Public Health System

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**Background:** The Brazilian Public Health System congregates diverse medical procedures that involve applying several devices. These technologies are available on the list of services covered by the government through reimbursement guides. However, despite of being already obsolete, many of those available devices are still financed with no re-assessment criteria, generating low clinical efficiency, health hazards and waste of financial resources in many cases.

**Objectives:** To propose strategic actions in the identification, prioritization and evaluation of obsolete medical devices, aiming to optimize reallocation resources and avoid exposing the population to health risks.

**Methods:** An exploratory search was carried out in of scientific literature and other documentary sources in order to identify how the disinvestment process is accomplished in other countries, regarding methodological issues and political strategies of resources management. A national survey was also conducted, with twenty-four health technology assessment centers in Brazil aiming conducted, aiming to identify the status of those centers related to disinvestment actions.

**Results:** It was noted that disinvestment actions are major challenges for most governments, since they face ethical and organizational issues, pressure coming from the industry and the absence of policies to foster researches for the assessment of technologies already incorporated into their public health systems. The survey carried out in twenty-four HTA centers installed in Brazil showed that the removing process of obsolete medical devices comes down in classical actions such as: risk management (techno-surveillance) and high maintenance costs.

**Conclusions:** Integrated actions within a network are necessary to guide managers to register, using a template, all discontinued technologies with the purpose of identifying and understanding the reasons that led to its obsolescence and then establish prioritization criteria and assessing. Effectiveness data should be increasingly used to assist policy makers in the correct decision when applying the disinvestment of a medical procedure that will impact on the medical care of citizens.

### OR17.4

#### A Rational Disinvestment Towards a Strategic Re-Allocation: the Debate in the Italian Health Policy Forum

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**Background:** Every day several innovative and cost-increasing technologies enter the health care market without a corresponding exiting flow of "obsolete" technologies. Therefore, a pressing issue arises: how

long is it sustainable? The fourth edition of the Italian Health Policy Forum (HPF) approached the topic of disinvestment in the Italian health care sector at all levels, involving in the discussion different stakeholders representing the perspective of public institutions, private companies, citizens and patients.

**Objectives:** The aim is to report the results of such debate, highlighting challenges and future opportunities in the Italian NHS

**Methods:** A review of the literature was carried out in order to inform the debate among HPF members and provide them with an overview of methods and practical approaches to disinvestment applied in different countries and levels of care. The Scientific Secretariat facilitated and led a roundtable discussion towards three main sub-topics: methods for disinvestment, stakeholder involvement and role of HTA in re-allocation processes.

**Results:** A desirable approach to disinvestment involves a delicate phase of re-assessment of existing technologies, aimed at estimating their value within patient pathways and specific organizational contexts. The same principles and methods of HTA can be easily generalizable to the disinvestment processes. An active involvement of stakeholders is a key factor for overcoming the natural resistance to change and reaching shared and balanced decisions.

**Conclusions:** Accepting new technologies indirectly implies that something else must be forgone. Re-assessment and disinvestment may therefore be viewed as an opportunity to ensure access to effective treatment in a context of economic and financial crisis, where "linear cuts" have been implemented as a rapid solution to the containment of public health expenditure. In this frame, decision makers are asked to take up the challenge of a rational disinvestment and a strong commitment is required for activating HTA processes supporting strategic re-allocation decisions.

## OR17.5

### MIDDIR – Methods for Investments/Disinvestments and Distribution of Health Technologies in Italian Regions

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**Background:** MIDDIR aims to develop an integrated and systematic approach to identify obsolete health technologies and plan the deployment of specific technologies in defined areas. One of the fields of the project is the transition to HPV-DNA as a primary test for cervical screening.

HPV as a primary screening test implies an increase in the number of HPV tests and a specular decrease in the number of Pap smears. Reorganization and downsizing of the structures for cytology are expected, whereas centralization of HPV testing and triage cytology is needed.

**Objectives:** To develop a shared methodological approach to address the introduction routine HPV-DNA testing as primary screening.

**Methods:** - Survey on screening programs.

- Definition of the queries to be answered, focusing on strategies to reduce the number of Pap smears.

- Definition of outcomes and related indicators.

- Definition of modalities for impact assessment.

- Implementation of a system for collection and analysis of data.

- Quantitative and qualitative analysis of data.

- Production of recommendations.

**Results:** (Project in progress) Presently, partial information is available for screening programs from Basilicata, Emilia-Romagna, Liguria, Piemonte, Toscana, Veneto, and the Province of Trento. All the programs

will implement the Italian Ministry of Health recommendations, with cytology as triage of HPV positive women. The age range for HPV testing is 30-64 in 3 Regions, 34-64 in 2 Regions, and 35-64 in 2 Regions. Programs will use for sampling liquid cytology, or liquid cytology for women screened with HPV and traditional cytology for women still screened with Pap smear. Molecular analysis will be centralised in all programs, whereas analysis of Pap smears will be centralised in 4 Regions (2 missing).

**Conclusions:** Screening programs that are planning the transition from cytology to HPV-DNA testing as a primary screening are a valuable source of information for the advancement of research.

## OR18.1

### Comparison of Methods of Value Engineering and Multi-Criteria Evaluation – Applied to Vital Signs Monitors

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**Background:** Utilization of QALYs in outcome assessment is irrelevant in some kinds of medical devices, such as vital signs monitors. Multi-criteria evaluation and value engineering seem to be reasonable alternatives in apparatus assessment.

**Objectives:** Within this study, both methods of value engineering and those of multi-criteria decision making are compared. The study was focused on vital signs monitors purchase for a department of anesthesiology and resuscitation. Clinical and user's data were taken from several units of anesthesiology and resuscitation. Technical data were supplied from a thorough market analysis.

**Methods:** Out of value engineering methods, the pair-wise comparison method and Saaty's method were studied. In the case of multi-criteria decision making, the TOPSIS method, the ideal point method, and the weighted sum method were analyzed. Individual variants were subsequently combined with each other. A statistical comparison of the resulting data and a sensitivity analysis were calculated, and the threshold values, where the assessment gives different results, were established.

**Results:** The combination of Saaty's method and the TOPSIS method showed to be the optimum variant for the assessment procedure. Moreover, the cost-effectiveness analysis and the cost-consequences analysis were calculated, giving the same resulting decision (purchase of the same brand of monitor).

**Conclusions:** The combination of value engineering and multi-criteria decision making seems to be adequate for those medical devices, where other effects than QALYs are important.

## OR18.2

### Prioritization, Selection and Procurement of Medical Devices Within Low-and Middle-Income Countries: Outcomes of a Systematic Review

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**Background:** There is a large and growing literature on the procurement of medical devices and equipment for low- and middle-income countries (LMICs). This is issued by international public health organizations (e.g. WHO), donor agencies (e.g. USAID) as well as research institutions and non-governmental organizations. As of yet there has been no systematic inquiry describing and appraising the guidance and recommendations offered in this literature, particularly around methods suggested for device and equipment prioritization.

**Objectives:**

- Identify medical device procurement and prioritization methods recommended for use in LMICs: explore commonalities and differences across methods.
- Identify and explore factors associated with medical device procurement and prioritization processes.

**Methods:** A systematic review of bibliographic and grey literature was conducted with no time or language restrictions. 36 databases were searched, including: OVID Medline, Cochrane Library, LILACS, INAHTA, HTAi, WHO Health Technology E-documentation Centre. Records underwent title and abstract screening and were included if freely available and were a guideline or document containing recommendations for LMICs, focused on medical devices in general and were not restricted to regulatory implications and policy.

**Results:** Out of 19284 initially identified documents, 237 were included in this systematic review. Explicit prioritisation and procurement methods were outlined in 43% of documents and primarily address the technology procurement and selection paradigms encountered at macro-, meso- and micro- health system levels. Across all documents, procurement is identified as a complex process, affected principally by health system infrastructure (care levels and packages), equipment life-cycle costs and availability of skilled human resources across the technology life-cycle. Trade-offs between consensus, evidence-based and heuristic device selection, prioritization and procurement methods are identified, exemplified and discussed.

**Conclusions:** A framework for the quality assessment of medical device procurement and prioritization methods recommended for LMICs, including suggestions on the incorporation of evidence, is formulated based on the above findings.

**OR18.3****Development of a Modular Design Applied to Dialysis Equipment**

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**Background:** Due to its potential impact on patients' health, medical machinery should be robust to failure and of quick and facilitated maintenance. A modular production model, which divides the product into independent modules formed by a set of systems or components, may facilitate medical machinery maintenance and shorten its unavailability when a defective component is detected. Additionally, modules can be built to be reused in other equipment.

**Objectives:** The objective of our study is to demonstrate the application of a modular method in order to conceive and evaluate modules for the dialysis machine case. The method used for modularization is the Modular Function Deployment (MFD).

**Methods:** The present study was conducted by researchers of the Industrial Engineering School of the Federal University of Rio Grande do Sul. This study was conducted with the help of a team composed by clinical engineers, maintenance technicians and representatives of a medical products development company. With whom we evaluated the dialysis machine complexity and novelty based on existing metrics, and proposed modules based on an adapted MFD method.

**Results:** Based on existing complexity and novelty metrics, we found that a dialysis machine has high production complexity but incorporates low novelty on its design. Thus, we adapted MFD method by suppressing the two initial steps (definition of product structure), and used a dendrogram to interpret the Module Information Matrix. The application of our adapted MFD to the dialysis machine generated 5 possible modules for it.

**Conclusions:** As MFD favors enterprises' objectives but overlooks physical relation between parts, we found that the modules generated

by our adapted MFD do not represent appropriately the final production modules. Therefore, we propose that a refinement considering parts-to-parts could be used to improve these modules.

**OR18.4****Multi-Criteria Decision Making as a Tool in Medical Devices Assessment**

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**Background:** Standard utilization of QALYs in cost analyses focused on pharmaceuticals appears to be inoperative in medical devices, especially the diagnostic ones. It is very difficult to express the effect of such equipment to the quality of life or life expectancy. On the other hand, very often we wish to take into consideration such benefits as technical parameters, maintenance requirements, radiation safety, patient's or clinician's comfort.

**Objectives:** One of the recent recommendations is to replace fully the cost effectiveness/utility analysis with multi-criteria decision methods (MCDM). In this paper, an alternative approach is chosen: the effects in the cost-effectiveness ratio are replaced with weights calculated by MCDMs, while the cost part stays unchanged. The paper shows practical applications of such an approach, and discusses pros and cons of individual methods.

**Methods:** Several methods of MCDM were applied to the selection of patient monitors in the intensive care unit, to cost effectiveness assessment of two remote catheter navigation systems in cardiology as compared with manual catheter manipulation, and to vital signs monitors. The compared methods included the ideal point method, the weighted sum approach, the TOPSIS method, and the analytic hierarchy process (AHP).

**Results:** MCDM proved to be instrumental in all three assessments. In each case, the best option was selected, and CEA and/or ICER calculated. As the accent of this paper is on the methods, particular results are not important.

**Conclusions:** The TOPSIS method proved to be the best for evaluations for device procurement by medical units (clinics, hospitals), while AHP was chosen for strategic decisions at the regulator's level.

**OR18.5****Health Technology Assessment for Driving Innovations Towards Best Performing Fields: the Case of Robot-Assisted Surgery**

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**Background:** Most innovative and impacting Health Technologies (HTs) (as the case of surgical robotic systems), entail, especially for hospitals, the need to find decision support evidence as regards the indication for implementing the robotic surgery programs. The process of uptake of these evolving technologies may be grounded in a standardized evaluation methodology.

**Objectives:** To define a new methodological approach through the identification of Key Performance Indicators (KPIs) needed to compare robotic, laparoscopic and open surgical techniques on clinical efficacy, cost-effectiveness and safety, from hospital and patients' perspective.

**Methods:** With the Eunehta Core Model® as a guidance, HTA reports, systematic reviews and primary studies about robotic surgery are searched from 2000 to 2013 along with a thorough analysis on principles of operation and related expected performances.

**Results:** A decision tree covering all the relevant assessment aspects (safety, efficacy, cost, organizational impact, etc.) of robotic surgery has been derived and weighted by means of pairwise comparisons (cfr Analytic Hierarchy Process -AHP). The combination of KPIs and AHP gave the opportunity to model expert judgments, supplementing the limited literature evidence.

**Conclusions:** Literature data about clinical, technical, economic and organizational characteristics of robotic surgery seem to point towards discouraging from buying. However, considering the clinical and technical potential of this new technology as well as the lack of scientific evidence (usually mentioned as a problem for most innovative HTs), starting from Eunehta Core Model® as a guidance, the combination of KPI and AHP may be considered as part of the HTs' assessment process to facilitate knowledge transfer in less standardized HTA approaches. That being so, this new methodology may be used to strengthen the decision support system, in particular within hospitals.

### OR18.6

#### The Prioritisation of Medical Devices and Opportunities for HTA in Low- and Middle-Income Settings: Findings from Two Qualitative Investigations

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**Background:** Prioritisation of scarce resources is of critical importance within low- and middle-income countries (LMIC) facing financial, human resource and infrastructural constraints. This talk presents two interlinked qualitative studies exploring the decision making processes and methods employed for the prioritisation of medical device and equipment purchasing in three contrasting settings: Gambia, Romania and Rajasthan (India).

**Objectives:**

- Explore the medical device and equipment prioritisation processes and barriers/facilitators within two contrasting settings: The Gambia and Romania as case studies of low- vs. middle-income countries.
- Explore the decision criteria and factors affecting the prioritisation process for medical device and equipment procurement in public versus private institutions within Rajasthan (India).

**Methods:** Semi-structured interviews with relevant health professionals, health economists, health facility managers and regional/national decision makers were undertaken in Gambia, Romania and India at small and medium-sized health facilities with up to 200 beds. Internationally active experts/consultants in the field were also interviewed to provide information on international macro-level decision making processes and paradigms. Ethics approval was granted either by a relevant national authority or by the health facility approached. The framework method was used for data analysis across studies.

**Results:** Prioritisation is a little explored and uncoordinated process in both low and middle income settings, across public and private institutions. A limited evidence base is employed and the methods used as well as procurement and patient outcomes obtained vary according to institutional discretionary income and autonomy, diverse national/regional financing structures, availability and involvement of biomedical engineers /health technology procurement specialists.

**Conclusions:** Transparent medical device and equipment prioritisation processes and methods are called for; the timely and strategic inclusion of health technology assessment evidence into decision

making processes may lead to substantially optimised health outcomes in LMICs.

### OR19.1

#### The Economic Impact of Drug Eluting Balloons for Patients with Femoral-Popliteal Artery Disease

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**Background:** Peripheral Artery Disease (PAD) is recognized as a major public health burden, associated with high rates of re-interventions and complications. Drug Eluting Balloons (DEB) may be a potentially cost-effective alternative for treatment of patients with PAD due to lower re-intervention rates and cost-savings, compared to other endovascular interventions commonly used.

**Objectives:** Assess the economic impact of DEB and other endovascular therapies for patients with femoral-popliteal disease.

**Methods:** A budget impact model was developed from the Italian National Healthcare Service (NHS) perspective with a 5-year time horizon to compare the relative impact of four different index procedure treatments (PTA with balloons, DEB, bare metal stents (BMS) and drug eluting stents (DES)) based on the repeat procedure rates (TLR - target lesion revascularization) over 1 year. A systematic literature review was conducted to determine TLR rates in patients with femoral-popliteal disease treated with one of the four treatment choices. Costs associated with each treatment were derived from the average DRG tariffs used for peripheral angioplasty procedures. A decision analytic model was developed to estimate total costs over 12 months of index procedures and possible revascularizations.

**Results:** Pooled 12-month TLR rates show clear patient benefit with DEB compared to plain PTA (8,6% vs 28,6%) and non-inferiority of DEB vs DES (9,4%) and BMS (11,5%). Total payment for index and repeat interventions (based on TLR rates estimation) across treatments suggested that DEB was the least costly treatment strategy over 1 year, with saving of almost €1,000 per patient with DEB vs PTA. Based on these per-patient savings, the potential total savings amounted to approximately €2 million for an assumed annual increase of 5% in DEB adoption rate over 5 years.

**Conclusions:** Compared to other technologies DEB may be considered clinically superior with predicted reductions in re-hospitalization resulting in cost-savings to the health system from the Italian NHS perspective.

### OR19.2

#### Cost-Effectiveness Evaluation of Novel Care Pathways in Glaucoma Diagnosis Using Imaging Technologies

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Unit, Royal Liverpool and Broadgreen University Hospitals NHS Trust, Liverpool, United Kingdom; 10. Centre for Experimental Medicine, Queen's University Belfast, Belfast, United Kingdom; 11. Vision & Eye Research Unit, Postgraduate Institute, Anglia Ruskin University, Cambridge, United Kingdom

**Background:** Around 40% of glaucoma referrals from community are discharged following first hospital appointment. New imaging techniques are available to aid glaucoma diagnosis. Novel technological solutions may have value in improving efficiencies in service delivery whilst maintaining effectiveness.

**Objectives:** To assess cost-effectiveness of imaging technologies as triage tests for glaucoma diagnosis.

**Methods:** A cost-effectiveness evaluation was embedded within a diagnostic accuracy study to compare four imaging tests (MRA, GPS, GDx-ECC, Spectralis-OCT) within a composite triage station (technology, visual acuity and intraocular pressure) for identifying appropriate referrals. Participants were adults newly referred for suspected glaucoma in the UK NHS. A multi-state Markov cohort model was developed informed by current evidence, study data and clinical experience. The reference standard was clinical evaluation by experienced glaucoma clinician. Trade-off exists between modelling diagnosis and/or clinical decision making: a challenge for model development. Deterministic sensitivity analyses were conducted around patient age, imaging costs, sight-test frequency and clinician diagnostic performance.

**Results:** Data from 943 of 955 participants from 5 centres were included. Diagnostic performance of triage tests varied. MRA and GPS had highest sensitivity (MRA:98%, GPS:97%, [95%CI-96,99]) but with lowest specificity (MRA:30%[25,34], GPS:28%[24,33]). GDx had best specificity (45%[40,50]), though the lowest sensitivity (83%[80,87]). OCT sensitivity was 90%[88,93] and specificity 35%[31,40]. Introducing a composite triage station into the referral pathway was cost-effective in the base case analysis. All triage strategies resulted in a cost reduction but with an associated reduction in effectiveness. Expected saving per QALY lost moving from standard-care was £156,985 for the most cost-effective strategy (MRA) and £22,429 for the least cost-effective (GDx). Results were driven by imaging costs, number of disease cases missed and their future management in community.

**Conclusions:** Alternative care pathways for glaucoma referral incorporating triage tests can be evaluated within a diagnostic accuracy study to model the potential for cost-savings and impact upon patient outcome.

### OR19.3

#### How to Choose the Best Biological Treatment for Rheumatoid Arthritis? Effectiveness and Costs

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**Background:** Rheumatoid arthritis (RA) is an autoimmune disease characterized by inflammation of the joints which leads to proliferative and destructive process of the cartilaginous and bone tissues. The main strategy for treating RA consists of Disease-modifying antirheumatic drugs (DMARDs) use.

**Objectives:** Assess the effectiveness of adalimumab (ADA), etanercept (ETA), infliximab (IFX) and rituximab (RTX) associated or not with DMARD in RA patients and its associated costs in Brazil.

**Methods:** We conducted a systematic review of cohort studies to assess the effectiveness of biological agents. We searched LILACS, EMBASE, CENTRAL and PUBMED databases. Two blinded researchers selected the studies. We evaluated effectiveness for Disease Activity Score (DAS 28), European League Against Rheumatism (EULAR) and American College of Rheumatology (ACR).

**Results:** The search identified 3475 articles, which 3462 were excluded for duplicates, type of intervention, other diseases and study design. Thirteen studies were included. No studies comparing ADA, IFX or ETA alone against RTX were included. Most studies did not show statistically significant differences in clinical and laboratory parameters to compare the effectiveness of ADA, IFX and ETA drugs. Therefore, we evaluated the cost of therapy. In Brazil, according to the chamber for regulating the drugs market (CMED) an annual cost of treatment with ADA (40 mg every two weeks), ETA (50 mg every one week) and IFX (3mg/kg every 8 weeks - patient 70 kg) of R\$ 46,762.08, R\$ 44,003.52 and R\$ 35,908.74, respectively. Some authors also concluded that IFX is the cheaper alternative, however when analyzing the cost-effectiveness of anti-TNF therapies, ADA and ETA are more cost-effective for the treatment of RA than IFX.

**Conclusions:** Effectiveness of the biological drugs evaluated was similar. Therefore, the choice between the biological agents must be based on cost of therapy, individual factors and treatment adherence.

### OR19.4

#### Cost-Effectiveness Analysis of Vemurafenib Compared to Dacarbazine for the Metastatic Melanoma Treatment in Brazilian Public Health System

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**Background:** Lately, new drugs for metastatic melanoma cutaneous treatment were launched; however, their costs are quite expensive.

**Objectives:** To estimate the incremental cost-effectiveness ratio of vemurafenib compared to dacarbazine, the standard treatment for metastatic melanoma in the Brazilian government perspective.

**Methods:** The Excel-based model was developed to compare two sets of strategies over 10 years: 1st) the use of BRAF-V600E mutation test to select BRAF+ patients to be treated with vemurafenib, while the BRAF- patients will be treated with dacarbazine; and 2nd) the use of dacarbazine or vemurafenib in BRAF+ patients. Three health states were considered: progression-free survival, disease-progression, death, whose transition probabilities were extracted from literature. The utilities were based on international data. Health care costs and resources were obtained from government databases in 2013, except the price of mutation test and the vemurafenib price, which were extracted from Emergency Care Research Institute (ECRI) and calculated based on the Maximum Public Sector Price, respectively. The annual discount of 5% was used for cost and outcomes.

**Results:** In the 1st sets of strategies the QALY for "BRAF+/vemurafenib" and "BRAF-/dacarbazine" were 1,06 and 0,92, respectively, while the costs were R\$ 64.909,00 (USD 33,100.00) and R\$ 11,117.00 (USD 5,670.00), respectively (ICER = R\$ 380.543,00/QALY ~ USD 194.055,00/QALY). In the 2nd strategy the QALY for BRAF+/vemurafenib" and "BRAF+/dacarbazine" were 1,20 and 0,92, respectively, while the costs were R\$ 118.501,00 (USD \$ 60.429,00) and R\$ R\$ 11.317,00 (USD 5.771,00), respectively (ICER = R\$ 379.132,00/QALY ~ USD 193.336,00/QALY). Considering the WHO threshold for Brazilian system (R\$ 75,000.00 ~ USD 34,890.00, three times GDP per capita) the cost-effective price to vemurafenib is R\$ 850.00 (USD 430.00), however the Maximum Public Sector Price for vemurafenib is R\$ 3,888.00 (USD 1,968.00).

**Conclusions:** In Brazil, vemurafenib is not cost-effective for melanoma metastatic, and its threshold price is 22% of the Maximum Public Sector Price.

**OR19.5****Model-Based Projection of Clinical Effectiveness and Cost Effectiveness of Catheter-Based Renal Denervation in Moderate Treatment-Resistant Hypertension**

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**Background:** Catheter-based renal denervation (RDN) is a new treatment for patients with resistant hypertension. While initial clinical experience was primarily gained in patients with stage II hypertension, recent study data report systolic blood pressure (SBP) reductions observed in moderate hypertensives.

**Objectives:** Our objective was to assess the clinical and economic effectiveness of RDN in moderate hypertension from a U.S. Medicare payer perspective.

**Methods:** We used a 34-state Markov model to predict cardiovascular endpoints, mortality, costs and quality-adjusted life expectancy. Input parameters were derived from multivariate risk equations and other published sources. We evaluated the impact of a 13 mmHg reduction in systolic blood pressure (SBP), from a baseline SBP of 151 mmHg, in a 30% female, 50% diabetic cohort with a mean age of 63.6 years, as observed at 6 months in the investigator-initiated, prospective, multicenter pilot study reported by Ott et al. (2013). We calculated ten-year relative risks and the lifetime incremental cost-effectiveness ratio (ICER) in \$/QALY discounted at 3% per year for numerator and denominator.

**Results:** Ten-year relative risks for clinical endpoints from our model calculations were 0.80 for stroke, 0.86 for myocardial infarction, 0.88 for all coronary heart disease, 0.90 for heart failure, 0.85 for end-stage renal disease, and 0.83 for cardiovascular mortality, respectively. The ICER was \$23,207/QALY.

**Conclusions:** Our model projections suggest that RDN reduces or delays relevant cardiovascular events in moderate resistant hypertension and is cost-effective when compared to other, well-accepted interventions.

**OR19.6****Economic Evaluation of Oxytocin in Uniject Injection System Versus Standard Use of Oxytocin for the Prevention of Postpartum Hemorrhage in Latin America and the Caribbean**Andres Pichon-Riviere<sup>1</sup> Demian Glujovsky<sup>1</sup> Ulises Garay<sup>1</sup> Federico Augustovski<sup>1</sup> Augstin Ciapponi<sup>1</sup> Magdalena Serpa<sup>2</sup>

1. IECS-Institute for Clinical Effectiveness and Health Policy, Buenos Aires, Argentina; 2. Maternal and Child Health Integrated - Program (MCHIP) - PATH, Washington, USA

**Background:** Postpartum hemorrhage (PPH) is a leading cause of maternal death. Although the strong evidence showing the efficacy of oxytocin in preventing PPH, its use remains suboptimal. The Uniject injection system prefilled with oxytocin (OiU) has the potential advantage, due to its ease of use, to increase oxytocin coverage rates (OCR).

**Objectives:** To evaluate the cost-effectiveness of OiU in Latin America and the Caribbean (LAC).

**Methods:** We built an epidemiological model to estimate the impact of replacing oxytocin in ampoules with OiU on the incidence of PPH, quality-adjusted life years (QALYs) and costs from a health care perspective. A systematic search for data on epidemiology and cost studies was undertaken. A consensus panel among LAC experts was performed to quantify the expected increase in OCR as a consequence of making OiU available. Deterministic and probabilistic sensitivity analyses were performed.

**Results:** In the threshold analysis the minimum required increment in the OCR to make OiU a cost-effective strategy ranged from 1.3% in Suriname to 16.2% in Haiti. In more than 60% of the countries, the required increment was below 5%. OiU could prevent more than 40,000 PPH episodes annually in LAC. In 27% of the countries OiU showed to be cost saving. In the remaining 21 countries OiU was associated with a net cost increment (\$ 0.005 to \$0.780 2013 US dollars per delivery). OiU strategy ranged from being dominant to having an ICER of \$ 9,454 per QALY gained. In the great majority of countries these ICERs were below one GDP per capita.

**Conclusions:** OiU was cost-saving or very cost-effective in almost all countries. Even if countries can achieve only small increases in OCR by incorporating OiU, this strategy could be considered an efficient use of resources. These results showed to be robust in the sensitivity analysis under a wide range of assumptions and scenarios.

**OR20.2****Cardiovascular Exams in a Pediatric Population Assisted by a Non-Profit Private Healthcare Organization in Brazil**Maria da Glorihorta Cruvinel Horta<sup>1,2</sup> Augusto Cesar Soares Dos Santos Jr<sup>1,2</sup> Daniela Castelo Azevedo<sup>1,2</sup> Lelia Maria Almeida Carvalho<sup>1,2</sup> Luiza De Oliveira Rodrigues<sup>1,2</sup> Sandra De Oliveira Saporì Avelar<sup>1,2</sup> Mariana Fernandes Ribeiro<sup>1,2</sup> Silvana Marcia Bruschi Kelles<sup>1,2</sup>

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**Background:** There are several publications suggesting that exams prescribed to assess the cardiovascular condition of pediatric patients are often not necessary and result in low clinical benefits.

**Objectives:** This study was aimed to evaluate the indications and frequency of cardiovascular exams in the pediatric population of a non profit private healthcare organization in Belo Horizonte, Minas Gerais, Brazil.

**Methods:** All pediatric patients assisted by Unimed-BH and submitted to cardiovascular exams from December 2009 to December 2011 were included in this study. The following variables were analyzed: age, sex, indication, the type, frequency and costs of the exams prescribed.

**Results:** 15.010 children, with age ranging from 0 to 18 years (median 10,28 ± 5,85 years), were included in this study. From December 2009 to December 2011, 27.056 exams were prescribed to assess the cardiovascular condition of these patients. There were 17.352 electrocardiograms, 9.346 echo-doppler-cardiograms and 358 treadmill testing. The requested exams resulted in a total cost of US\$705,800.00. The most common indications were: unexplained (46.76%), screening for cardiopathy (19.03%), routine screening (9.4%), pre-surgical assessment (3.10%), cardiovascular screening (1.32%), follow up of systemic cardiovascular disease (0.39%). Pediatric cardiologists requested 19.65% of the preformed tests and adult cardiologists 40.94%. Most of the exams were performed by the same professional responsible for the prescription.

**Conclusions:** This study suggests that in the pediatric population cardiovascular exams are often indicated without following a specific protocol. Studies evaluating the role of continued medical education and the development comprehensive guidelines are needed in order to approach this question.

**OR20.3****The Effectiveness of Artificial Urinary Sphincter Implantation: a Retrospective Analysis from 2004 to 2011**

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1. NATS UFMG, Belo Horizonte, Brazil; 2. Unimed BH, Belo Horizonte, Brazil

**Background:** Urinary incontinence after prostatectomy for benign or malignant disease is a well known and often feared outcome. The artificial urinary sphincter (AUS) has been recognized for many years as the most effective long-term treatment for men with severe stress incontinence. However, currently, there is only one clinical randomized study assessing the safety and effectiveness of AUS implantation.

**Objectives:** The purpose of this study is to evaluate the effectiveness and rate of adverse effects in a series of cases of artificial urinary sphincter implantation in prostatectomized patients at Unimed-BH.

**Methods:** This retrospective study consisted of a convenience sample of 50 individuals treated for prostate cancer from January 2004 to December 2011 which underwent implantation of an AUS after radical prostatectomy.

**Results:** Patients were followed for a mean 25.4 months. 9 (18%) patients were lost during the follow up period. From the remaining 41 patients, 22 (53.65%) presented severe adverse effects. There were two deaths at 25 and 62 months after the implant of the AUS, however due to causes not directly associated to the AUS. The AUS presented malfunction resulting in the substitution of the apparatus in 8 (19.51%) patients. The most common causes of the AUS malfunction were: reservoir failure, failure in activating and need to substitute the cuff. The total costs associated with the implantation of the artificial urinary sphincter were US\$1,290,200.00 or US\$25,800.00 per patient.

**Conclusions:** There was a high prevalence of AUS malfunction resulting in the substitution of the material in the series of cases analyzed. Further studies are needed in order to address the long term safety and the cost-effectiveness of the AUS.

**OR20.4****Proton Therapy for Cancer in Northeast Brazil**

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Department of Health of the State of Ceara, Fortaleza, Brazil

**Background:** Radiation therapy used to treat tumors has been a mainstay of cancer treatment for more than a century. The proton therapy seems to be able to treat hard to reach cancers such as spinal tumors, with less risk of causing side effects. The center of health technology assessment (CHTA) in Department of Health in State of Ceara, northeast, Brazil, received a demand for evaluating evidence on the use of proton therapy for cancer due to a financial proposal for the construction of a Reference Center which will cost for the state around U.S. \$ 225 MI.

**Objectives:** The purpose of this HTA was to evaluate the scientific evidence of efficacy, safety and cost-effectiveness in the use of proton therapy to patients with cancer in the state of Ceara, Northeast, Brazil.

**Methods:** This HTA was based on a PICOS Method, a structured question and a search on the scientific databases like as PubMed, Cochrane Library, CRD and EMBASE. The selected studies were systematic reviews and economic evaluations.

**Results:** Systematic reviews have described the clinical efficacy and safety of the use of proton therapy in the treatment of prostate cancer,

uveal melanoma, head and neck cancer, gastrointestinal cancer, chondrosarcoma of the skull base, cervical and bladder cancer. The economic studies have explored methodologies and recommended collection and analysis of data from proton therapy centers with greater rigor.

**Conclusions:** The incorporation of proton therapy can be hindered by shortage of clinical and economic data to justify the capital investment and operating costs results. There are no data and evidence for all types of cancers. Comparative effectiveness studies of higher quality are needed to provide better evidence for the incorporation of proton therapy in the state of Ceara, Northeast, Brazil.

**OR20.5****Recent Trends in Multiple Sclerosis-Related Health Technology Assessment Decisions: an Assessment of Five Countries**

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**Background:** As innovative therapies for treatment of multiple sclerosis (MS) and management of MS symptoms continue to be approved, high expense associated with these novel treatments must be evaluated alongside the clinical benefit provided. Health technology assessments (HTAs) in MS result in policies with the goal of optimizing value while improving patient care and health outcomes.

**Objectives:** To evaluate recent patterns in MS-based HTA decisions in selected countries.

**Methods:** HTA surveillance was conducted for Australia, Canada, France, Germany, and the United Kingdom (UK) from January 1, 2012 to January 28, 2014. MS-based HTAs were evaluated by indication, decision, and rationale for the decision. Decisions were categorized as favorable or unfavorable.

**Results:** 17 MS-related HTAs were published in the study timeframe for 7 unique products. Across studied nations, 8 (47%) decisions were favorable and 9 (53%) were unfavorable. The UK made the highest number of favorable decisions (2 of 2; 100%), followed by Australia (1 of 2; 50%) and Canada (3 of 6; 50%), France (1 of 3; 33%), and Germany (1 of 4, 25%). The most common rationale for an unfavorable decision was insufficient or weak clinical data, followed by insufficient economic data or an improperly high cost. No therapy that was indicated to prevent MS, improve spasticity in patients with MS, or improve walking in patients with MS received a favorable decision; whereas all therapies with indications for improved urinary incontinence received a favorable decision. The majority of therapies indicated to treat MS received favorable decisions (6 of 8; 75%).

**Conclusions:** Just over 50% of MS-related therapies received unfavorable decisions over the last 25 months. Those therapies indicated to treat MS or improve urinary incontinence in patients with MS were the most successful. Based on this analysis, enhanced clinical and economic data may be beneficial in garnering a favorable HTA decision in certain countries.



**OR20.6****Natalizumab Retention Rates in Multiple Sclerosis (MS) in Brazil: a Retrospective Descriptive Cohort Study**

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Ministry of Health, Brasilia, Brazil

**Background:** Since 2011, natalizumab is available in the Brazilian public health system (SUS) to treat patients with Multiple Sclerosis (MS). Data about the profile of this use and its retention rates can guide budget impact analyses and other issues in Health Technology Assessment (HTA).

**Objectives:** To determine the natalizumab retention rate in a cohort of patients with MS treated in the SUS.

**Methods:** A retrospective descriptive cohort study based on SUS administrative data (DATASUS). Records of natalizumab dispensed between January, 2011 and September, 2013 for MS (ICD-10: G35), linked with patient's unique codes (anonymous), were available. Each patient no longer claiming for natalizumab after January, 2013, was defined as a discontinuation. The retention rate and time were determined with Kaplan-Meier survival analyses, conducted in a descriptive fashion with the SPSS Statistics software, version 21.

**Results:** During 2011, a total of 276 patients started the treatment with natalizumab (93.5% after June). The median follow-up was 14 months (range: 0-24, 3,853 person-months). Most of patients were treated in the state of Sao Paulo (50.4%), Parana (9.8%) and Rio Grande do Sul (8.0%). Female gender represented 72.1% (n = 199) of the cohort, with a mean age of 37.23 years (SD: 11.09; median: 35), similar to men, with 37.90 years (SD: 11.11; median: 36). At 24 months, the estimated retention rate was 0.76 (SE: 0.03) and the mean retention time was 20.37 months (SE: 0.44). Considering the first year of treatment, the retention rate was 0.83 (SE: 0.02). These estimates reflected an overall retention rate of 0.82 patients per person-year. The data limitations didn't allow evaluating the reasons for discontinuation (i.e. death or adverse reactions).

**Conclusions:** Data about natalizumab use, based on administrative databases, can provide useful information about its patients profile and drug retention estimates. A longer follow-up could improve these estimates.

**OR21.1****Access to Therapies for Rare Diseases in Canada: the Role of HTA, Safety Nets, and One-Offs**

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**Background:** Since the US Orphan Drug Act of 1984, the number of therapies developed for rare diseases has rapidly increased. Often, these therapies represent the only active treatment for debilitating and/or life-threatening conditions. However, they create significant challenges for public and private payers. Because they target small patient populations, clinical evidence of efficacy/effectiveness is typically limited, while the cost per patient is high. In Canada, each province/territory establishes its own mechanisms for determining which such therapies to provide.

**Objectives:** To compare current mechanisms across provinces and territories, and explore their impact on access

**Methods:** A systematic review of relevant published and unpublished documents was performed. Electronic bibliographic databases, the internet, and government websites were scanned using structured search strategies. Information was extracted independently by two researchers, and included aspects such as program type, condition/patient/therapy eligibility criteria, role of HTA, decision options, ethical assumptions, and stakeholder input. It was validated through

member-checking with provincial/territorial policy experts and tabulated to facilitate qualitative analyses. Impact on access was assessed through a cross-province/territory comparison of the coverage status of all therapies reviewed by the Common Drug Review for indications affecting <1/2,500 Canadians using the Kappa statistic. Reasons for variations were explored using qualitative techniques.

**Results:** Each province/territory has formal and informal mechanisms through which such therapies may be accessed. In most cases, formal mechanisms constitute the centralized HTA processes that also apply to common therapies. While several provinces have established dedicated processes/programs, whether they have affected access is not clear. The status of individual therapies across provinces was broadly similar. This may be explained by availability of informal, generic 'exceptional' access programs and one-off decision-making in all provinces/territories.

**Conclusions:** Mechanisms for accessing these therapies largely comprise safety-net type options. However, as the number increases, a more systematic approach to decision-making may be needed.

**OR21.2****Is It Possible to Demonstrate Cost Effectiveness of Ultra-Orphan Therapies Within Current Thresholds? Lesson Learned from Published HTAs and Studies**

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**Background:** Ultra orphan therapies are indicated for rare diseases affecting less than a few thousand patients. The annual and lifetime per patient cost of these treatments have generated controversy and policy questions regarding cost effectiveness and reimbursement.

**Objectives:** The objective of this analysis was to review all available cost effectiveness studies and develop lessons for policy development for ultra orphan therapies.

**Methods:** Fifteen European Medicines Agency (EMA) and Food and Drug Administration (FDA) approved ultra orphan drugs were identified and reviewed for their published cost effectiveness studies in peer-reviewed journals and Health Technology Assessments (HTAs). Data were collected for (1) Product (2) Indication (3) Model design and assumptions (4) Author of the analysis (manufacturer, HTA or academic group) (5) Cost effectiveness results and (5) Sensitivity analysis results. All cost effectiveness ratios were converted to 2103 US Dollar using historical currency conversion rates.

**Results:** For fifteen EMA and FDA approved ultra orphan therapies, eight cost effectiveness studies were identified for seven products (50%). Four of these studies were conducted by the sponsor (as part of the HTA submission), two were conducted by HTAs and two were from academic groups. All models were developed for life time horizon. In the base case scenario, the median base case incremental cost effectiveness ratio (ICER) was \$591,200 per quality adjusted life years (QALYs) (range, \$391,120 to \$7,425,000). The sensitivity analyses results had a median ICER of \$1,958,674 per QALY, with a maximum ICER of \$10,395,000. All reported ICERs exceeded the maximum accepted thresholds for end of life care therapies.

**Conclusions:** Review of cost effectiveness studies for ultra orphan therapies shows that none were able to show ICERs within typical thresholds. These results suggest a need for new policy regarding acceptable threshold, or type of models for assessing cost effectiveness of ultra orphan therapies.

**OR21.3****Assessment of Medicines for Rare Conditions and End of Life Care: Experience of a Rapid Review by the Scottish Medicines Consortium**

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**Background:**

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 processes for medicines used to treat patients at the end of life and those with rare conditions. This would be the first step in a process to determine a value-based approach for the assessment of new medicines in Scotland.

**Objectives:** The objective of the review was to recommend process changes for SMC that would increase access to these groups of medicines in Scotland.

**Methods:** SMC convened a group of key stakeholders (including clinicians, patient interest groups, pharmaceutical industry representatives, health economists and ethicists) to undertake the rapid review. The group agreed definitions that SMC would adopt for medicines for end of life, medicines for rare conditions and for very rare conditions (ultra-orphans). Drawing on literature and international experience, the group considered several options that could be incorporated into SMC methodology to reflect the policy imperative. These included QALY weights, increasing the cost per QALY threshold, enhanced use of decision modifiers, cost-consequence analysis, multi-criteria decision analysis or the use of a clinician and patient focused managed entry mechanism. The group assessed these options against a set of agreed principles in order to identify the preferred approach.

**Results:** Through a deliberative process, the group agreed that the preferred approach was to use a system of patient and clinician engagement (PACE) in the appraisal of medicines for end of life or rare conditions (orphans). For the evaluation of medicines for very rare conditions (ultra-orphans) a cost-consequence decision framework was agreed. In January 2014 the Scottish Government accepted the recommendations and SMC is now working to implement these changes.

**Conclusions:** Traditionally assessment of new medicines by HTA agencies has used a utilitarian approach, this is an additional new methodology for these challenging areas. The impact of these changes will be reviewed after 1 year.

**OR21.4****Economic Evaluation in the Context of Rare Diseases: is This Possible?**

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**Background:** Rare diseases have demanded attention of researchers and decision makers in order to verify if they must gain a special status related to other diseases particularly in the context of health technology assessment.

**Objectives:** To systematize the available evidence on the appropriateness of the use of economic evaluation on incorporation/exclusion technologies for rare diseases.

**Methods:** Structured review of the literature in Medline via PubMed, CRD, Lilacs, SciELO and Google Scholar (gray literature).

**Results:** The economic evaluation studies originate in Welfare Economics, in which individuals maximize their utilities, based on allocative efficiency. There is not a criterion widely accepted in the lit-

erature to examine the expected utilities in order to give more weight to individuals with higher health need. Thus, generally the economic assessment studies not asymmetrically balance the utilities, all are treated equally, which, in Brazil, is also a constitutional principle.

**Conclusions:** Health care systems have ratified the use of economic evaluation as the main tool to assist in decision making. However, this approach does not exclude the use of other complementary methodologies to studies of cost-effectiveness, as the person trade-off and rescue rule.

**OR21.5****Value Assessments for Orphan Drugs: a Systematic Comparison of HTA Decision-Making Processes Across Countries**

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**Background:** HTA is widely used to support coverage decisions and helps estimate the incremental benefits and costs of new technologies compared to existing treatment alternatives. For the same technology, HTA has often resulted in differential coverage decisions across settings despite the same clinical evidence being appraised. This may relate in part to legitimate contextual differences or to controversies over the HTA process itself. Consequently, there is a need to further explore these areas of intense debate and provide recommendations for methodological improvements in the conduct of HTA.

**Objectives:** To identify similarities and differences in HTA decision-making processes and outcomes, and explore the criteria driving these decisions in different settings analysing a sample of orphan drugs.

**Methods:** Countries sampled were England, Scotland, Sweden, and France. Ten drug-indication pairs with EMA orphan designation and appraised by NICE in England were selected. Data sources comprised publicly available HTA reports, including recommendations on coverage. A mixed methods qualitative research approach was used to systematically compare the decision-making processes using thematic analysis and adopting an iterative approach, to ensure that the results capture the numerous dimensions of the decision-making process.

**Results:** Important differences and similarities in decision-making were seen across the study drugs, for each step of the decision-making process. This included situations where the countries sampled interpreted the same evidence differently; variations in how uncertainty in the evidence was handled; the extent to which stakeholder input influenced the decision; and whether other considerations beyond the quantitative estimates of incremental costs and benefits influenced the final decision. Results were subsequently used to determine the criteria driving HTA-based recommendations in the study countries.

**Conclusions:** Systematically comparing the decision-making processes of ten orphan drugs has led to better understanding how different HTA bodies conduct value assessments and identify areas where differences arise due to the processes and methods adopted in each jurisdiction.

## OR21.6

### Methodological Development of a Comprehensive MCDA Framework Based on Real Life Issues in Appraisal of Treatments for Rare Diseases

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**Background:** Patients affected by one of the 6,000–8,000 rare diseases represent 6–10% of the population. Although regulatory policies have been devised to help overcome barriers to drug development in this field, appraising drugs for rare diseases is a major challenge for HTA agencies. Because of the multiple issues involved, MCDA-based approaches are uniquely suited for this purpose.

**Objectives:** To adapt an established multi-criteria-based framework (EVIDEM) to further decisionmaking in the rare disease field across the healthcare continuum.

**Methods:** Development of the framework was guided by review and application of MCDA methodological principles (including completeness, non-redundancy, operationalizability and independence), pragmatic considerations for real life application and issues specific to rare diseases. These issues were identified through review and analysis of existing and proposed appraisal frameworks and policies for rare diseases, comprehensive literature reviews and an international survey.

**Results:** The framework consists of a hierarchical, quantitative MCDA model covering six domains of value (Need, Type of benefit, Outcomes, Economic consequences, Knowledge and Established priorities) as well as a tool for qualitative consideration of contextual criteria. The framework explicitly incorporates issues specific to rare diseases including disease complexity, treatment outcomes complexity, multiple economic and social consequences, data quality limitations, healthcare system priorities, ethical questions of efficiency and fairness, and implementation issues. Multiple sensitivity analyses explore uncertainty stemming from differences of individual perspective and judgment, MCDA model design, and data limitations.

**Conclusions:** This framework promotes a comprehensive appraisal of rare diseases treatments, with a design rooted in real-life issues faced by decisionmakers.

## OR22.2

### A Decisional Strategy to Determine the Appropriate Measure to Prevent Contrast-Induced Nephropathy

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**Background:** Several measures are suggested to prevent contrast-induced nephropathy (CIN) in high risk patients. The decision process making should adopt a comprehensive approach. Although the effectiveness of these interventions to prevent CIN has been evaluated in many systematic reviews, their real benefits remain controversial.

**Objectives:** To compare the effectiveness to prevent CIN, adverse effects, feasibility and organisational impacts of intravenous (IV) administration of sodium bicarbonate (Na-Bic) hydration, N-acetylcysteine (NAC), and IV saline hydration.

**Methods:** Literature search was performed in Medline, Embase, Cochrane Library and grey literature to retrieve SR, clinical practice guidelines and randomized controlled trials on saline hydration, Na-Bic and NAC administration to patients undergoing computed tomography or angiography procedures. Relevant outcomes were CIN (according

to the author's definition), renal replacement therapy and in-hospital mortality. Two reviewers independently performed article selection, quality assessment and data extraction. Costs were estimated according to standard procedure for each intervention. Results were shared with an interdisciplinary group of experts.

**Results:** Sixteen relevant publications were included. Available evidence suggests few clinical benefits associated with IV administration of Na-Bic when compared to saline hydration and does not support the use of oral or IV NAC for CIN prevention. Evidences were insufficient to conclude on renal replacement therapy and in-hospital mortality. Few minor adverse effects were observed with NAC. Some trials suggest that a rapid protocol administration (7h total) of saline hydration could be as effective as a standard procedure of hydration (24h total) to prevent CIN. Based on the estimation of high-risk patient per year requiring injection of contrast agent for radiological examination, data suggest that administration of Na-Bic or NAC for CIN prevention is more expensive than saline hydration.

**Conclusions:** Based on efficacy, adverse events and costs, saline hydration should be considered as the appropriate measure to prevent CIN. In addition, an adequate identification of high-risk patients remains mandatory.

## OR22.3

### Producing Rapid Assessments of "Other Technologies" in European Collaboration – Experiences from Work Package 5, Strand B of EUnetHTA JA2

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**Background:** Work Package 5 is currently testing the HTA Core Model for Rapid Relative Effectiveness of pharmaceuticals for the production of rapid assessments in European collaboration. Even though the Model was initially developed for pharmaceuticals, it is currently also applied to "other technologies" including medical devices or surgical interventions within Strand B.

**Objectives:** At least 4 joint assessments of non-pharmaceuticals will be compiled within Joint Action 2 (2012 – 2015). These assessments should then be used by member agencies for producing local reports. Further, experiences gained will be used to adapt the Model to "other technologies".

**Methods:** N/A

**Results:** Since October 2012, 2 joint assessments have been published. Stages for the compilation of the assessments comprise topic selection by authoring agencies, identification of co-authors and dedicated reviewers from member agencies followed by a scoping and an assessment phase. Stakeholders, including manufacturers and medical experts are involved at several stages.

The first two pilots were produced on average within 7 months by teams consisting of 8 institutions. Challenges encountered comprise short time-frames, modes of collaboration, methods chosen and quality assurance issues. Based on these experiences, processes were adjusted to improve the feasibility of collaboration. Some member agencies have already used these assessments for the production of local reports and assessments were also used directly.

**Conclusions:** The production of assessments in European collaboration has proven feasible, but adaptations and changes of processes are still needed. If and how these assessments will ultimately be used by national agencies has to be evaluated in the coming years.

**OR22.4****Optimising the Use of Data in Modelling the Cost-Effectiveness of Acupuncture: Methodological Opportunities and Challenges**

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**Background:** Increasingly economic evaluation is used to inform decisions about which health care technologies to fund given available resources. The gold standard for quantitative synthesis is to utilise outcomes measures from multiple individual patient level sources in order to derive estimates of treatment effect: a key parameter of use in a cost-effectiveness model.

**Objectives:** This paper reviews novel methods aimed at fully exploiting the available evidence, regardless of its format, highlighting the strengths and challenges of synthesising it. A motivating example to illustrate this is an economic evaluation of acupuncture versus usual care and/or sham in patients with chronic, non-cancer pain in three conditions (i.e. headache, musculoskeletal pain and osteoarthritis of the knee) in primary care.

**Methods:** The analysis evaluated the cost-effectiveness of acupuncture using outcome data over a three month time horizon. It included 28 high quality randomised controlled trials. Two continuous effectiveness outcomes were assessed: standardized mean difference in pain and EQ-5D scores. Using Bayesian mixed treatment comparison models, these outcomes were independently modelled. To analyse the data WinBUGs was used, implementing McMC methods to fully characterise the relevant uncertainties. Regression analysis was used to predict the effect of changes in standardized pain and health-related quality of life on resource use.

**Results:** Challenges included that EQ-5D scores were not always available. Data from generic preference instruments and disease-specific quality of life measures were mapped to EQ-5D using published algorithms. To assess the impact of patient and study-level treatment effect modifiers and the quality of the evidence, scenario analysis was employed.

**Conclusions:** Bayesian modelling provides a flexible framework to address the challenges posed by a heterogeneous, fragmented evidence base. Time invested in processing the data for this task should not be underestimated.

**OR22.5****Identifying Complications of Interventional Procedures from National Routine Healthcare Databases: a Review of Methods**

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2. Regional Medical Physics Department, Newcastle, United Kingdom

**Background:** Complications are an important consideration in assessing the safety and efficacy of new interventional procedures, but reliable data are difficult to acquire. In recent times, the complications of devices, either used to do a procedure or implanted at the time of the procedure, have become a particular concern, with the high profile examples of breast implants and metal-on-metal hip implants.

Several authors have developed and applied methods to routine data sets to identify the nature and rate of complications following interventional procedures. But, to date, there has been no review of such methods.

**Objectives:** To find, classify and appraise published methods which used routine United Kingdom (UK) healthcare databases to identify complications from interventional procedures.

**Methods:** Thirteen data sources were searched to identify studies from the published literature that referred, in the title or abstract, to the name or acronym of a known routine healthcare database and to complications from procedures or devices. Methods reported in eligible papers were identified and inductively classified.

**Results:** From 3688 papers, 100 met the eligibility criteria. Ten distinct methods of identifying complications were found: 3 used clinical codes, 5 used surrogate indicators and 2 relied on manual review of patient records. The benefits and limitations of each approach were assessed.

**Conclusions:** Methods using clinical codes to identify procedural complications were the most commonly applied and have the greatest potential to generate new evidence on the quality and safety of new procedures. The ICD-10 scheme includes provision for the clinical coding of complications but these codes have been used rarely in research, and much valuable observational data are being ignored. Methods using surrogate indicators of complications are subject to serious methodological limitations and methods based on free-text fields are not reliably scalable to large studies.

**OR22.6****Improving Rapid Access to Reports of RCTs in Embase: Innovative Methods to Enhance the Cochrane Central Register of Controlled Trials (CENTRAL)**

[Julie May Glanville](#)<sup>1</sup> [Gordon Dooley](#)<sup>2</sup> [Anna Noel-Storr](#)<sup>3</sup> [Ruth Foxlee](#)<sup>4</sup>

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**Background:** Health technology assessments ranging from rapid reviews to the most extensive projects, rely on the efficient identification of research evidence, in particular the evidence from randomised controlled trials (RCTs). The largest single source of RCTs is the Cochrane Central Register of Controlled Trials (CENTRAL), available as part of The Cochrane Library. CENTRAL mostly contains records from Medline, but also has many records from Embase. The annual addition of Embase records to CENTRAL has been undertaken for several years, but more frequent updates are required.

**Objectives:** To identify reports of RCTs and quasi RCTs from Embase for more rapid publication in CENTRAL.

**Methods:** In March 2013 the Cochrane Dementia and Cognitive Improvement Group, Metaxis and York Health Economics Consortium began work to identify reports of RCTs and quasi RCTs from Embase for publication in CENTRAL. We developed and validated a sensitive search filter to identify reports of RCTs using textual analysis of 10,000 RCT records (published 2000-2010). The filter performance was tested on an additional 10,000 RCT reports. An analysis of the records retrieved has resulted in a tiered record assessment process, where the most obvious RCT reports are fast-tracked, leaving more capacity to assess the relevance of the less obvious RCT records. Records are assessed for relevance by a novel use of internet crowdsourcing, with between two and six people assessing whether a record is really a report of an RCT.

**Results:** The validated search filter to identify reports of RCTs in Embase performs at over 97% sensitivity. We will report the first six month's experience of crowdsourcing.

**Conclusions:** Through a new search filter and crowdsourcing the currency of record availability in CENTRAL will be enhanced. The number of irrelevant and duplicate records will be fewer. Searchers will be able to identify more RCTs more accurately than previously by a rapid search of CENTRAL.

**OR23.1****Methodological Guidelines for the Clinical Development of Dressings**

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**Background:** The National Committee for the Assessment of Medical Devices and Health Technologies (CNEDiMITS) advise health authorities on the reimbursement of medical devices by National Health Insurance. In the framework of this mission, the CNEDiMITS is frequently hampered by the poor quality of clinical trials evaluating dressings.

**Objectives:** To identify key elements of a protocol that improve the quality of chronic wound dressing clinical studies.

**Methods:** After a systematic review of literature on the topic, we selected and analyzed 3 methodological guidelines for chronic wound dressing clinical studies and 8 clinical studies evaluating the validity of intermediate endpoints as a predictor of complete healing for chronic wounds.

The literature review was discussed and used by a multidisciplinary working group to elaborate draft of methodological guidelines. These guidelines were reviewed by a multidisciplinary reading group and stakeholders before submission to the CNEDiMITS for final approval.

**Results:** The main methodological guidelines identified were:

- Follow the methodological framework of randomized controlled trials
- Include patients representative of real life settings
- Blind the endpoints assessment
- Use the following endpoints for the wound healing assessment: complete wound healing assessed at a time depending on the etiology and the stage of the wound or time to achieve complete wound healing. Indeed, there is no sufficient evidence on the validity of intermediate endpoints for prediction of complete healing.
- Use the following comparator: gold standard dressing of the pathology and of the stage of healing studied
- Use standard of care associated to the dressing in accordance with the current clinical guidelines
- Report the associated treatment in relationship with the study objective

**Conclusions:** Clinical studies supporting dressing reimbursement requests should follow the above guidelines.

**OR23.2****SkillScribe™: An Innovative Electronic Platform for the Development and Distribution of Educational Programming**

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**Background:** Electronic Continuing Medical Education (CME) is emerging as a popular option for physicians to conveniently gain knowledge leading to CME credit. SkillScribe™ is an innovative electronic platform designed to facilitate opportunities for higher education in specialized fields. Designed in response to administrative, educator and learner needs, it is a user-friendly electronic application that can offer specialized educational programming to a range of professionals and learners through hand-held devices including smartphones, computers and tablets. Moreover, SkillScribe™ offers educators the opportunity to collaboratively design, market and sell their own educational programming through the online electronic platform.

**Objectives:**

1. Present the innovative technology and the scholarship supporting the SkillScribe™ platform;
2. Describe how SkillScribe™ can be tailored and applied to facilitate self-directed learning in a range of diverse educational fields;
3. Present and discuss potential uses of the platform as an educational tool
4. Present on the potential for SkillScribe™ to offer educational facilities additional revenue streams to supplement traditional opportunities for learning

**Methods:** Here's how it works:

Step 1: Sign up as a team of educators at [www.skillscribe.com](http://www.skillscribe.com)

Step 2: Invite existing SkillScribe™ members to your Team if you require their specific expertise to supplement your team's knowledge

Step 3: Use your Team's knowledge to build SkillSets - modules that represent a CME program

Step 4: Publish your Team's SkillSets and earn revenue when learners sign up

**Results:** Results pending official launch and evaluation scheduled for March 2014.

**Conclusions:** This recently launched, innovative electronic platform for self-directed learning represents a new approach to designing and offering continuing professional development. SkillSets are currently being designed to support the learning needs of medical professionals in specialty areas, primary care physicians, faculty, administration, and education technology

**OR23.3****Health System Guidance Appraisal - Better Guidance for Better Health Systems**

Denis Ako-Arrey

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**Background:** Health systems guidance are systematically developed statements that assist decisions about appropriate options for addressing a health system challenge, assist with the implementation of these options, and direct the monitoring and evaluation of the implementation efforts. However, development of health system guidance poses unique conceptual and methodological challenges related to the different types of evidence to be considered, the complexity of health systems, and the pre-eminence of contextual factors that directly influence recommendations.

**Objectives:** Our goal is to develop a HSG Appraisal Tool (HSG-AT) that will be used to direct the development, reporting, and appraisal of HSG. Development of high quality health system guidance will impact the type of recommendations being formulated, the degree to which they get implemented, the methods of dissemination, and the extent to which they impact on the usual operations of the health system.

**Methods:** We have conducted a knowledge synthesis of the literature to generate a candidate list of items that will be used to develop the HSG-AT.

**Results:** We identified 33 papers that met eligibility criteria. No existing appraisal tool (draft or final version) was identified. Over one third of the authors explicitly identified the need for a high quality tool aimed to systematically evaluate HSG and contribute to its development/reporting. Thirty concepts were identified that may be relevant to the appraisal of HSG: problem definition, coverage, stakeholder involvement, evidence-based, operationalization, feasibility of implementation, ethical, politically sound, socio-culturally acceptable, prioritization, relevance, clarity of presentation, transparency, flexibility, outcome indicators, resources, cost, affordability, effectiveness, cost-effectiveness, external factors, dissemination/reporting plan, updating,

benefits/harm, process evaluation, impact evaluation, generalizability, sustainability, competing interests.

**Conclusions:** Objectively discriminating between good and poor guidance is an arduous task since HSG quality can be regarded upon as an inherently subjective assessment that depends on a variety of factors.

## OR23.4

### A Collaborative Approach to Guideline Development

Liz Avital; Katie Jones

National Clinical Guideline Centre, London, United Kingdom

**Background:** Pressure ulcers are serious adverse events, the prevention of which is a priority for the UK National Health Service. If a pressure ulcer develops, it is imperative that treatment is effective. In 2012, the National Clinical Guideline Centre (NCGC) began updating the National Institute for Health and Care Excellence (NICE) guidelines on pressure ulcer prevention and management.

**Objectives:** For the NCGC and Belgium Knowledge Centre (KCE) to work in collaboration, according to an agreed methodology, to develop pressure ulcer prevention and management guidelines for both organisations.

**Methods:** The NCGC and KCE divided 18 topics of shared relevance; 18 systematic reviews. Reviews for remaining topics were undertaken by the group to whom they were relevant. Protocols were agreed as were search strategies, inclusion and exclusion criteria. For consistency, the systematic reviews were undertaken according to NCGC methodological practices.

Detailed timelines were developed to facilitate the exchange of reports and ensure deadlines were met.

Each review was quality assured by the organisation in receipt of the review. The NCGC presented the reviews to the guideline development group and KCE to their expert panel, from which guideline recommendations were made. Changes, (following quality assurance or presentation to committee) were made by the group who carried out the review.

Contact was maintained throughout development. Process was reviewed at regular intervals.

**Results:**

- Successful completion, quality assurance and presentation to committee of 18 systematic reviews.
- By June 2013 KCE published both their guidelines.
- The NCGC will publish their guidelines in May 2014.

**Conclusions:** The collaboration was successful, allowing the NCGC to experience working with another organisation and benefit from external input and interpretation. An excellent relationship between was established. The experience was rewarding yet not time saving for either party. 'Lessons learnt' should be explored and incorporated into future collaborations to ensure truly effective joint working.

## OR23.5

### Searching for the Development of Diagnostic Guidance at the National Institute for Health and Care Excellence in the UK

Jenny Kendrick

National Institute for Health and Care Excellence, London, United Kingdom

**Background:** This presentation will describe the literature searching undertaken by the Guidance Information Services (GIS) team at the National Institute for Health and Care Excellence (NICE) in the UK, which supports the development of Diagnostics guidance. The GIS team offers tailored support to the different Centres and Directorates

within NICE, providing professional expertise to enable access to high quality information to support the development of guidance. The GIS team carry out literature searching using a variety of databases and websites. The searches can be broad scoping searches or more focused systematic literature searches.

**Objectives:** One of the programmes we support is the Diagnostics Assessment Programme (DAP) which produces the Diagnostics guidance. This guidance focuses on the assessment of new and existing medical diagnostic technologies, which can either be single or multiple diagnostic technologies or products, to ensure that the National Health Service in the UK is able to rapidly and consistently adopt the technologies that are shown to be clinical and cost effective.

**Methods:** This particular presentation will focus on the searches carried out on the My5-FU assay (and other alternative technologies for monitoring plasma levels of fluorouracil (5-FU) to guide dose adjustment in patients receiving 5-FU chemotherapy for the treatment of cancer by continuous infusion.

**Results:** This assay is intended to facilitate accurate dosing in order to achieve an optimal plasma level. This in turn may increase treatment efficacy and reduce toxicity associated with under- or over-dosing in patients.

**Conclusions:** This presentation will describe the different searches undertaken by the Information Specialist, the specific challenges faced, the processes that have been put in place to address these and how the evidence retrieved is taken forward in the development of Diagnostic guidance.

## OR23.6

### The Ghost in the Machine: the Role of the Expert in the Production of Evidence-Based Guidance

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2. University of Cambridge, Cambridge, United Kingdom

**Background:** Information and opinions from clinical experts may be desirable during health technology assessment for production of evidence-based clinical guidance, as an adjunct to published, peer-reviewed evidence. However, little is known about what aspects of expert advice are most useful and influential.

**Objectives:** To examine which aspects of expert advice were considered most valuable by decision-makers evaluating new procedures to produce recommendations on their use for UK health services.

**Methods:** Semi-structured interviews with 17 members of the Interventional Procedure committee of the UK's National Institute of Health and Care Excellence (NICE), asking them about the aspects of specialist advice they found most useful when creating evidence-based guidance. Interview transcripts were analysed inductively for themes.

**Results:** Committee members described the typical inadequacies of evidence from published literature, which advice from clinical experts most may ameliorate. These are (a) limited quantity and/or quality of evidence (a particular issue for interventional procedures); (b) restricted scope (specifically, information on patient selection and on training and experience of operators is rarely presented); and (c) timeliness (for example: adverse events take time to reach the literature). Committee members were aware of both bias and confounding in specialist advice, but nevertheless considered it important to know what clinical experts think. They believed that asking for advice is useful for developing a relationship with the specialist community, which may enhance uptake of guidance.

**Conclusions:** The aspects of expert advice most valued by committee members were those that address limitations in the published literature. Expert advice can complement published evidence, provided that the inherent biases and confounding both in the literature and

the advice are understood. Advice from clinical experts is a valuable adjunct and could be included within the definition of "the evidence base" during health technology assessments to produce evidence-based guidance.

### OR24.1

#### Pay for performance in Brazil: an initial assessment of the Program Improving Access and Quality in Primary Care of Brazilian Ministry of Health

Jorge Maia Barreto

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**Background:** In 2011, the Brazilian Ministry of Health launched the National Programme for Improving Access and Quality in Primary Care (PMAQ), a pay-for-performance (P4P) scheme to improve health standards and ensure access and quality in Primary Health Care including more than 15,000 local health teams and representing US\$ 37 million in monthly financial incentives transferred for municipalities. A expected effect of PMAQ is the reduction of rates in hospitalizations for sensitive primary health care.

**Objectives:** To evaluate PMAQ's initial results on the hospitalizations for Primary Care Sensitive Conditions in Brazilian municipalities.

**Methods:** We analyzed the the association between PMAQ and rates of hospitalizations for PCSC, from January to July 2012, using multiple linear regression model applied on sample strata (n=5,396) categorized according to quartiles of municipal household income average.

**Results:** The effects of PMAQ were more evidenced in the municipalities with two lower income strata (first and second quartile), where expanding the proportion of PHC teams participating in the PMAQ was associated with the reduction of rates of hospitalization. In the highest income stratas (third and fourth) no significant results was showed, making the assumption that the program has provided greater effects in higher socioeconomic shortages scenarios, which implies in an possible effect on health inequities.

**Conclusions:** In analyzed period, the hospitalizations for PCSC represented an expense of US\$ 400 millions for the Brazilian government. PMAQ could be amplified and monitored in order to reduce these avoidable costs for the public health system and to improve PHC access and quality in Brazil. However, also is necessary expand studies on the PMAQ effects, as well as its permanent monitoring in order to better understand its impacts.

### OR24.2

#### Real Life Treatment Costs of Telaprevir in a Tertiary Hospital Setting in Brazil

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**Background:** Approximately 170 million people worldwide are chronically infected with hepatitis C virus (HCV). Hepatitis C is considered the main cause of liver disease, sometimes progressing to cirrhosis and hepatocellular carcinoma. Telaprevir is a direct-acting antiviral used for the treatment of chronic genotype 1 HCV infection.

**Objectives:** To estimate the real life treatment costs associated with telaprevir in combination peginterferon and ribavirin (TVR+PR) for genotype 1 chronic HCV infected patients in the largest Public Hospital of Latin America.

**Methods:** It is a descriptive study conducted from July 2013 to January 2014. The population was delineated with the outpatients who were being treated with TVR+PR. It was collected socio-demographic information, related to treatment and records relating to the dispensing pharmacy. The economic evaluation was performed by analysis of cost per patient, for drugs used during treatment, based on unit values paid by the institution, through the purchase by bidding in the form of outcry trading. The research was approved by the Ethics Committee.

**Results:** It was analyzed 29 patients, 16 (55.2%) men and 13 (44.8%) women, and mean age were  $55.8 \pm 10.7$  years. At pretreatment, 22 (75.8%) were null responders, 3 (10.4%) partial responders and 4 (13.8%) relapsers. The average cost to treat (TVR+PR) was R\$ 46,947.58  $\pm$  9,886.75, per patient. Expenses were also added concomitant medications and average cost was R\$ 390.39  $\pm$  337.81, per patient. The most commonly prescribed concomitant medications were epoetin alfa (72.4%), moisturizing cream (68.9%), acetaminophen (44.8%), folic acid (41.4%) and omeprazole (37.9%). Five patients (17.2%) did not complete the 12-week with telaprevir in combination peginterferon and ribavirin. (On January 22, 2014, US\$ 1.00 = R\$ 2.36).

**Conclusions:** Concomitant medication costs are smaller compared to the cost of treatment with triple therapy. There were few drugs prescribed to treat concomitants diseases and adverse events during this period.

### OR24.3

#### Coverage with Evidence Development: Bronchial Thermoplasty, a Case Study

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**Background:** Managing introduction of new health technologies challenges all health systems, when evidence is limited. "Coverage with evidence development" aims to accrue data but methodology varies and funding data collection is often difficult. This case study on bronchial thermoplasty - a novel treatment for severe asthma which reduces the amount of muscle in the airway walls and so limits their ability to constrict - describes a coordinated national approach to coverage with evidence development.

**Objectives:** To provide access to bronchial thermoplasty for appropriate patients in specialist centres whilst evaluating its efficacy and safety

**Methods:** A sequential approach comprising: (a) Publishing recommendations in HTA guidance (b) Developing a national commissioning policy to support evidence development (c) Establishing a register with key outcomes including quality of life, unscheduled healthcare visits, days lost from work/school, rescue steroids, lung function (d) Updating HTA recommendations (scheduled for 2015).

**Results:** HTA (NICE) guidance for the UK national health services recommended use of thermoplasty only with data submission to a register. This recommendation was specially supported by the national commissioning board for England in its payment policy. A register was developed within the UK wide National Difficult Asthma Research Database.

Data on 37 patients treated in 7 UK centres were submitted by January 2014. Updated numbers will be presented. No serious adverse events or deterioration in lung function have been reported to date. Patients reported less frequent exacerbations with quicker recovery but quality of life improvements have not matched those reported in major trials.

**Conclusions:** Coverage with evidence development can be achieved at national level (England population 53 million) for promising new technologies through collaboration between the HTA organisations, professional societies, and funding organisations. However, patient

accrual has been slow and a delay in HTA guidance review may be necessary.

#### OR24.4

##### Indirect Costs of Rheumatoid Arthritis, Crohn's Disease and Psoriasis in Poland. Results of Move to Work (M2W) Study

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**Background:** Immune-mediated inflammatory diseases are proven to influence workers' productivity. Data on the order of magnitude of that influence in Poland and of the consequent indirect costs is absent.

**Objectives:** To present the indirect costs of absenteeism and presenteeism of rheumatoid arthritis (RA), Crohn's disease (CD) and psoriasis (Ps) in Poland.

**Methods:** In M2W, the cross-sectional, multicenter study set in 89 outpatient centers, patients in productive age (women 18-60, men 18-65), who had CD, RA or Ps were asked to complete a survey containing WPAI (Work Productivity and Activity Impairment) questionnaire, while specialists assessed their disease activity level. 814 RA, 464 CD and 822 Ps patients with dominantly low or moderate disease activity (mean DAS28 score: 4.27, CDAI: 193, PASI: 10.79) were assessed. Respectively, 42%, 56% and 57% of respondents with RA, CD and Ps were employed. Absenteeism, presenteeism and overall work impairment due to the disease (OWI) rates were estimated. Indirect costs were calculated for each diagnostic group using human capital approach. Unit cost of work was estimated using 2012 GDP per worker and corrected for diminishing marginal work productivity.

**Results:** Mean OWI for RA was 43% of work time, for CD it equaled 36% and for Ps 35%. An average hour of work was valued at PLN 33.18. Annual indirect cost of RA per patient amounted to PLN 29 727, for CD mean annual cost summed up to PLN 23 682 per patient. In both cases cost of absenteeism constituted about 43-44% of this amount, the rest was attributed to presenteeism. Ps annual cost was PLN 24 434 per patient, 74% of which was due to presenteeism.

**Conclusions:** The highest annual cost per worker among analyzed diseases was generated by RA, but indirect costs of remaining conditions was only slightly lower. In case of Ps presenteeism seems to influence strongly work productivity.

#### OR24.5

##### Expenditures on the Treatment of Osteoporosis in the Elderly in Brazil (2008-2010): Analysis of Associated Factors

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**Background:** The aging of the Brazilian population is reflected in the more than 21 million Brazilians aged over 60 years, representing on average 10% of the population. Aging brings chronic diseases and increases comorbidities, among them osteoporosis. Osteoporosis has a significant portion of the morbidity and mortality rates of the elderly population that can lead to significant Brazilian Public Health System (SUS).

**Objectives:** To analyze the expenditure of the Ministry of Health with osteoporosis treatment in the Brazilian Public Health System (SUS) in 2008-2010 triennium and estimate the impact of demographic, regional and disease related variables on average expenditure per procedures performed

**Methods:** A cross-sectional, descriptive and analytical study based on secondary data from Datasus related to procedures for the elderly with a diagnosis for osteoporosis and related fractures. The statistical analysis and multivariate model (OLS) used Stata 11.0.

**Results:** We performed 3,252,756 procedures related to the osteoporosis treatment among the elderly in Brazil during the 2008-2010 period, totalizing R\$ 288,986,335.15. The age group that most had procedures was 60-69 years (46.3%). Nevertheless, the population of 80 years or older showed the highest spending per procedure, around R\$ 106 million in three years. The women were majority in terms of quantity (95.6%) and expense (76%) of procedures. The average cost per procedure showed a large gap between men and women, nearly seven times (R\$ 480.14 vs. R\$ 70.85 respectively). The ambulatory care procedures predominated in quantity (96.4%) and the hospital procedures in resources (70.4%). It was found that there is no single standard for groups of procedures when these are analyzed separately.

**Conclusions:** A disaggregated analysis of expenditure by procedures groups extracted from the SUS Management Procedures Table, Medicines, Orthotics, Prosthetics and Special Materials System allowed a detailed overview of federal spending on the osteoporosis treatment in the elderly.

#### OR24.6

##### Patterns of Generic and Proprietary Prescribing of Proton Pump Inhibitors (PPIs) Over Time in England

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**Background:** While health technology assessment (HTA) has found generic drugs to be more cost-effective than proprietary alternatives, barriers to their uptake remain. Introduced in England in 2006, the Better Care, Better Value (BCBV) indicators aim to promote prescribing of low-cost generic drugs as opposed to high-cost proprietary drugs by GPs, when a substitution can be made without compromising patient care.

**Objectives:** To evaluate patterns of proprietary versus generic prescribing of proton pump inhibitors (PPIs) since the introduction of the BCBV indicators.

**Methods:** Prescription Cost Analysis databases were reviewed for the years 2007-2012. Data extracted were the number of prescription items dispensed yearly in the community in England for 5 commonly prescribed PPIs, along with the preparation class and net ingredient cost (NIC) of each item. The overall NIC (sometimes used as a proxy of budget impact to the NHS) for PPIs and the proportion of proprietary items prescribed each year for each drug were compared.

**Results:** Between 2007 and 2012 the total NIC of PPIs decreased by 38%. Over the same period, the decrease in the proportion of proprietary prescriptions was greater for PPIs (78%) than previously reported for statins (65%); however, this did not translate into a greater saving in total NIC. This could be due to the higher average number of prescriptions per year and the higher average NIC per prescription item for statins than for PPIs. Analysing data for each PPI, we found dramatic decreases in proprietary prescribing (100% to <11%) within two years following patent expiry of the proprietary form.

**Conclusions:** There was a decrease in the proportion of proprietary prescribing of PPIs in England between 2007 and 2012, with rapid declines following patent expiry of proprietary drugs. This suggests that the BCBV indicator is being met for PPIs.



## OR25.1

### A Review on the Economic Evaluations of Factor VIII/IX for Prophylaxis in Hemophilia: What Do We Know and Where Do We Go from the Health Technology Assessment (HTA) Perspective?

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**Background:** Among patients with severe hemophilia, prophylactic treatment with factors VIII/IX is effective but at substantial costs compared to on-demand therapy.

**Objectives:** To review the published economic evaluations on prophylaxis with clotting factors in hemophilia patients without inhibitors, and to understand the current evidence on cost-effectiveness and gaps from a HTA perspective.

**Methods:** A literature search was conducted mainly in PubMed/Medline and Cochrane Library (1993/10/06 to 2013/10/06). The identified economic studies on prophylaxis with clotting factors in hemophilia were summarized and analyzed.

**Results:** Seventeen cost-effectiveness/cost-utility analyses and one cost analysis were found in hemophilia A/B, with perspectives mostly taken from society (n=7) or third-party payers (n=5). Studied countries included UK (n=6), Sweden (n=6), US (n=3), Germany (n=3), Italy (n=3), the Netherlands (n=2), Canada (n=1), Iran (n=1), Mexico (n=1), Norway (n=1), Taiwan (n=1), and others. Prophylaxis appears to be clinically superior and produces better health-related quality of life compared to on-demand therapy. The incremental cost-effectiveness ratio (ICER) ranged from \$13,000 to >\$650,000 per quality-adjusted life year (QALY) due to the small gain in utilities, and ranged from \$165-\$11,090 per bleeding event avoided. The cost-effectiveness results varied greatly given different study designs, time horizon, clinical outcome measures, direct/indirect cost components, treatment regimens/initiation/duration, and utility estimates. A number of questions remained unanswered, including long-term bleeding pattern under different treatment strategies, the most cost-effective dosing and duration of prophylaxis, as well as the relevant patient-reported outcomes.

**Conclusions:** Determining the value of prophylaxis vs. on-demand therapy is challenging due to the lack of long-term outcomes data for different treatment strategies. Overall, the use of full-dose prophylaxis appears to be less attractive given the most common willingness-to-pay thresholds of most payers. However, ranking life-saving treatments for rare chronic disorders such as hemophilia together with normal interventions may be inappropriate. Meanwhile, more research should be conducted on how to optimize treatment strategies to improve cost-effectiveness (e.g., utilizing pharmacokinetically-tailored regimen to lower factor consumption and costs).

## OR25.3

### Challenges for Systematic Review of Nonanimal Research

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**Background:** A little evidence showed that animal-based models adequately reflect human diseases. Non-animal approaches are considered as advanced methods that can overcome some limitations of animal experiments.

**Objectives:** Systematic review the studies of animal alternatives research and identify relevant challenges.

**Methods:** We use key words, MESH terms and title searched Animal Use Alternatives or Animal Testing Alternatives in MEDLINE, EMBASE (Search date in January 2013). Included all studies with methods reported, excluded duplications, editorial reviews, news and letters, etc. Both authors independently determine which studies met the inclusion criteria and extract data, descriptive the results.

**Results:** 1) 3867 references searched and 14 studies included.

2) The validation study on alternative methods include replace the Draize rabbit eye irritation test, alternative in vitro, non-mammalian models relevant to neurotoxicity evaluation, skin test, physiological education and surgical training, etc.

3) The main challenges of nonanimal studies include: (a) poorly methodology of primary experiments on design, conduction and analysis; (b) inadequate methodologically review and summaries of evidence from nonanimal research; (c) barriers existed in the validation process, as some regulatory agencies still consider the gold standard to be animal test data and use in evaluating a new test method, etc.

**Conclusions:** It is necessary to develop an innovative strategy for systematically developing alternatives to the current array of animal models in biomedical research and develop methods guidelines for standard publication checklist on journals demands for description of nonanimal studies in future.

## OR25.4

### Pitfalls in Systematic Reviews of Interventions in the Elderly and Frail Elderly

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**Background:** Randomised trials (RCTs) are seldom performed on a group of only elderly. The trials normally include a wide range of ages and elderly dominate (pending type of intervention) the included population. Baseline demographic data, including ages, of the population are, often but not always, given in the publications in the form of a mean or a median age and a variation estimate.

**Objectives:** Swedish SBU has made systematic literature reviews of different types of interventions among elderly and frail elderly with the aim to GRADE evidence for benefits/risks of oral anticoagulants, organizational changes in health care and treatment of urine incontinence, malnutrition, and chronic ulcers

**Methods:** We made systematic literature searches using both controlled vocabulary and free text terms. The searches were built up by synonyms to reflect the age group, the intervention, and the study design. We searched different databases depending on the topic, for example Pubmed, EMBASE, Cochrane Library, and AMED. Data in included studies were extracted. Results were synthesized and critically assessed according to GRADE.

**Results:** A large number of abstracts were found. Following reading of full text articles it was found that few studies reported data on elderly in spite of the fact that the articles were indexed with the search term "Aged" since the study population contains elderly. A significant number of RCT's included pre-specified subgroup analysis of effects and/or risks in different age groups which could be used for the project.

**Conclusions:** The inborn statistical weaknesses and risks of overinterpretation of subgroup analysis data has to be considered. Clearly, there is a need for more clinical studies on elderly, in order to better define benefits and risks with different interventions.

## OR25.5

### Development of Search Strategies for Systematic Reviews: Objective versus Conceptual Approach

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**Background:** Different approaches can be adopted for the development of search strategies of systematic reviews. The objective approach draws upon already established text analysis methods for developing and testing search filters and is based on an analysis of relevant references identified beforehand.

**Objectives:** Our aim was to determine whether the objective approach for the development of search strategies was non-inferior to the conceptual approach commonly used in Cochrane Reviews (CRs).

**Methods:** On 8 June 2012 we conducted a search for original and updated CRs published in the Cochrane Library. The studies included in the CRs were searched for in MEDLINE (Ovid) and represented the total set, which was divided randomly into a) the test set: references for objective development of the search strategies, and b) the comparator set: references for subsequent evaluation of these strategies. We then tested whether the references previously removed from the comparator set could be identified via the objective approach. We also reconstructed the original search strategies from the CRs to determine why references could not be identified by the objective approach.

**Results:** 470 references from 13 CRs were identified as the total set in MEDLINE (Ovid): 112 were included in the comparator set and 358 were therefore available in the test set. Overall, the objective approach yielded a sensitivity of 96% (95% CI [92%; 99%]). The non-inferiority test showed that this approach was non-inferior to the conceptual approach used in the CRs ( $p < 0.002$ ), which yielded a sensitivity of merely 86% (95% CI [73%; 98%]).

**Conclusions:** To the best of our knowledge, our findings indicate for the first time that the objective approach for the development of search strategies is non-inferior to the conceptual approach.

## OR25.6

### Ophthalmic Prostaglandin Analogues for Ocular Hypertension or Primary Open-Angle Glaucoma: a Systematic Review and Network Meta-Analysis

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**Background:** Prostaglandin analogues (PGAs) lower ophthalmic intraocular pressure (IOP) and are widely used as first-line therapies for ocular hypertension (OH) or primary open-angle glaucoma (POAG).

**Objectives:** This study evaluated efficacy and safety of bimatoprost, latanoprost, tafluprost and travoprost as first-line monotherapy for OH or POAG.

**Methods:** A Bayesian network meta-analysis which uses both direct and indirect comparisons of randomized controlled trials (RCTs) was conducted to compare the four PGAs and timolol, the most common comparator used in PGA trials. PubMed and the Cochrane Library were systematically searched for relevant articles published up to May 2013. RCTs comparing PGAs or PGA with timolol were eligible. Two reviewers independently conducted the data extraction and quality assessment of included studies. The main outcome measure was efficacy as assessed by the mean IOP reduction at one month. Hyperemia, the most common side effect and other frequently reported events were also examined.

**Results:** Thirty eight suitable trials were identified. Bimatoprost, latanoprost and travoprost were significantly more efficacious in IOP reduction compared to timolol but not tafluprost. The mean IOP

reductions with 95% credible intervals were: bimatoprost 2.1 mmHg, 1.6 – 2.5; latanoprost 1.1 mmHg, 0.7 – 1.5; travoprost 1.0 mmHg, 0.6 – 1.4; and tafluprost 0.4 mmHg, -0.4 – 1.1. Relative risks (RR) compared to timolol for hyperemia ranged from 1.9 for the latanoprost to 3.0 for bimatoprost; for pruritus and pain 1.3 (latanoprost) to 2.0 (travoprost); and for eyelash changes 4.5 (latanoprost) to 7.5 (bimatoprost), with the differences being statistically significant. No significant differences were observed between PGAs for other adverse events.

**Conclusions:** Our findings suggest that bimatoprost, latanoprost and travoprost are the preferred agents for IOP-lowering in patients with OH or POAG. Among them, latanoprost has a better tolerability profile in terms of hyperemia and eyelash changes compared to bimatoprost, and pruritus and pain compared to travoprost.

## OR26.1

### Valuing Health in the UAE: an Investigation of the Feasibility and Cultural Appropriateness of Using the TTO and DCE Methods to Generate Health State Values

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**Background:** EQ-5D-5L is a widely-used measure of patient-reported health. Its use in economic evaluation requires a 'value set': numerical summaries of how good or bad each health state is. No EQ-5D-5L value sets are currently available in the Middle East. Our study is, to our knowledge, the first to investigate the potential for using standard health state valuation methods in this region.

**Objectives:** To test the feasibility of eliciting EQ-5D-5L values from a sample of the UAE general public using the EuroQol Group's standardised protocol; and to investigate any cultural issues relating to the use of the methods amongst Emirati nationals.

**Methods:** Values were elicited using face-to-face computer-assisted personal interviews, following the standardised protocol for valuing EQ-5D-5L. Adult members of the Emirati general public were recruited in public places. Respondents each completed 10 time trade-off (TTO) tasks and seven discrete choice experiment (DCE) tasks. In addition, they answered debriefing questions about their experience of completing the valuation tasks. Descriptive analyses were used to assess the face validity of the data.

**Results:** Two-hundred individuals were interviewed in December 2013. The face validity of the data appear to be reasonably high, with higher (lower) values elicited for mild (severe) health states. In the TTO tasks, mean values ranged from 0.812 for the mildest state (21111) to 0.194 for the worst state (55555). Health states were rarely valued as being worse than dead (6.1% of all observations). In a rationality check included in the DCE tasks, 99.5% of the respondents chose the dominant state (55221) over the dominated state (55554).

**Conclusions:** Analysis is currently underway - final conclusions will be available by the time of the HTAi meeting. We will discuss whether the standard methods are suitable for use in the UAE (and other countries with predominantly Muslim populations), or if some adaptation of the methods is required.

**OR26.2****Did the Economic Reform Affect the Equity of Health Resources Distribution in China? a National Study in 1970-2010**Yuan Huang<sup>1</sup> Yingyao Chen<sup>1</sup> Hao Yu<sup>2</sup>

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**Background:** Since the economic reform was implemented in 1978, China has had an impressive progress in its economic development. While many studies have noted that China is facing a daunting challenge on health equity in the context of economic reform, few studies have focused on how the reform affected the equity status of health resources in China.

**Objectives:** To exam the equity of the distribution of health resources in China over the past 40 years and analyze the impacts on the equity of health resources in the unique economic environment.

**Methods:** The study was conducted using information of 31 provincial level regions from 1970 to 2010. Data were collected about numbers of hospital beds and health technicians, permanent population and GDP of all the 31 provinces from the yearbooks of national health statistics and China Compendium of statistics. Equity of health resources was assessed using Lorenz curves and Gini coefficients. Correlation analysis was conducted to examine the relationship between health resources distribution and provincial economic development.

**Results:** Both the hospital beds per 1000 population and health technicians per 1000 population have had steady increases from 1975 to 2010 across 31 provinces. The equity status of each of the two types of resources has been improved. Gini coefficient of hospital beds distribution decreased from 0.183 in 1970 to 0.079 in 2010. Gini coefficients of health technicians showed an overall declining trend from 0.165 in 1970 to 0.096 in 2010. Despite of the equity improvement, the distributions of hospital beds and health technicians were significantly positively correlated with economic development across the nation for every study year ( $P < 0.05$  and  $R > 0.5$ ).

**Conclusions:** The equity status of these two types of health resources has been improved in the economic transformation especially in the early 2000s. Still considerable inequity exists among different areas with different economic development levels.

**OR26.3****Judicialization of the Right to Health**Alicia Aleman; Alejandra Croci; Ana Kuster; [Ana Perez](#); Elena Villamil

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**Background:** Most Latin American countries have Constitutions guaranteeing the right to health for all their citizens. Health system reforms have led to the development of National Drug Formularies (NDF) regulating coverage within the system. Many of the new high-cost non-curative drugs are not yet included in the NDF. However, Constitutions' characteristics and judicial systems are nowadays mandating governments the allocation of public resources to cover the cost of some of these drugs. This situation has led patients to use writs of protection requesting access to these new treatments or services.

**Objectives:** To describe the population that has received treatment by writs of protection in Uruguay during 2011-2013.

**Methods:** A national database of clinical records of patients receiving treatment by writs of protection during 2011-2013 were reviewed by Ministry of Health staff. Information on demographics, epidemiology, clinical evolution, follow-ups and survival data was obtained in each case. When necessary, health providers were interviewed.

**Results:** 112 clinical records were reviewed out of 181. Patients were 66.1% men, median age 59 years old (IQ range 44-72). Regarding disease conditions, 51.1% had oncologic pathology, 34.8% vascular

diseases and the rest had rheumatologic diseases, inflammatory bowel diseases or rare diseases. All oncologic patients had received at least two previous treatments before the current one. 64.3% of the patients were alive in at the time of the review.

**Conclusions:** Writs of protection are a growing and difficult problem that the Uruguayan Ministry of Health has to face. Most oncologic patients receiving these treatments are in their last year of life, while patients with other diseases are pleading for drugs that may improve their quality of life. Better communication and an in-depth discussion between the judicial and the health care system might be the only possibility to solve this problem.

**OR26.4****Interventions for Ultra-Rare Disorders (URDs): How to Assess "Value for Money"?**[Michael Schlander](#)<sup>1,4,5</sup> [Silvio Garattini](#)<sup>2</sup> [Sören Holm](#)<sup>3</sup> [Peter Kolominsky-Rabas](#)<sup>6</sup> [Erik Nord](#)<sup>8,7</sup> [Ulf Persson](#)<sup>9</sup> [Maarten Postma](#)<sup>10</sup> [Jeffrey Richardson](#)<sup>11</sup> [Steven Simoens](#)<sup>12</sup> [Oriol Sola-Morales](#)<sup>13</sup> [Keith Tolley](#)<sup>14</sup> [Mondher Toumi](#)<sup>15</sup>

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**Background:** Given the economics of biopharmaceutical research and development (R&D), characterized by substantial fixed and often low variable (volume-dependent) cost, many drugs for ultra-rare disorders (URDs) fail to meet widely used benchmarks for cost effectiveness.

**Objectives:** To identify key issues arising when interventions for URDs are subjected to formal Health Technology Assessments (HTAs), and to deliberate potential solutions.

**Methods:** An international group of clinical and health economic scholars met twice in conjunction with Annual European ISPOR Congresses in November 2012 and 2013.

**Results:** The group reached consensus that the complexities of R&D of new treatments for URDs may require conditional approval and reimbursement policies, but this should not be used as a justification for showing surrogate endpoint improvement only. Strong evidence of clinical effectiveness should be expected within reasonable time-frames. In contrast to well-established principles of evidence-based medicine, the logic of cost effectiveness (including benchmarks for incremental cost per quality-adjusted year, QALY, applied by some agencies as a measure of "value for money") does not adequately capture prevailing social norms and preferences regarding health care resource allocation. Such preferences include, but are not limited to, a priority for care for the worst off (related to initial health state), for those with more urgent conditions (the so called "rule of rescue"), and a relatively lower priority based upon capacity to benefit, as well as a dislike against "all or nothing" resource allocation decisions that might deprive certain groups of patients from any chance to access effective care.

**Conclusions:** There is a strong need for an improved paradigm to determine value for money. Promising candidates include direct social value measurement using the relative social willingness-to-pay or person trade-off instruments, and a greater role for budget impact

analysis. As a pragmatic alternative, multi-criteria decision analysis may be useful as an interim tool for assessment.

## OR26.5

### The Economics of Rare Diseases: Theory and Regulation

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**Background:** Rare diseases occur with very low prevalence, around 1 to 10 cases by 10.000 inhabitants. They're chronics, progressive, degenerative, 80% are of genetic origin, 50% affect children - 30% of this children will die before 5 year-old. They represent risk of death and a high socioeconomic cost to the patient and his/her family. In the most of cases doesn't exist methods of diagnostic and treatment available. Because of the rarity, pharmaceutical industry doesn't have interest in develop new orphan drugs. Although rare individually, it's estimated that the number of cases reach 420 to 560 million people around the world.

**Objectives:** The objective of this paper is analyze the rare disease's socioeconomic implications and related them with the economic regulation tools to orphan drugs production.

**Methods:** The theoretical reference is the economic model developed by DeBrock (1985), who presents the simultaneous determination of innovation effort and length of patent protection. In this model, the innovator's problems correspond to maximize net present value of cash-flow from innovation, while the regulator's problem corresponds to maximize the present value of returns from innovation.

**Results:** We identified the main incentives and economics regulation tools. They were the protocol assistance, centralized procedure, fee reductions, funded research access and market exclusivity. We analyzed each of them and we showed that they affect in the investment decision of the firms, making feasible and profitable the development of new methods of diagnostic and treatment of rare diseases.

**Conclusions:** The most important regulatory tool was the market exclusivity, because it guarantees extraordinary profits to the innovative firm. In this case, the development of new drugs became economically feasible. However, we emphasize that all the analyzed mechanism has an important role to encourage the development of orphan drugs and each of them must be considered for development of public policies for rare diseases.

## OR26.6

### What Could the Future Hold? Simulating the Demand for Osteoarthritis ((OA) Care in Alberta to Plan a Sustainable OA Care System

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**Background:** Osteoarthritis (OA) and the demand for OA care are increasing with the aging population. Policy-makers seek to identify policies to sustainably manage this growing demand, yet envisioning the short- and long-term effects of policy options is difficult within chronic care.

**Objectives:** We aimed to develop a decision-support tool enabling policy-makers to explore policies and their effects.

**Methods:** We developed a system dynamics (SD) simulation of patient flow across the continuum of OA care in Alberta: from self-directed to primary and specialist care, through surgical interventions, post-surgical follow-up and subsequent re-operations. The simulation was developed using SD modeling principles and an iterative, integrated knowledge translation process, including multiple workshops with clinicians and administrators to define the problem, system boundaries and current patient flow. The resulting simulation was populated with data extracted from administrative databases (e.g. physician claims, inpatient records).

**Results:** The model yields patient population, OA care resource requirements and associated cost results at each stage of care over 10 years by region and patient characteristics (e.g. sex). If current practices continue, annual hip and knee replacement surgery volumes are estimated to increase by approximately 40% between 2015 and 2025. If a 14 week surgical wait-time is implemented in 2015, 600 additional surgeries must be performed in the first year to "catch-up" on the existing surgical queue, yet long-term surgery rates are similar to those without the wait-time target. The costs of the additional surgeries are partly offset by the savings achieved by fewer patients requiring care while awaiting surgery.

**Conclusions:** This simulation can be used as a decision-support tool to estimate changes in patient populations, resource requirements and costs over time that may result from various OA management scenarios. Such results can equip policy makers with additional evidence to make more informed OA care policy decisions.

## OR27.1

### Liaison Officers – CADTH's "Boots on the Ground"

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**Background:** Recognizing the importance of local context to best support evidence-informed decisions at all levels of Canada's distributed health care systems CADTH created its Liaison Program in 2004 to assist health care decision makers in accessing evidence-based information while providing local context to CADTH in addressing health technology questions. Specific activities undertaken by members of the Liaison team are geared to the unique needs of their customers and, therefore, may vary considerably from jurisdiction to jurisdiction. Activities include facilitating the translation of policy questions into research questions for the rapid response program to supporting stronger understanding of research obtained.

**Objectives:** This is a unique program which takes advantage of where the Liaison Officers (LO's) come from, both geographically and professionally. LO's reside in the jurisdictions they represent and most have worked within their respective health systems before joining CADTH. Being so connected with their respective healthcare systems and paying attention to local realities has allowed CADTH to develop the capacity to identify and respond promptly and effectively to local issues and values.

**Methods:** N/A

**Results:** The team members support their customers by facilitating access to evidence products not just from CADTH, but from HTA agencies across Canada and around the world. They follow up to ensure that reports are meaningful and meet the customer's needs. Of late, their focus has turned to increasing customers' capacity to find and use evidence by offering customized educational workshops. By collaborating with one another and across their now extensive networks of contacts, LO's continue to find new and innovative ways to support their customers' understanding of the value of evidence in their local context, and to build awareness of the value of HTA.

**Conclusions:** Liaison Officers extend CADTH's reach and by having those "boots on the ground" CADTH is able to be more nimble in responding to customers' needs.

## OR27.2

### The Influence of FDA and EMA Risk Management Requirements on Reimbursement Outcomes

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**Background:** The Food and Drug Administration's (FDA's) Risk Evaluation and Mitigation Strategies (REMS) and the European Medicines Agency's (EMA's) Risk Management Plan (RMP) are guidelines used to monitor and minimize risk to patient safety.

**Objectives:** This paper explores if reimbursement outcomes differ significantly whether a drug has only an FDA REMS requirement, only an EMA RMP requirement, or if the drug has both REMS and RMP guidelines in place.

**Methods:** HTA reimbursement outcomes were evaluated for 145 HTAs from 32 drugs that had a risk management requirement between 2008 and 2012. This study examines the relationship between these reimbursement outcomes and the presence of an FDA REMS requirement, an EMA RMP requirement, or both. The clinical rationale for the reimbursement decision and the presence of a risk management requirement are also examined. Reimbursement agencies assessed are NICE, SMC, HAS, IQWiG, and G-BA.

**Results:** When comparing reimbursement outcomes for drugs with REMS requirements, drugs with RMP requirements, and drugs with both, we found there was no significant difference in rates of positive or negative reimbursement decisions for NICE ( $p = .429$ ), SMC ( $p = .233$ ), or HAS ( $p = .567$ ). Similarly, there was no difference found between these categories and positive or negative clinical rationale for NICE, SMC, HAS, IQWiG, or G-BA ( $p = .292$ ,  $p = .770$ ,  $p = .367$ ,  $p = .775$ ,  $p = .913$  respectively). HAS demonstrates no difference in risk management requirements and ASMR score ( $p = .310$ ). G-BA shows no difference between the risk management categories and additional benefit score ( $p = .738$ ), while IQWiG approaches traditional levels of statistical significance regarding the additional benefit score ( $p = .119$ ).

**Conclusions:** There is no significant difference in positive and negative reimbursement outcomes with respect to the presence of REMS requirement, RMP requirement, or both requirements among NICE, SMC, HAS, IQWiG, and G-BA.

## OR27.3

### Impact of Multidisciplinary Group Practices in Primary Care on Efficiency – Evaluation of a French Experiment of Integrated Primary Care Organization

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**Background:** The development of integrated organisations delivering primary care and services is considered as a central lever for improving the performance of healthcare systems. French ambulatory care system is fragmented and integrated organization less developed.

**Objectives:** We are paying special attention here to multidisciplinary group practice in primary care (MGPC) as it can be analysed in France through the Experiment of New Mechanisms of Remuneration (ENMR), scheduled for a period of 6 years (2008-2013), and dedicated to MGPC. We aim to evaluate the impact of MGPC on GP's quality of practice patterns, GP's technical efficiency of production and patient's ambulatory care utilization and expenditures.

**Methods:** Our study uses a case/control scheme and individual panel data (2009-2012). We compare three principal efficiency outputs between GPs (and their patients listed) practicing in MGPC and enrolled within the experiment and GPs (and their patients listed) GPs practis-

ing in solo in control catchment areas (control). Data are mainly from the French National Health Insurance claims data.

First, we estimate the GPs' quality of practice pattern, with multilevel and longitudinal latent variable models of the patients' probabilities to be adequately followed-up for standard procedures: 10 for diabetes; 6 for vaccination, screening and prevention; 7 for efficiency of pharmaceutical prescription. Second, we estimate GPs' technical efficiency, with longitudinal stochastic frontier analysis. Third, we estimate ambulatory health care utilization and logarithmic transformation of expenditure, with two-part specifications to deal with the zeros.

**Results:** We observed, for 94 MGPC and 280 GPs in the intervention group (for 219.127 patients) and 2123 GPs in the controlled group (2.678.880 patients), that in the intervention group: patients have more chance to be correctly followed-up, patient's ambulatory care expenditures were 5% lesser and GP's technical efficiency is equivalent nor higher.

**Conclusions:** The opportunity of introducing specific measures for incentivising group practices in France is now reinforced.

## OR27.4

### Let There Be Light: Fit for Purpose Methodologies to Support Decision-Making Regarding Health Technology

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**Background:** HTA must be tailored to the needs and requirements of health care systems in specific countries to be most useful as an aid to decision-making.

**Objectives:** To obtain insight into methods and processes that can support timely decisions on reimbursement of health technologies, especially in Brazil, Serbia, Slovakia and Taiwan.

**Methods:** Desk research (2000 to 2013) and interviews with key HTA staff, governments, academics, third party payers, regulatory agencies, professionals and patient representatives. In Serbia, Slovakia and Taiwan we performed 22 in-depth interviews. For Brazil, we received 10 written responses to our interview questions and we conducted 1 interview by telephone.

**Results:** Use of HTA in reimbursement decisions is still in its early stages with varying levels of HTA implementation. Overall, the processes adopted are new and not very robust and transparent, leading to less predictability for relevant stakeholders. HTA funding is often not substantial and sustainable; and countries often have poor availability of local data. Information as well as methods/procedures from HTA in industrialized countries is often used. With the exception of Brazil, we found limited capacity to conduct HTA, especially with regard to economic evaluations and assessment of social, legal and ethical issues.

**Conclusions:** HTA is less well developed in Serbia, while Brazil is rapidly developing effective HTA. However, the processes are not yet fully developed in terms of transparency and inclusiveness. Slovakia and Taiwan are in an intermediate position. Increased collaboration across countries can support shared evidence generation and may lead to increased capacity to undertake assessments. This leads to a bigger scope and impact of the work of evidence producers and simplifies evidence production. There is no one size that fits all. It is recommended to investigate if and how countries follow HTA decisions in other countries and how to make best use of it to ensure fitness for purpose.

**OR27.5****More Bricks, Less Straw: Geographical Validation of a Risk Estimation Algorithm for Optimizing Chlamydia/ Gonorrhea Case Finding**Titilola Falasinnu<sup>1</sup> Paul Gustafson<sup>1</sup> Mark Gilbert<sup>2</sup> Jean Shoveller<sup>1</sup>

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**Background:** One component of effective sexually transmitted infections (STI) control is ensuring those at highest risk of STIs have access to clinical services because terminating transmission in this group will prevent the most future cases. We previously developed a risk-scoring algorithm for the identifying individuals at increased risk for chlamydia and gonorrhea (CT/GC) infection among patients attending two Vancouver, British Columbia (BC) STI clinics, 2000-2006. The final logistic regression model included younger age, non-white ethnicity, multiple sexual partners, and previous CT/GC diagnosis. We successfully validated the algorithm in a later time frame (2007-2012).

**Objectives:** To validate an existing risk-scoring algorithm for screening asymptomatic CT/GC infection in additional geographic settings.

**Methods:** We examined electronic records (2000-2012) from clinic visits at seven sexual health clinics in geographical locations outside Vancouver. The model's calibration and discrimination were examined by the AUC and the Hosmer-Lemeshow (H-L) statistic, respectively. We also examined the sensitivity and proportion of patients that would need to be screened at different cutoffs of the risk score. Statistical analyses were performed using SAS, version 9.3.

**Results:** The prevalence of infection was 5.3% (n=10,425) in the geographical validation population. The algorithm showed good performance in this population (AUC, 0.69; H-L p=0.265). Possible risk scores ranged from -2 and 27. We identified a risk score cutoff point of  $\geq 8$  that detected cases with a sensitivity of 86% by screening 63% of the geographical validation population.

**Conclusions:** This geographical validation study showed that a risk-scoring algorithm for screening asymptomatic CT/GC infection can be identified solely using routinely collected electronic medical records. The algorithm showed good generalizability in STI clinics outside of Vancouver with improved discriminative performance when compared to temporal validation. The algorithm has the potential for augmenting triaging services in STI clinics and enhancing targeted testing in population-based screening programs.

**OR27.6****Is MCDA the Future of HTA in the Americas?**Mireille M. Goetghebeur<sup>5,1</sup> Hector Castro<sup>2</sup> Clarice Petramale<sup>3</sup> Alexandre Lemgruber<sup>4</sup>

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**Background:** As the number and cost of healthcare interventions is rising, governments need to find efficient ways to assess their real life value to individuals and society. Pragmatic multicriteria approaches are being tested and implemented around the globe to integrate relevant criteria into the decisionmaking process and tackle this challenge.

**Objectives:** Introduce MCDA, present current initiatives related to multicriteria development in South America and discuss the potential strengths and weaknesses of these approaches in this region of the world.

**Methods:** An analysis of current processes and potential developments was performed which resulted into strategic developments at the country level.

**Results:** In Columbia, as part of the Government effort to set priorities for health and use HTA in a more systematic fashion, it created the Health Technology Assessment Institute (IETS). The IETS is currently testing and implementing multicriteria methods to support its role of resource allocation decisionmaking. In Brazil and Chili, pilot testing of multicriteria tools is on-going to explore resource allocation at the hospital as well as for strategic development at the National Commission for Incorporation of Technology in the Brazilian Public Health System (CONITEC). Strategic reflection on multicriteria applications at the Pan American level is on-going.

**Conclusions:** Pragmatic multicriteria tailored to the specificity of served population has the potential to shape more efficient, sustainable and equitable healthcare systems by promoting healthcare interventions which are most beneficial to individual and population health. These approaches may also provide a common road map at the regional level.

**OR28.1****Brazilian Valuation of EQ-5D Health States- Results from QALYBrasil Project**Marisa Santos<sup>1</sup> Andréa Libório<sup>1</sup> Monica Cintra<sup>1</sup> Bernardo Tura<sup>1</sup> Monica Viegas Andrade<sup>2</sup> Kenya Noronha<sup>2</sup> Luciane Cruz<sup>3</sup> Suzi Camey<sup>4</sup>

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**Background:** The EQ-5D-3L is a multiattribute preference-based instrument which provides a simple, generic measure of health outcome for clinical decision-making and economic evaluation. Current evidence points that values and preferences regarding health outcomes differ between countries, so to enable local high-level decisions regarding resources allocation it's essential to have country-specific data.

**Objectives:** To develop a country-specific set of values for the EQ-5D health states for use in Brazil.

**Methods:** A multicentric cross-sectional study was conducted in four Brazilian urban centers aiming to derive Quality Adjusted Life Years (QALYs) based on estimates obtained from EQ-5D-3L valuation. A probabilistic sample of the Brazilian general population, aged from 18 to 64 years, stratified by age and gender were recruited and interviewed. The study applied the "Paris Protocol" for MHV studies, proposed by EuroQol group, with the exception that all 243 health states were valued. Each respondent ranked and valued seven health states using the Time Trade-Off (TTO) in a face-to-face interview.

**Results:** Data were collected from 9148 subjects (47.4% male, 52.6% female). The mean age was 37.8 years (SD=13.1). Given our methodological option to elicit the full set of 243 health states generated by EQ-5D-3L, there was no need to resort to modelling to obtain the preference weights. According to the Brazilian population the dimensions "Mobility" and "Usual Activities" were the ones associated with higher losses in Health Related Quality of Life (HRQOL). Contrariwise the "Anxiety and Depression" dimension did no shown to be particularly important in the HRQOL valuation. We did not found significant differences on the HRQOL between men and women

**Conclusions:** This study generated decision-relevant data that can be applied to health technologies assessment and economic analysis in Brazil. The results obtained are an important source of insight on Brazilian population health preferences and allow us to raise hypothesis for further investigation.

**OR28.2****Does the Socioeconomic Status Influence HRQOL Preferences? Results from QALYBrasil Project**

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**Background:** It is vital to understand how society values different attributes of health to supply policymakers with decision-relevant data for the sake of health care planning and health technologies assessment process. Given the well-known Brazilian socioeconomic inequality, it could be expected that the valuation of different health states could change throughout social economic status (SES). If this difference really occurs it may enhance the complexity associated to the health care planning, mainly, in the investment prioritization process.

**Objectives:** The aim of this study is to investigate the impact of socioeconomic status on Health Related Quality of life (HRQOL) valuation.

**Methods:** A Multicentric Cross-sectional study was conducted in four Brazilian urban centers (QALYBrasil Project) aiming to derive Quality Adjusted Life Years (QALYs) based on estimates obtained from EQ-5D-3L valuation. A probabilistic sample of the Brazilian general population (n = 9148) stratified by age and gender valued 243 health states. Each respondent ranked and valued seven health states using the Time Trade-Off (TTO). Face-to-face household interviews were conducted by trained interviewers. To define the SES categories, we adapted the Brazilian Market Analysis Association (ABEP) classification that categorize the population into 8 classes (A1, A2, B1, B2, C1, C2, D or E) considering values in the residence and education level. The statistical analysis was carried using R Statistical Software.

**Results:** The TTO weigh estimates distribution was stratified by the socioeconomic categories: A1 0.5(-0.75-0.95); A2 0.35 (-0.95-0.95); B1 0.35 (-0.95-0.95); B2 0.35 (-0.95-0.95); C1 0.45 (-0.95-1.00); C2 0.45 (-0.95-0.95); D 0.45 (-0.85-1.00); E 0.45 (-0.95-0.95). Considering the confidence interval, it wasn't found significant variation on the valuation HRQOL throughout socioeconomic categories.

**Conclusions:** This evidence suggest that despite the socioeconomic inequalities intrinsic to Brazilian population the QALY estimates obtained in this study may be applied to make decisions that affect all the population

**OR28.3****Getting the Right Focus in Economic Assessment of Telemedicine in HTA**

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**Background:** Reviews of economic assessments of telemedicine show that economic studies are generally not in accordance with guidelines for design and reporting of results (Mistry 2011). To expand the current evidence base for telemedicine a large EU project Renewing Health was initiated in 2010 including 20 RCTs and economic studies.

**Objectives:** To describe the overall results from the 20 economic assessments of telemedicine in the project.

To identify the cost elements having the most impact on the costs per patient and thereby give guidance to future economic assessments of telemedicine with regard to which costs to focus on.

**Methods:** The Renewing Health project involves 7.000 patients with diabetes, COPD or CHF and has been reported to the European Commission. Based on the 20 reports the results are analysed in accordance with the Drummond (2005) guideline and the estimated differences between the cost in the interventions and control groups are described. The cost element having the most impact on the total cost per patient is also identified.

**Results:** The preliminary analysis of the data shows that the design and reporting generally are in accordance with the guideline. The mean costs per patient using telemedicine are by 1%-135% higher than the costs of usual care in 80% of the trials. The cost element with the highest impact on the results is the costs of the telemedicine equipment. This costs €330-1480 per patient.

**Conclusions:** The results show that telemedicine interventions as currently designed, often do not reduce the costs per patient, contrary the expectations. Therefore, if telemedicine is not having clinical impact on patients' health, more focus is needed on reducing the price of the equipment and on optimizing the organisation to ensure savings in use of inpatient and outpatient treatment. This focus is critical if telemedicine should have influence on the development of healthcare in the future.

**OR28.4****Efficacy and Safety of Biologics in the Treatment of Moderate to Severe Psoriasis: a Mixed-Treatment Comparison Meta-Analysis**

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**Background:** The short follow-up of randomized controlled trials comparing different biologics or with placebo, makes the results of direct meta-analysis insufficient to define superiority of efficacy and safety among biologics, justifying the necessity of MTC meta-analysis.

**Objectives:** To evaluate and compare the efficacy and safety of biologics in the treatment of moderate to severe psoriasis through MTC meta-analysis.

**Methods:** Randomized Controlled Trials were published up to January 2012 in Cochrane Central Register of Controlled Trials, MEDLINE, International Pharmaceutical Abstracts, EMBASE, Literatura Latino-Americana e do Caribe em Ciências da Saúde, Scielo, Science Direct, Scopus and Web of Science databases. The assessed outcomes were Psoriasis Area and Severity Index 75 (PASI75), Psoriasis Area and Severity Index 90 (PASI90), Dermatology Life Quality Index (DLQI), any Adverse Drug Event (ADE) and serious Adverse Drug Event (sADE). Each outcome measure was extracted and analyzed using traditional pairwise meta-analysis followed by a MTC meta-analysis. The consistency assumption was checked using the posterior plots and the Bayesian p-values produced by the node-splitting method.

**Results:** Were included 91 articles corresponding to 41 RCTs (15,686 patients), assessing 11 biologics. For PASI75, infliximab 5mg/kg and ustekinumab 90mg showed superiority statistically significant compared to the others. Regarding PASI90, ustekinumab 90 mg/kg showed superiority. For DLQI, adalimumab 80/40mg is the drug with the highest probability of being more efficacious. Concerning ADE, infliximab is the worst drug and adalimumab 40mg is the safest. No inconsistency was detected in the network.

**Conclusions:** For public health services our recommendation is that adalimumab 80/40mg must be the first choice. In this context, ustekinumab 90mg would be the second choice in cases of intolerance or inefficacy to adalimumab, since it is the biologic with better profile for efficacy and safety according to our findings.

## OR28.5

### Reporting of QALY Estimation in Applied and Published Cost-Effectiveness Analyses

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**Background:** There has been an exponential increase in the number of published cost-effectiveness analyses based on Quality Adjusted Life Years (QALYs) over the last few years. A search in EMBASE on the term "cost-utility analysis" resulted in 37 hits in 1992 and 1694 hits in 2012. This increase partly reflects the increased focus on cost-effectiveness analyses as part of implementation or reimbursement decisions in many countries.

A QALY is however not always a QALY. Different primary methods for QALY estimation, i.e. time trade off, standard gamble and visual analog scale, and also different Multi Attribute Utility Instruments (MAUs), such as EQ-5D, SF-6D, HUI etc. has been shown to yield different utility values for the same health states in the same individuals. Choice of utility instrument has also been shown to result in very different ICERs and also conclusion on cost-effectiveness. As values based on different methods can warrant different interpretations and implications, the transparent reporting of methods used for QALY estimation is crucial.

**Objectives:** To investigate to what degree applied and published cost-utility analyses report their QALY estimation in a transparent manner.

**Methods:** We searched Medline, EMBASE and NHS EED for cost-effectiveness analyses reporting QALY as an outcome. The search was for convenience limited to 2010 and resulted in 644 identified studies, of which 370 met our inclusion criteria.

**Results:** Of the identified studies, 45% reported either primary method or MAU used for QALY calculations, while 18% reported both valuation method and MAU instrument. Reporting was more complete in health economic journals as compared to medical journals, 29% vs 14% respectively. The EQ-5D was by far the most prevalent instrument, applied in 77% of analyses that reported the MAU instrument used.

**Conclusions:** Reporting of methods for QALY estimation is generally inadequate in published cost-utility analyses.

## OR28.6

### From the Minimum Clinically Important Difference to the Minimum Cost Effective Difference for EQ-5D in Patients with Chronic Widespread Pain

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**Background:** The minimal important difference (MID) represents the smallest amount of benefit that the patient can recognize and value. It is useful in the design of clinical trials for sample size calculations and in the interpretation of results. However, it does not help in the allocation of healthcare resources. Minimum cost-effective difference (MCED) can be used to bridge MCID and cost-effectiveness, being defined as the smallest improvement in the HR-QoL instrument associated with a cost-effective outcome. MCED allows understanding whether the minimum change perceived as meaningful is cost-effective, given a certain acceptability threshold.

**Objectives:** i) estimate the MCID for EQ-5D in patients with chronic widespread pain; ii) estimate the MCED for patients undergoing

cognitive behavior therapy (CBT), prescribed exercise therapy (EX), and combination therapy, i.e. cognitive behavior therapy and prescribed exercise together (COMB).

**Methods:** Using data from a multi-center RCT, MCID was estimated through regression analysis and ROC curves. Moreover, average change, minimum detectable change and change difference approaches were applied. The minimum cost-effective difference (MCED) for the three patients' subgroups allocated to each of the active treatments of the trial was estimated through ROC curve approach and through regression analysis. The MCED was computed using a threshold of £20,000-£30,000 per QALY as cost-effectiveness anchor. Ordinary least squares was used in regression analysis while ROC were estimated based on logistic analysis.

**Results:** Estimates of MCID range between .05 and .33. Adopting a cost-effectiveness threshold of £20,000/QALY, the MCED was equal to .226, .062 and .104, for CBT, EX and COMB respectively. Adopting a cost-effectiveness threshold of £30,000/QALY, the MCED equaled .315, .067 and .119, for CBT, EX and COMB, respectively. However, estimates were sensitive to the choice of the anchor and the estimation method.

**Conclusions:** Estimates of MCED for EQ-5D have been provided for patients with CWP. However further research should validate estimation methods.

## OR29.1

### Assessing the Impact of Changes in Patient Management and Therapy Sequences Using an Early Decision Model

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**Background:** Treatment paradigms for certain diseases are undergoing transformations through the emergence of new therapies. This is true in metastatic prostate cancer or relapsing multiple sclerosis where several new treatment options have become available over recent years.

**Objectives:** The objective here was to create a tool to anticipate patient distribution across the new range of therapeutic options available at time of launch for a new product, and the resulting evolution of clinical and economic outcomes such as time to disease progression, overall survival and market share for the different therapies.

**Methods:** A flexible modeling tool was created to simulate future scenarios of therapeutic pathways through specific disease stages. As a basis, existing disease progression models in the clinical and pharmacoeconomic literature were reviewed. These models were predominantly based on past and present treatment pathways, and therefore a new model was developed to simulate future pathways based on clinical trials (pipeline products) and real world evidence (existing therapies). Structured interviews were undertaken with clinical experts to refine and inform future pathways and data inputs.

**Results:** An early decision model was created to predict the impact of launching a new therapy within a particular disease in 2-3 years' time. The model outcomes were: (i) number of patients receiving each treatment at each line following diagnosis, (ii) number of patients who remain on active therapy after each line of therapy, (iii) market share for each treatment, (iv) time to progression, (v) overall survival. Simulated scenarios included a base case without the new product, and scenarios with the new product used in different patient segments: 1st line in slow or fast progressors, 2nd line, or in both 1st and 2nd line.

**Conclusions:** The clinical and economic impact of introducing a new therapy into the future therapeutic landscape for a particular disease was evaluated using an early decision model.



**OR29.2****Intervention, Improvement and Impact: the NPS Medicinewise Evaluation Approach**

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**Background:** The increasing focus on optimal use of health resources demands greater attention on the systematic evaluation of the implementation and impact of policies, programs and guidelines to encourage better practice.

NPS MedicineWise develops evidence-based education programs for health professionals and consumers on quality use of medicines and medical tests. Programs assist implementation of evidence based guidelines and improve the quality of medicines and medical test use to create better health and economic outcomes.

We have conducted a range of evaluation studies over the past 15 years to assess the impact of these national, comprehensive educational programs.

**Objectives:** To evaluate the impact of six NPS MedicineWise programs designed to improve management of dyslipidemia, gastro-oesophageal reflux disease, type II diabetes, stroke, osteoporosis and dementia.

**Methods:** We employed qualitative and quantitative evaluation methods including: semi-structured interviews and focus groups to obtain in-depth understanding of needs and wants of audiences; cross-sectional pre and post surveys to assess impacts on knowledge; and, more recently, linked data (questionnaire, prescribing, hospitalisation and death) to assess the impact on health outcomes.

To assess prescribing change and financial impact we used interrupted time series analysis with longitudinal claims data from the Australian Pharmaceutical Benefits Scheme (PBS).

**Results:** Programs took between 12 and 18 months to complete. Participation rates ranged from 33% to 37% of the national workforce of general practitioners in Australia. The average differences in expenditure on targeted medicine or medicine class with and without NPS MedicineWise intervention was 11.7% per program per year. The annual financial saving to the PBS attributable to these NPS MedicineWise programs was AU\$81.7 million in the most recent evaluation year. Typically, the cost of evaluation was about 5% of total program cost.

**Conclusions:** Investment on rigorous evaluation is critical for informing subsequent program improvement, demonstrating accountability to stakeholders and facilitating assessment of impact on health resources.

**OR29.3****Facilitating a Patient-Centered Approach to Medication Adherence Among Type 2 Diabetes Patients: Differences Between Patient and Provider Understandings of Information Requirements**

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**Background:** Poor adherence to prescribed medication regimens leads to several types of adverse outcomes for patients with Type 2 diabetes. Improving medication adherence is a growing priority for clinicians and health care systems.

**Objectives:** This study examined the differences between patient and provider understandings of barriers to medication adherence for patients with Type 2 diabetes, focusing on differing perceptions of information requirements about medication and treatment regimens.

**Methods:** A systematic search for qualitative literature on the topic of barriers to medication adherence among Type 2 diabetes patients

was performed, resulting in 86 relevant empirical qualitative studies published between 2002-2013. Using the methodology qualitative meta-synthesis, findings from the published literature were coded and analyzed thematically, both integrating and comparing findings across studies to yield both a synthetic interpretation and new insights from this body of research.

**Results:** Patients and providers discussed different understandings of what information patients require to improve adherence. Patients, informed by their health beliefs, life context and lay understandings of diabetes and medication, are described as concerned about administration of medication and how to adapt medication regimens to their lifestyle and everyday routines. In contrast, literature about providers' understandings of why patients don't adhere to medication regimens focuses on the need for more information about the physiological and bio-medical aspect of diabetes. This literature reported that providers infrequently considered the need to provide practical information about how patients could alleviate negative emotional and social impacts of medication.

**Conclusions:** This study highlights the conceptual and communication discrepancies between patients and providers about the information required to facilitate medication adherence. Understanding this divergence may provide insight on how to improve medication adherence among patients with Type 2 diabetes, potentially reducing the burden of diabetes on the patient and healthcare system.

**OR29.4****Arthroplasty for Hip Fracture in Uruguay. Earlier Surgery and Better General Care Rather Than New Devices**

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**Background:** 14.1% of Uruguay population is older than 65 years. Hip fracture risk increase with age and consequences may be devastating. Arthroplasty for hip fracture is funded by the National Resources Fund (NRF) for all citizens. Registry was developed and performance indicators evaluated. Delay between fracture and surgery exists and affects functional results and mortality. Surgery is provided with a cemented prosthesis produced by regional manufacturer at a low cost. Progressive pressure emerges for incorporation of new and high cost prosthesis.

**Objectives:** Analyze medium and long term mortality and risk factors for, and incidence of revision surgery, to optimize resources allocation.

**Methods:** Cohort of years 2003-2006 of hip fracture arthroplasty was analyzed, and logistic regression model for one year-mortality was developed. Model performance analysis and competing risk for time to revision and mortality were applied to 2008 cohort.

**Results:** 3146 arthroplasties were done between 2003 and 2006, risk factors for mortality were age (OR=1.05 per year above 74), male (OR=1.76), renal failure (OR=1.53), Parkinson (OR=1.59), diabetes (OR=1.58), disseminate cancer (OR=8.12), respiratory disease (OR=1.42), dementia (1.73), partial arthroplasty (OR=2.49) and days until surgery (OR=1.014 per day). The median of the time between fracture and surgery was 6 days (IQ range 5-12).

In 2008, 870 arthroplasties was done (79.5 years old, 17% male). Performance of the model in 2008 cohort was good for one year (c-index:0.67,0.62-0.73) and for 5 years mortality (c-index:0.69,0.65-0.72). At one, three and five years, incidence of revision request was 0.57%, 0.92% and 1.26%, and mortality was 13.1%, 29.3% and 46%, respectively.

**Conclusions:** Mortality at follow-up was high and factors susceptible to improve were identified (care of diabetes, dementia, Parkinson, chronic respiratory disease and renal failure). Incidence of revision was very low at five years. Invest in earlier surgery and in improve medical

care will be more cost-effective than incorporate new devices for arthroplasty.

## OR29.5

### Patient Reported Outcomes in Diabetic Patients in Slovenia

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**Background:** Patients with chronic conditions, like diabetes mellitus (DM), consume a big share of the healthcare resources, and the re-organisation of the care for them is a target for improving effectiveness and efficiency of care. Patient reported outcomes enable policy makers to consider patient perspectives when evaluating the delivery of care.

**Objectives:** The aim of the study was to measure patient reported outcomes, such as health related quality of life (HRQoL) of diabetic patients in Slovenia.

**Methods:** A cross-sectional study of diabetes mellitus patients was carried out. The Audit on diabetes-dependent quality of life (ADDQoL) and EQ-5D surveys were conducted between January and May, 2012. Statistical analysis was performed using IBM SPSS Statistics software, version 20.0.

**Results:** A total of 563 patients participated in the study, of which 482 (85.6%) were diabetes mellitus type 2 patients, ranging from 22-93 years (average 61.9 ± 12.8). Twenty four (4.3%) patients report no impact of diabetes on their HRQoL at all, while in the remaining respondents, particular reference is put to the effects on freedom to eat, dependency on others and family life. There was no significant difference between the older people living in urban and rural areas.

**Conclusions:** The findings of the present study highlight the impact of diabetes mellitus on HRQoL. DM imposes a personal burden on individuals. Information on the quality of life of diabetes patients is important to Slovenian policy makers and family physicians in order to identify and implement appropriate interventions for achieving better management of diabetes and ultimately improving the HRQoL of diabetes patients.

## OR29.6

### Does Postoperative Management of Patients with Obstructive Sleep Apnea Required Routine Admission to an Intensive Care Unit?

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**Background:** Obstructive sleep apnea (OSA) is a common disorder presumed to predispose patients to postoperative complications. However, no consensus exists regarding the optimal postoperative management. Question was raised in our institution about the use of intensive care unit (ICU) as a postoperative monitoring practice in OSA patients.

**Objectives:** 1) To assess the relationship between OSA and postoperative complications, and 2) to determine the most appropriate postoperative management.

**Methods:** A literature search was performed in PubMed, Embase, the Cochrane Library and the grey literature between 1966 and August 2013. Data were retrieved from systematic reviews (SRs), evidence-based practice guidelines, randomized controlled trials, and observational studies (OSs). Studies reporting data on postoperative complications in adult with OSA compared to those with mild or without OSA

were eligible. Synthesis review was shared with an interdisciplinary group of experts.

**Results:** A total of 23 OSs were included. Clinical heterogeneity was observed between the studies including definition and methods for OSA diagnosis. Results showed that the incidence of total postoperative complications is higher in OSA patients compared with those without OSA. Increased rate of oxygen desaturation episodes were reported in 11 of 12 OSs. The frequency of postoperative respiratory failures, cardiovascular events or deaths did not increase significantly in OSA patients. However, few data were adjusted to take into account factors other than OSA associated with postoperative complications. Literature was insufficient to evaluate the impact of postoperative management practices in OSA patients, such as analgesia, oxygenation, patient positioning and monitoring including use of ICU, on postoperative outcomes.

**Conclusions:** Current literature suggests that postoperative complications, mainly oxygen desaturation episodes, are higher in OSA patients. Unfortunately, it remains unclear whether these complications are caused by OSA itself or other co-morbidities. Consequently, routine postoperative monitoring in an ICU environment does not appear justified in patients with OSA.

## OR30.1

### Cost-Utility Analysis of Adalimumab, Etanercept and Infliximab for the Treatment Psoriatic Arthritis

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**Background:** Psoriatic arthritis (PsA) is a complex, multisystem disease with musculoskeletal and skin manifestations. During the last years new high cost therapies have emerged in a context of economic constraints. Economic evaluations considering the characteristics of our Health System may be a useful information to decision making.

**Objectives:** To support an evidence-based decision regarding the inclusion of adalimumab, etanercept or infliximab to the National Formulary for the treatment of psoriatic arthritis, in patients non-responders to first-line treatment.

**Methods:** We perform a cost-utility evaluation using a Markov model, to estimate the incremental costs and quality adjusted life years (QALY) gained with each of these biologic drugs compared with palliative care only. The model considered the perspective of the National Health System, with a time horizon of 40 years.

**Results:** Under base-case assumptions, infliximab results in an incremental cost-effectiveness ratio (ICER) of United States Dollars (USD) 47,294 respect to palliative care only. Adalimumab was extendedly dominated and etanercept was dominated. On the other hand, infliximab requires intravenous administration which could significantly reduce access to treatment, thus producing inequities between patients from different contexts. The probabilistic sensitivity analysis shows that all biologics had null probabilities of being cost-effective considering a willingness-to-pay (WTP) threshold of one time the gross domestic product per capita of Uruguay per QALY (USD 15.000).

**Conclusions:** In our analysis from the perspective of the National Health System, the use of biologic drug treatments for psoriatic arthritis results in an ICER above the WTP ceiling proposed by the World Health Organization of one time the gross domestic product per capita per QALY. Inequities in access must be carefully addressed, prior to decide the inclusion of these drugs into the National Formulary.

## OR30.2

### Fingolimod Versus Natalizumab in Multiple Sclerosis (MS): an Indirect Treatment Comparison

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**Background:** Multiple sclerosis (MS) is a chronic autoimmune disease that affects the central nervous system. Natalizumab is available in the Brazilian Public Health System (SUS) to treat patients refractory to interferon beta and glatiramer. Fingolimod, an oral medicine, is not available in SUS and could be evaluated as a new option. To date, there are no direct comparisons of these technologies.

**Objectives:** To compare, indirectly, the safety and efficacy of natalizumab and fingolimod in MS.

**Methods:** Searches for randomized clinical trials (RCTs) were conducted in MEDLINE, CENTRAL and Clinicaltrials.gov. Meta-analyses adopting a Bayesian approach (Mixed Treatment Comparison - MTC), with GeMTC software, and a frequentist approach (Bucher's method), with the ITC (Indirect Treatment Comparison) Program, were run. The potential effect modifiers were assessed and sensitivity analyses were performed.

**Results:** Four RCTs were included (n = 3,364). The studies evaluated the relapsing-remitting form of MS and compared mainly against placebo. None of the comparisons of fingolimod against natalizumab were statistically significant in Bayesian models. Regarding the rankings, natalizumab was the best treatment in the nine efficacy outcomes evaluated, with an average probability of being the best treatment of 73.6 % (range: 52.7 to 95.6%). In frequentist models, the outcomes related to the absence of lesions showed better results in the natalizumab arm: Odds Ratio of 3.77 (95%CI: 2.07 to 6.87) and 2.34 (95%CI: 1.46 to 3.77) assessed with T1-gadolinium and T2, respectively. The safety outcomes evaluated were not statistically significant and their imprecision did not allow the production of rankings. The sensitivity analyses did not change substantially the results.

**Conclusions:** These indirect analyses indicate that natalizumab seems to have equal or superior efficacy compared to fingolimod in MS. Both benefits of natalizumab and fingolimod in MS should be balanced with their side effects and costs. These results are limited by the potential bias of indirect comparisons.

## OR30.3

### Interventions to Treat Premature Ejaculation: Methods for a Rapid Review and Meta-Analysis

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**Background:** A HTA short report was required to identify the most effective treatment option or combination of options for the treatment of premature ejaculation (PE)

**Objectives:** To undertake a rapid systematic review of the evidence for the clinical effectiveness of behavioural, topical and systemic treatments for PE (ejaculation shortly after penetration and before the person wishes it)

**Methods:** To summarise the current evidence base within the time and resource constraints, randomised controlled trial (RCT) data were extracted from clinical guidelines, systematic reviews and meta-analyses without revisiting original RCT publications. This was supplemented by a literature search to identify further RCTs not captured by existing reviews. Methodological quality of reviews and additional RCTs was assessed. The primary efficacy outcome was intra-vaginal ejaculatory latency time (IELT). Other outcomes included sexual satisfaction, control over ejaculation, relationship satisfaction, self-esteem,

quality of life, treatment acceptability and adverse events. RCT data reported in existing reviews were pooled, where possible, with subsequent RCT data in a meta-analysis. Heterogeneity was assessed

**Results:** One hundred two RCTs were included. Data for 65 RCTs were extracted from 25 reviews. The majority of reviews were of low methodological quality. The majority of the 37 additional RCTs were of unclear methodological quality. Meta-analysis was possible and errors in existing reviews (combining RCTs with observational studies, double-counting participants, pooling data from crossover and pairwise RCTs) were addressed by re-pooling data, also including data subsequently published RCTs. Drug treatments, anaesthetic creams and behavioural therapies were significantly effective at increasing IELT and improving sexual satisfaction and other outcomes. Adverse events were evident for some pharmacological therapies. Further research priorities were identified

**Conclusions:** Extrapolating RCT data presented in existing reviews to pool with additional RCT data might provide a useful method for reviewers undertaking rapid reviews to help provide an informative summary of the evidence base

## OR30.4

### Bubble Humidifiers in Low-Flow Oxygen Therapy: Effectiveness and Cost

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**Background:** Bubble humidifiers are designed to add humidity to inspired gas, helping to control the drying and irritation of the respiratory mucosa. However, it is not clear whether they are beneficial in the administration of low-flow oxygen.

**Objectives:** To systematically appraise the effectiveness of bubble humidifiers in low-flow oxygen therapy and to perform an economic analysis to determine its cost.

**Methods:** MEDLINE, EMBASE, EBM Reviews and CINAHL databases were searched and a manual search was conducted to locate further references. Information on each one of the studies was extracted and their quality was assessed.

From the viewpoint of the financier and for two economic scenarios (1. the humidifier is not changed each time it is used and 2. the humidifier is changed) the direct daily costs were calculated.

**Results:** Four studies (494 participants) were included in the review. Studies were old and of low quality. Data was not conclusive regarding nasal dryness since just two of the studies found significant differences between the patients who used the humidifier and those who did not. No differences were found in relation to dry throat, nose bleeding, headache and chest discomfort.

The daily cost of the humidifier (flow of 5 l/min) was 0.48€ and 0.58€ for scenarios 1 and 2 respectively. The sensitivity analysis indicated that an increase or decrease in the duration of use of a humidifier of 15% for scenario 1 and of 18% for scenario 2, caused a decrease or increase in the daily cost of 15% and 12% for the former and of 15% and 22% for the latter.

**Conclusions:** Ensuring efficient use of resources is a must in this moment of economic uncertainty. Therefore given the few benefits of using bubble humidifiers in low-flow oxygen therapy, its generalised use is not recommended. Further high quality studies performed in current clinical conditions are needed.

**OR30.5****Clinical Effectiveness and Safety of Robot Assisted Radical Prostatectomy versus Laparoscopic Radical Prostatectomy: Using Systematic Review Approach**

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**Background:** Recently, incidence of prostate cancer has increased in Korea. Also, robot-assisted radical prostatectomy(RARP) is becoming more common but its effectiveness and safety compared to laparoscopic radical prostatectomy(LRP) are different among research results.

**Objectives:** To assess comparative effectiveness of robot-assisted radical prostatectomy(RARP) versus Laparoscopic radical prostatectomy(LRP) in patients with localized prostate cancer.

**Methods:** We performed a systematic review using existing systematic reviews to investigate clinical effectiveness and safety of RARP. Electronic databases were searched from 1948 to July 2013, including ovidMEDLINE, ovidEMBASE, Cochrane Library, Koreamed, Kmbase, etc. We assessed the relevance and quality of selected systematic reviews related to the research question through the revised assessment of multiple systematic reviews(R-Amstar). We also searched additional studies regarding RARP after 2010. Two independent reviewers extracted data and assessed the quality using revised Cochrane Risk of Bias tool(ROB). Meta-analysis was carried out by Revman 5.2 and Comprehensive meta analysis 2.0(CMA). Cochrane-Q-statistic and I<sup>2</sup>-statistic were used to assess heterogeneity.

**Results:** We selected two existing systematic reviews of RARP in patients with prostate cancer as best available evidence and found 16 additional studies from new search after the latest search that was done by existing SRs. Finally, we evaluated 30 articles. There were two randomized controlled clinical trials and 28 non-randomized comparative studies. The risk of complication, such as organ injury, major complication in Clavien Dindo classification was lower in RARP compared LRP. When it comes to functional outcomes, RARP has a better recovery than LRP.

**Conclusions:** This study presented that RARP is superior in terms of safety, peri-operative outcome, functional outcome and oncological outcome compare the LRP. However it was not sufficient to support long term outcomes. Well designed prospective studies are needed.

**OR30.6****Patient and Household Costs Associated with a Tuberculosis Treatment Under DOT Strategy in Colombia**

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**Background:** Tuberculosis (TB) is a disease that causes 9 million cases every year worldwide, out which 2 million die. DOTS (directly-observed treatment short-course) is a supervised system of drug-intake by patient, widely accepted as the most cost-effective strategy for TB control. However, some costs may result from patients.

**Objectives:** This research is aimed to estimate overall economic impact under DOTS-strategy (Directly Observed Therapy Short Course) from patient perspective.

**Methods:** A cross-sectional survey of 91 adult tuberculosis patients in treatment for at least two months was conducted from the patient perspective. A standardized questionnaire was used in three different cities of Colombia: Medellin (poverty index 17.7%), Monteria (poverty index 36.9%) and Quibdó (poverty index 51.2%). Costs were converted

to 2013 USD\$ and categorized into two periods: diagnostics phase and treatment.

**Results:** The median cost during diagnostics was USD\$13 (±SD 9.5). The median monthly patient out-of-pocket costs during treatment were USD\$32 (±SD 6.8), equivalent to 17% of patient's median monthly income, estimated in USD\$186 (±SD 23). Costs recorded in Medellin were USD\$47 in Monteria was USD\$18 and in Quibdó was USD\$13.

**Conclusions:** Patient costs under DOTS strategy are high even when services are provided free of charge by public sector. In settings with limited resources, these costs can be a possible cause of treatment default.

The creation or strengthening of community-based treatment supervisors could greatly impact costs of tuberculosis and lower drop-outs.

**OR31.1****HTA Process in Updating the Catalogs of Essential Health Technologies: Lessons Learned**

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**Background:** General Health Council (CSG by its acronym in Spanish) is a Constitutional body that provides national guidance on health care policy priorities in Mexico. CSG through the Inter-institutional Commission of essential health technologies (CICByCISS) is in charge of develop, disseminate and maintain updated catalogs of essential health technologies with public funding in the Mexican Health System. CICByCISS is comprised of the General Secretary of the General Health Council along representatives from public institutions of social security and other national institutions responsible for providing health care services (Ministry of Health, IMSS, ISSSTE, DIF, ISSFAM, SEMAR, PEMEX and GDF health services).

Since 2003 CICByCISS has required an economic evaluation as criteria for public funding of health technologies in the Mexican health care system, but it was not until mid-2011 that explicit health technology assessment criteria were included with this purpose.

**Objectives:** To describe the impact of implementing HTA criteria in evaluating health supplies to update Mexican catalogs of essential health technologies, for the period September 2011-December 2013.

**Methods:** N/A

**Results:** 614 health products were evaluated during the period described above. Of these, 395 were drugs (64%) and the remainders were medical devices.

Of the 395 drugs analyzed, only 262 (66%) met the requirements for assessment and 42% was approved. The main causes of non-adoption was the lack of clinical evidence and methodological shortcomings in the economic evaluation.

For medical devices only the period January to December 2013 was analyzed. From 70 products 42 met the criteria to be evaluated, and 47% were approved.

**Conclusions:** Health Technology Assessment has allowed the optimization of public resources for the care of the health problems of the country through the use of health supplies that have proven their safety, therapeutic efficacy and efficiency.

**OR31.2****Economic Evaluation of Health Technologies: a Checklist for Critical Assessment**

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**Background:** Given a large number of steps of an economic evaluation, there have emerged check-lists in the literature to critically assess papers in this field. Their main goal is to examine the quality of evidence, in order to assess if the methodology employed in the study is appropriated and the results are valid to the decision making setting.

**Objectives:** This paper reports the results of a systematic review of the available check-lists in the field, which supported a proposal of a new check-list for critical assessment of economic evaluation.

**Methods:** Systematic review in the following electronic databases: MEDLINE, Embase, Center for Reviews and Dissemination (CRD) and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

**Results:** Nineteen check-lists were analyzed, from which 562 questions were identified. More emphasis was given to the following topics: outcomes (19%); costs (17%); analytical model (13%); generalization of results (10%), and uncertainty (9%). We elaborated a proposal of check-list along with explanatory notes for identifying key elements in each question.

**Conclusions:** This check-list can improve critical assessment for decision-making process and also provide minimum criteria for authors to report their economic evaluation results, promoting transparency and reproducibility.

**OR31.3****Upgrading and Extending the Possibilities of the HTA Core Model®**

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**Background:** The HTA Core Model, produced within the European Network for Health Technology Assessment (EUnetHTA) facilitates joint production and sharing of HTA information. Until recently, the Model enabled assessment of medical and surgical interventions, diagnostics and screening technologies, as well as rapid relative effectiveness assessment of pharmaceuticals. We report developments within Work Package 8 of EUnetHTA Joint Action 2 (2012-2015).

**Objectives:** We aimed at improving and expanding the overall usability of the Model and related website containing an online tool for using the Model and database of HTA information. The aim is also to add new features to the web site to assist local (national/regional) HTA report production.

**Methods:** International working groups updated the Model during 2013, reorganising the content and bringing it up-to-date and adding content for pharmaceutical assessments. The new version is available online and piloting is ongoing. Terms of use and policies were crafted to steer its utilization. Key stakeholders were involved through a Stakeholder Advisory Group (SAG). New features related to rapid assessments and local report production will be added within first half of 2014.

**Results:** Version 2.0 of the HTA Core Model was published in November 2013 at [www.corehta.info](http://www.corehta.info). Most contents are updated, with an application to allow full assessment of pharmaceuticals. Contents related to legal issues within HTA will be updated during spring 2014.

New documents defining Terms of Use and a more extensive Policy are available at the same location.

**Conclusions:** The HTA Core Model has undergone a major overhaul during 2013, through updating and expanding the contents and developing the online interface. Pilot testing during the remaining project time, as well as feedback from stakeholders and the public will be considered for further refinement of the Model and related tools and services. The Model is available also to organizations that are not members of the EUnetHTA.

**OR31.4****Keeping Up to Date with Information Retrieval Research: Summarized Research in Information Retrieval for HTA (SuRe Info)**

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**Background:** Increasing numbers of research papers about information retrieval for health technology assessments, systematic reviews and other evidence syntheses are being published. It is time-consuming and demanding for information specialists and researchers to keep up-to-date with the latest developments in the field, and to ensure potential efficiencies arising from new evidence are incorporated into HTA evidence identification processes. To help to meet these challenges, the Interest Sub-Group on Information Resources (IRG) of HTAi has launched a web resource entitled SuRe Info.

**Objectives:** To present the SuRe Info resource.

**Methods:** Information retrieval methods publications are identified by running topic-specific search strategies in selected relevant databases. Publications fulfilling the SuRe Info inclusion criteria receive a structured abstract along with a brief critical appraisal prepared by one SuRe Info information specialist and checked by another. The key messages from the appraisals are summarized into topic-specific chapters.

**Results:** SuRe Info is published as a part of the HTAi Vortal. It has two sections: 1) chapters on general search methods common across all health technologies and 2) chapters describing the methods to use when searching for specific aspects of health technologies, such as clinical effectiveness, safety and economic evaluations. Chapters summarize the current evidence from research. The references listed at the end of each chapter are linked to structured abstracts of the included publications.

**Conclusions:** SuRe Info is a new open-access web resource that provides research-based information relating to the information retrieval aspects of producing health technology assessments and systematic reviews. It seeks to help information specialists stay up-to-date in the latest developments in the field by providing easy access to summaries of current methods papers and by supporting timely uptake of potential new efficiencies in information retrieval practice.

### OR31.5

#### Is a Consensus Required on Use of Surrogate Parameters in Health Technology Assessments? A Comparison of Recommendations from 8 HTA Agencies (CADTH, G-BA, IQWiG, HAS, NICE, SMC, PBAC and CONITEC) in the Treatment of Hepatitis C with Protease Inhibitors

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**Background:** Due to ethical reasons, clinical trials for chronic diseases frequently use surrogate parameters (SP) as primary outcomes, e.g. HbA1c in diabetes or sustained virological response (SVR) in hepatitis C (HCV). Often, the correlation between long-term and patient-relevant outcomes like survival, myocardial infarction or cancer is not known. Methodology for the validation of SPs varies. To date, there is no consensus among HTA agencies about the use of SP in health technology assessments (HTAs).

**Objectives:** To evaluate HTA agency recommendations on the inclusion of SVR as a SP in HCV protease inhibitor HTAs.

**Methods:** HTA reports for HCV were screened for the use of SVR and its classification as a SP. Relevant HTA reports for protease inhibitors were identified using the Reimbursement Risk Tracker Database from Context Matters Inc.

**Results:** Eight HTAs were identified. One HTA agency (IQWiG) excluded the use of SVR and classified SVR as a non-validated SP. One agency (CONITEC) included SVR and classified SVR as a validated SP. One HTA agency (G-BA) included SVR in its assessment, while still classifying it as a non-validated SP. Three agencies (SMC, HAS, PBAC) used SVR as a SP and made no statements regarding its validity. Two agencies (CADTH, NICE) included SVR and used it to estimate the hard outcome life-expectancy. Ethical issues in the use of SVR were not discussed in any of the HTAs. All agencies used the same underlying evidence but their decisions regarding the use of SVR were different.

**Conclusions:** The wide range of different interpretations of SVR as a SP shows the necessity for a consensus on the use of SPs in HTAs. An international working group with HTA experts, ethical and statistical experts is needed.

### OR31.6

#### A Comparative Analysis of the Role and Impact of Health Technology Assessment

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**Background:** HTA systems continue to proliferate. Fundamental principles are universal but practical application varies. Overarching principles of "best practice" exist and comparison of HTA systems against those principles can assist in understanding this variation and identifying improvements. Charles River Associates ("CRA") was asked by EFPIA and PhRMA to update the report undertaken in 2010/11 (CRA 2011), and to extend the analysis to include a comparison of how different systems treat the same technology.

**Objectives:** To develop a neutral and objective comparison based on the stated methodologies used in different HTA processes, taking into account the actual behaviour of the agencies and their observable impact. This includes:

- An update on recent changes in use of HTA,
- An expanded set of countries including emerging markets recently implementing HTA,
- An analysis of the impact of HTA, how it is used in decision making and its impact on health system efficiency.

**Methods:** N/A.

**Results:** Significant improvement was observed in the impact of HTA, including more timely processes and a greater commitment to monitoring impact. Concerns include the lack of clarity regarding the link between price, reimbursement, market access and HTA assessments. In terms of the new countries, the assessment showed strength and weakness in each. All of them could improve the process for including different stakeholders. The impact of HTA was the weakest area assessed.

**Conclusions:** Undertaking objective assessments of international HTA systems on an on-going basis allows us to identify both areas where HTA processes are improving, to the benefit of all stakeholders, and areas where further improvement is required and allows us to compare established approaches of HTA to the new systems that are emerging.

### OR32.1

#### Estimation Measure Weighted of Patient Groups Based on Risk Management

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**Background:** The groups of patients based on diagnosis are increasingly used for the study of patients per capita cost. But it must determine measure estimate that best fits the balancing of patient groups from the budget perspective clinic.

**Objectives:** Estimate the measure of best fit for calculating the weights of groups of patients in risk management, using total cost, logarithm of the cost and use of resources, based on a sample of information RIPS in Colombia.

**Methods:** Under an alternative group of diagnostic, patients were classified into ten major chronic diseases using CIE-10, with a minimum of two contacts with the same diagnosis, estimating their risk through the cost and use of resources. Thereafter, the patients were divided into five groups of health states from none to four or more major chronic diseases. Through an econometric model, based on the total cost, the logarithm of the cost and use of resources, it was estimated the better adjust measure for the weighting of patient groups.

**Results:** 946.372 patients were analyzed, with a total of 743.571 in the healthy group, 193.366 with a chronic disease, 8.590 with two diseases, 805 with three diseases and 40 with four or more diseases. The dependent model of total cost has a global adjustment of 5,98%, the model of resource usage an adjustment of 9,09%, while the logarithm of the cost model is an adjustment of 29.13%. With the latter model, healthy patients have 1 as weight, while a chronic disease is 6,64 times more complex, with two diseases is 33,58, with three diseases is 71,98 and with four or more is 123,63 times complex, both in cost as gravity.

**Conclusions:** The measure that presented the best fit for the establishment of data weighted in grouping of patients based on risk management was the logarithm of the cost.

### OR32.2

#### Publication Rate for Funded NIHR HTA Studies: a Cohort Study

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**Background:** For innovation to thrive it is vital that findings from funded projects are published, irrespective of whether results are positive, negative or equivocal. Failure to publish can lead to waste of resource, unnecessary repetition of work already done; delays in new

innovation because of a lack of evidence base, and potential publication bias in systematic reviews.

**Objectives:** This study aimed to investigate what percentage of National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme funded projects have published their findings in the programme's journal (monograph series), and to explore the reasons for non-publication.

**Methods:** A cohort of NIHR HTA projects covering a period of 18 years was classified according to type of research, whether they had published or not; if not yet published, whether they would be published in the future or not. Reasons for non-publication were investigated.

**Results:** 628 projects were included: 582 (92.7%) had published a monograph; 19 (3.0%) were expected to publish a monograph; 13 (2.1%) were discontinued studies and would not publish; 12 (1.9%) submitted a report which did not lead to publication as a monograph; and two (0.3%) did not submit a report. Overall 95.7% of HTA studies either have published or will publish a monograph: 94% for those commissioned in 2002 or before and 98% for those commissioned after 2002. Reasons why projects failed to complete included: issues concerning the organisation where the research was taking place; drug licensing issues; staffing issues; access to data; and failure to recruit.

**Conclusions:** The percentage of projects for which a monograph is published is high. The advantages of funding organisations publishing funded research in their own journal include improved evidence base to aid innovation, and avoidance of publication bias and research waste.

### OR32.3

#### Low Back Pain in Brazilian Public Healthcare System: Relationship with Disability Pensions and Hospitalizations

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**Background:** Pain and discomfort from the low back are very common complaints in the general population, and the majority of middle aged people have experienced such symptom for shorter or longer periods. In Brazil, musculoskeletal disorders are common reasons for sick leave and disability pension, and, in spite of the fact that low back pain is so frequent, we still have limited knowledge about its economic and social costs.

**Objectives:** To analyze the relationship between low back pain diagnosis and economic losses related to hospitalizations and disability pensions among people attended by Brazilian Public Healthcare System.

**Methods:** The sample was composed by patients of the Brazilian Public Healthcare System, which were interviewed during 2013 in basic healthcare units. Low back pain assessment was made by an investigation of morbidities, based on the Standard Health Questionnaire for Washington State. Hospitalizations and disability pensions were assessed through face-to-face interviews. Statistical analysis was composed of Spearman rank correlation ( $\rho$ ) due to non-parametric distribution of several variables. Statistical significance was set at  $p$ -value  $<5\%$ .

**Results:** The sample was composed by 353 adults of both sexes (83 men and 270 women) and age ranging from 45 to 64 years old. Low back pain was positively related to number of hospitalizations in the last year ( $\rho=0.14$ ;  $p$ -value=0.008). Moreover, low back pain was also

positively related to amount of money paid in disability one year prior to the interview conducted in the study ( $\rho=0.12$ ;  $p$ -value=0.024).

**Conclusions:** In summary, low back pain was related to increased number of hospitalizations and economic losses among patients of the Brazilian Public Healthcare System.

### OR32.4

#### The French National Authority for Health's Recommendations to Address MoM Hip Implants Survival Issue

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**Background:** Total hip implants are implanted to restore a painless mobile hip in patients with hip osteoarthritis or femoral neck fracture. Four types of implants with different bearing surfaces are used in France. Although total hip arthroplasty is highly successful in terms of functional results, the major issue remains the implants long-term survival.

The first metal-on-metal (MoM) hip implant was reimbursed in France in 1997. In 2007, the French National Authority for Health (HAS) assessed all hip prostheses types and confirmed 1- the indication of MoM implants in young patients with a high level of physical activity and 2- the need for long-term survival data for each MoM device. In 2012, national registries reported higher revision rates for MoM implants compared to other bearings.

**Objectives:** In this context, HAS decided to reassess MoM hip implants in order to establish whether their funding by the community is still justified.

**Methods:** A literature review (2006 - 2013) and individual hearings of orthopaedic surgeons were performed.

**Results:** Fifteen references were selected, including 3 national arthroplasty registries. These registries have a high compliance rate and include 8 to 10 years follow-up. The methodological quality of the selected literature was globally fair.

Based on the available evidence, HAS recommends to:

- continue to reimburse MoM traditional hip implants with small femoral heads (diameter  $\leq 32$  mm) in the current indications.
- no longer reimburse MoM traditional hip implants with large femoral heads (diameter  $\geq 36$  mm).
- continue to reimburse hip resurfacing implants in a selected population of young active patients and set conditions for hip resurfacing arthroplasty.

**Conclusions:** For both MoM traditional hip implants with small femoral heads and hip resurfacing implants, HAS highlights that the benefit of each implant depends on its specific conception and long-term survival data. Each MoM implant will be reassessed within 5 years.

### OR32.5

#### The Economy of Repugnance: Theory and Evidence for the Case of Kidney Transplants

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**Background:** Economists, such as Becker and Elías (2007) and Alvin Roth (2007) found a big difference between supply and demand for kidney and they look at obstacles to market balance. In the case of organ transplants, the obstacles are obvious, because many countries do not allow monetary incentive to the donor or the donor's family.

**Objectives:** The aim of this work is to examine the economic theory of repugnance and analyze the specific case of kidney transplants. We understand as repugnance, the feeling that some people have about the practice of certain activities, that they believe should not be carried out, neither by them nor by others. Also important is the notion developed by Debra Satz (2010) for the noxious market to understand this situation and their implications.

**Methods:** Through the analysis of the markets considered repugnant [Roth (2007) and Elias (2012)] or noxious [Debra Satz (2010)] it can be verified if the repugnant factor is acting, or has already acted, in the structuring and development of new markets and the consequences generated by it. For this purpose, an analysis of the main ideas and authors, who study repugnance and noxious market in the economic theory, was performed.

**Results:** What was observed, throughout the work was, that repugnance acts on the way how some markets arise and become structured but also curbing their existence and, it was noticed that the repugnance factor can be altered throughout time, since it responds to costs and benefits. When the costs of maintaining the market limited are high, such as the case of kidney transplants, a liberalization of the market will occur; otherwise, it remains limited or simply remains underground.

**Conclusions:** The moral precepts against these markets operate against them and are modified over time, since the maintaining cost, are too high given the benefit of the market.

### OR33.1

#### Decision Making Under Uncertainty: Coverage with Evidence Development in the Context of Medical Devices

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**Background:** Coverage with evidence development (CED) is increasingly being used to provide provisional coverage for promising, but unproven, interventions, while additional data are generated.

**Objectives:** This study aimed to explore the application of CED across different jurisdictions and in the context of medical devices.

**Methods:** First, a literature review was conducted on international CED schemes and the CED approach more generally. In total, 50 articles were gathered and reviewed. Second, semi-structured telephone interviews were conducted with different expert groups (payers/HTA bodies, industry, and academics/policy analysts) to better understand the use of CED in seven jurisdictions; identify device CED cases studies; and, gather expert opinion on the challenges associated with the CED approach and potential strategies to improve current policy and practice. A total of 27 experts were invited to participate, of which 21 (81%) agreed and were interviewed.

**Results:** Canada, Switzerland, the UK, and US have the most experience with CED, especially applied to devices; Germany and the Netherlands have both recently introduced new policies for devices and procedures. Devices that have undergone CED in the jurisdictions studied include ICDs, stents, TAVI, laparoscopic surgery, total disc replacement, and spinal cord stimulators. While there are distinct differences in the national approaches to CED, common challenges were identified: 1) establishing a clear framework for initiating, overseeing, and stopping CED studies, 2) identifying and applying appropriate study methods, 3) funding studies, 4) incentivizing studies, and 5) applying new evidence to inform coverage decisions.

**Conclusions:** Devices are viable candidates for CED, given some of their unique characteristics and often uncertain evidence base at the time of coverage determination. However, improvements are needed,

including enhanced clarity and predictability of CED selection criteria and processes, greater stakeholder collaboration, new models to fund studies, better incentives to engage physicians, and strengthened requirements for use of evidence in coverage policies.

### OR33.2

#### Use of Health Technology Assessment in Decision-Making Processes by the Brazilian Ministry of Health on the Incorporation of Technologies in the Brazilian Unified National Health System - 2008 to 2010

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**Background:** Health technology assessment (HTA) for decisions on coverage and financing is studied in various countries. In Brazil, structured processes for the assessment and decision-making are recent.

**Objectives:** To analyze the performance of the Department of Science and Technology (DECIT) within the Commission on Technology Incorporation of the Ministry of Health (CITEC) in analyzing and making decisions on incorporating technologies into the Public Health System (SUS) from 2008 to 2010.

**Methods:** Methods: A descriptive study based on the analysis of documents and official records and development of a new record based on the literature reviewed.

**Results:** DECIT analyzed 70% of the technologies planned by CITEC from 2008 to 2010, 82% had a therapeutic purpose. There was a gradual growth in studies by DECIT and the Brazilian Network for Health Technology Assessment (REBRATS). Conclusions: The role of DECIT was essential for the CITEC and the participation of the REBRATS contributed to independence of the assessments. The proposal for a registry of the assessments will contribute to monitor impacts.

**Conclusions:** The role of DECIT was essential for the CITEC and the participation of the REBRATS contributed to independence of the assessments. The proposal for a registry of the assessments will contribute to monitor impacts.

### OR33.3

#### Judicialization and Evidence-Based Assessment

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**Background:** In assessing health technologies for further recommendation for Public Health coverage, Health Technology Assessment (HTA) agencies consider the best available scientific evidence and cost-utility, centred on the patient. Many countries' Constitution includes total access to these health technologies as a human right, an argument commonly used in litigation to obtain total reimbursement.

**Objectives:** To compare the outcome of writs of protection demanding access to total health care coverage in Uruguay to the recommendations from international HTA agencies.

**Methods:** A search was performed of the results of writs of protection demanding full financial coverage by the Ministry of Health of Uruguay, comparing them with HTA decisions of two prestigious international HTA agencies (Institut National d'Excellence en Sante et en Service Sociaux [INESSS] and National Institute of Care and Health Excellence [NICE]).

**Results:** From the 19 health technologies for which the Uruguayan legal system has asked for and has obtained individual patient coverage from the Ministry of Health (e.g. for oncology [bevacizumab, crizotinib, pazopanib, pazopanib hydrochloride, sorafenib, rituximab];



copaxone for multiple sclerosis; rituximab for chronic ulcerative colitis and for Wegener's granulomatosis; etc), 10 (53%) technologies have been considered not viable according to INESSS, while 8 (42%) have not being recommended by NICE. The national health reimbursement system falls behind major International HTA agencies, despite having the national HTA infrastructure in place.

**Conclusions:** These results indicate that there is a large disparity between the judicial and the evidence-based approach. There is need to understand and differentiate the concept of health in the present health system framework. New strategies that allow for an overall inclusion of all factors that lead to the present misinterpretation are necessary to reach a dialogue and a further agreement between systems.

### OR33.4

#### Quantification of Health by Scaling Similarity Judgments

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**Background:** Comprehensive and generic health-related quality of life measures have been designed to capture an individual's health status in a single index or weight.

**Objectives:** The current study introduces a novel method based on similarity responses to derive health-state values. It could be well suited to overcome the problems that are encountered with methodologies such as standard gamble, time trade-off, and discrete choice experiments.

**Methods:** Three samples of approximately 500 respondents were recruited via an online survey. Each sample received a different judgmental task in which similarity data were elicited for the top seven health states in the quality of life instrument (DQI). These states were '111111' (no problems on any domain) and six others with some problems (level 2) on one domain. The tasks presented two (dyads), three (triads), or four (quads) DQI health states. Similarity data were transformed into interval-level scales with metric and non-metric multidimensional scaling algorithms. The three response tasks were assessed for their feasibility and comprehension.

**Results:** In total 532, 469, and 509 respondents participated in the dyads, triads, and quads tasks respectively. In all three response tasks, the best health state '111111' was positioned at one end of the health-state continuum and state '111211' was positioned at the other. The correlation between the metric scales ranged from 0.73 to 0.95, while the non-metric scales ranged from 0.76 to 1.00, indicating strong to near perfect associations. There were no apparent differences in the reported difficulty of the response tasks, but the triads had the highest number of drop-outs.

**Conclusions:** Multidimensional scaling proved to be a feasible method to scale health-state similarity data. The dyads and the quads response tasks warrant further investigation, as these tasks provided the best indications of respondent comprehension. Suggestions to apply this method to obtain values for the entire health-state continuum are provided.

### OR33.5

#### High Performance in Priority Setting and Resource Allocation

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**Background:** Priority setting (PS) is a key function in the healthcare system--yet there is limited research as to how decision-makers attempt to achieve high performance in this sphere. HTAs consider whether or not to adopt new technologies but seldom consider these in relation to opportunity cost or in a larger contextual framework.

**Objectives:** Our aims were to develop a framework defining high performance in PS and operationalize it in an evaluative tool; these will support senior leadership teams in making critical healthcare management, decisions, including all forms of HTA.

**Methods:** In phase one, we conducted an on-line survey with senior healthcare decision-makers across Canada. The survey inquired about structures, processes and behaviours related to organization-wide PS. Decision-making rules & criteria, enablers & constraints, and internal and external communications were among topics addressed.

In phase two, case studies of six healthcare organizations from different regions allowed for in-depth investigation of PS practice. Interviews were conducted with senior and middle managers, and Board members. Qualitative data were analyzed iteratively in the context of empirical examples of PS practice from the literature. This provided cross-case learnings about features which facilitate high performance.

**Results:** The findings of the first 2 phases were synthesized in a framework defining high performance in PS: it consists of four domains--structures, processes, attitudes & behaviours, and outcomes--within which are 19 specific elements. We operationalized each element in a series of questions to be posed of executive and clinical leaders. Their answers identify strengths and weaknesses of an organization's PS efforts. We successfully piloted the tool with 2 Canadian health organizations.

**Conclusions:** Our presentation shows this framework and tool to be rooted in the current literature, validated by examination of case study organizations, and confirmed in pilot tests to generate meaningful information for performance enhancement in respect of HTA and other health resource decisions.

### OR33.6

#### Prioritizing Topics for HTA in the Republic of the Kazakhstan

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**Background:** HTA in the Republic of Kazakhstan (RK) was developed in conjunction with training organized by the Canadian Society for International Health (CSIH). This led to an initial 5 assessment reports on topics proposed by the Ministry of Health (MOH). There was then a need to determine future directions to be taken by the HTA program.

**Objectives:** To develop criteria for prioritization of HTA topics in RK

**Methods:** Initial proposals for criteria were suggested through consultation with relevant MoH policy areas. These were refined through a training course organized with the support of CSIH and MoH and attended by the faculty of the medical schools and research institutes. This included discussion on methods and criteria used in international HTA practice.

**Results:** Initial criteria, which informed preparation of a further 3 HTA reports, included expensive technologies, those with low or non-regulated effectiveness, low cost technologies intended for small numbers of patients, and technologies for which there were significant ethical aspects. Further criteria, emerging from discussion at the training, decided to include the treatments alternative technology, clinical influence, budget impact in a context of Kazakhstan, burden of a disease and the ethical, legal and/or psychosocial aspects.

**Conclusions:** Criteria for prioritization have evolved with development of the HTA program in RK. It is expected that the criteria developed in collaboration with the group at the training will make the process in prioritizing topics for HTA open and transparent, and at the same time identification and selection of the theme of the technology investment will be adequate.

### OR34.1

#### University Hospital in the Context of Financial Restrictions

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**Background:** The Uruguayan Integrated National Health System, created in 2007, introduced new policies to promote the rational use of health technologies. A National Drug Formulary (NDF) and a National Procedure Formulary (NPF) have been established so that all health services must provide them.

Uruguay since 1980, founded the National Resources Fund (NRF) that is in charge to provide financial to those technologies defined as "high specialized technologies"

Moreover, the University Hospital provides technologies not included in the formularies mentioned above (i.e. not financed by the NFR), led by academic objectives. Growing financial restrictions are posing a priority dilemma in this public educational organization.

**Objectives:** To describe all the procedures included in the mandatory NPF and the additional procedures provided by the hospital that are not in the formulary.

**Methods:** chiefs of clinical services were interviewed during 2013 to analyse the list of procedures that every service is providing at present. A member of the manager team of the hospital interviewed each chief to revise each diagnostic and therapeutic procedure that are at present being provided in the service.

**Results:** 22 interviews were carry out and the approximately 5.097 procedures of the NPF were revised and other technologies were identified in many services. Some of the high technologies out of the NPF were: reno-pancreatic tansplantation, epilepsy surgery, endovascular treatment of abdominal aortic aneurysm, endovascular intracranial repair and gastrointestinal endoscopic imaging capsule.

**Conclusions:** the study showed that the hospital provides 87% list of NPF and add other complex technologies. Chiefs of clinical services are suggesting incorporation of many technologies based in academic purposes, but growing financial restrictions poses a dilemma for the authorities of the hospital. The manager team is envisaging to establish a mechanism of priority setting based in HTA.

### OR34.2

#### How Local HTA Support Decision Making: Experience from the CHU De Québec

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**Background:** Local/hospital-based health technology assessment (HB-HTA) is an emerging approach in many countries. There is a grow-

ing awareness that local context needs to be taken into account to implement value-added health technologies or disinvest in obsolete or ineffective technologies. Questions remain about the usefulness of HB-HTA in local decision making.

**Objectives:** To evaluate the influence of HB-HTA to support evidence-based decision making and change current clinical practices in a major university hospital center of Québec city.

**Methods:** HTA reports published since the year of implementation of the HB-HTA unit (2006) was retrieved to look at the follow-up of the recommendations. A questionnaire to assess the level of satisfaction about HTA process was also sent to the applicants. The main topics included: 1) timeliness (completion time), 2) utility for decision-making, 3) utility for knowledge transfer to improve clinical practice and 4) involvement of stakeholders throughout the HTA process.

**Results:** CHU de Québec is a major teaching hospital with 1755 beds, 14 000 nurses and hospital staff, 1700 physicians and 500 researchers. Until December 2013, 40 HTA reports have been published including full reports (n=14), informative notes (n=4), rapid reviews (n=15) and updates (n=7). A total of 26 reports included recommendations about introducing new health technology, withdrawing or maintaining medical practice or health technology. Recommendations have been implemented in 73 % of cases. The response rate to the satisfaction questionnaire was 62 %. Applicants strongly agree (76 %) or agree (24 %) with the HTA process and services (preliminary results).

**Conclusions:** The experience from the CHU the Québec has successfully demonstrated the value of HB-HTA process to support evidence-based decision-making at the local level. We have learned from this experience that credibility is an essential factor. Also, a strong link with both the top management and the field throughout the process is important.

### OR34.3

#### Who Should Receive Vocationally Oriented Multidisciplinary Intervention for Work Ability?

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1. The Social Insurance Institution in Finland, Helsinki, Finland; 2. Summaryx, Helsinki, Finland

**Background:** Vocationally oriented multidisciplinary intervention is offered in Finland for employed people with mild symptoms but no long-lasting disabling or severe diseases, with the emphasis to maintain and improve work ability. Each year the Social Insurance Institution of Finland uses 45 million USD for this activity, in a country with 5.4 million inhabitants. The effectiveness of the intervention has been questioned lately and the major criticism is whether the selection of participants is correct.

**Objectives:** To examine to whom should preventive work ability focused interventions be targeted.

**Methods:** A systematic review of literature to answer following questions: 1) Which factors predict reduced work ability, 2) What kind of screening tools are available, 3) What are the best means to approach people, 4) What are the personal or work related factors which predict the ability to benefit from preventive interventions in general 5) or of certain type?

**Results:** Factors that strongest predict reduced work ability are: physical and shift work, reduced control over work, perceived injustice or bullying, low level of education and income, previous sick leaves, stress at work, chronic diseases, multisite pain, use of medications, sleeping problems, and general dissatisfaction and worry. There are several instruments to screen psychosocial conditions at work but fewer for pain, attitudes or perceptions. Mobile solutions for screening at construction sites and tailored email-counseling for older workers were successful solutions, but evidence was scarce.

**Conclusions:** If high risk of work ability reduction is considered a relevant criterion to attend the intervention, our results imply changes to the current system in Finland. Screening instruments should be revised to better identify the individuals with any of the identified risk factors. More information is needed of how to best approach and motivate individuals at risk.

#### OR34.4

##### Five Years of the Brazilian Network for Health Technology Assessment (REBRATS)

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**Background:** The Brazilian Network for Health Technology Assessment (REBRATS) was launched by the Ministry of Health in August 2008, being one of the tools of the institutionalization of Health Technology Assessment in Health System, which began in 2000 with the creation of Department of Science and Technology. The Health Technology are all medicines, equipment, organizational systems, protocols and welfare programs, technical, educational and informational procedures used in health, with the Technology Assessment in Health an ongoing process of analysis and synthesis of these benefits, for through which they evaluated their social, clinical and economic impacts with well-defined techniques.

**Objectives:** The aim of this study is to evaluate the composition and production of the Brazilian Network for Technology Assessment in Health since its inception in August 2008 until December 2013,

**Methods:** The methodology used is the evaluative research with strategic analysis, logical and efficient production

**Results:** The network has 64 members from different types of institutions, qua form six working groups responsible for the activities of creation and revision of methodologies to be used by managers to the ATS. The notices are posted periodically to promote funding for health research, with thematic focused on Technology Assessment in Health where these studies are incorporated into the Information System, which has more than 300 studies of Systematic Review, Economic Evaluation, Technical Opinion scientific Studies in Management of Technology Assessment in Health among others.

**Conclusions:** The REBRATS have with their growth in number of members increased its scientific and its production gradually becoming a tool for the manager when making the decision to incorporate a Health Technology in Health System, creating a culture of evidence Science, reducing the risk of medical errors to users.

#### OR34.5

##### Occupational Physical Activity and Economic Losses Due to Absenteeism: Case of Brazilian Public Healthcare System

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**Background:** Physical activity is a behavioral variable, which is divided into different domains. Leisure-time physical activity is commonly related to better health, while the occupational domain has been related to a large variety of diseases, but it is still unclear the burden over economic variables, such as absenteeism.

**Objectives:** To analyze the relationship between economic losses related to absenteeism and occupational physical activity among people attended by Brazilian Public Healthcare System.

**Methods:** The sample was composed by patients of the Brazilian Public Healthcare System, which were interviewed during 2013 in basic healthcare units. Occupational activity was measured through Baecke's questionnaire. Occurrence and number of absenteeism events in the last 12 months were assessed through face-to-face interviews. Economic losses were estimated using the number of absenteeism events and monthly income. Statistical analysis was composed of Spearman rank correlation ( $\rho$ ) due to non-parametric distribution of several variables. Statistical significance was set at  $p$ -value  $<5\%$ .

**Results:** The sample was composed of 353 adults of both sexes (83 men and 270 women) and age ranging from 45 to 64 years old. Occupational physical activity was positively related to absenteeism during 12 months ( $\rho=0.17$ ;  $p$ -value=0.002) and economic losses related to absenteeism ( $\rho=0.16$ ;  $p$ -value=0.002). Occupational activity and monthly income were not significantly related ( $p$ -value  $>5\%$ ).

**Conclusions:** In summary, higher physical effort in occupational physical activity was related to increased economic losses among patients of the Brazilian Public Healthcare System.

#### OR34.6

##### Bariatric Surgery Access Across Global Markets: are Clinical Guidelines and HTA Requirements Aligned?

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**Background:** Health technology assessments (HTA) of bariatric surgery have often employed divergent evidence strategies to make their decisions.

**Objectives:** The objectives of this study were to:

- 1) Identify evidence criteria that impact HTA decisions,
- 2) Characterize similarities and differences between clinical guidelines and HTA recommendations, and finally
- 3) Assess potential barriers to bariatric surgery adoption globally.

**Methods:** A multi-country review was conducted of bariatric surgery clinical guidelines and HTAs published from 2008-2013 from 12 countries, representing major markets in the Americas, Europe, and Asia-Pac. Bariatric surgery procedures included gastric banding, gastric bypass, and sleeve gastrectomy. Practices recommended by clinical guidelines were assessed for their alignment with evidence requirements of HTAs.

**Results:** Bariatric surgery was typically recommended as a third-line treatment for patients with  $BMI \geq 40$  kg/m<sup>2</sup> and for those with BMI in the 35-40 kg/m<sup>2</sup> range and one or more weight-related co-morbidity, however currently not recommended for treating diabetes in patients with  $BMI \leq 35$  kg/m<sup>2</sup>. In Asia, it was recommended that those BMI thresholds be lowered by 2.5 kg/m<sup>2</sup>, even as HTAs in this region continue to evolve. Overall, HTAs primarily evaluated: 1) Survival, 2) Economic impact, 3) Weight loss, 4) Time to remission of weight-related co-morbidities, and 5) Safety. Both HTAs and clinical guidelines recommended an integral approach including patient participation in decision-making, pre- and post- treatment.

**Conclusions:** HTAs largely aligned with available clinical guidelines in terms of evidence requirements. Currently, bariatric surgery is highly recommended for a limited subset of obese patients, with a growing realization about benefits on weight-related health comorbidities. Most importantly, increasing need for long-term treatment efficacy and remissions indicates a shift away from acute weight loss to emphasis on long-term health benefits. Optimal market access strategies for bariatric surgery rely on characterizing longer-term health and economic impact and communicating those to the stakeholders and importantly, patients.

**OR35.1****Cost-Effectiveness of a Hpv-Vaccination Catch-Up Program for Females Up to 26 Years Old in a Norwegian Setting**

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**Background:** The current Norwegian, publicly-funded, human papillomavirus (HPV) vaccination program covers the expenses of vaccinating 12-year-old girls with the quadrivalent vaccine. Several EU-countries have implemented catch-up vaccination programs for older females.

**Objectives:** To evaluate the cost-effectiveness of expanding the Norwegian HPV vaccination program to include females aged 26 or younger, born 1989-1996.

**Methods:** We adapted a published economic model to the Norwegian setting with respect to incidence rates of HPV-related outcomes, costs and health-related quality-of-life (HRQoL). We also incorporated our published vaccine effect estimates and made the model probabilistic. We performed analyses from both public health budget and societal perspectives, assuming coverage rates of 31% and a price equal to the current public price per dose of \$172 (\$1=NOK5.8768). We calculated Incremental Cost-Effectiveness Ratios (ICER) in NOK/Quality-adjusted Life Year (QALY) gained and compared the result to a reference value of \$103,500/QALY.

We examined the uncertainty in our base case results and conducted Value-of-Information analysis by estimating the Expected Value of Perfect Information. We investigated several scenarios using vaccine prices below the public price and excluding the effect on genital warts.

**Results:** Our initial results indicate that from a public health budget perspective, expanding the vaccination program led to higher costs and health gains and an ICER=96000\$. From a societal perspective, the incremental costs were lower than from a public budget perspective, resulting in an ICER=47423\$.

Value-of-Information analysis indicated a non-negligible probability that expanding the vaccination program was more costly and less effective than maintaining the current practice.

For prices below \$172/dose, the ICER from the public budget perspective was well below the reference value. When excluding the vaccine effect against genital warts, the ICER was above the reference value.

**Conclusions:** Expanding the HPV-vaccination program to females aged 26 or younger, born 1989-1996 appears to be cost-effective for prices below \$172/dose of the quadrivalent vaccine.

**OR35.2****Quadrivalent HPV Vaccine in Argentina: Cost-Effectiveness Analysis**

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**Background:** The quadrivalent human papillomavirus (HPV) vaccine has been shown to be effective to prevent cervical cancer, cervical intraepithelial neoplasia (CIN) and also genital warts.

**Objectives:** To assess the cost-effectiveness of the introduction of the quadrivalent HPV vaccine in Argentina.

**Methods:** Using a transmission dynamic model developed and published by Elbasha in 2008 we evaluated the routine vaccination of

11-year-old girls over a time horizon of 100 years from the perspective of the health care system.

**Results:** The model showed that the introduction of the vaccine will gradually reduce the incidence of cervical cancer, CIN 1/2/3, and genital warts related to HPV 6/11/16/18.

When compared with non-vaccination, a women who completed the three dose scheme will experience a reduction of cervical cancer incidence and death, CIN2/3, CIN1 and genital warts of 58,6%, 59,2%, 56,7%, 56,3% and 67,3% respectively.

Considering a 5% discount rate and a 43.8% of complete scheme coverage without herd immunity, the incremental cost-effectiveness ratio (ICER) was 795 USD per quality-adjusted life-year (QALY) gained.

The additional protection against HPV types 6/11 has a great influence in the cost-effectiveness, the ICER was almost doubled when not contemplated the protection against HPV 6/11.

The most influential parameters on the scenario analysis were the discount rate, the cost of the vaccine and the cost of treatment. However, the vaccine was very cost-effective (less than one gross domestic product=7844 USD) in all the tested scenarios.

**Conclusions:** The implementation of routine HPV vaccination with the quadrivalent vaccine in 11-year-old girls in Argentina could provide significant benefits to public health by reducing cervical cancer incidence and death rates and the incidence of CIN 1/2/3 and genital warts, making it a highly cost-effective intervention.

**OR35.3****Immunochemical Fecal Occult Blood Testing: Determination of an Effective Cut-Off Value for Quebec's Colorectal Cancer Screening Program when the Colonoscopy Capacity is Limited**

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**Background:** Colorectal cancer (CRC) screening by colonoscopy is highly sensitive but resource intensive. Guaiac fecal occult blood test (gFOBT) combined with colonoscopy significantly reduces CRC-related mortality. However, the low uptake rate of the gFOBT and its limited sensitivity for CRC reduces the expected gain in mortality. Auto-mated immunochemical faecal occult blood testing (iFOBT) provides quantitative results allowing optimisation of positivity for follow-up colonoscopy.

**Objectives:** To propose a positivity cut-off for the iFOBT in the testing phase of the Quebec's colorectal cancer screening program (PQDCCR). The PQDCCR screening strategy targets average risk individuals aged between 50 and 74 years old for a biennial one sample iFOBT.

**Methods:** Papers that examine the use of a quantitative iFOBT at various positivity thresholds were retrieved in electronic databases and grey literature. All studies that used a device approved in Canada to screen for CRC in average risk people were included. Our primary outcome was diagnostic accuracy for colorectal neoplasms compared to gFOBT.

**Results:** iFOBT detects twice more CRC than gFOBT at any cut-off value. However, the comparison of performance at intermediate thresholds is compromised by sample size and the low number of CRCs detected in average-risk populations. Compared to 100 ng/ml, as recommended by manufacturers, increasing to 175 ng/ml would reduce the use of colonoscopy by 25% without affecting the sensitivity for CRCs. Using a cut-off lower than 175 ng/ml is liable to reduce the positive predictive value for CRC and may lead to a higher number needed to scope to detect one CRC when compared to gFOBT.

**Conclusions:** To limit false-positive results without affecting CRC sensitivity, a biennial one fecal sample iFOBT at a 175 ng/ml positivity threshold is the most effective CRC screening strategy for the testing phase of the PQDCCR.

## OR35.4

### The Strategies to the HPV Vaccine Implementation in Brazil

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**Background:** During the last years, Brazilian Ministry of Health was discussing about the HPV vaccine implementation as an additional technology to reduce cervical cancer mortality.

**Objectives:** To present strategies to the vaccine HPV implementation in Brazil.

**Methods:** A technical group in the Ministry of Health was created to analyze the incorporation of HPV vaccine in the immunization schedule, and a cost-effectiveness study was funded. The expert opinion and the cost-effectiveness study were submitted to National Committee of Health Technology Incorporation (CONITEC) that decided in favour of tetravalent vaccine. This committee decides about technologies that must be incorporated to or reimbursed by the Brazilian public health system.

**Results:** The results of the cost-effectiveness study were favorable to the incorporation of the vaccine, only on girls, age group 9-13 years. To enable the incorporation several strategies have been designed: 1. Implementation Strategy – the vaccination strategy will be mixed, in health units and in schools. 2. Vaccinating scheme - after the first dose, the second must occur within six months, and the third, five years after the first dose; 3. Communication Strategy - need to inform about the continuity the preventive test and condom use during the intercourse; 4. Sustainability Strategy – it was realized a technologic transfer agreement for the national vaccine production joining Merck and Instituto Butantã; 5. Price - less than \$15.00 a dose; 6. Monitoring Strategy – need to monitor the effectiveness and safety of the vaccinated population.

**Conclusions:** The vaccination will be started from March, 2014. The implementation will be gradual. In 2014, the HPV vaccination target population will consist of female adolescents aged 11-13 years, in 2015, adolescents aged 9-11 years, and in 2016 girls aged 9 years.

Only on the first year of vaccination will be offered 15 million doses, which is a big challenge for Brazil.

## OR35.5

### Cost Effectiveness Analysis of a Vaccine to Prevent Herpes Zoster and Postherpetic Neuralgia in Italy

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**Background:** Herpes zoster (HZ) is characterized by a painful skin rash. Its main complication is postherpetic neuralgia (PHN), a nerve pain due to damage caused by the zoster virus, which can last a few years. HZ treatment aims to reduce acute pain, impede the onset complications and reduce the risk of progression to postherpetic neuralgia. In Italy, the incidence of HZ is less than 0.05%. Estimates from other European countries range between 2.0 and 4.6%.

**Objectives:** The aim of this study was to assess the cost-effectiveness of HZ vaccination compared to an alternative protocol which only involves the treatment of patients affected by HZ, within the Italian context.

**Methods:** The natural history of HZ and PHN was mapped through a Markov model with lifetime horizon and cycles lasting one month. Both third party payer (the Italian National Health Service) and societal perspectives were adopted. Costs and Effectiveness data was derived from literature and discounted by 3.5%. Model results are expressed in terms of incremental cost-effectiveness ratio (ICER). Both deterministic

and probabilistic sensitivity analyses were performed to appraise the effect of parameters' variation on model results.

**Results:** A population of patients with HZ aged between 60 and 79 years was hypothesized. The ICER of the vaccination equaled € 12,155 per QALY under the NHS perspective and € 11,118 per QALY under the societal perspective. Moreover, under NHS perspective the cost per HZ-episode avoided and the cost per PHN-episode avoided amounted to € 1,098 and € 8,742 respectively. Considering a cost-effectiveness threshold of €30,000/QALY, vaccination was cost-effective regardless of the perspective adopted, in 99% of scenarios.

**Conclusions:** Results showed that a vaccination program against herpes zoster and post-herpetic neuralgia is cost-effective in Italian patients aged between 60 and 79 years.

## OR35.6

### Economic Impact of Alberta's PCV7 Childhood Immunization Program (2003-2008)

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**Background:** Acute respiratory tract infections caused by *Streptococcus pneumoniae* (SP) are a leading cause of morbidity and mortality in young children and the elderly. In 2002, Alberta introduced a pneumococcal universal immunization program for children, using Pfizer's Prevnar 7 (PCV7).

**Objectives:** In this study, we assess the economic impact of PCV7 on the Alberta health care system.

**Methods:** Using active surveillance data from Alberta, we examine the net costs averted as a result of a decline in PCV7 serotypes, accounting for the increase in costs due to serotype replacement. We also calculate the magnitude of positive externalities (herd immunity) in terms of costs averted.

**Results:** We find that following the introduction of PCV7 (2003-2008), the number of cases of invasive disease caused by vaccine serotypes declined significantly across all ages. Specifically, by 2008, there was considerable evidence of herd immunity as the incidence rates had declined nearly 100% across all ages. However, non-PCV7 cases, on the other hand, increased. Assuming serotype replacement is a result of the introduction of PCV7, net costs averted are in the range of \$5 million as a result of the implementation of PCV7 universal vaccination in Alberta. Over the time period, direct protection resulted in net cost savings of \$2.6 million, and indirect benefits \$2.4 million; the indirect benefits derived by elderly populations were more than one third of the total benefits derived across the population.

**Conclusions:** This study is unique in that it uses validated surveillance data from the Province of Alberta to retrospectively assess the economic benefit of a public health policy, and describes the distribution of benefits across different segments of the population. From 2003 to 2008, the cumulative cost impact of introducing PCV7 in the childhood immunization program to the Alberta health system is approximately \$5 million, half of which were a result of herd immunity.

**OR36.1****Systematic Critical Review of Economic Evaluations of the Elimination of *H. pylori* for Gastric Cancer Prevention**Arianna Waye<sup>1,2</sup> Karen Goodman<sup>1</sup> Philip Jacobs<sup>1,2</sup>

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**Background:** Chronic *H. pylori* infection causes gastric cancer, a cancer responsible for a large global disease burden. Evidence suggests that elimination of *H. pylori* may reduce the frequency of gastric cancer, but prevention strategies based on this approach have not been adopted by health care systems due to uncertainties regarding the feasibility and cost-effectiveness of specific infection control strategies.

**Objectives:** This review summarizes existing information of relevance to establishing cost-effective international guidelines for the elimination of *H. pylori* infection as a cancer prevention strategy.

**Methods:** Comprehensive systematic electronic searches of electronic databases were conducted through September, 2013. Studies examining the cost-effectiveness of *H. pylori* elimination as a means of reducing gastric cancer incidence were considered in this review. Data extraction included: country, perspective, target population, screening instrument, prevalence of *H. pylori*, costs and health outcomes, and ICER. The methodological quality of studies was appraised using the Quality of Health Economics Studies (QHES) instrument. A narrative synthesis approach was used to summarize the evidence.

**Results:** Over 1743 titles and abstracts were screened, with 45 full-text articles reviewed for eligibility. The fifteen studies included conclude that elimination strategies were cost-effective under a subset of conditions considered, or that conclusions regarding cost-effectiveness could not be drawn without better data. Study findings conflict on the specific factors that determine when it is cost-effective to screen and treat, especially in terms of the target population. Furthermore, current practice, costs, and the distribution of disease and relevant population characteristics introduce uncertainty regarding the validity of transferring findings from one jurisdiction to another.

**Conclusions:** At present, it does not appear possible to generate a cost-effective international guideline for screening practices for *H. pylori* infection aimed at cancer prevention. This study furthers current discussions concerning the transferability of findings derived from cost-effectiveness studies across jurisdictions. To inform cost-effective international guidelines, a new methodological approach is necessary.

**OR36.2****Diagnosing Carpal Tunnel Syndrome with Hand-Held Nerve Conduction Device**Marjukka Mäkelä<sup>1</sup> Ulla Saalasti-Koskinen<sup>1</sup> Iris Pasternack<sup>1</sup> Jaana Isojärvi<sup>1</sup> Eero Waris<sup>2</sup>

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**Background:** Carpal tunnel syndrome (CTS) is a common neuropathy (prevalence 1-3,5%). Nerve conduction studies with electroneuro-myography (ENMG) are important in diagnosing CTS. Hand-held nerve conduction devices can provide a new point-of-care (POC) diagnostic method for CTS in primary care, as individuals without formal neuro-physiological training can confirm the diagnosis of CTS using these devices. Some devices measure sensory nerve conduction delay only, some also motor nerve delay.

**Objectives:** For reimbursement decisions, information of the accuracy, cost and added value (e.g. easier patient and work flow) of hand-held nerve conduction devices was requested. These devices were spreading rapidly to use in private health clinics in Finland.

**Methods:** EUnetHTA Core Model was used for structuring the report: relevant research questions were selected from the model. A systematic literature review was done partly jointly with the French HTA Agency (HAS). The practical diagnostic process was mapped by questionnaires to health care units.

**Results:** Only three accuracy studies with sufficient quality were found, showing a sensitivity of 85-94% and specificity of 84-85%. All studies showed good correlation between hand-held nerve conduction device and ENMG (Pearson Correlation Coefficient 0.87-0.94). The problem is a lack of consensus on the reliability of ENMG as a gold standard for CTS diagnosis. ENMG also identifies diseases that the POC device can't find. Usually, before surgery, ENMG is anyway needed. The advantages of POC devices are easy accessibility with no queues and lower costs.

**Conclusions:** The role of hand-held nerve conduction devices in diagnosing carpal tunnel syndrome is unclear and better studies are needed. The prognostic power of any nerve conduction test for selecting correct patients for hand surgery is not well established.

**OR36.3****Assessing the Value of a Comprehensive Model of Care for the Treatment of Hemophilia A in Colombia**Rafael Alfonso-Cristancho<sup>1</sup> Oscar Diaz-Sotelo<sup>2</sup> Diana Tellez<sup>3</sup> Adriana Linares<sup>4</sup> Luz Andrea Ramirez<sup>3</sup>

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**Background:** Patients with inherited factor VIII deficiency (Hemophilia-A) require life-long care as soon as the diagnosis is made, preferably through a Comprehensive Model of Care (CMC). Although there is evidence suggesting better outcomes through CMC the return of investment (ROI) in the short and long-term is unknown.

**Objectives:** Our aim is to assess the effectiveness of a CMC required to demonstrate value compared to patients outside of this model from the perspective of the Colombian Health care system.

**Methods:** A systematic review (SR) defined the CMC components. Standard practice (SP) followed international guidelines. An integrated Markov model simulated health states associated with Hemophilia A in adults and compared the costs of CMC versus SP. Patients transitioned every cycle from a controlled state without bleeding to bleeding or death. Patients alive at each cycle could enter into independent sub-models simulating development of inhibitors, arthropathies and surgery. All patients received recombinant third generation Factor VIII and bypassing agent if inhibitors were developed. Transition probabilities and inputs were extracted from the literature and validated by experts. Costs were calculated from databases from the Ministry of Health and 3 health institutions. Time horizon was 10 years.

**Results:** CMC components, informed by the SR, included individual risk profiling, educational and self-awareness components, and a network of healthcare professionals coordinated by a case manager. The annual difference in cost per patient was USD\$180 higher in the proposed CMC compared to usual practice. Sensitivity analysis revealed that the costs of Factor VIII and major bleeding complications were driving the results of the model. To offset these additional costs patients in the CMC should have 12 fewer bleeding events per year per 100 patients.

**Conclusions:** A CMC for Hemophilia-A in Colombia could lead to savings to the healthcare system in the short and long term with a moderate reduction of major bleeding events.

**OR36.4****Accuracy of a Dengue Immunochromatographic Strip Test in a Predominant DENV 4 Setting**

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**Background:** Dengue is endemic in Rio de Janeiro, and early diagnosis is important for decision-making and timely implementation of preventive measures. In 2010, dengue virus type 4 (DENV-4) was reintroduced in the country, and in 2011 in Rio de Janeiro. NS1 capture assays have been used for the early diagnosis of dengue infections since 2008; however its performance on DENV-4 cases was never fully accessed.

**Objectives:** To evaluate the accuracy of the NS1 Bioeasy® immunochromatographic strip test during a DENV-4 epidemic.

**Methods:** A cross sectional study was conducted during the 2013 epidemic season in Rio de Janeiro. Patients presenting an acute febrile illness within 72 hours were prospective and consecutively enrolled and evaluated according to the WHO 2009 classification (two or more of nausea/vomiting, rash, aches and pains, leukopenia). Sera were processed in the Laboratory of Flavivirus, FIOCRUZ using RT-PCR as reference. We analyzed sensitivity, specificity and likelihood ratios of NS1 Bioeasy® with and without the WHO 2009 criteria.

**Results:** RT-PCR for DENV-4 was positive in 149 out of 341 patients included. Positive likelihood ratio (+LR), sensitivity and specificity of NS1 Bioeasy® with and without WHO 2009 criteria were 14(CI-95% 6-32), 45%(CI-95% 37-58) and 97%(CI-95% 93-99) and 15 (CI-95% 6-37); 41% (CI-95% 33-50) and 97% (CI-95% 94-99), respectively.

**Conclusions:** Even though this test was fourteen times more likely to be positive in patients with dengue infection than in those with other febrile illness, the test failed in confirming almost a half of DENV-4 cases due to false negative results. This sensitivity was worse than that described in Asia for similar rapid test used in other three dengue serotypes. Immunochromatographic strip tests are rapid and convenient to use and does not involve special laboratory equipment, but are still not good enough due to the false negative results.

**OR36.5****Biochemical Characterization of a Sample of Brazilian Patients with Mucopolipidosis II / III and a Purpose of Diagnostic Protocol**

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**Background:** Mucopolipidosis (ML) II and III are rare lysosomal diseases secondary to GlcNac-phosphotransferase deficiency, leading to increased activity of lysosomal hydrolases in plasma, reduced in fibroblasts and normal in leukocytes. First step in diagnosis is having clinical suspicion; the definite involves identification of the deficiency in the GlcNac-fosfotransferase activity, available only in rare centers of research. Thus, the GlcNac activity is measured indirectly, by assessing many lysosomal enzymes in leukocytes, fibroblasts and plasma. However, there is no consensus to what enzymes should be investigated and a panel is randomly researched in different places, with weak evidence that give basis to this practice.

**Objectives:** Characterize lysosomal hydrolases activity in ML II/III, in order to propose a diagnostic protocol.

**Methods:** cross-sectional study, including patients with clinical and biochemical diagnosis of ML II or III. We analyzed enzymes investigated at least in 4 patients, measured in plasma and fibroblasts, electing to the protocol those enzymes with the largest differences from the reference values and lower costs. Mean difference in activities between ML II and III were compared using t test.

**Results:** 37 patients were included (type II= 24, III=13), all with lysosomal enzymes evaluated in plasma and 15 in fibroblasts. Among enzymes in plasma, there was a mean increased activity: alpha-mannosidase, alpha-L-iduronidase, alpha-N-acetylgalactosaminidase, alpha-N-acetylglucosaminidase, hexosaminidase, iduronate sulfatase, beta-glucuronidase; only chitotriosidase was normal. Among enzymes evaluated on fibroblasts, there was diminished activity: neuraminidase, alpha-L-iduronidase, alpha-mannosidase, beta-galactosidase, esfingomielinidase, beta-glucuronidase, hexosaminidase, iduronate sulfatase, alpha-N- acetylglucosaminidase; only beta-glucosidase was normal.

**Conclusions:** Our data suggests some differences in biochemical phenotype of ML II and III. Taking into consideration the cost of the enzyme assay, number of patients evaluated in our sample, the biggest difference of normal values and the possibility of performing the same test on different samples, the following were chosen: Arylsulfatase A, alpha-mannosidase, alpha-iduronidase, and Hexosaminidase.

**OR37.2****Cost-Effectiveness of Electroconvulsive Therapy Compared to Repetitive Transcranial Magnetic Stimulation for Treatment-Resistant Severe Depression: a Decision Model**

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**Background:** Electroconvulsive therapy (ECT) is widely applied to treat severe depression resistant to standard treatment. Other treatment alternatives have been introduced, including repetitive transcranial magnetic stimulation (rTMS), which is related to fewer side effects but some evidence suggests that is not as effective as ECT in the treatment of severe depression. Moreover, results from previous studies comparing the cost-effectiveness of these two techniques are conflicting.

**Objectives:** The aim of this study is to compare the clinical benefits and the costs of ECT versus rTMS for treatment-resistant severe depression based on all available information.

**Methods:** We conduct a cost-effectiveness analysis comparing ECT alone, rTMS alone and rTMS followed by ECT when rTMS fails under the perspective of the Spanish National Health Service. The analysis is based on a Markov model with a one-year time horizon which synthesises the evidence from a series of randomised controlled trials and other studies. We measure effectiveness using Quality-Adjusted Life Years (QALY) and characterise the uncertainty using probabilistic sensitivity analyses.

**Results:** ECT alone is found to be less costly and more effective than rTMS alone, while the strategy of providing rTMS followed by ECT when rTMS fails is the most expensive and effective option. The incremental cost per QALY gained of this latter strategy was found to be above the reference willingness to pay threshold used in these types

of studies in Spain and other countries. The probability that ECT alone is the most cost-effective alternative was estimated to be around 70% for a willingness to pay of 30,000 €/QALY.

**Conclusions:** ECT is likely to be the most cost-effective option for the care of treatment-resistant severe depression.

### OR37.3

#### The Cost-Effectiveness Analysis of a Social Market Delivery Programme of Long-Lasting Insecticidal Net (LLIN) to Control Malaria in Children Less Than Five Years in Nigeria; a Decision Analysis

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**Background:** Cost-effectiveness information on key malaria prevention strategies, such as LLIN delivery is limited in Nigeria, even though this provides essential evidence for planning and policy in the provision of malaria control services

**Objectives:** The study estimated the cost-effectiveness of a social market delivery model for LLIN, for the control of malaria in children less than five years, through private health facilities, as part of Global Fund for Malaria project in Enugu state, South East Nigeria

**Methods:** From a provider perspective, a spreadsheet model was used to estimate the economic costs and effects of the intervention on incremental basis. Effects were measured as malaria cases averted, deaths prevented and disability adjusted life years averted. Regional estimates were used to model malaria cases. Cost data were obtained from financial reviews and interview with key stakeholders. Univariate sensitivity analysis was used to test the robustness of study results

**Results:** Total financial cost of the programme was \$930,860 over a three year period, including the user contribution for net purchase. Economic costs averaged \$6.23 per LLIN delivered, taking into account saved treatment costs. Assuming 40% of shared costs with two other malaria projects, a total of 50,310 children were protected at the net costs of \$10.96 per malaria case averted, \$661 per death prevented and \$22.32 per DALY averted. Variations in coverage and transmission levels showed significant impacts on the cost-effectiveness results

**Conclusions:** Results demonstrated high cost-effectiveness of social market delivery model of LLIN as a key strategy in reducing malaria morbidity and mortality in sub-Saharan Africa (SSA), and greater efficiency gains are derived from joint delivery of the intervention with other healthcare programmes

### OR37.4

#### Rhythm Control Versus Rate Control for Atrial Fibrillation: a Comparison of Economic Costs

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**Background:** Rhythm control and rate control are two main treatments for atrial fibrillation. Various studies have been conducted to compare the merits of the two therapies, but have failed to reach an agreement on which one is dominant.

**Objectives:** An economic cost analysis on rhythm control vs. rate control was performed in order to provide references for therapy selection in the treatment of atrial fibrillation in China.

**Methods:** A prospective comparison of the two therapies was conducted among new patients with atrial fibrillation from 14 tertiary hospitals in 10 provinces in China from February to November 2010. During the study period, 2 follow-ups were conducted to collect data.

**Results:** 418 patients with full treatment records in the two follow-ups (166 in the rhythm-control group and 252 in the rate-control group) were enrolled in the study. A comparison of economic costs indicated that the difference in indirect costs was statistically significant (rhythm control vs. rate control = US \$ 45097.54 vs. US \$ 192567.04 by annual average wage of the work force, or US \$37322.10 vs. US \$15936.55 by GDP per capita,  $P < 0.05$ ) between the two therapies; but was not significant in direct costs (rhythm control vs. rate control = US \$204587.85 vs. US \$304471.26,  $P > 0.05$ ). In terms of annual per capita total costs, the rhythm-control group spent \$1504.13 per capita a year by annual average wage of the work force, and US \$1457.29 per capita a year by GDP per capita, while the rate-control group reached US \$1972.37 per capita a year and US \$1840.62 per capita a year.

**Conclusions:** The annual per capita cost of rhythm control was lower than that of rate control ( $p < 0.05$ ). Thus, in selecting treatments for atrial fibrillation, rhythm control may generate greater economic benefits than rate control, assuming an equal clinical and physiological status of patients.

### OR37.5

#### Comparison of Off-Pump and On-Pump Coronary Artery Bypass Graft (CABG) in Korea

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**Background:** The benefit of performing CABG with a beating-heart (off-pump CABG), as compared with cardiopulmonary bypass (on-pump CABG), are still undetermined.

**Objectives:** We aimed to compare Postoperative 30 days mortality, Postoperative Length of stay, Operation time among two groups.

**Methods:** We analyzed the Korea National Health Insurance claims data and the clinical data documented by hospitals of all patients received isolated CABG from July 2008 to June 2012. A total of 10,981 patients underwent isolated CABG in 82 hospitals.

We categorized patients into the two groups: group I (off pump CABG,  $n = 6,507$ ) and group II (on pump CABG,  $n = 4,474$ ).

Multiple logistic regression which was developed with the risk factors (Total 11 factors: age, sex, ejection fraction and etc.) was analyzed to evaluate the difference of post-op 30 days mortality.

The analysis between the duration from post-op to extubation and LOS used the multiple linear regression which was developed with the risk factors (Total 14 factors: age, sex, ejection fraction and etc.).

T-test was analyzed to evaluate the difference of operation time according to subgroups.

**Results:** Post-op 30 days mortality was significantly lower in group I as compared with group II (1.6% vs. 6.0%; Odds Ratio for the off pump CABG, 2.946; 95% confidence interval [CI], 2.306 to 3.764;  $p < .0001$ ).

Post-op LOS was significantly lower in group I as compared with group II (14.5 days vs. 20.0 days; parameter estimate for the off pump CABG, -0.29229;  $p < .0001$ ).

Operation time was shorter in group I as compared with group II (280min vs. 357min,  $p < .0001$ ). Similarly in a subgroup analysis, operation time for the group I was also reduced significantly in high-risk subgroups, including patients older than 75 years of age ( $p < .0001$ ), those with low ejection fraction ( $p < .0001$ ), those high serum creatinine ( $p < .0001$ ).

**Conclusions:** We were able to confirm the cost-effectiveness in off-pump CABG.

We will take into consideration not only the risk factors but also individual characteristics or skills of surgeon and need to confirm long-term mortality.



**OR37.6****An Empirical Study Comparing Health Technology Assessment Reports for Drugs versus Medical Devices in the Field of Cardiovascular Disease**

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**Background:** Health Technology Assessment (HTA) is increasingly used worldwide by policymakers to inform decisions about health technology coverage and reimbursement. However, the current HTA framework may not fully address the challenges presented by non-drug technologies, in particular the differences of medical devices relative to drugs (i.e. rapid changes overtime, clinical outcomes dependency on the training and experience of the operator, and dynamic pricing in contrast to drugs).

**Objectives:** To compare published HTA reports of drug and medical devices therapies for cardiovascular diseases.

**Methods:** sample of HTA reports will be selected from the University of York Centre for Review and Dissemination HTA database. Sampling will be undertaken to obtain an equivalent number of reports that consider drug and medical devices therapies matched on factors such as HTA agency, cardiovascular indication and year of publication. The contents of reports will be reviewed at four levels: (i) nature of evidence included (i.e. study design considered, quality of evidence), outcomes (e.g. use of surrogate endpoints) and scope; (ii) HTA methods applied by reports (e.g. systematic review, meta-analysis), consideration of device specific factors (e.g. learning curves, organizational impact, and incremental evolution); (iii) approaches and methods used to address uncertainty; (iv) magnitude of treatment effect and incremental cost-effectiveness.

**Results:** Data synthesis and presentation will primarily be descriptive and include detailed tabular comparisons between drug and device report for data from (i) to (iii). For (iv) we will seek to quantitatively synthesize treatment effects and cost-effectiveness ratios across reports in order to compare drugs and medical devices

**Conclusions:** We believe this to be the first empirical study to formally compare HTA reports of drugs and medical devices. The results of this study will provide important data to contribute to the current debate on adapting the HTA evaluation framework to meet the needs of non-drug technologies

**OR38.1****Efficacy, Cost-Effectiveness and Budget Impact: Temozolomide Plus Radiotherapy in Adjuvant Treatment of Patients with High-Grade Gliomas**

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**Background:** For more than three decades, postoperative radiotherapy has been standard treatment for newly diagnosed glioblastoma. Chemotherapy for patients with glioblastoma (GBM) has also become part of adjuvant treatment. Temozolomide has a Brazil marketing authorization for the treatment of newly diagnosed GBM concomitantly with radiotherapy and subsequently as monotherapy treatment for the treatment of malignant glioma showing recurrence or progression after standard therapy. However, temozolomide is not available in the Brazilian public health system.

**Objectives:** The goal was to provide data for the Brazilian Unified Health System to evaluate the possible incorporation of temozolomide for patients with resected high-grade gliomas.

**Methods:** Two independent researchers performed the searches in electronic databases with broad search terms related to temozolomide and randomized studies. A Markov model was developed to evalu-

ate progression, mortality and cost of the disease in two cohorts of patients treated with radiation therapy with or without temozolomide from the SUS perspective. The assessment of budget impact was calculated using cost for treatments and the incidence and prevalence of gliomas in Brazil.

**Results:** Two randomized clinical trials were found and one systematic review with meta-analysis. The results showed that the combination of radiotherapy plus temozolomide was associated with better overall survival (HR 0.58, 95% CI 0.50-0.68,  $p < 0.001$ ) and progression-free survival (HR 0.52, CI 0.42 to 0.64,  $p < 0.001$ ) when compared to exclusive radiation therapy. Regarding the economic evaluation, the use of temozolomide was associated with an increase of 0.36 LY and an ICER of US \$29,220/LY. We also found that the incorporation of temozolomide in the SUS would generate an incremental annual cost of US \$9,306,783.

**Conclusions:** We can conclude that temozolomide is effective when combined with radiotherapy in the postoperative treatment of patients with high-grade gliomas. The estimated ICER is very close to a hypothetical threshold of three times GDP per capita.

**OR38.2****Evaluation of the Routine Use of Cintigraphy to Detect Bone Metastases in Patients with Hepatocellular Carcinoma in the Waiting List for Liver Transplantation**Giacomo Balbinotto<sup>1</sup> Santiago Rodriguez<sup>2</sup> Ajacio Brandão<sup>2</sup>

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**Background:** Evaluate the routine use of scintigraphy to detect bone metastases in patients with HCC in the waiting list for liver transplantation is very important to increase the efficiency of the Brazilian Health System.

**Objectives:** The specific objectives is to evaluate the maintenance of routine use of Scintigraphy in terms of cost-effectiveness, as well as determine whether there is a relationship of cause and effect between the etiology of liver disease and the development of bone metastases and the behavior of the different prognostic factors in these patients.

**Methods:** The study population will be composed of adult patients of both sexes diagnosed CHC confirmed by biopsy or imaging criteria in the waiting list for liver transplant (Guido Cantisani Team) in the Irmandade da Santa Casa de Misericórdia de Porto Alegre, RS, Brazil.

Medical records will be reviewed of patients eligible for the study so that the clinical, biochemical variables and image can be analysed and correlated with the identification of bone metastases.

**Results:** In terms of the cost-effectiveness literature provides some data about the routine use of scans in some malignant diseases, so, for example, it has been demonstrated that the chest computed tomography (CCT) and not cost-effective in detecting pulmonary metastases in patients with soft tissue sarcoma and thoracic not generating a cost of \$ 59,772 and \$ 27,594 per patient and in the study of Koneru B, et al., the cost for detecting bone metastasis in a patient was \$ 277,798, so you have to revise the policies of clinical practice to avoid unnecessary expenses to the health system.

**Conclusions:** The very preliminary results shows that the this procedure is not cost-effective.

The results makes sense because in the evaluation of this protocol in liver transplantation is important to avoid unnecessary expenditures and procedures to the CHC patients on the waiting list.

**OR38.3****Health Economic Evaluation of Bevacizumab in Patients with Metastatic Colorectal Cancer in Argentina**

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**Background:** Colorectal cancer is the third most commonly diagnosed cancer in Argentina with about 30 % of patients presenting metastases at diagnosis, while 20 % develop them later on, becoming a main aspect of Argentina's burden of disease.

**Objectives:** To quantify the incremental costs and health effects of adding the costly monoclonal antibody bevacizumab to standard treatment with 5-FU and calcium folinate combined with oxaliplatin (FOLFOX) or irinotecan (FOLFIRI) in metastatic colorectal cancer in Argentina.

**Methods:** A Markov model was developed. Two main treatment pathways were used, one with bevacizumab, and one without bevacizumab (but with FOLFIRI or FOLFOX) in first line treatment. In second and third line, the treatment was considered equal in the two pathways. Tunnel stages were used to represent the use of chemotherapy beyond the first line for up to 6 months. Temporal horizon was 40 months. A systematic search for local and international randomised controlled trials and economic evaluations was performed by two independent researchers to feed the model and quality assessment using GRADE was performed before inclusion. Costs and health effect (life years) were compared for the two pathways. Main outcome was cost per life year gained. Costs and health effect were analysed from two perspectives: national health care perspective and societal perspective. Discounting was done to future costs and effects. A sensitivity analysis was performed.

**Results:** Life year gained with addition of bevacizumab was 1.67 year per patient, and cost for bevacizumab treatment in the health care perspective was \$ AR 86,725 per life year gained, main part of the incremental costs being related to acquisition costs of bevacizumab. The incremental cost in our main scenario was \$ AR 144,753 per average patient, seen in the health care perspective.

**Conclusions:** Adding bevacizumab to standard first line treatment of metastatic colorectal cancer is not cost effective in Argentina.

**OR38.4****The Value of Personalizing Medicine: Medical Oncologists' Views on Gene Expression Profiling in Breast Cancer Treatment**

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**Background:** Guidelines recommend gene-expression profiling (GEP) tests to identify early-stage breast cancer patients who may not benefit from chemotherapy, potentially reducing toxicity and healthcare costs. Several GEP tests are clinically-validated yet limited evidence exists about their impact on chemotherapy decisions (clinical utility).

**Objectives:** We explored medical oncologists' perspectives on GEP's clinical utility.

**Methods:** We used a qualitative study design, comprising individual interviews with medical oncologists (n=14; 10 academic, 4 in the community) from Ontario, Canada. Academic oncologists were recruited through participating academic clinics, professional advertisements and referrals from the research team. Medical oncologists practicing in community hospitals were recruited through e-mail invitations and referrals from the research team. Qualitative data were analysed using interpretative methods, including content analysis and constant comparison techniques.

**Results:** Oncologists' opinions were mixed about GEP's utility for early-stage breast cancer chemotherapy decisions. Some considered it as a tool that provided additional comfort or confidence to their established approach to risk assessments, while others described it as 'critical' and used it to resolve their uncertainty about recommending chemotherapy. Some community oncologists also valued the test as confirmation of what they felt were inconsistent pathology reports. On balance, oncologists believed GEP tests led to 'more appropriate chemo use'. However, some raised concerns about its reliability, proprietary nature, high cost, inappropriate/over-use and variability in interpretation of results within their medical community. Paradoxically, oncologists felt it was simple to explain the test to patients but remained uncertain about patients' understanding of the results and their implications for treatment.

**Conclusions:** Oncologists valued the test as an additional decision support tool, despite their concerns about its reliability, cost, inappropriate use by other oncologists and patients' limited understanding. Results identify a need for patient decision aids and clinical practice guidelines to support patients' understanding and standardized use and interpretation of the test.

**OR38.5****Surrogate vs Final Outcomes: Comparison of Effect Sizes from a Meta-Analysis of RCTs in Metastatic Colorectal Cancer**

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**Background:** Evidence from surrogate endpoints, that are biomarkers or intermediate outcomes intended to substitute for final patient-relevant endpoints, is currently used not only for regulatory approval of new health technologies but also to inform coverage and reimbursement decisions. Nevertheless, relying on evidence from surrogate endpoints is controversial and has been shown to lead to potential overestimation of treatment benefits.

**Objectives:** This study aims to compare treatment effect sizes of progression-free survival (PFS), time-to-progression (TTP) and objective tumour response (TR) with that of overall survival (OS) in metastatic colorectal cancer.

**Methods:** Randomised controlled trials (RCTs) of drug interventions for metastatic colorectal cancer reporting both OS and at least one surrogate outcome (PFS, TTP, TR) were identified by systematic review. Random-effects meta-regression models were used to estimate the ratios of odds ratios (ROR) and hazard ratios (RHR) for OS vs PFS or TTP or TR. An ROR or RHR > 1.0 indicates that the treatment effect is larger on the surrogate than on OS. Spearman's correlation coefficient ( $\rho$ ), R<sup>2</sup> and the surrogate threshold effect (STE) were also determined.

**Results:** Overall, 101 RCTs were identified including over 40,000 patients. The estimated RHR of OS vs PFS was 1.12 (95% CI: 1.02 to 1.24), with STE = 0.80,  $\rho$  = 0.75 and R<sup>2</sup> = 0.34. The RHR for OS vs TTP was 1.26 (1.08 to 1.47), with STE = 0.61,  $\rho$  = 0.80 and R<sup>2</sup> = 0.65. The ROR of OS vs TR 1.32 (1.08 to 1.61), with STE < 0.20,  $\rho$  = 0.53 and R<sup>2</sup> = 0.06.

**Conclusions:** According to these findings, treatment effects are larger on surrogate outcomes than on OS by 12 to 34% in metastatic colorectal cancer. Decision-makers are encouraged to take this fact into account when assessing the value of health technologies using surrogate outcomes rather than final patient-relevant outcomes.

### OR38.6

#### The Impact of NICE's End-of-Life Threshold on the Availability of New Cancer Therapies in England and Wales

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**Background:** In January 2009 the National Institute for Health and Care Excellence (NICE) introduced supplementary advice to aid patient access to end-of-life treatments. As cost-effectiveness is a primary factor affecting recommendations, this advice allowed existing cost-effectiveness thresholds to be extended for treatments indicated for patients with a short life expectancy, provided they applied to small patient populations and had been shown to extend life by at least 3 months. Previous research has determined this extended threshold to be around £50,000 per quality-adjusted life-year (QALY).

**Objectives:** To investigate the trends in end-of-life cancer appraisals since the guidance introduction in 2009, and to explore the impact these may have on patient access to cancer therapeutics in the future.

**Methods:** NICE single technology appraisals for cancer therapeutics were reviewed from 2009 to 2013. The incremental cost-effectiveness ratios (ICERs) were extracted from appraisals evaluated against the end-of-life criteria.

**Results:** During the timeframe considered, 31 appraisals were evaluated against the end-of-life criteria. Of the 21 appraisals considered to meet the criteria, 13 were recommended for use on the NHS, with ICERs ranging from £31,800 to £51,800 per QALY. However, between 2009 and 2013, the average yearly ICERs for end-of-life appraisals increased from £41,633 to £72,667. This general increase was reflected by a subsequent decrease in approved treatments over time. Between 2010 and 2012, 8 end-of-life treatments were approved; this is compared to 5 recommendations issued in 2009 alone. In 2013, no new end-of-life treatments were approved by NICE, with a lowest ICER in the submitted appraisals of £50,200 per QALY.

**Conclusions:** The general trend of increasing ICERs in new end-of-life cancer appraisals has resulted in fewer treatments being approved by NICE in recent years. If this trend continues, NICE's end-of-life criteria may have limited effectiveness in aiding access to novel end-of-life cancer therapeutics, unless thresholds are increased further.

### OR39.1

#### Budget Impact Analysis for Support Decision-Making: Case of the Bevacizumab in Brazilian Health System

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**Background:** Decisions on medical coverage require scientific evidence, in particular for high prevalence diseases and those involving continuous and costly treatments. Determining the extent to which alternative therapies impact the budget of the Unified Health System is critical for decision making.

**Objectives:** To analyze the budget impact of therapies to treat age-related macular degeneration.

**Methods:** Selection of the systematic review funded by the Ministry of Health and applied to assess treatment options for age-related macular degeneration. The budgetary impact was estimated using 2008 as the baseline year, when the results of the systematic review were made available to the Ministry of Health. The therapeutic rationale was delineated with experts, and prevalence estimates for Brazil were calculated through meta-analyses published in international cross-cutting studies. The direct costs involved in the treatment demand scenario were weighed in accordance with regulated prices and expert opinions. Analysis of the budgetary impact for the public health system was adopted to estimate potential efficiency gains measured on the basis of reduced costs and the use of alternative therapies recommended by the systematic review.

**Results:** the Bevacizumab SR for eye diseases completed in 2008 was selected to estimate the budgetary impact on the SUS. If the Ministry of Health adopted the Age-Related Macular Degeneration treatment pursuant to the recommendation of the systematic review, the budgetary impact would be US\$ 146 million on the provision of access to Bevacizumab (4 ml fractionated) for the entire estimated study population (306,244 patients). This would lead to a cost savings of US\$ 1.15 billion for the incorporation of fractionated Bevacizumab in a monthly treatment regime of photodynamic therapy with Verteporfin and an annual reduction of US\$ 3.35 billion for a monthly treatment regime of Ranibizumab.

**Conclusions:** We recommend the incorporation on bevacizumab for age-related macular degeneration in Brazilian Health System,

### OR39.2

#### HTA Knowledge Translation in China: from the Perspective of Researchers with the Major of Medicine and Non-Medicine

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**Background:** Although some HTA units have been set up in China, the application of HTA findings to policy-making is not widespread and the integration of HTA in the policy-making processes is still in its infancy.

**Objectives:** To describe the status of HTA knowledge translation (KT) and examine the gaps between HTA researchers with the major of medicine and non-medicine on KT.

**Methods:** Snowball sampling method was used. A cross-sectional survey was obtained from structured questionnaires applied to a sample of 382 HTA researchers (247 with the major of medicine and 135 with the major of non-medicine). The questionnaires contained two dimensions, namely perceptions of influencing factors on KT and assessments of KT activities. Five-point Likert scales were used to measure the perceptions and assessments, with the higher score representing more active results. Wilcoxon rank sum test was applied to compare the difference of the items under the two dimensions between the HTA researchers with the major of medicine and non-medicine.

**Results:** For almost all of the items under the dimension of perceptions of influencing factors on KT, the ratings were between 3 and 4 for both the HTA researchers with the major of medicine and non-medicine. Besides, for the items under the dimension of KT activities assessments, the scores ranged from 2 to 3 for both two groups, except the item of academic translation with the score more than 3. The gaps between these two groups on KT were not statistically significant in all items.

**Conclusions:** The perceptions on KT influencing factors and KT activities were not statistically different between two groups. However, the scores were low in KT activities. Enhancing collaborative relation-

ships among relevant stakeholders, issuing KT guidelines and training toolkits, are suggested to promote HTA knowledge translation.

### OR39.3

#### Kazakhstan's Benefits from Collaboration with NICE

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**Background:** The interest of the Center for health services and standardization of healthcare the Republic of Kazakhstan (CHSS) to the National Institute for Clinical Excellence, UK (NICE) due to the presence in this organization unique standards of technical, methodological and procedural organization of the process for healthcare standardization; huge experience in pharmacoeconomics research and health technology assessment.

**Objectives:** With the purpose of implementing in the Republic of Kazakhstan the methodology for a comprehensive health technology assessment, based on the principles of evidence-based medicine, rational pharmacotherapy, clinical and pharmacoeconomics analysis methodology we are developed a vision of the working committees in the Kazakhstan for conducting the HTA reports, conducting pharmacoeconomics studies and the development of national clinical guidelines on analogy with the same work in the NICE.

**Methods:** Creating a sustainable system and database of developers and experts for developing the Clinical Guidelines and Standards of healthcare and standards relevant services through the establishment of professional associations responsible for participation in the development of HTA reports will guarantee productive work and increase the maximum applied significance for the healthcare system. CHSS initiated drafting legislation in this matter.

**Results:** Within the framework of realization the strategic direction of the CHSS is tasked to provide methodological support for the development and improvement of clinical practice guidelines, clinical protocols, standards of care in accordance with the principles of EBM, conducting implementation of clinical guidelines in the educational process and clinical practice, the organization coordinating the development of standards of care, methodological and advisory support comprehensive standardization of the main processes of the health system, as well as analysis of the effectiveness of measures for the development of standardization in healthcare.

**Conclusions:** The solution of the question of the provision of consulting services by NICE is an important step to promote the effective implementation of the strategic directions.

### OR39.4

#### HTA of Adalimumab for Rheumatoid Arthritis in Germany

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**Background:** Rheumatoid Arthritis (RA) can be treated with TNF $\alpha$  inhibitors after the failure of conventional disease-modifying antirheumatic drugs like methotrexate. The percentage of German patients treated with TNF $\alpha$  inhibitors has been rising from 2% in 2000 to 20% in 2008. In 2012, adalimumab was the most popular TNF $\alpha$  inhibitor and the best selling drug in the German statutory health insurance system with net expenditure of 581 mn €.

**Objectives:** We aim to analyze the cost-effectiveness of adalimumab for the treatment of RA in Germany.

**Methods:** We set up a Markov Chain Monte Carlo lifetime model to simulate 10,000 hypothetical patients. Initially, patients can achieve one of three responses according to American College of Rheumatol-

ogy criteria or fail the therapy. Each response is associated with an initial improvement in functional status. In each cycle, treatment might be discontinued due to loss of efficacy or adverse events.

**Results:** In the base case, patients gain 3.72 quality-adjusted life years (QALYs) with methotrexate monotherapy and 6.34 QALYs if adalimumab combination therapy is added to the treatment algorithm. The incremental cost-utility ratio (ICUR) is 34,803 € based on German list prices. After deduction of mandatory rebates and taxes, the ICUR is only 25,242 €. Adalimumab combination therapy lowers indirect cost from 276,380 € to 231,875 €. The ICUR based on total cost is 17,850 € (8,290 € after deducting taxes and rebates). If taxes and rebates are deducted, the ICUR becomes negative for baseline age 30, i.e. adalimumab combination therapy is more effective at smaller total cost. Limiting the simulation time to 5 or 10 years increases ICURs as long-term benefits of adalimumab combination therapy are ignored.

**Conclusions:** HTA of drugs for chronic diseases needs to consider indirect costs. A lifetime modeling perspective is required in order to estimate the long-term benefits of a therapy.

### OR40.1

#### HTA: Hampering or Guiding Innovation?

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**Background:** HTA is mainly based on published research results, and as such a retrospective activity. It is time consuming, resource demanding, and has a rigorous methodological apparatus. Hence, it may be argued that it stifles innovation.

**Objectives:** To scrutinize the statement that HTA is stifling innovation.

**Methods:** Literature search (of HTA literature) and content analysis (of articles, reports, books and webpages).

**Results:** Due to the slowness and the rigor of the HTA processes, it is argued that HTA stifles innovation. However, the slowness may give little influence from HTA on innovation, as its input comes late in the development of a health technology. It is argued that HTA curbs the implementation of useless health technology, and in the long run also directs innovation towards useful health technologies. HTA may balance hype and hope effects. "Early warning," "alert systems," and "horizon scanning" indicates potential stifling, but also intends to "identify those technologies with the potential to have a significant impact in the future." Hence, many of the stifling aspects may not be hampering for health promoting innovation. However, in two aspects HTA may stifle innovation. First, because the HTA process may asphyxiate good ideas and initiatives, because of the long way from innovation to implementation. Second, HTA traditionally addresses health technologies as artifacts (objects) implemented in health care. Innovation and assessment are separate processes. This can stifle a dynamic development and more attuned innovation.

**Conclusions:** HTA guides innovation through clarifying goals and endpoints. The slowness and rigor of the HTA process may stifle innovation. More dynamic HTA processes may enhance innovation without losing the guiding and watchdog effect.

### OR40.2

#### Parallel Review System of New Health Technology for the Early Introduction in Clinical Field

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**Background:** New health technologies to be entered into Korean market and create profit must go through 'Medical device Approval' 'New Health Technology Assessment' 'Decision on Health Insurance

benefits Coverage' process sequentially. This takes up a considerable period of time until the practice of the new health technology steps in the market. The medical professionals and medical related industries have demanded for shortening of the assessment period.

**Objectives:** To improve the current system, we will suggest a model fit to Korean healthcare situation by analyzing foreign similar cases and organizing a working consultative body to provide practical ways to perform the new system.

**Methods:** Roles and regulations of the related Korean institutions (MFDS, NECA, HIRA) which is closely associated with the new health technology assessment and foreign cases were analyzed to draw a proposal that can be effectively achieved under our system. Each institution's role and management plan to run a pilot project were discussed, and collaborative project indicator was selected by a working consultative body.

**Results:** After the analysis of current our system and overseas examples, 'medical device approval' and 'new health technology assessment' processes could be proceed simultaneously (concurrent) through the collaboration of MFDS and NECA. Also, with the cooperation of HIRA, the decision on 'determination of existing technology' can be made sooner. Therefore, it is concluded that with the cooperation of all related organization, the total assessment time could be shortened.

**Conclusions:** Based on the results of this study, <One-stop services of the new health technology assessment> system could be performed since Nov. 2013. Now we expect that it will shorten the introduction period of the new health technology to Korean healthcare system approximately six months or more. And this will be effective on expansion of patients' option for promising health technologies through early commercialization.

#### OR40.4

##### Is Horizon Scanning in Accordance with Demanded Health Technological Innovations?

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**Background:** many countries worldwide have structured horizon scanning systems to identify new and emerging technologies but important doubts have been raised regarding their timeliness or efficacy to select technologies for formal assessment. Building on the results of a PubMed literature search, we engaged a panel of clinicians to select technologies that were anticipated to be highly relevant for clinical practice.

**Objectives:** 1) assess the efficacy of the PubMed approach to identify innovative technologies of high clinical value 2) analyze the evaluation of selected technologies by international HTA organisms.

**Methods:** 146 eligible key experts (42 specialties; min 3-per-specialty) scored the potential impact (9 point rating-scale) of the new and emerging technologies identified by the systematic PubMed search strategy (January 2012-June 2012). The main databases of ongoing and finalized HTA reports (EUnetHTA, INAHTA and EuroScan) were searched to identify how many of the prioritized technologies (mean > 6) were subject to formal HTA reports in the next 2 years (January 2014).

**Results:** of the 263 technologies identified by the PubMed search (published between 2011 to 2012), 52 were anticipated to be of high clinical value. Inter-rater agreement differed greatly between specialties but overall concordance was high. Of prioritized technologies, 17% (n = 9) ended in a finished or ongoing report. Of these, 3 (33%) had been assessed previous to our identification.

**Conclusions:** the current study suggests that technologies that might be prioritized and assessed by current detection systems do not always coincide with those demanded by clinical practice or that formal evaluation is not in enough advance to allow for early assessment. The methodology proposed can probably contribute to improve the impact of horizon scanning systems and could be useful to many HTA organizations worldwide.

#### OR40.5

##### Early Assessment of New Technologies: the Case of Whole Exome Sequencing as a Diagnostic Tool in Complex Pediatric Neurology

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**Background:** Innovative medical technologies often improve health care, making swift implementation into the clinic desirable. Prior to implementation of new technologies however their additional value should be evaluated to prevent ineffective and expensive technologies to be widely diffused in health care. If the results of early assessment are positive, implementation into clinical practice could be accelerated, thereby enhancing technological innovation.

**Objectives:** To determine the value of such an early assessment before clinical implementation, exemplified by the potential use of whole exome sequencing (WES) as a novel genetic test in the diagnostic trajectory of complex pediatric neurology.

**Methods:** The current diagnostic trajectory and its associated costs were assessed by evaluating health care resource use of 52 pediatric patients with complex neurological disorders of suspected genetic origin. To explore the potential cost-effectiveness of WES, scenario analyses were performed. We assessed the costs of implementing WES as a replacement for all other diagnostics and as replacement for only the genetic tests.

**Results:** In the current diagnostic trajectory, a diagnosis could be established in only 6% of the patients. The average costs per patient were €12,241. The major cost driver were genetic tests, accounting for 42% (€5,130) of total costs. The costs of WES are currently €3,600, possibly resulting in savings of €1,530 (12%) per patient if WES would replace all other genetic tests.

**Conclusions:** Our results demonstrate that implementation of WES within the diagnostic trajectory of complex pediatric neurology seems valuable. Assuming that WES does not result in less diagnoses or decreased quality of life, savings of €1,530 per patient could be achieved, only by replacing currently used genetic tests. Notably, it may be expected that WES precludes from further diagnostic testing, thereby increasing savings even more. Thus, our early evaluation suggests that WES should be implemented into clinical practice.

#### OR40.6

##### Developing a Primary Submission Process to Promote Early Assessment and Adoption of Promising Non-Medicine Technologies

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**Background:** NHS Scotland aspires to be a world leading centre for innovation and health. Technology assessment plays a key role

in encouraging timely and appropriate adoption and diffusion of health technologies. However, HTA methods in Scotland as elsewhere have increasingly shifted to adopt rapid review methodologies that concentrate on reviewing published, often secondary level, clinical and cost-effectiveness evidence. This has mitigated against consideration of innovative technologies for which available evidence is often emergent and partial eg available efficacy and safety data is promising but clinical effectiveness not fully established and cost effectiveness not yet addressed.

**Objectives:** To develop a primary submission process for non-medicine technologies for the Scottish Health Technologies Group (SHTG).

**Methods:** N/A

**Results:** An SHTG primary submission process has been purposely designed in collaboration with key stakeholders to expedite evidence-based adoption and diffusion of non-medicine technologies and their associated health gain for patients of NHSScotland. Key stages: registration of the technology on NHSScotland's Health Innovation Portal; sign-posting to existing support bodies; securing a 'letter of support' from NHSScotland; referral of CE marked technologies to SHTG for assessment; high-level technology scope and review; primary submission case prepared; feedback to develop the evidence submission, if required; detailed review of the primary submission; presentation of evidence review to SHTG members; SHTG advice statement prepared for NHSScotland and disseminated nationally. Early submission is encouraged to assist proposers to develop their value proposition in the context of NHSScotland. In-built support and feedback are key features of this process. This process is currently being piloted and evaluated.

**Conclusions:** The SHTG has developed its HTA processes to promote and support the innovative culture aspired to within NHSScotland. It is hoped that having a clear and transparent primary submission process in place will enable proponents of innovative non-medicine technologies to submit their technologies for early assessment and encourage timely adoption.

### OR41.1

#### Inequitable Access to Innovative Technologies for Diabetes Treatment and Management in Australia

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**Background:** Diabetes places a large economic burden on the Australian healthcare system in terms of expenditure on hospitalisations, medications and out-of-hospital care.

Insulin pump therapy is currently the only treatment that replicates normal insulin secretion by a healthy pancreas, which is especially important for individuals with type 1 diabetes, who rely on insulin therapy for survival.

Currently in Australia, the Federal Government provides some funding (up to 80%) for insulin pumps to individuals with type 1 diabetes under the age of 18 years who have low income or receive government support payments. However, despite financial assistance from the government, use of insulin pumps in Australia remains lower than other countries such as the UK. The majority of insulin pump users require financial assistance to purchase their pump, with almost all provided by private health insurance funds (97%).

**Objectives:** To determine whether insulin pumps compared to other insulin therapies would provide better health outcomes for individuals with diabetes, and provide cost savings for the healthcare system.

**Methods:** N/A

**Results:** Insulin pump therapy was found to be more beneficial and cost-effective compared to other insulin therapies. Insulin pumps can also be linked to continuous glucose monitoring (CGM) systems, which have great potential to improve patient compliance and quality of

life, and provide better health outcomes for individuals with diabetes, particularly those living in rural and remote areas.

**Conclusions:** MTAA recommends the use of insulin pumps for children and adolescents with type 1 diabetes remains funded, while some subsidy for the use of insulin pumps should be provided for adults with type 1 diabetes and those with type 2 diabetes and gestational diabetes, who would clinically benefit from insulin pump use.

### OR41.2

#### Using Childhood Obesity to Predict Adult Morbidity: a Systematic Review

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**Background:** The nature of the link between childhood obesity and adult obesity and morbidity is unclear.

**Objectives:** The study investigated the ability of simple measures such as BMI to predict the persistence of obesity from childhood into adulthood and to predict adult morbidities (type II diabetes, cardiovascular disease and cancer).

**Methods:** Systematic reviews were conducted to identify large prospective cohort studies reporting on the association between childhood obesity and adult obesity or obesity-related morbidities. A number of measures of obesity were considered including, BMI, waist circumference, waist-to-hip ratio, waist-to-height ratio, and skinfold thickness. Sources including MEDLINE, Embase, PsycINFO and CINAHL were searched (2008-2013). Results for predictive accuracy were combined in meta-analyses.

**Results:** The review included 60 studies. There was a strong association between high childhood BMI and adult obesity (OR 5.21, 95% CI 4.50 to 6.02). A positive association was found between high childhood BMI and adult coronary heart disease, diabetes and a range of cancers, but not stroke or breast cancer. The predictive accuracy of childhood BMI to predict any adult morbidity was very low, with most morbidities occurring in adults who were of healthy weight in childhood. Predictive accuracy was moderate for predicting adult obesity, with a sensitivity of 30% and a specificity of 98% when using the 95th centile of BMI as the obesity threshold. Very few studies evaluated a childhood measure of obesity other than BMI.

**Conclusions:** Assessment of childhood BMI is not a good predictor of adult obesity or adult disease: the majority of obese adults were not obese as children and most adult obesity-related morbidity occurs in adults who were of healthy weight in childhood. Due to a lack of data, the review was unable to determine whether simple measures of obesity other than BMI might improve the prediction of obesity-related adult morbidities.

### OR41.3

#### The Agency for Healthcare Research & Quality's (AHRQ) "Methods for Insulin Delivery and Glucose Monitoring: Comparative Effectiveness" Results Revisited Regarding Randomized Trials Comparing of Real-Time Continuous Glucose Monitoring (rt-CGM) Versus Self Monitoring of Blood Glucose (SMBG) Stratified for Different Insulin Delivery Modes

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**Background:** The authors Golden and Bass stated that the current literature does not allow a comparison of rt-CGM versus SMBG in

patients only using Continuous Subcutaneous Insulin Infusion (CSII), or only using Multiple Daily Injections (MDI).

**Objectives:** We aimed at testing this statement.

**Methods:** Within our systematic review research protocol, we used

- more search terms,
- more flexible search term combinations,
- a shorter literature search timeframe (1994-2012),
- further detailed comparisons of insulin delivery, glucose monitoring and their combinations.
- We allowed a broader inclusion of observational evidence to complement clinical trial data in terms of generalizability beyond their importance for long-term outcomes.

Within glucose monitoring studies comparing rt-CGM with SMBG versus SMBG, we stratified the analysis by type of insulin delivery and age.

**Results:** We found potentially clinically relevant hemoglobin A1c (HbA1c) effects in adults with type 1 diabetes while only limited data on severe hypoglycemia was found.

For children and adolescents jointly no effect on HbA1c could be found while data on severe hypoglycemia was scarce. For sensor-augmented pumps (SAP) clearly clinically significant results on HbA1c were found in comparison to MDI in combination with SMBG. The French Haute Autorité de Santé requested in addition a comparison of SAP versus CSII with SMBG in patients who are eligible for SAP to differentiate the effect of the pump from rtCGM or other features of a SAP.

**Conclusions:** Stratifying for insulin delivery modes is possible while comparing rtCGM with SMBG and yields useful information for assessing the respective role in the treatment pathway. Whether or not a certain reduction in HbA1c should be used to assess clinical relevance and whether the clinical relevance thresholds prevalent in the literature are appropriate from patients' and providers' perspective is a relevant research question. Future research in the area of rtCGM and SAP should especially further investigate effects on (severe) hypoglycemia.

#### OR41.4

##### Budget Impact Analysis of Insulin Analogues for Type 1 Diabetes: the Case of Brazilian Public Health System

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**Background:** Type 1 Diabetes Mellitus (T1DM) is an endocrine autoimmune disease with onset usually in childhood and which, being chronic, affects people of working age. It affects approximately 0.3% of the population and has high personal and social impact. The National Committee for Incorporation of Technologies in Health System (CONITEC) is responsible for recommending the inclusion or not of technologies in Brazilian public health system.

**Objectives:** To elaborate a budget impact analysis (BIA) of insulin analogues for the treatment of T1DM for help the decision making.

**Methods:** A BIA of insulin analogues in SUS compared to human insulin (NPH and Regular) was performed. The analysis' time horizon was 5 years, using a diabetes prevalence of 7.6% and 5% of T1DM between them (602,742), considering an annual growth rate of 0.8143% and a market share of 20%, 30%, 40%, 50% and 100%. The mean total insulin dose considered was 0.75IU/kg/day, with an average personal weight of 70kg, which means 52.5IU/day, 50% of each insulin type (basal and rapid). Unit purchase prices of insulins were obtained in the health system prices database and calculated the weighted average. For human insulins, were considered the values of last purchase of the Ministry of Health.

**Results:** The budget impact of basal analogues would be 202.8m reais (\$83.6m) in the 1st year, considering 20% of target population, reaching approximately 1 billion reais (\$412.2m) in 100% of patients. For rapid analogues, the budget impact would be 62.9 million reais (\$25.9m) in the 1st year, reaching 324.9 million reais (\$133.9m) in 100% of patients.

**Conclusions:** This BIA will be essential to support CONITEC's decision about insulin analogues for T1DM patients in Brazil. Treatment costs still impressive, considering that analogues' values reach 10 times the unit values of human insulins, fact that did not happen in other countries where they are already covered.

#### OR41.5

##### Key Influencing Parameters of a Research Protocol: the Agency for Healthcare Research & Quality's (AHRQ) "Methods for Insulin Delivery and Glucose Monitoring: Comparative Effectiveness" Review Protocol Revisited

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**Background:** The number of systematic reviews and Health Technology Assessments in glucose monitoring and insulin delivery is increasing steadily.

**Objectives:** We aimed at reconsidering key parameters of the AHRQ review protocol and developing an alternative approach.

**Methods:** Starting from the AHRQ review protocol, justified deviations were documented mainly in terms of refinement of search criteria, comparisons of interest, as well as inclusion of observational studies beyond long-term outcomes.

**Results:** In our systematic review, we decided to use

- more search terms ("multiple daily injections" (MDI), "intensive insulin therapy" and a broader search for Self-Monitoring of Blood Glucose (SMBG) and real-time Continuous Glucose Monitoring (rtCGM) including brands of marketed devices) and
- more flexible search term combinations (e.g. "continuous subcutaneous infusion of insulin" or "insulin infusion pump(s)", "continuous blood glucose monitoring" which were not covered by the AHRQ search): This approach increases the chances of identifying technologies that are not expressively mentioned in an abstract or represented in the keyword terms.

In order to capture evidence that is relevant for therapies using current technology, we restricted the search to publications from 1994 to 2012.

In contrast to Yeh et al. and Golden et al., regarding comparisons our protocol

- was designed to detect differences of rt-CGM versus SMBG
  - in patients only using insulin pumps or
  - only using MDI and
- further detailed the comparisons of insulin delivery and glucose monitoring and included mixed comparisons.

Finally, observational evidence can complement clinical trial data beyond their importance for long-term outcomes in terms of relevant real-world information and therefore has been included.

**Conclusions:** A growing number of systematic reviews on insulin delivery and glucose monitoring differ substantially in methods: important influential parameters include literature research specifications and timeframes, details of comparisons, and selection criteria for study

types. These differences may contribute to diverging conclusions and hence affect decision making.

## OR41.6

### The Impact of an Imperfect Diagnostic Reference Standard on the Cost-Effectiveness of HbA1c Testing in the Diagnosis of Type II Diabetes

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**Background:** Glycated haemoglobin (HbA1c) testing in the diagnosis of diabetes is recommended by several international and national committees as it has less biologic variability and pre-analytic instability, and is more acceptable to the patient when compared to currently available tests.

**Objectives:** An economic evaluation was conducted as part of a health technology assessment to determine whether public funding of HbA1c testing was warranted.

**Methods:** A Markov model was developed to simulate the long term costs and benefits (measured in quality-adjusted life years) of HbA1c testing compared to fasting plasma glucose (FPG) and/or oral glucose tolerance (OGT) testing. Accuracy inputs of HbA1c testing were based on a systematic review and meta-analysis of studies which compared HbA1c to FPG and/or OGT testing (known imperfect reference standards). Two HbA1c testing scenarios were considered; HbA1c in the diagnosis of diabetes only (base case), and in the diagnosis of diabetes and pre-diabetes (alternative scenario).

**Results:** The base case was observed to be less expensive and less effective than the comparator, due to the inability of HbA1c testing in this scenario to identify pre-diabetes (which is possible with the comparator). The alternative scenario is dominated by the comparator, due to the poor accuracy of HbA1c, relative to FPG and/or OGT testing. However, as FPG and/or OGT accuracy is imperfect, the relative accuracy of HbA1c testing is uncertain. When test accuracy is excluded from the analysis, the base case continues to be less costly and less effective; however, the alternative scenario becomes dominant.

**Conclusions:** In the diagnosis of diabetes, HbA1c testing was consistently found to be less expensive and less effective than the comparator. In the diagnosis of pre-diabetes and diabetes, the true measure of cost-effectiveness of HbA1c testing is likely to lie between modelled estimates that include or do not include test accuracy data.

## OR42.1

### Hospital Based HTA in the Republic of Kazakhstan

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**Background:** The growth of GDP on health care in the RK, allows increasing funding for the development and transfer of technologies. This situation gives an opportunity to physicians' to increase the implementation of new technologies in the hospitals. Regarding this, the mature of necessity to develop HTA, in order to improve quality of medical services and the rational use of resources. HTA began to develop in Kazakhstan in 2010. Conducting various training made health managers use HTA tools. Chief of the General Hospital in Astana with the support of the National Center for Medical Education decided to implement the HTA to assess the innovative technologies in hospital.

**Objectives:** To create the first HBHTA in Kazakhstan

#### Methods:

- We studied the experience of countries that have established a HTA in hospitals. Research was conducted from various databases HTAi, PubMed, etc.
- Consultation with hospital clinical and administrative staff to identify role and scope of HTA.

**Results:** Several trainings on HTA were organized, where participants were familiarized with the purpose and work of the HTA. For this hospital, we developed a model of HTA, established a Committee for HTA, which includes the heads of the departments in hospital, leading doctors, specialist of the economic department, managers from the innovative technologies department, Professors of National Center for Medical Education. We developed criteria for prioritizing topics for HTA in the hospital. We include criteria relevance to availability of technology in the hospital, clinical effectiveness, cost to budget etc.

**Conclusions:** International experience shows that level of complexity and urgency of technology assessment in the context of hospital time of HTA process can cover more than 3-6 months. We started a prioritization process and on January, we are planning to determine the technology, which needs to be assessed until mid-2014, the result we are going to present in the future.

## OR42.2

### The Role of Hospital Based Health Technology Assessment in the Uptake of Health Technologies: Evidence from AdHopHTA

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**Background:** The decision making process on uptake of healthcare technologies (HTs) is a relevant topic in healthcare systems. Specifically, the adoption process in hospitals is of particular interest. Scholars have been discussing the role played by several factors, but there is a scant of knowledge on the role of Hospital Based Health Technology Assessment (HB-HTA) on adoption. AdHopHTA, an EU project aimed to strength the use of HB-HTA, deals with this matter.

**Objectives:** The aim of the research was to characterize the process of uptake of HTs in hospital contexts.

**Methods:** A survey with closed-ended questions was carried out among Hospital Managers and Clinical Directors from European hospitals with different organizational features, including the presence of HTA. Respondents were asked to provide information on (i) hospitals' characteristics, (ii) the process of adoption and (iii) involved actors from its inception to the final decision and to rank relevant competences.

**Results:** 165 professionals affiliated to 85 hospitals participated in the survey. 65% of them declare that HTA activities or initiatives are carried out in their hospitals. Preliminary results show that the first proposal on uptake of technologies comes from clinicians regardless of hospitals' characteristics for 63% of respondents. Final decision is mostly taken by the Chief Executive Officer (62%) and the Chief Medical Officer (45%). Organizational features such as size and HTA play a role when competences in the process of adoption are ranked. Hospitals with HTA are more likely to consider organizational and technical issues. Impact of nursing competence is generally acknowledged as relevant.

**Conclusions:** The study provides useful information for decision makers. The understanding of factors influencing the decision making process on HTs uptake help to design strategies/actions to promote an



inclusive competences in the final decision. It seems that HB-HTA, as a systematic assessment of innovations, could reinforce the involvement of hospital stakeholders.

### OR42.3

#### Advancing Health Technology Assessment in Finnish Hospitals

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**Background:** The Finnish Health Care Act 2011 demanded coordination in assessment and uptake of new technologies in hospitals. Collaboration between the national HTA unit and Finnish hospitals, which started in 2006, had increased awareness of HTA, but not, according to interviews of health care decision makers, clearly the use of HTA in hospital decision making. Therefore, a new model for more hospital-oriented HTA was required.

**Objectives:** To develop and describe new ways to strengthen the role of HTA in hospitals, and to introduce clinicians to HTA methodology.

**Methods:** N/A

**Results:** Three Finnish university hospitals decided in 2013 to introduce the mandatory use of the mini-HTA approach, i.e., the in Denmark developed management and decision support tool, when considering the uptake of new technologies. Furthermore, to support assessment of technologies needing more elaborate evaluation, a three-tiered approach was designed:

1. Multi-specialist hospital assessment teams responsible for rapid assessment (within 1-3 months) of new technologies within single hospitals.
2. Network of hospital HTA-specialists for rapid assessment (2-3 months) of technologies associated with broader, national interest.
3. National "Managed Uptake of Medical Methods Program" for detailed assessment (6-18 months) of technologies of broad national interest.

Although the adoption of the new approach has been slow as indicated by the fairly low number of mini-HTAs so far, the involvement of hospital assessment teams appears promising, and hopefully will hasten the penetration of HTA-information in hospitals.

**Conclusions:** Information from national HTA agencies does not readily reach the hospital level. The ongoing, EU-funded AdHopHTA project attempts to find new ways to ensure penetration of HTA information to clinicians. However, also hospital decision makers must learn to demand HTA when deciding on adoption of new technologies. In the case of pharmaceuticals this is already understood, however, the adoption of other hospital technologies remains poorly justified regarding proven effectiveness and safety.

### OR42.4

#### Collaboration Between Hospitals and National HTA Agency in Finland

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**Background:** The Finnish healthcare system is extremely decentralized and steered using voluntary guidelines. There are marked regional differences on how and when hospitals take up new technologies. In 2007 the Ministry of Social Welfare and Health identified the goal to improve the evidence base of Finnish health care. The Health Care Act in 2011 further demanded hospitals to coordinate the uptake of new

technologies on regional level. The national HTA agency Finohtha has been established in 1995.

**Objectives:** As part of the EU-funded Adopting Hospital Based Health Technology Assessment –project (AdHopHTA) to examine the impact and perceived barriers and facilitators of collaboration between Finnish hospitals and the national HTA agency in Finland.

**Methods:** A case study was performed based on a literature review and semi-structured interviews of 12 key individuals. Hypotheses and contextual factors were identified a priori and used to guide the interviews. Data were collected in structured tables and analysed qualitatively.

**Results:** A formal collaborative program called "Managed Uptake of Medical methods"(MUMM) started in 2006 with the aim to enhance the use of HTA for decision making in hospitals and to coordinate the uptake of new technologies across regions. Fifty MUMM reviews and recommendations have been completed, and their methodological quality is considered high. The collaboration has increased the general knowledge of HTA in hospitals but managerial commitment to the use of HTA in decision making is still elementary. This is mainly due to inadequate timing of the HTA products, low added value of the information they contain, and mistrust or role conflicts between the partners.

**Conclusions:** The results of HTA should reach hospitals earlier and have more information on organisational and cost consequences for the hospitals, even at the expense of the full methodological rigor of the HTA. Power balance and roles need to be discussed openly.

### OR42.5

#### Collaboration Between Hospitals and HTA Agencies: Facilitators and Barriers

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**Background:** Hospital-based HTA (HB-HTA) functions have been set up in many countries to produce timely and relevant information to guide decision making at local level, whereas national or regional HTA agencies typically focus on decision making at the national level. As the HTA methodology is in principle the same at both levels, collaboration between these two kinds of HTA-producing entities can be assumed to be useful. This was examined as part of the EU-funded Adopting Hospital based HTA project (AdHopHTA).

**Objectives:** To examine perceived barriers and facilitators of collaboration between hospitals and HTA agencies in different countries.

**Methods:** A survey of nine AdHopHTA partner countries and case studies from the two countries with formal collaboration between hospitals and HTA agencies, Norway and Finland, were used as basis. More information was retrieved from publications and through personal contacts. Data were categorized using a draft framework for good HB-HTA practices model by AdHopHTA. The role of contextual factors affecting the success of collaboration was qualitatively analysed.

**Results:** Information was received from nine European countries, Turkey and Canada. There was a lot of variation in the formality and duration of collaborations. Exchange of documents, methodological advice and joint preparation of HTAs were most frequent collaborative functions, but several other functions occurred or were suggested. Approximately half of the survey respondents, both from hospitals and HTA agencies, perceived collaboration very useful. A general lack of culture and knowledge of HTA in hospitals was the most frequently mentioned barrier of collaboration. Formal structures were considered useful but the importance of additional personal and informal contacts were underlined.

**Conclusions:** A set of barriers and facilitators identified in this study can be used to delineate recommendations for successful collaboration between hospitals and national and regional HTA agencies in the preparation of the handbook of best HB-HTA practices of the AdHopHTA project.

## OR42.6

### Results of a 13-Year Hospital-Based HTA Program in a Public Pediatric Hospital in Argentina

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**Background:** Despite fast growth of central level HTA in Latin America, hospital-based experiences are still scarce in our region.

**Objectives:** To report the impact of a 13-year hospital-based HTA program at the Hospital de Pediatria Garrahan in Buenos Aires, Argentina.

**Methods:** To promote a rational and evidence-based technologic development, a hospital-based HTA program started in 2001 at Hospital Garrahan, a 500-bed public national referral pediatric facility with a self-managed budget. The author serves as a full-time coordinator of the program, and a group of multidisciplinary hospital staff professionals form a part-time HTA Committee. The assessment cycle includes 4 main phases: prioritization, evidence synthesis, dissemination and monitoring. The program comprises 4 pillars: HTA reports to assist hospital administration in decision-making regarding technology acquisition, clinical practice guidelines for healthcare professionals, capacity building in research and management, and technical support for health services research.

**Results:** The program has produced 25 HTA reports on drugs, devices, equipment and institutional programs, shared at national level through the UCEETS ministry unit and the RedARETS network. Fifteen evidence-based guidelines submitted to peer-review and multidisciplinary expert consensus are available full-text at the hospital website for open consultation. In 8 consecutive years, 293 professionals have completed a 1-year course on research and management and designed 74 projects for certification. The HTA coordinator participates in utilization studies and monitoring activities with the Pharmacy and Medical Technology departments, and has coached 29 health services research protocols to assess the impact of institutional programs and quality improvement interventions.

**Conclusions:** This first hospital-based HTA program in a public hospital in Argentina shows that it is a viable and useful strategy at the public setting of a developing country. Promotion of hospital-based HTA and network collaboration can facilitate rational use of hospital budgets and generate other economic and organizational benefits like professional cost-awareness, an evidence-based culture and multidisciplinary interaction.

## OR43.1

### HTA of Critical Information System Anesthesia (CIS AN)

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**Background:** CIS AN, an electronic anesthesia record, was implemented in an anesthesia section and a postoperative care unit at Odense University Hospital (OUH) in 2012. The primary purpose of implementing CIS AN was to reallocate staff time from the continuous data registration to more patient related tasks, and to improve data quality.

**Objectives:** The aim of this HTA was to assess the effects of CIS AN at OUH compared to paper records with focus on technological, organizational and economic outcomes.

**Methods:** Six outcomes were investigated in a before/after design; Data completeness and data retrieval were investigated by comparing CIS with paper records, whereas system failure and errors in registration were outlined through interviews with staff. Time consumption on registrations was measured for CIS AN and paper records, and staff opinions were examined through interviews. Furthermore, a business case of economic consequences was performed.

**Results:** Data completeness and data retrieval have improved, and CIS AN is considered robust and the data is more reliable. Moreover, CIS AN may result in reduced time consumption on registrations. Furthermore, the staff are satisfied with CIS AN. The costs of full implementation in the hospital during three years were estimated to 2.35 mio. €. These costs are not counterbalanced by similar savings. Thus, the cost of the system should be compared to the qualitative gains.

**Conclusions:** Several methodological aspects should be considered; e.g. the general shortcomings of the before/after design and the sample sizes of the time studies. Despite these, it is believed that the quality of the anesthesia records, and thus patient safety have improved with CIS AN. CIS AN is not the only electronic anesthesia record, and it is recommended to investigate the market of alternative systems before further implementation. This HTA constitutes the basis of further implementation in the Region of Southern Denmark.

## OR43.2

### Drug Negotiation in a HTA Perspective: Experiences and Expectations Among Stakeholders

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**Background:** Drug pricing & reimbursement (P&R) processes are a complex system with many stakeholders that exercise different levels of influence on final decisions. Health Technology Assessment (HTA) plays a crucial role in reimbursement decision making process as well. Stakeholders as regulatory agencies, pharmaceutical companies, patients and their associations, healthcare providers, and research institutes don't have the same perception of HTA.

**Objectives:** To identify similarities and differences among stakeholder perceptions and expectations on the HTA role into the P&R.

**Methods:** An online survey was developed. It was structured to collect experiences and expectations of stakeholders involved in the P&R process, at national (Italian) and international level. The HTA Core Model elaborated by EUnetHTA was adopted to share a common language. The first section of the survey investigated the involvement and experience level of each responders in HTA assessment and P&R processes. Then perceptions of the current processes leading to price definition was inquired. Finally, the expectations on the evolution of price negotiation were gathered. The survey was composed by open and closed-ended questions.

**Results:** The Italian survey was conducted in the period June-October 2013. With a response rate of 44%, 54 replies were collected mainly from representatives of pharmaceutical companies (n=19) and patients'/citizens associations (n=20). The majority of responders had direct experience of HTA during P&R processes. According to a SWOT analysis, at Italian level despite the relevant role recognized to HTA by all stakeholders, still some methodological and procedural issues remain unresolved. The need to make public P&R criteria will justify the National Regulatory Agency to public its first guidelines to submit a drug dossier.

The international survey is underway. Results are expected for May 2014.

**Conclusions:** Perception of HTA's role and P&R processes by different stakeholder provide insight into necessary step to improve involvement into and quality of P&R decisions.

### OR43.3

#### The Clinical Relevance and Newsworthiness of UK NIHR HTA Funded Research

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**Background:** If HTAs are to encourage innovation, they must be based on questions of relevance to clinicians. Asking questions of low importance or where the answer is already known represents a potentially significant waste of research funds. The McMaster Online Rating of Evidence (MORE) system assesses the clinical relevance and newsworthiness of publications from 120 international high impact journals, thus providing an indicator for the relevance of funded research.

**Objectives:** To assess the clinical relevance and newsworthiness of UK National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme funded reports.

**Methods:** A cohort was selected of 311 NIHR HTA funded reports publishing in the Programme's host journal 'Health Technology Assessment' in the period Jan 1 2007 – Dec 31 2012. The MORE system was used to identify clinical relevance and newsworthiness of publications in 'Health Technology Assessment' and to compare these with non-NIHR HTA funded publications. The MORE system involves >4000 physicians rating publications on scales of relevance and newsworthiness.

**Results:** 286 / 311 (92.0%) of NIHR HTA reports were assessed by MORE. The average clinical relevance rating for NIHR HTA reports was 5.48, higher than the 5.32 rating for non-HTA publications (mean difference = 0.16, P = 0.01). Average newsworthiness ratings were similar between NIHR HTA reports and non-HTA publications (4.75 and 4.70 respectively; mean difference = 0.05, P = 0.402). NIHR HTA funded original research reports were higher for newsworthiness than reviews (5.05 compared with 4.64) (mean difference = 0.41, P = 0.001).

**Conclusions:** Funding research of clinical relevance is important in maximising opportunities for innovation and the value of research investment. The NIHR HTA Programme is successful in funding projects that generate outputs of clinical relevance.

### OR43.4

#### A Taxonomy of Medical Devices in the Logic of HTA

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**Background:** The suitability of general HTA methodology for medical devices has been gaining interest as a topic of scientific discourse, especially in light of new regulatory provisions for their marketing authorization. A number of classifications and nomenclatures for medical devices based on varying rationales are being used for different regulatory purposes and decisions on value and coverage in different contexts.

**Objectives:** To compare and analyse existing classifications of medical devices and develop a taxonomic model which aims to a) highlight

the suitability of different device categories for HTA, b) determine the respective data generation requirements and b) indicate if and how assessment tools can and should be modified to achieve best results depending on taxonomic position.

**Methods:** The classifications included in the EU licensing process for medical devices (Directives 90/385/EEC, 93/42/EEC, 98/79/EC), the international classification for medical devices used by the Global Medical Device Nomenclature (GMDN) as well as the categorization employed in the OECD Classification of Health Care Functions were analysed in combination to develop a comprehensive taxonomic model.

**Results:** A matrix was created based on relevant aspects from the existing classification schemes, incorporating the elements of risk and role/functionality of device types. The matrix further incorporates an additional distinction between the diagnostic or therapeutic nature of devices, which can be crucial for HTA purposes. The relevance of different device categories in regard to HTA was found to vary considerably and is color-coded in the matrix, covering a range from high suitability to non-applicability.

**Conclusions:** While HTA methodology already considers different approaches depending on the therapeutic or diagnostic nature of technologies, other elements such as whether or not the device is used in the context of a procedure, device-operator interaction, duration of patient-device contact, level of device activity or combined diagnostic/therapeutic functionality require further methodological discussion.

### OR43.5

#### Technology Assessment at the Service of the Brazilian Public Health System (SUS)

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**Background:** Since 2005, in order to establish a HTA culture in a country where isolated actions were noticed, the Brazilian Ministry of Health, through the Department of Science and Technology created a coordination unit to implement health technology management and assessment policies. This unit, the Health Technology Assessment General Coordination (CGATS) is responsible for the coordination, promotion and diffusion of HTA in the Brazilian Public Health System (SUS).

**Objectives:** To show the actions of the Brazilian Ministry of Health on the HTA field.

**Methods:** N/A

**Results:** The CGATS currently consists of 25 professional in-house staff and acts on improving skills and partnerships to link science with the decision making process, including:

- Introduction of HTA practices in governmental sectors;
- Management of the Brazilian Network for Health Technology Assessment - REBRATS);
- HTA production to support Public Health Programs and CONITEC;
- Encouraging HTA area in hospitals, universities and States Health Secretariats;
- Funding HTA studies;
- Investing in professional training and capacity-building;
- Conferences and summit making;
- Legal support – HTA Institutionalization in hospitals;
- Standardization of HTA methods;
- International cooperation with INAHTA, HTAi, NICE, RedETSA and MERCOSUR.

Such operational axes match the legal attribution of DECIT to "coordinate the creation and implementation of policies, programs and actions

of health technology assessment in the Brazilian Public Health System (SUS) – Decree 7797/2012”.

The referred activities show the intention to maximize the health benefits to be obtained through the available resources and through conditions of access and equity, in the health system.

**Conclusions:** The result of this process was a HTA and incorporation national policy (Law 12.401/2011), besides an agenda of Priorities in Health Research .

The Brazilian experience could prove that variations in the use and application of HTA findings in decision making reflects that the link between science and policy-making must be permanent.

## OR43.6

### Challenges to Establish a Health Technology Assessment (HTA) Unit in Cipto Mangunkusumo Hospital

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**Background:** Cipto Mangunkusumo Hospital (CMH), a national referral hospital located in Jakarta, Indonesia, is visited by a large number of patients who vary greatly in terms of patient characteristics such as disease type and severity, demography, and socioeconomic status. Consequently, CMH functions as a large health care center serving some patients who could be handled by a lower tier level of care. This high patient burden at CMH is due to problems in the referral system that should start from the primary health center up to the national hospital, if needed. Furthermore, in early 2014, the Indonesian government enacted a National Health Insurance for all Indonesian citizens. Without a support system to oversee the making and monitoring of health policy, as well as properly evaluate health care quality, the problem faced by CMH will continue to increase.

**Objectives:** To address the problem, the Director of CMH, through the Center for Clinical Epidemiology and Evidence-Based Medicine (CEEEM), established a HTA unit consisting of experts in HTA, physicians, clinical epidemiology and project management in 2011. It was established to provide evidence-based recommendations for policy-makers to anticipate or overcome problems.

**Methods:** N/A

**Results:** Challenges faced in the development of the HTA unit included the lack of understanding of the importance of health-policy making based on evidence, among the CMH staffs. Furthermore, the lack of research culture, physicians' high clinical workload, and the lack of reliable supporting data make the priorities assessment fall behind the arranged plan. These challenges were overcome, among others, by conducting a dissemination program through staff workshops.

**Conclusions:** The next important steps for HTA development in CMH are to set up regulations regarding HTA commission and a rapid HTA process for providing valid scientific evidence.

## OR44.1

### Comparison of Health Technology Assessments from seven HTA Agencies (CADTH, G-BA, HAS, NICE, SMC, PBAC and CONITEC) in the Treatment of Hepatitis C with Protease Inhibitors

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**Background:** Treatment of chronic hepatitis C (HCV) with protease inhibitors (PI) is a costly treatment with significant impact on health

care budgets. For countries with universal health care coverage, health technology assessment (HTA) is standard. The influence of a country's aggregate economic key indicators on HTA recommendations has not been assessed to date.

**Objectives:** To determine whether HTA reimbursement recommendations are related to gross domestic product (GDP) per capita.

**Methods:** Agencies were screened for HTAs in HCV treatment.

Relevant HTA reports were identified using the Reimbursement Risk Tracker Database from Context Matters Inc. Countries were ranked by GDP per capita using 2012 World Bank data. HTA recommendations (restrictions to subpopulations compared to label, additional constraints, and price reductions) were extracted from the HTA reports and compared to GDP per capita.

**Results:** Six countries (Brazil/CONITEC; UK/NICE, SMC; France/HAS; Germany/G-BA; Canada/CADTH; Australia/PBAC) were identified. GDP per capita: 11,340, 39,093, 39,772, 41,863, 52,219 and 67,556 US\$, respectively. CADTH recommended a restriction to a fibrosis stage F2, F3 and F4. CONITEC to F3 and F4. PBAC announced restrictions, but these have not been published. Four agencies in the middle of the high economic class (Germany, UK and France) accepted the label population. HAS requested a re-evaluation after one year, CONITEC a patient registry. All agencies with exception of the German agency requested price reductions compared to the list price. G-BA makes in general no economic recommendations. No clear relationship between economic strength and restricted recommendation was observed.

**Conclusions:** Recommendations for a restricted use in a subpopulation, price reductions or other constraints were unrelated to GDP per capita for PIs in HCV for the countries included in the analysis. Further research with the inclusion of additional countries and more HTAs is necessary to clarify a dependency between economic strength and HTA recommendations.

## OR44.2

### Challenges Faced by Decision Makers from Middle Income Countries in Transferring Economic Evaluations from Other Jurisdictions

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**Background:** Decision makers in middle income countries are using economic evaluations (EEs) in pricing and reimbursement decisions for pharmaceuticals and other health technologies. However, whilst many of these jurisdictions have local submission guidelines and local expertise, the studies themselves often use economic models developed elsewhere and elements of data from countries other than the jurisdiction concerned.

**Objectives:** The objectives of this study were to assess the challenges faced by decision makers in transferring data and analyses from other jurisdictions.

**Methods:** We conducted an interview survey of representatives of decision making bodies from 12 jurisdictions in Asia, Central and Eastern Europe, and Latin America that had at least one year's experience of using EEs in pricing and reimbursement decisions. Representatives of the relevant HTA organizations in the 12 countries were interviewed.

**Results:** All 12 jurisdictions had developed official guidelines for the conduct of EEs. All but one of the organizations evaluated studies submitted to them, but 9 also conducted studies and 7 commissioned them. Nine of the organizations stated that, in evaluating EEs submitted to them, they had consulted a study performed in a different jurisdiction. Data on relevant treatment effect was generally

considered more transferable than those on prices/unit costs. Views on the transferability of epidemiological data, data on resource use and health state preference values were more heterogeneous. Eight of the respondents stated that analyses submitted to them had used models developed in other jurisdictions. Four of the organizations had a policy requiring models to be adapted to reflect local circumstances.

**Conclusions:** Decision makers in middle income countries are facing several challenges in transferring data or studies, mainly due to differences in current standard of care, practice patterns or GDP between the developed countries where the majority of the studies are conducted and their own jurisdiction.

### OR44.3

#### Adopting Health Technologies in Hospitals: a Multiple Case Study Analysis on Decision-Making Across Europe

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**Background:** The adoption of health technologies (HTs) is a central topic in the scientific arena. Although this decision is mostly taken at the organizational level, literature argued that hospitals fail to follow an evidence based decision making process and little is known about those models carried out by when they decide to implement HTs.

**Objectives:** This working study attempts to describe decision making models addressing the adoption of HTs in hospitals.

**Methods:** Data used were gathered within the European Project AdHopHTA, granted under the 7th Framework Research Programme and aimed at strengthening the use and impact of HTA in hospital settings. 38 case studies on decision making process of adoption of selected technologies within European hospitals were elaborated and explored the characteristics of HTs, hospitals' organizational attributes, the decision making process of their adoption and the role of HTA in the process. These data were integrated with information on the decision making models, according to the Contingency Decision Making Framework provided by literature. Data analysis was performed according to multiple case study method.

**Results:** Our analysis show that type of technology, organizational attributes and external constraints play role in defining decision making. Costly and complex technologies follow a rational decision making model: economic and organizational efforts are required for their implementation, thus the availability of information, alternatives and consensus on clinical needs are relevant issues. Organizational initiatives aiming at systematically assess possible solutions, as is HTA, enhance rationality and reduce imitation effects or random choices. Also it can mitigate external constraints, such as national or regional intervention, which limit organizational rationality.

**Conclusions:** Our study provides useful information for hospital decision makers, since the formalization of HTA could ensure rationality of choices and favor evidence-based decision making. Moreover, a stronger collaboration across decision making levels could moderate external pressures.

### OR44.4

#### Do HTA Experts Assess a Systematic Review in the Same Way? a Case Study Using AMSTAR and GRADE

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**Background:** In health technology assessment (HTA) an increasing number of tools have been developed to assist researchers in quality

assessment and evidence grading. AMSTAR has been developed to assess the methodological quality of systematic reviews. GRADE has been developed to grade evidence. In this study we investigate whether HTA researchers come to the same conclusion when they independently assess the quality of a systematic review and grade the quality of evidence using these tools.

**Objectives:** To assess the reliability between HTA researchers by applying AMSTAR and GRADE on a Cochrane review.

**Methods:** 21 HTA-researchers at SBU and regional HTA-organizations were invited to participate in a survey. The participants were instructed to do an independent review of the Cochrane report "Exercise for depression" applying AMSTAR and GRADE.

**Results:** 18 of 21 completed the survey (response rate 86%). All participants rated the review to be of moderate to high quality using AMSTAR. We found that question 11, referring to conflicts of interest, was answered most inconsistently (9 Yes, 8 No and 1 Cannot answer). This may be due to the fact that two different questions lie within question 11, one pertaining to potential conflicts of interest of the review authors and the other referring to potential conflicts of interests of the authors of the included studies. 11 (61%) participants graded the quality of evidence to be low and 7 (39%) graded the quality of evidence to be very low. Several reasons were given for lowering the evidence quality rating, but the main reasons were risk of bias and imprecision.

**Conclusions:** The reliability of quality assessment of a systematic review with AMSTAR is high and the reliability of using GRADE is moderate. However, the high agreement by researchers with AMSTAR does not say anything about the validity of the tool. More research is needed.

### OR44.5

#### To What Extent Can We Agree on the Methods for Economic Evaluations? – a Common Framework for Economic Evaluations Within EUnetHTA

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**Background:** Due to specificities in the recommended methods and health care contexts, economic evaluations are generally country and context dependent. However, there are also common practices and core elements that may be shared among different health care settings, countries and regions. To make economic evaluations as useful and as applicable as possible to different countries in Europe, there is a need for more knowledge on similarities and differences in methods for economic evaluations between the European countries.

**Objectives:** The objective of this study is to increase the knowledge about similarities and discrepancies between national guidelines for health economic evaluations in European countries, set a European framework for economic evaluations, and increase the transferability of economic evaluations between the collaborating partners in the European Health technology assessment (HTA) network EUnetHTA.

**Methods:** To collect information on national requirements for economic evaluations, we gathered available methodological guidelines for economic evaluation in the countries that are involved in EUnetHTA. The guidelines were reviewed and the similarities and discrepancies between the countries were summarized. Based on the common denominators between the guidelines, a general framework for EUnetHTA is developed.

**Results:** Out of the 33 countries involved in EUnetHTA, 23 reported that they had some kind of methodological guideline for economic analysis, 5 reported that their country did not have a guideline and 5 did not respond. The guidelines differed in their extensiveness but all of them covered similar issues. Various differences were encountered, e.g. regarding what costs to include. However, there were also various similarities concerning for example the choice of analysis, presentation of results and the recommended time horizon.

**Conclusions:** The identified similarities and discrepancies between national guidelines constitute useful information in future collaborations between European countries. There are several important principles where the level of agreement is high, which enables a common European view on these general issues.

## OR44.6

### Health Technology Assessment in Low- and Middle-Income Countries: Findings from a Survey and Case Studies

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**Background:** There is growing interest in health technology assessment (HTA) in low- and middle-income (LMIC) countries though little is known about the extent of its use and the barriers to its adoption.

**Objectives:** The objective was to assess how HTA is being used in a wide range of LMICs, paying particular attention to barriers to its uptake and effective utilization.

**Methods:** We developed and administered a landscape survey with 22 questions to assess the use of HTA in selected LMIC countries. We received 12 completed surveys from these countries: Democratic Republic of Congo, Ethiopia, Namibia, Rwanda, Swaziland, Kenya, Afghanistan, Dominican Republic, Bangladesh, Jordan, South Africa, and Vietnam. We also conducted in-depth interviews and case studies in three countries: Kenya, South Africa, and Vietnam

**Results:** In the landscape survey, we found little formal HTA in these countries, and in countries where it exists, HTA is limited, and is not a high health sector priority. Activities to raise awareness of the functions of HTA and its utility would be useful.

The qualitative data obtained via open-ended questions suggested the following barriers to HTA development.

- The need for raising awareness and consensus building among HTA stakeholders;
- Building capacity and an increased quantity and quality of human resources for HTA;
- Development of standards and policies to enforce the use of HTA.

**Conclusions:** As HTA evolves in LMICs, it will be critical to align incentives between the macro-level health system technologies (e.g., health system organization), and the appraisal of specific micro-level technologies (e.g., medicines and associated clinical practice guidelines).

It is also important to distinguish the HTA functions that should be conducted locally and what is best shared. Information about the performance of health technologies is a global public good, and some sharing of information is optimal and needs to be supported to sustain globally efficient HTA.

## OR45.1

### Early Access to Technologies Ensuring Safety and Quality: the Galician Experience (Spain)

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**Background:** Coverage with evidence development schemes are felt to be very promising for providing early access to innovative technologies but little has been published regarding their impact on decision making or to how they have contributed to specific actions aimed at improving health care quality.

**Objectives:** Describe the strategic plan designed to improve the application of transcatheter aortic-valve implantation (TAVI) at the level of the Spanish National Health System, that emerged as a consequence of the post-introduction observational study undertaken in the Galician Health Care Service (2) explore the opportunities and challenges for HTA bodies with regards to the implementation of these schemes (methodological adjustments and collaborations).

**Methods:** N/A

**Results:** A project was implemented within the "Spanish NHS Network of Health Technology and Service Assessment Agencies" to develop appropriate use criteria for supporting decision making on definitive reimbursed indications and requirements. A data extraction RAND/UCLA appropriateness method was used for this purpose. The indications represent evidence based clinical scenarios (n=224) that were rated by panelists of related healthcare disciplines: appropriate (8.5%); uncertain (23.7%). Within this framework, key evidence based performance indicators (structure, process and outcome), along with reference standards, were also developed (n=23) in collaboration with key stakeholders to allow for a continuous measurement of TAVI performance and identify areas for improvement (pending implementation).

**Conclusions:** The current study constitutes a reference experience which serves to show how post-introduction studies can be relevant for re-evaluating or updating reimbursed indications and establishing investigation areas that can lead to improvements in health care delivery. The paper illustrates how HTA methodologies can incorporate existing tools to build sound approaches for the early introduction of new technologies that present uncertainties.

## OR45.2

### Agency Preferences in HTA Clinical Evaluations

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**Background:** While evaluating clinical efficacy is a universal goal, different agencies emphasize different topics in their health technology assessments. A precise understanding of the evaluation criteria of each agency would aid in constructing a successful submission.

**Objectives:** This analysis will use a case study approach to identify and evaluate key differences between agencies' clinical evaluation methods.

**Methods:** Evaluations of fingolimod and erlotinib by CADTH, HAS, HIRA, NICE, SMC, G-BA, IQWiG, and PBAC were grouped by drug and compared. HTAs were included only if they evaluated the same indication on the basis of the same evidence. All clinical commentary was compiled, systematically characterized, and qualitatively assessed.

**Results:** Seven agencies assessed fingolimod on the basis of TRANSFORMS and FREEDOMS for MS after failure of IFN-beta. Four agencies assessed erlotinib on the basis of BR.21 for NSCLC after failure of chemotherapy. On major topics like final recommendations, clinical significance, adverse events, and appropriate comparators there was strong if not unanimous agreement amongst agencies. However,

agencies varied in critical depth. In the erlotinib comparison, NICE uniquely made note of a significant limitation of the characteristics of the trial population, HAS had multiple unique disagreements, and PBAC did not report any of the other agencies' concerns. In the fingolimod comparison, CADTH uniquely disregarded statistically significant results because they were clinically insignificant, GBA and IQWiG were the strictest about use of an approved comparator and appropriate trial population, and HIRA did not report any of the concerns other agencies. There is also a wide variance in which topics are emphasized or addressed. In both comparisons NICE and SMC strongly emphasized patient experience considerations, SMC uniquely emphasized real-world effectiveness, and HIRA uniquely emphasized non-clinical secondary sources.

**Conclusions:** Initial results indicate that while most agencies agreed on major points, significant differences remain. Further research could enable submissions specialized per agency preferences.

### OR45.3

#### System of Tutelage of Health Technology (STHT) - Superintendencia De Servicios De Salud

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**Background:** In the health sphere, technological advancement and the economic impact caused by certain diseases oblige evaluators and decision-makers to plan and organize services without sufficient information regarding new technologies. An HTA team dependant on the Ministry of Health has designed a methodology to diminish the uncertainty related to this issue.

**Objectives:** To describe the design and implementation of a tool that helps reduce uncertainty, facilitating access to recent technologies at National and International level by means of reimbursement to National Medical Insurance in Argentina.

**Methods:** The System of Tutelage of Health Technology (STHT) is a monitoring tool of certain pairs of need-technology included in the Resolution SSS No 1561/2012.

A group of technologies intended to control dangerous diseases has been analyzed in order to produce Rapid Assessment Reports on Health Technologies using methodology adopted by MERCOSUR.

These reports could suggest including the pair of "need-technology" for reimbursement, not including it or including it by means of tutelage.

The STHT includes technologies recently applied based on weak scientific evidence, those with safety issues, compassionate use or of treatments of second or third line of oncology.

In connection with the pairs of "need-technology" included in the tutelage use, the conditions under which they should be provided have been determined together with the information that should be provided about effectiveness and safety.

**Results:** 46 out of 227 pairs of need-technologies are included in the STHT. The use of technologies and of safety and effectiveness data to be reported by Health Insurances has been circumscribed to specific population groups. This will serve as the basis to obtain information that supports future decision making.

**Conclusions:** It is estimated that the STHT will enable to make decisions in connection with the application of technologies when the balance between benefit and cost-risk is not clear enough, saving time and relieving uncertainty.

### OR45.4

#### Lack of Recycling is Wasteful- Time to Start Reusing Models for Economic Evaluation?

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**Background:** An increasing number of HTA-organisations include economic evaluations in their assessments. However, there seems to be little cooperation between organisations developing decision models for these analyses. As many HTA-organisations assess the same technologies, there clearly exists a potential to reduce duplication of work by reusing models. At the HTAi meeting in Singapore 2009, we advocated more collaboration in a separate session on the topic. Little seems to have been done to encourage such collaboration from HTAi, EUnetHTA or other central agencies since then.

**Objectives:** To spark a debate around possible ways of cooperation, sharing and reuse of existing models for economic evaluation.

**Methods:** Since presenting at HTAi in 2009, we have tried to increase our collaboration through sharing models. We have also developed some new ideas as to how collaboration can be developed further.

**Results:** Based on our experience with model sharing and the HTA community, we propose that possible ways ahead might be:

- A separate unit for model development which creates models for HTA agencies (funded by the agencies)
- An HTAi interest subgroup with some kind of database where all models or information about models are published for later reuse and sharing
- Team up with health economist from other organisations and work together on model development
- An EUnetHTA project developing health economic models within different disease groups which can be shared and re-used by all partners/all external parties.

**Conclusions:** Model sharing has the potential to improve analyses and save resources. Sharing models can also have important learning effects and function as a form of quality control. Challenges still exist in finding the best way to facilitate cooperation between agencies

### OR45.5

#### Rapid Evidence Reviews: the CADTH Experience

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**Background:** Constant, rapid, and often expensive advances in medical technologies make evidence-based information essential in healthcare decision-making. While comprehensive systematic reviews are used to support many deliberations, the urgency of some decisions requires a more immediate response.

**Objectives:** The objective of CADTH's Rapid Response Service is to provide Canadian healthcare stakeholders with timely, relevant evidence to support informed decision-making.

**Methods:** Federal and provincial government bodies, regional health authorities and hospitals can request topics from the Rapid Response service, without charge. Modified review techniques accommodate accelerated evidence synthesis and can be tailored as needed. For more in-depth reviews, a one-page plain language Report-in-Brief is prepared in English and French and posted with the full report on the CADTH website. Findings inform purchasing decisions, or support policy and practice change.

**Results:** In 2012-13, 235 reports were produced with 65% addressing a question on non-drug health technologies. A variety of report types are available – from reference lists to summaries with critical appraisal – however in recent years more requests for the latter may indicate that these reports represent the ideal balance of rigour and timeliness for decision-makers. Customer evaluations of the reports and the Reports-in-Brief have demonstrated the success of the program.

**Conclusions:** Making crucial decisions about health technologies is difficult and even more so during times of economic uncertainty. Using rapid review techniques, CADTH ensures our customers have the evidence they need in time to help with their decision-making processes about drugs and health technologies. Through knowledge mobilization techniques we assist our customers to effectively share information with their teams while also broadening the reach of our reports. Improvements to the rapid review methodologies and processes will continue to be made based on our evaluations and advances in the field.

#### OR45.6

##### **Fast-Track HTA Assessments: Different Mechanisms by Which HTA Agencies Facilitate Rapid Review in Exceptional Circumstances**

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**Background:** Health Technology Assessment (HTA) of new technologies is a time-consuming process and the delay from marketing authorisation to patient access can have a significant impact on the health of patients. Consequently, some HTA agencies are utilising mechanisms to “fast-track” promising technologies in circumstances where there is either high unmet need, where standard HTA review processes are lengthy or where the HTA itself may create resource concern such as at the local level. Consequently, a variety of different approaches have been developed across Europe and as such there is a need to systematically review, describe and compare these mechanisms.

**Objectives:** The objective of this research was to (i) identify and describe the different mechanisms for fast-track HTA in Europe, (ii) to develop a taxonomy of these processes and (iii) to examine evidence of their use and effectiveness.

**Methods:** N/A

**Results:** Six different categories of fast-track HTA were identified: (i) rapid reviews as a component of the HTA process; (ii) formal reduction in review time; (iii) simplified HTA review; (iv) mini-HTA; (v) immediate reimbursement at the hospital level; and (vi) temporary authorisation mechanisms. Evidence of the utilisation and impact varied between mechanisms in development (e.g. EUnetHTA rapid REA) versus those that were established (e.g. French ATU or English STA). For established systems, fast-track HTA was shown to provide earlier patient access to technologies.

**Conclusions:** Overall, Fast-Track HTA are being used for a variety of purposes from prioritising the assessment of particular medicines, to reducing long review times, to reducing regulatory burden at the local level. While Fast-Track HTA needs to match the problem with the HTA process in question it could be applied more generally in circumstances where HTA is conducted on new technologies prior to launch, where the current HTA review process is lengthy or where a national HTA is not implemented.

#### OR46.1

##### **Health Technology Assessment of Medical Devices in Europe**

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**Background:** Europe is one of the biggest markets for medical devices, which encompass a broad and heterogeneous range of technologies. The rapid pace of innovation in the medical device industry has been an important driver of rising health care expenditures in recent years. Most decision-making systems on coverage involving HTA were initially developed to evaluate pharmaceuticals, a fact which is reflected in the methods and processes employed. However, assessing the value of medical devices entails important differences and may merit a more tailored approach.

**Objectives:** To identify and compare current methods, processes and institutional practices for the evaluation of medical devices in European countries in order to advance the debate on how existing assessment tools can be modified or adapted with a view to producing robust methods for evaluating medical devices.

**Methods:** A comprehensive approach was adopted to identify institutions involved in HTA in European countries. We systematically searched institutional websites and other online sources by using a structured tool to extract information on the role, structure, scope, methodological approach and available HTA reports for each included institution.

**Results:** Information was obtained on 84 agencies. 35 methodological documents from 20 agencies in 15 countries were identified. Only 4 agencies had separate documents for the assessment of medical devices. 5 additional agencies made separate provisions for the assessment of medical devices in their general methods, most notably concerning the type of evidence admissible. The amount of publicly available HTA reports on medical devices varied by device category and agency remit.

**Conclusions:** Despite growing recognition of their importance and international initiatives, such as the EUnetHTA Core Model, specific tools for the assessment of medical devices are rarely developed and implemented at the national level.

#### OR46.2

##### **Technology Assessment in Health Services – the Newborn REBRATS Working Group**

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**Background:** Brazilian health services have different responsibilities and capabilities. The autonomy of federated entities and the economic and population concentration provide a heterogeneous scenario and asymmetric information. This scenario induces a pattern of inequity in access and disparity in evaluation of technologies used in health care process.

Considering this, the members of Brazilian Network for Health Technology Assessment - REBRATS noted the need to create a specific working group (WG) to exchange experiences between member institutions to enhance the performance and use of HTA products in primary care.

**Objectives:** Creating a new WG in REBRATS aiming to promote and assist the institutionalization of HTA in health services and provide a space for exchanging experiences.

**Methods:** n/a

**Results:** The WG on Technology Assessment in Health Services met for the first time on 2013 and defined the issues to be addressed.

Soft technologies with emphasis on primary health care



Procedures, programs, clinical protocols and therapeutic guidelines  
Medical and hospital equipment  
Access to databases and information systems  
Health institutions logical models  
Standardization of raw-materials  
Judicialization  
Influence of industry on health professionals  
Patient Safety  
Misuse and unnecessary procedures  
Overdiagnosis or overuse  
Ethical aspects  
Lack of resources

**Conclusions:** The Executive Committee of REBRATS before the demand arising among the members of the network, and in exercise of his powers, created a new WG for REBRATS. It is expected that the newly created group can supply the gap between network members, providing a forum for discussion, exchange of experiences, and construction of methodology oriented to the needs of health services. The creation of a new WG in REBRATS is a sign that the network is not configured as a static structure; it can mold itself to the needs of its members. Interactivity and participation of all members of the network are of utmost importance to its operation and demonstrate its vitality.

#### OR46.3

##### Health Technology Assessment of Robot-Assisted Surgery at “Bambino Gesù” Children’s Hospital

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**Background:** The worldwide spread of robotic surgery entails, especially for hospitals, the need to find decision support evidence as regards the indication for use of robotic systems in surgical practice as well as the need to set up an accurate analysis on cost and overall impact.

**Objectives:** (i) To collect the evidence on the efficacy, cost-effectiveness and safety of robotic surgery compared to laparoscopic and open interventions from hospital and patients’ prospective; (ii) to assess robotic surgery’s hypothetical impact on hospital budget and organization.

**Methods:** The Eunehta Core Model<sup>®</sup> is used to assess this technology on clinical, technical, organizational, economic, social, ethical and safety domains. Subsequently, assessment elements are integrated in a decision tree and weighted by means of pairwise comparisons (cf Analytic Hierarchy Process); finally surgical alternatives are compared on each leaf of the decision-tree.

**Results:** Robot-assisted surgery is safe and feasible for a range of pediatric procedures. It may offer advantages to patients, like reduced blood loss and transfusion, fewer postoperative complications, shorter length of stay in hospital. Surgeons may also benefit from better precision and articulation of instruments and a three-dimensional visualization. Nevertheless, robotic surgery is associated with high fixed costs and it has to be performed in a dedicated operating room to avoid moving the robotic system and risking mechanical damage to the components.

**Conclusions:** Despite the first economic and organizational data of this report would seem to point towards discouraging from buying, considering clinical and technical findings, this scenario would change

under a more profitable sell proposal by the manufacturer (hence taking into account lower buying expenses). However, the Board of Directors may consider the clinical and technical potential of this new technology of strategic relevance for future scientific and clinical developments and improvements.

#### OR46.4

##### A Review of International HTA Activities on Medical Devices

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**Background:** Policymakers increasingly rely on Health Technology Assessment (HTA) to make coverage and reimbursement decisions. While there have been a number of international surveys of HTA policies, few have reviewed medical device evaluation.

**Objectives:** To review and compare current medical device (MD) HTA activities across non-European Union (EU) HTA agencies.

**Methods:** Agencies were selected based upon membership (as of February 2013) in: Health Technology Assessment International (HTAi), European network for Health Technology Assessment (EUnetHTA), International Network of Agencies for Health Technology Assessment (INAHTA) and World Health Organization (WHO) Collaborating Centers for HTA. Included agencies’ HTA procedures for MDs were evaluated from three perspectives: (i) structure: organizational framework; (ii) process: HTA standard operating procedures; (iii) methods: scientific methodologies underpinning assessment. Data collection consisted of two phases: web-based survey of included agencies and semi-structured interviews with agencies adopting MD specific procedures.

**Results:** The sample included 36 agencies across 19 non-EU countries. The majority (88%) of agencies assessed MDs in parallel to drugs and other medical technologies. Of 36, 27(75%) had MD specific assessment and appraisal procedures. Seventy-eight (21/27) and sixty-seven percent (18/27) of agencies had structural and procedural processes for MD evaluation, respectively. One agency, Department of Science and Technology in Brazil, reported the use of a specific methodological guidance for MD HTA. Interviews confirmed commonly cited challenges with HTA of MDs: relatively poor evidence quality, inability to generalize evidence across settings, ‘learning curve’ (i.e. clinical outcomes dependency on user experience or setting), and difficulty scoping the decision problem.

**Conclusions:** While international regulatory requirements may be fairly consistent, HTA procedures for MDs vary widely. It is accepted that MDs differ from non-device technologies (e.g., learning curve). Little evidence of differentiation in the methods adopted for MD assessments relative to non-devices begs the question of whether the challenges presented by MDs demand modifications to HTA procedures.

**OR46.5****Development of Guidelines on New Health Technology Assessment in South Korea**

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**Background:** Following the growing demand for New Health Technology Assessment (nHTA) there needs to be clear guidelines on nHTA. A developed guideline will resolve the current confusion about nHTA.

**Objectives:** The purpose of this study was to develop a guideline that clarifies the standard of judgment for nHTA as well as the standard of assessment for a health technology's safety and effectiveness.

**Methods:** We analyzed 1,122 health technologies that previously submitted to nHTA from April 28th, 2007 to December 31st, 2012. The subjects included interventional procedures, diagnostic tests, and gene tests, and were divided into to the technology which had to be assessed as a new technology and the technology which did not need to be assessed. In order to develop a new guideline on nHTA, we set up a task force consultative group which includes experts from the Ministry of Health & Welfare, National Evidence-based Collaborating Agency, health technology industry, and Health Insurance Review Agency.

**Results:** In the case of interventional procedures, in order to be recognized as new health technology, the submitted technology should have similar or higher level of efficacy and safety, compared to existing technologies. To evaluate efficacy of interventional procedures in the process of nHTA, the committee members considered the factors, such as: appropriate comparator; population size; consistency among studies; homogeneity between groups; proper health outcomes; follow-up period; analysis method; and conflict of interest. In the case of diagnostic tests, nHTA assessed analytical performance, diagnostic performance, and clinical utility of the tests.

**Conclusions:** With the developed nHTA guideline, all stakeholders, including health technology applicants, health industry, and nHTA assessors should constantly improve the guideline to achieve the standardized assessment system and to enhance the receptivity of relevant organizations, such as HIRA and others. It is expected that the developed guideline on nHTA will provide an opportunity to upgrade nHTA system.

**OR46.6****Characterization of Handbooks and Toolkits in Healthcare and in HTA - Tips for Improvement**

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**Background:** Handbooks (HB) and Toolkits (TK) are terms frequently used when produced guidance documents in the healthcare field. Definitions of their meaning and aim are widely available. Several HTA organizations have produced them as a tool to standardize or guide methods and processes in the field. However, there is a lack on gold standard regarding their content.

**Objectives:** To review HB&TK published in HTA and to compare them with those in the healthcare field with the aim to propose areas of improvement for the former, and build a framework for the development of a HB&TK for Hospital Based HTA (HB-HTA). This work is performed under the EU project AdHopHTA, which aims to produce a HB&TK for HB-HTA.

**Methods:** Literature review of Medline (Pubmed), Cochrane Library, grey literature and international HTA projects and organizations.

Content analysis of HB&TK identified in clinical and HTA field was performed. Similarities and singularities for HTA HB&TK have been identified. Through a brain storming discussion with HTA experts, a specific model for HB&TK has been developed.

**Results:** The literature search identified 553 HB and 1336 TK records. Initially, 47 and 71 were selected, respectively. Inclusion criteria were: context-insensitive HB&TK, HB&TK for hospital setting, papers dealing with implementation, comparison, impact of HB&TK. HBs are designed to facilitate "making appropriate decisions rather than to dictate arbitrary standards" or "provide detailed recommendations". TKs are defined as "sequence of steps to be taken"; "text and web-based summary of approaches" to achieve certain goals. Preliminary results show an important heterogeneity among HTA HB&TK and those in healthcare field. However, a minimum set of information is expected to be present.

**Conclusions:** HTA aims to be rigorous and transparent in their processes and methods. The availability of evidence-based guidance for HB&TK development in this field will contribute to improve and reinforce its robustness.

**OR47.1****Comparison of Convergence of Health Indicators between China and United States: an Empirical Study**

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**Background:** From a long-term perspective, within-country convergence of health outcome can reflect the changes of effectiveness of policies or health technologies over time. As the biggest developing country, China's regional economic development imbalances brought regional disparities in health. United States is one of the most developed countries whose health resource quantity per capita is also one of the highest.

**Objectives:** This study was aimed to compare the convergence of health indicators between China and U.S. to see whether China has shown significant  $\beta$  convergence.

**Methods:** The study was an empirical study using data from 31 provinces in China from 1981 to 2010 and 51 states in U.S. from 1980 to 2010 due to the accessibility of data resources. Number of beds and physicians per 1,000 persons were chosen as indicators of health resource, while infant mortality rate (IMR) and life expectancy (LE) were selected as indicators of health outcome. The models of convergence derived from neoclassical economics were adopted. This study used non-linear regression model simulating the relationship between the annual growth rate and the initial levels of each indicator to analyze  $\beta$  convergence.

**Results:** In China, both number of beds and physicians showed significant absolute  $\beta$  convergence. But after adjusting population and GDP per capita, only number of beds showed significant conditional  $\beta$  convergence which coefficient was 0.032. Number of physicians in U.S. had absolute and conditional  $\beta$  convergence, which coefficient were 0.007 and 0.006, respectively. But number of beds in U.S. didn't show  $\beta$  convergence. Referring to health outcome, IMR in China showed absolute  $\beta$  convergence (0.031) but not significant conditional  $\beta$  convergence, while LE had both absolute (0.022) and conditional (0.044)  $\beta$  convergence. In U.S., those two indicators of health outcome neither showed  $\beta$  convergence.

**Conclusions:** The results showed that  $\beta$  convergence were more obvious in China than in U.S. Those results can reflect the changes of effectiveness of policies or health technologies over time and then support the health decision-making.

**OR47.2****Value Judgments in the Health Technology Assessment Process in Brazil**

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**Background:** Treating the shortage of health resources ethically and rationally seems to be the best way to face the dilemmas related to health technology assessment. Many aspects influence this process, including ethical, economic and social issues, which should serve as a basis for setting priorities in health and for the development of decision analysis.

**Objectives:** To evaluate the value judgment on critical decisions involving the allocation of resources and the use of technologies in the Brazilian Health System, through the vision of health professionals and managers, and, by this appraisal, estimating implications that have potential influence on the health policies in the country.

**Methods:** Cross-sectional exploratory study applied online, through a decision-making questionnaire for incorporation of health technologies, endowed with four scenarios that simulate real situations of resource allocation in an environment of severe budget constraints, which was completely answered by 193 managers and professionals from various health sectors. The scenarios presented trade-offs such as patient age, disease prevalence, reduction/extinction of current health programs, creation of taxes, and choices between prevention and treatment. The variations found in the responses were measured by Chi-square test.

**Results:** The survey had a response rate of 27.3 %. Of these, almost half were medical doctors, 90% had at least one post-graduation, and there was an equal distribution between men and women, as well as among those working in the public and private system. There was a diverse sample of respondents with participation of all proposed segments. Of the four presented scenarios, Scenarios 1, 2 and 3 involved some form of incorporation. In Scenario 1, 78% of respondents opted for decisions that nothing, or very little, affected the budget. In Scenario 2, 68% of respondents also opted for decisions that nothing, or very little, affected the budget. In Scenario 3, we find the highest trend for the incorporation among the studied scenarios, with 58% of respondents choosing for one of the options that involved incorporation. In Scenario 4, when comparing the results between treatment and prevention programs, the latter was prioritized for resource allocation, with 65% of responses.

**Conclusions:** This study suggests that Brazilian health professionals and managers are significantly influenced by economic and budgetary issues when deciding about the allocation of resources for health technologies assessment in the country. In search of a paradigm for decision-making, most professionals and managers generally prioritized to save resources, instead of incorporating the technologies. Among the segments, the pharmaceutical industry showed the greater tendency for technological incorporation. We hope that this and other studies are able to collaborate in the establishment and strengthening of health policies that ensure economic feasibility for an effective incorporation of progressive technologies, avoiding an undesirable technological gap, because of the severe budget constraint of Brazilian health.

**OR47.3****Appropriate Evidence Sources for Populating Decision Analytic Models Within Health Technology Assessment (HTA): a Systematic Review of HTA Manuals and Health Economic Guidelines**

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**Background:** Decision analytic modellers use numerous types of evidence for populating model parameters. Detailed methodological advice on which type of data is to be used for what type of model parameter is required.

**Objectives:** We aim at reviewing existing HTA manuals and health economic (modelling) guidelines in order to gain advice on appropriate evidence sources for populating models.

**Methods:** We identified manuals and guidelines via the International Network of Agencies for Health Technology Assessment (INAHTA) and by hand search. We included documents from Europe, the USA, Canada, Australia and New Zealand as well as transnational guidelines written in English or German. We systematically summarised recommendations on appropriate evidence sources for different model parameters in a narrative manner. Additionally, information on advantages and disadvantages of sources, on evidence identification methods and on data quality issues was extracted.

**Results:** 28 documents fulfilled our inclusion criteria. We identified a large variety of evidence sources for informing model parameters on clinical effect size, natural history of disease, resource use, unit costs and health state utility values. They comprise research and non-research based sources. The documents do not provide structured advice on the hierarchy of evidence and on the limitations of evidence sources. The information is presented fragmentarily and is not tailored to specific model types.

**Conclusions:** The usability of guidelines and manuals for modelling could be improved by addressing the issue of appropriate evidence sources in a more structured and comprehensive format.

**OR47.4****The Completeness of Intervention Descriptions in Published UK NIHR HTA Funded Trials: a Cross Sectional Study**

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**Background:** The publication of unbiased and usable reports is essential to ensure that funded clinical research can be used by clinicians to benefit patients. There are many guidelines available for researchers when writing up their research findings which include describing the intervention. Adequate intervention description is essential to ensure that innovative interventions are transferred to practice. The UK NIHR Health Technology Assessment (HTA) Programme produces independent research information about the effectiveness and cost-effectiveness of health care interventions for the UK NHS and publishes all funded research in its own journal.

**Objectives:** The objective of this study was to assess whether HTA funded randomised controlled trials (RCTs) published in Health Technology Assessment Journal were described in sufficient detail to replicate in practice.

**Methods:** A published checklist which included assessments of participants, intensity, schedule, materials and settings was piloted twice on a sample of 10 reports. Kappa scores were generated to assess agreement in the checklist application. The checklist was modified and applied to all ninety eight RCTs published in the HTA Journal up to March 2011. Completeness of the intervention description was assessed independently by two researchers and disagreements in scoring were discussed by the team; differences were then explored and resolved.

**Results:** Components of the intervention description were missing in 68 / 98 (69.4%) reports. Baseline characteristics and descriptions of settings had the highest levels of completeness with over 90% of reports complete. Reports were less complete on patient information with 58.2% of the journals having an adequate description.

**Conclusions:** Ensuring the replicability of study interventions is an essential part of adding value in research. All those publishing clinical trial data need to ensure transparency and completeness in the reporting of interventions to ensure that study interventions can be replicated and innovation can be used to benefit patients.

## OR47.5

### A Reflection on Systematic Search Strategies for Qualitative Health Research to Inform HTA: to Find the Needle, You Must Get Rid of the Hay

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**Background:** Systematic searches of qualitative literature are becoming increasingly prevalent in HTA, especially as a way of informing social and ethical implications of technology. Despite the growing demand for systematic reviews of qualitative research, existing filters do not have recall and precision results that are comparable to those for quantitative research. An exhaustive search for qualitative research typically involves hand-searching thousands of references, which is not time or resource-efficient.

**Objectives:** Identify why systematically searching for qualitative literature continues to be so challenging and suggest strategies that may be useful to those who write qualitative research and those who search for qualitative research.

**Methods:** This conceptual research draws upon the research team's experience conducting six systematic reviews, including testing the use and combination of several qualitative filters.

**Results:** Much of the difficulty using search filters for retrieving qualitative research results from the lack of consistent descriptions of qualitative methods in a way which is effective for automated searching. We outline some of the potential reasons for this inconsistency, drawing on ideas of interdisciplinarity, qualitative methodology, and the history of health sciences. From this literature and our experiences systematically searching for qualitative literature, we offer some suggestions that may help the sorting process based on a process of categorizing excluded papers and developing a list of exclusionary terms found in retrieved groups of irrelevant papers.

**Conclusions:** Search filters work by identifying ways that researchers name or categorize their work. For many reasons, qualitative researchers tend to use a broad variety of eclectic terms that may not be consistently included in or recognized by search filters. Describing search filters as diagnostic tools that possess an inherent specificity and sensitivity may conceal the fact that search filters rely on shifting, culturally-created, evolving ways that researchers and publishers describe qualitative research.

## OR47.6

### Information Retrieval: the Impact of a Clinical Librarian in Health Technology Assessment

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**Background:** Librarians can assist health professionals to retrieve information that will subsidize the process of health technology assessment (HTA). The number of published articles has increased greatly in recent years and there is a need to search for scientific studies of better quality and to recover consistent and relevant information about the benefits and risks of technologies and their impact on health care.

**Objectives:** To report the role of the librarian in the process of HTA in a Health Maintenance Organization in Brazil (HMO, Unimed-BH).

**Methods:** HTA studies carried out by the HMO HTA Group from 2012 to 2013 were analyzed to assess the impact of a librarian in providing search strategies that could enhance the process of scientific information retrieval.

**Results:** 90 out of 107 HTA studies (85%) were performed with the participation of a librarian. The most common fields studied were drugs for treating cancer and health devices. 7% of the HTA produced had their final result modified due to the changes in the research strategy advised by a librarian.

From 2012 to 2013, with the advice of a librarian, the capacity of the group to perform inquiries to medical databases increased progressively. In 2013, 587 scientific articles were retrieved from electronic databases (61.1% from Medline, 27.8% from electronic journals, 4.7% from Cochrane Library and 6.2% from other sources). Our analysis showed a 30% increase in the capacity of producing HTA when using the help of a librarian.

**Conclusions:** Our results showed that a librarian can play a decisive role in the activity of HTA.

## OR48.1

### Guidelines of the Brazilian Ministry of Health: Drafting Tools for Research in Health Technology Assessment in Brazil

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**Background:** The Working Group on Development and Standardization of Methodologies of the Brazilian Network for Health Technology Assessment (REBRATS) is formed by members of major universities and rating agencies in Health Technology Assessment (HTA) in Brazil. The main goal of the group is to establish methodological HTA research standards.

**Objectives:** To present Brazilian Ministry of Health's guidelines for drafting, revising, updating and validating methodological standards.

**Methods:** The group gathers in annual meetings led by the Brazilian Ministry of Health. Each member gives a presentation about recent developments. The presentation enables discussion and collaboration among all members. All documents are available to the public in the REBRATS website. This encourages social participation and allows for a transparent process. The reviewing process involves two additional reviews. One is internal and performed by the staff of Brazilian Ministry of Health. The other is external and performed by invited specialist and the working group itself. Mainly, the Brazilian Ministry of Health assesses the need to update guidelines through training workshops and opinions of users. The validation process is dynamic. It is made

both during the drafting process and after the publication where the guidelines may be used by managers and practitioners.

**Results:** Currently, eight guidelines are in different drafting stages. These Guidelines are: Systematic Reviews and Meta-Analysis of Diagnostic Accuracy Studies; Development of HTA Appraisals (mini HTA); GRADE Translation to Portuguese; Systematic Reviews of Observational Studies; Indirect Comparisons; ADAPT Translation to Portuguese; Economic Evaluations; and the Multiple Technologies Assessment.

**Conclusions:** These documents serve as reference literature for everyone involved in HTA in Brazil, including the general public seeking basic knowledge for their participation in health policies.

## OR48.2

### Analysis of the Global Clinical Trials for Health Technology Horizon Scanning

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**Background:** To obtain relevant targets for (emerging) health technology horizon scanning, it is worth to analyze the global clinical trials. There are registries where researchers and health industries upload their clinical trials. The registries have emerged as a key element of many public health policy initiatives aimed at improving the clinical research.

**Objectives:** To identify major areas, keywords, and countries' collaboration in the global clinical trials in order to predict targets for health technology horizon scanning.

**Methods:** We analyzed 150,756 clinical trials collected from ClinicalTrials.gov and ICTRP (International Clinical Trials Registry Platform). We used Vantage Point (Georgia Tech, USA) and VOSviewer (v.1.5.5., Netherlands) programs which provide various maps to identify major areas, keywords, and countries' collaboration in the global clinical trials.

**Results:** There has been an upward trend in clinical trials from 2000 to 2013. Most of the clinical trials we collected from ClinicalTrials.gov were in the areas of HIV, cancer, and type 2 diabetes. The clinical trials in their stage of phase II and III, which are the potential targets for health technology horizon scanning, were 13.63 % and 17.82 %, respectively. In ICTRP data, we used 'cancer' as a keyword and found that 41,988 clinical trials. The most frequent keywords in the cancer clinical trials were chemotherapy (1,372, 6.88%), breast cancer (1,042, 5.23%), surgery (1,189, 5.97%), and radiation therapy (920, 4.62%). In the map showing countries collaboration in cancer-related clinical trials, South Korea, Taiwan, Russia, Australia, Italy, Germany, and the UK had a close collaboration.

**Conclusions:** Analysis of the clinical trials collected from ClinicalTrials.gov and ICTRP provides the current scope of emerging health technology clinical trials. The findings can be useful for health technology horizon scanning activity and R&D investment by governments and researchers.

## OR48.3

### A Systematic Review of Health Technology Assessment Tools in Sub-Saharan Africa: Methodological Issues and Implications

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**Background:** Health Technology Assessment (HTA) is mostly used in the context of high-and middle-income countries. Many resource poor settings, which have the greatest need for critical assessment of health technology, have a limited basis for making evidence-based choices. This can lead to inappropriate use of technologies, a problem addressed by HTA enabling efficient resource use which is especially crucial in resource limited countries.

**Objectives:** There is a lack of clarity which HTA tools should be used in these settings. This research aims to provide an overview of proposed HTA tools with a specific focus on Sub-Saharan African (SSA).

**Methods:** A systematic review according to PRISMA guidelines was conducted for studies sufficiently detailing HTA tools that are applicable for resource-limited settings in SSA, published between 2003 and 2013. The identified tools were assessed according to a checklist with methodological criteria.

**Results:** From 43 identified studies, four appropriate tools apply different criteria and evidence needs that are applicable in resource-limited settings, and cover methodological robustness and ease of use. The KNOW ESSENTIALS and Mini-HTA tool fulfil these criteria, but have not been applied in a low-income SSA setting yet. Multi-Criteria Decision Analysis (MCDA) shows value in assessing evidence and has a strong potential to be used by different stakeholders. The WHO CHOICE method is a standardized decision making tool for choosing interventions limited to their cost-effectiveness.

**Conclusions:** Most evaluation of health technology in SSA focuses on priority setting. There is a lack of HTA tools that can be used for systematically assessing technology in the SSA context. An appropriate HTA tool for resource-constrained settings and especially SSA should address all important criteria of decision making. By combining the two most promising tools, KNOW ESSENTIALS and MCDA, appropriate analysis of evidence with a robust and flexible methodology could be applied for the SSA setting.

## OR48.4

### Results from the Survey of Decision Making for Medical Devices in Argentina

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**Background:** Most Latin American countries face a tricky dilemma: to finance new promising, costly medical devices (MD) with limited resources, while risking neglect of essential health interventions, vs preventing innovation. Shortage of human resources to assist rational decision making further aggravates this problem.

**Objectives:** To understand argentinian policy makers perception about regulation, evaluation and incorporation of medical devices in Argentina.

**Methods:** A web-based auto-administered survey was designed and mailed to 104 strategic health decision makers in Argentina, through snowball sampling. The survey evaluated: 1) Key actors in different regions and health sectors, 2) Inputs for decision making, 3) Priorization, 4) Rol and barriers of HTA, 5) Interactions. In depth interviews were also used.

**Results:** 97 surveys were received (response rate 93%), 33% from social security, 24 % public hospital level, 31% regulatory authorities, 9 % from private health system and 3 % from University.

Key regulatory inputs were manufacturer habilitation, comply with safety and efficacy requirements, and adequate risk-benefit balance, matching national registration agency criteria, highlighting its influence. Cost-effectiveness, budget and organizational impact, market factors or international regulations were not perceived as important. 42% of respondents use some form of HTA, mainly in coverage decisions of high cost MD. The largest utilization occurs in private sector (43%), followed by Provincial Ministries (26%), Social Security (22%) and National Hospitals (9%). The use of HTA for divestment is very low. Most HTA are performed in private sector (31%) and government HTA network UCEETS (21%), followed by Provincial Ministries (18%). Considering federal HTA network RedARETS, public HTA production rises to 39%, ranking as first producer. Main barriers were lack of knowledge about HTA possible applications (43%), and shortage of technical resources to perform and understand HTA reports (22%).

**Conclusions:** This survey provided a peeping inside health decision makers heads, useful to improve HTA uptake in developing countries.

## OR48.6

### Health Technology Assessment and Efficient Health Care Decision Making by the Judiciary System in Brazil: the NATS-UFGM Experience

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**Background:** In Brazil, because health is a citizen's right and a duty of the state, patients often ask judges to issue court orders obliging health managers to purchase expensive and experimental drugs or to provide elective medical procedures immediately. This practice has a critical impact in the healthcare budget once it frequently results from irrational prescribing practices and often takes resources away from priority areas. In 2008, the State of Rio Grande do Sul spent 22% of its drug budget to comply with 19,000 court orders. In 2012 a partnership was established with the Nucleo de Avaliação de Tecnologia em Saúde from the Hospital das Clínicas at the Universidade Federal of Minas Gerais (NATS-UFGM) in order to increase the efficiency of the healthcare decisions provided by the judiciary system from the State of Minas Gerais.

**Objectives:** To describe the results obtained from the partnership between the judiciary system from the State of Minas Gerais and the NATS-UFGM.

**Methods:** All judicial healthcare demands analyzed by the NATS-UFGM from October to December 2012 were included in this study.

**Results:** 62 judicial healthcare demands were analyzed by the NATS-UFGM during the period of this study. Most of the cases were associated to the treatment of chronic non transmittable diseases (60; 96.8%). The most frequent conditions were: endocrine/nutritional/ metabolic (17.7%), neoplasms (14.5%) and cardiovascular diseases (11.3%). The

demands were mostly related to drug requests (44.79%), medical procedures (17.7%) and medical devices (5.8%). 70% of the treatments under judgment were considered not adequate or worse than the essential medications already provided by the Sistema Unico de Saúde (SUS). Because of that a total of US\$370,000.00 could be saved.

**Conclusions:** The partnership between the State of Minas Gerais and the NATS-UFGM has greatly contributed to improve the judiciary decisions allowing better allocation of healthcare resources.

## OR49.1

### Matching Research with Decisions: How Rapid HTA Based on Patients` Outcomes Can Support Evidence Based Decision Making (EBDM)

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**Background:** The lack of timeliness between decision and availability of research results is a relevant barrier to the implementation of EBDM. Policy makers are willing to sustain innovations claiming a large impact on healthcare, even when definite empirical data is lacking. Reconciling expectations and data is a major challenge in HTA.

**Objectives:** To develop a methodology for a rapid delivery of essential context-based information to decision-makers, which allows quick identification of real potentials of health innovations.

To test the application of this methodology in the evaluation of innovative health technologies (new devices for diabetes treatment, genetic tests in breast cancer).

**Methods:** A rapid assessment of innovative health technologies was developed through the following steps:

- 1) technology description and context analysis: the theoretical rationale in support of the innovative health technologies was investigated to establish potential clinical benefit; a retrospective audit on local target populations was carried out; incidence and prevalence of patient-important outcomes and complications were assessed; potentially attainable margin of improvement was estimated;
- 2) evidence mapping: for each HTA domain (from technical performance to costs), a systematic search of the literature was carried out to identify the number and the quality of studies available;
- 3) additional evidence appraisal: a systematic search of the ongoing trials was carried out.

**Results:** The first step allowed to quickly rule out technologies of limited interest in terms of added benefit (genetic tests in breast cancer) contributing to the prioritization in HTA research programme. The second step allowed to identify research gaps for technologies ruled in with step one (new devices for diabetes). The final step allowed to evaluate whether ongoing studies would be able to resolve major areas of pending uncertainty.

**Conclusions:** This process increased speed and transparency in decision-making, improved estimate of risks/benefit ratio of investments in new technologies, contributed to the prioritisation of competing innovations.

## OR49.2

### A Tiered Approach to Prioritisation

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**Background:** The National Health Committee (NHC) is the New Zealand body tasked with improving pathways of care while increasing

cost effectiveness. Through the innovative use of a 'tiered' assessment methodology, the NHC can move beyond the more reactive 'classic' HTA approach to become a more flexible, fit-for-purpose entity that offers novel solutions to complex problems.

**Objectives:** Combined with extensive and continuous health sector engagement, the NHC expects to identify, prioritise and implement improvements to identified disease pathways of care.

**Methods:** In a fiscally constrained environment, the NHC has taken a strategic approach to its assessments. Through the use of a programme budget, the NHC identified respiratory and cardiovascular disease, specifically ischaemic heart disease (IHD) and chronic obstructive pulmonary disease (COPD), as the first areas with high potential materiality for improved health outcomes and cost effectiveness.

The tiered approach is supplemented by a regular referral round where the sector can raise interventions outside of the disease areas examined ('classic HTAs'), allowing the NHC to prioritise the classic HTAs against those identified through the tiered approach.

In addition the NHC can refer interventions that require additional evidence, in particular NZ specific evidence, to the Health Innovation Partnership.

**Results:** By using a series of tailored assessment products, the NHC has identified specific areas along the pathways of care for IHD and COPD where improvements are possible. With the assistance of a sector working groups, the NHC will prioritise and implement improvements that are material and feasible.

**Conclusions:** The NHC's tiered approach allows to identify and prioritise interventions without being limited to those raised through referrals only. This provides a greater certainty that the identified improvements to the pathway of care are sustainable, most important and implementable in a fiscally constrained environment.

### OR49.3

#### Dissemination Bias and Evidence-Based Decisions on Pharmaceutical Coverage

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**Background:** Dissemination bias occurs when results emerging from clinical research reach or do not reach their intended audience in the knowledge translation process depending on their nature. It can lead to an overestimation of positive effects and an underestimation of both lack of effect and harm. Given that pharmaceutical coverage decisions rely increasingly on evidence, the consideration of dissemination bias becomes particularly important.

**Objectives:** To examine the evidence base and evidence procurement mechanisms used by regulatory institutions involved in pricing and reimbursement processes in a broad range of European countries (n=36) as well as their awareness of and approach towards dissemination bias.

**Methods:** Regulatory documents (guidelines, manuals, directives, submission requirements etc.) were identified by means of a systematic search of institutional websites; a systematic literature search in Pubmed, EMBASE and the Cochrane Library was used to supplement information. All documents meeting pre-specified inclusion criteria were analysed. An online survey among institutions was carried out to verify and expand insights.

**Results:** Despite a distinct lack of transparency regarding both processes of evidence-based decision-making and approaches towards unpublished information, dissemination bias and its effects were found to be only rarely consistently considered. Practices for the identification and inclusion of all available evidence or the potential influence of missing evidence on decision-making processes varied considerably, although differences were often attributable to the

regulatory context and/or institutional principles. Concrete measures to address dissemination bias included mandatory trial registration, quality standards for trial registers, giving preference to non-commercially funded studies and an obligation for manufacturers to submit all evidence.

**Conclusions:** Given the observed variations in both context and processes across countries, best practice is difficult to generalize. Individual exemplary practices were identified and further support the necessity for institutional exchange at international level. Increased institutional commitment to transparency of methods and processes should be advocated.

### OR49.4

#### Using Indirect Evidence to Fill Evidence Gaps in Disinvestment Decision-Making: Depression and Anxiety Associated with Failed Assisted Reproduction

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**Background:** Assisted reproductive technologies (ART) are a case study in disinvestment decision making. Notwithstanding differential effectiveness of ART by parental age, stakeholder deliberations reveal preconceptions about positive psychosocial outcomes associated with having an opportunity to undergo ART. In the absence of direct evidence of the impact of parental age on psychosocial outcomes, indirect evidence examined psychosocial outcomes associated with ART outcome. Linking success/failure and psychosocial outcomes to age profiles elucidates potential harms, and informs disinvestment deliberations.

**Objectives:** To determine the relationship between ART treatment outcomes and depression and anxiety.

**Methods:** MEDLINE, Psycinfo, CINAHL, Informit Health, Cochrane Library, Current Contents Connect and EMBASE were searched for studies on psychological outcomes among couples undergoing ART. This analysis includes those studies that used quantitative outcomes. The meta-analysis calculated the standardised mean difference for paired samples and ran a random-effects model using DerSimonian and Laird method. Bias and between-study heterogeneity were investigated.

**Results:** Of 908 articles yielded, 14 were meta-analysed, reporting psychological outcomes on 2,215 women and 566 men. Both men and women were significantly more likely to be depressed and anxious after a failed ART treatment. Depression significantly decreased after a successful treatment. Year of study and duration of infertility explained 60% of the heterogeneity observed between the studies.

**Conclusions:** ART treatment in older couples, compared with younger couples, is associated both with well documented reduced success in terms of liveborn infants and – as demonstrated by indirect evidence, an increase in adverse psychological outcomes. Indirect evidence of harms has a role within disinvestment decision-making where there is an absence of direct evidence and little likelihood of primary research being conducted

**OR49.5****The Characteristics of Expert Advisors and the Usefulness of Their Advice in Evidence-Based Guidance Production**

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**Background:** Advice from clinical experts can be influential in health technology assessment of new procedures and technologies, because of the practical issues they involve and the frequent paucity of published evidence. Expert opinions can aid interpretation of published evidence and form part of the 'evidence' in their own right. However, little is known about how best to select experts and the usefulness of the advice they provide.

**Objectives:** To examine the characteristics of clinical experts and the usefulness of their advice in health technology assessment.

**Methods:** The Interventional Procedures committee of the National Institute of Health and Care Excellence (NICE) develops recommendations for the UK health services on new procedures, based on published evidence and other information, including specially developed questionnaires completed by clinical experts, nominated by their specialist organisations. Data were extracted from completed questionnaires for consecutive procedures assessed between July 2011 and April 2013. Usefulness of advice from each questionnaire was scored using an index developed through qualitative work with committee members.

**Results:** Data were extracted from 211 expert questionnaires on 41 procedures. In univariate analyses experts who had done procedures, had undertaken research on them or who declared potential financial conflicts of interest gave significantly more useful advice than those without these characteristics ( $p=0.05$ ,  $0.001$  and  $0.007$  respectively). In multivariate analysis, only those who had done research on procedures gave significantly more useful advice than those who had not ( $p<0.001$ ). However, experts who had experience of a procedure were also more likely to consider it established.

**Conclusions:** Those wishing to use expert advice to inform decision making in HTA could optimise this by recruiting advisers who have undertaken research on the technology, to get the most useful advice, but should also select experts who have no experience of the technology in order to minimise bias.

**OR49.6****Evidence-Based Decisions on Pharmaceutical Coverage in 36 European Countries: a Comparison**

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**Background:** Coverage decisions for health technologies have been increasingly relying on evidence; most formally established decision structures incorporating evidence-based approaches are aimed at the reimbursement and pricing of pharmaceuticals. At a time when both pharmaceutical expenditures and the need for cost-containment are high, the necessity for rational pharmaceutical policies has been amplified.

**Objectives:** To identify institutions in a broad range of countries ( $n=36$ ) in the European Region in charge of determining the value of pharmaceuticals for pricing and reimbursement purposes and map their practices regarding a spectrum of different elements in the decision-making process; to examine current approaches and consider national and supranational possibilities for best practice.

**Methods:** Institutions were identified through the websites of international networks, related Ministries and published literature resulting from a systematic search (Pubmed). Details on institutional practices were further gleaned from institutional websites and linked online sources.

**Results:** The type and extent of information available varied considerably across countries. Different types of public regulatory bodies are involved in pharmaceutical coverage decisions, assuming a range of responsibilities within the process. As a rule, the assessment of scientific evidence is kept structurally separate from its appraisal. Recommendations on value are uniformly issued by specific Committees within or commissioned by responsible institutions. These institutions often ( $n=23$ ) also act as decision-makers on reimbursement status, reimbursement level or market price. While (relative) effectiveness and cost-effectiveness are considered important criteria in all countries, the latter is often evaluated on a case-by-case basis ( $n=13$ ). In all countries, manufacturer submissions are used as the (initial) evidence base for the assessment. Reimbursement restrictions usually depend on indication ( $n=21$ ), product specifications, or patient, population or provider group. Issues like stakeholder participation and reassessment vary considerably.

**Conclusions:** Transparency of evidence-based coverage decisions should be enhanced. International collaboration can facilitate knowledge exchange, efficiency of information production and strengthen new or developing systems.

**OR50.1****Brazilian Ministry of Health's Investment in HTA Training in 2013**

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**Background:** Technologies play an important role in health care. Training in the HTA area is important to improve the decision-making capacity in the process of assessment and incorporation of technologies in the Brazilian Public Health System (SUS). Since 2005 the Department of Science and Technology (DECIT) of the Brazilian Ministry of Health have been promoting many courses in order to capacitate health professionals, managers and researchers in the field of HTA.

**Objectives:** To describe the HTA courses sponsored and done by the Brazilian Ministry of Health in 2013, the investment made on these, and the number of people trained in HTA.

**Methods:** A survey was conducted among 64 members of the Brazilian Network for Health Technology Assessment (REBRATS) to identify specific HTA training needs. A documental research was used to check the courses, participants and the value invested.

**Results:** In 2013, a total of 13 courses were held, including one Masters Course and one MBA in Health Economy & HTA, among others basic courses and workshops, and a total of 2.366 professionals were trained. DECIT invested approximately \$ 1,469,000.00. The participants were mostly from REBRATS working at public hospitals, National Supplementary Health Agency (ANS), National Health Surveillance Agency (ANVISA), academic and research institutions, Ministry of Health, City and State Health Secretariats.

**Conclusions:** The investment strategy subsidizes the decision-making process in health services, since professional qualification is essential to enlarge and to disseminate the HTA culture in Brazil. In 2014, the Brazilian Ministry of Health will continue to foster at least 9 courses that were already programmed and a survey will be conducted among participants to evaluate the courses and its application on daily bases.



## OR50.2

### Pharmacoeconomic Education in Brazilian Schools of Pharmacy

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**Background:** With limited financial resources for health, it is important to optimize the costs and maximize the health outcomes of the population. The Pharmacoeconomics allows economic evaluation of products and services for health and helps a lot the healthcare decision-making. Therefore, there is a need for training of human resources with solid knowledge in pharmacoeconomics in Brazil. However, little is known to what extent Pharmacoeconomics is taught in schools of pharmacy in this country.

**Objectives:** The objective of this study was to survey the pharmacy schools in Brazil to determine the extent of education in pharmacoeconomics offered during the school year 2012-2013.

**Methods:** A questionnaire based on previous studies was developed. This was emailed to 55 pharmacy schools in Brazil during October and December 2013. The schools were selected from the Ministry of Education website. University schools of public and private (only those that have high concepts in the National Examination Performance of Students) were included. In addition, a search was made in the database directories of research groups from National Council for Scientific and Technological Development (CNPq).

**Results:** Results of the questionnaires sent 55, 14 went unanswered. Only one school does not address the teaching of Pharmacoeconomics in no time. Most discuss some concepts within various disciplines (see 8:0). Four schools have formal disciplines that teach only Pharmacoeconomics or health technology assessment (more than 30 hours). All agree that the education of pharmacoeconomics is important.

**Conclusions:** Pharmacoeconomics education in Brazil is still in its infancy and there is a unique opportunity for well-trained instructors and researchers to fill this gap.

Provide an education in Pharmacoeconomics to pharmacy students is especially important in the context of evidence-based decisions and when health issues and allocation of scarce resources is a priority for Brazil.

## OR50.3

### Pharmacoeconomic Education in Brazilian Schools of Pharmacy - 2012

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**Background:** The Pharmacoeconomics and HTA allows economic evaluation of products and services for health and helps a lot the healthcare decision-making.

Therefore, there is a need for training of human resources with solid knowledge in pharmacoeconomics and HTA in Brazil. However, little is known to what extent Pharmacoeconomics is taught in schools of pharmacy in Brazil.

**Objectives:** The objective of this study was to survey the pharmacy schools in Brazil to determine the extent of education in pharmacoeconomics offered during the school year 2012-2013.

**Methods:** A questionnaire based on previous studies [Rascati (1998, 2005, 2013) was developed. This was emailed to 55 pharmacy schools in Brazil during October and December 2013. The schools were selected from the Ministry of Education website. University schools of public and private (only those that have high concepts in the National Examination Performance of Students) were included. In addition, a

search was made in the database directories of research groups from National Council for Scientific and Technological Development (CNPq).

**Results:** Results of the questionnaires sent 55, 14 went unanswered. Only one school does not address the teaching of Pharmacoeconomics in no time. Most discuss some concepts within various disciplines (see 8:0). Four schools have formal disciplines that teach only Pharmacoeconomics or health technology assessment (more than 30 hours). All agree that the education of pharmacoeconomics is important. In the search for directories of research groups were found 23 groups that develop research in the area of Pharmacoeconomics in Brazil.

**Conclusions:** Pharmacoeconomics education in Brazil is still in its infancy and there is a unique opportunity for well-trained instructors and researchers to fill this gap. Provide an education in Pharmacoeconomics to pharmacy and economists students is especially important in the context of evidence-based decisions and when health issues and allocation of scarce resources is a priority for Brazilian Health System.

## OR50.4

### Brazilian Network for Health Technology Assessment (REBRATS) Growth Indicators

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**Background:** The Brazilian Network for Health Technology Assessment (REBRATS) spreads the HTA culture in health services and academic institutions, and also supports policy makers and managers in the decision-making process. It works through six working groups that prioritizes HTA settings and themes; develops methodological guidelines; trains professionals; and manage and disseminates information.

**Objectives:** This study aims to demonstrate REBRATS' s advances based on the productivity of the network members.

**Methods:** Analysis of the network performance through the number of publications available on the REBRATS database; number of accesses to the REBRATS webpage obtained through the access tool and data extraction by Google Analytics, monitoring the participation on the REBRATS social networking and computing new network members.

**Results:** Since REBRATS' implementation in 2008, it was made available on its website 62 publications including Guidelines, HTA Bulletins and others, and 364 studies in its database. In 2014, 64 institutions are already member of the network, representing an increase of over 45% compared to 2008. Additionally, the site began to be tracked in mid-2012, when the average number of accesses was 36,659 and approximately 2037 per monthly in more than 85 countries.

Since March 2012, when REBRATS social network on Facebook was created, there have been more than 300 published news with approximately 43,891 views and an average of 143 visualizations per issue reported by the network.

**Conclusions:** The strategies for advertising the network and disseminate the HTA products produced by its members have contributed significantly to the advance of HTA in Brazil, beyond the reach of people interested in this research field. Efforts should be directed towards advertising the production internationally.

**OR50.6****The Epidemiological Profile of Oral Health Professionals Working in the National Health System in Nova Friburgo, Brazil**

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1. UFF, Rio de Janeiro, Brazil; 2. UFF, Nova Friburgo, Brazil

**Background:** The insertion of oral health teams in the Family Health Strategy (FHS) in the Brazilian National Health System (NHS) in 2000 was to increase access of the population to the actions of Oral Health. The FHS care model points to multiprofessional teamwork for organization of the work process, through longitudinal health promotion actions, replacing the traditional primary care model. But many professionals were not trained to work with the specific tasks of this strategy.

**Objectives:** Trace the epidemiological profile of oral health professionals working in the NHS in Nova Friburgo, Brazil.

**Methods:** A cross-sectional study was conducted in Nova Friburgo, Brazil, between 2011 and 2013. The sample comprised dentists working in NHS. A semi-structured questionnaire was used for data collection. The study was submitted to and accepted by the local ethics committee (192/11). The respondents received and signed a consent form. Data were entered and analyzed in Microsoft Excel 2013.

**Results:** Of 45 dentists, 27 were interviewed (58%), aged between 33-70 years (median=52 years), with training time between 8-45 years (median=28.5 years). They work in the NHS between 1-37 years (median=17 years), with 38.5% allocated in units of FHS. During graduation training, 19.2% reported receiving information on ESF, and 35% on SUS. Only 10.4% reported meeting with local management. The FHS concept was reported as recommended by the Brazilian Ministry of Health by 38.5% of the respondents.

**Conclusions:** Among respondents, the majority is still working in units with the traditional care model and not in FHS; has over 8 years trained, and therefore did not receive information on NHS or ESF during their training; and reports no meetings team with local management.

The oral health teams still have difficulty in performing activities such prevention and health promotion, as well as meetings with local management, actions highly recommended by the Brazilian Ministry of Health .

**Poster Presentations****PO.001****Indirect Comparison of Drug Treatment Effect in Adult ADHD**

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**Background:** Indirect comparison methodology is appropriate as a method to conduct HTA (Health Technology Assessment) when head-to-head trials are absent or lacking.

**Objectives:** The purpose of this research is to compare atomoxetine and methylphenidate effects using a common comparator through indirect comparison in adult ADHD.

**Methods:** We searched for published studies until February 2013 in 9 databases. Firstly, we identified randomized controlled trials (RCTs) of ADHD medication efficacy. Secondly, we assessed each research quality and exchangeability. Finally, we conducted indirect comparison of atomoxetine and methylphenidate in adult ADHD using a common comparator.

**Results:** For the comparison of efficacy by methylphenidate and atomoxetine in adult ADHD patients, RCT including each drug was systematically searched and resulted in the selection of 25 researches. For the "Blinding of participants and personnel" and the "Blinding of outcome assessors" criterion selected as the important key domain in this research, the risk of bias was generally considered low. Indirect comparison methodology was implemented to compare the treatment effect of the two drugs using a placebo as the common comparator. Pooled estimate using the investigator outcome CAARS-Inv:SV and AISRS tool as an ADHD symptom score, it showed that methylphenidate to be more significantly effective in improving ADHD symptoms compared to atomoxetine. Furthermore, when using the CGI tool as the general mental symptom score, methylphenidate showed significant reduction in ADHD symptoms compared to that of atomoxetine. When comparing the rate of dropout and adverse events (sleep problem/appetite problem) of the two drugs, there were no statistical significances. Accordingly, such results have been proved in previous researches that were conducted against children and adolescents.

**Conclusions:** Therefore, although there were not enough appropriate head-to-head trials for adult ADHD patients to compare the treatment effects of the two drugs, indirect comparison using a common comparator showed to be effective.

**PO.002****Health Technology Assessment in Cerebrovascular Stroke Patients: an Economic Model to Estimate Savings from Thrombolysis**

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**Background:** Stroke is the second leading cause of death and the leading cause of disability worldwide. In Italy, there are approximately 200,000 new cases each year, of which about 80% are ischemic. The Rivoli hospital scheduled intensive staff training and a specific treatment pathway involving thrombolysis therapy as it has been demonstrated to reduce post-stroke disability.

**Objectives:** To measure effectiveness in terms of reduced disability and efficiency, including overall cost reduction arising from the introduction of new health technologies.

**Methods:** To calculate savings arising from thrombolytic treatment, we extracted therapeutic efficacy data in terms of reducing post-stroke disability from the third international stroke trial (IST-3). To assign costs according to the degree of disability, we used recent Italian and international cost of illness studies for medical, non-medical, and indirect costs accrued following an ischemic event.

Drug administration costs were added to the cohort of patients treated with thrombolysis.

According to a specifically designed economic model, the data have allowed us to estimate the potential savings from early thrombolytic treatment.

**Results:** Since thrombolysis was introduced in the Rivoli Hospital, 146 patients received efficient stroke treatment due to improved therapy protocols resulting from staff training.

In addition to the significant improvement in quality of life, the reduced disability observed in patients following timely stroke treatment resulted in a total savings of € 217.349,50 since 2005.

Projecting the set of health technologies to the entire Piedmont region (4,357,663 inhabitants) would have resulted in an economic savings of € 311,476 over the past three years (2011-2013).

**Conclusions:** Employing the economic model, the savings calculated for a single neurological disease enhance the efficiency of health technology assessment project. Furthermore, projection to the entire region suggests implementation of this therapeutic pathway may ensure desired results in terms of disability reduction and economic savings.

## PO.003

### Developing HTA for German Hospitals

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**Background:** The implementation of HTA in German hospitals is quite basic. The different education of hospital administration and medical staff is hindering a common understanding of the background of information and decision-making. There is a huge need of sustainable decision making as well as reacting on actual needs to survive under a huge economic pressure.

**Objectives:** How can the international experience being used to develop a model for German hospital based HTA approaches support by a national agency? How can HTA help to improve quality (person related), effectiveness (medical and organizational) and sustainability within a hospital setting?

**Methods:** For the development of a concept for Health Technology Assessment (HTA) in hospitals there is looked for

- Published knowledge in the internet and in electronic databases
- Documentation and interview of partners of specific projects (e.g. EUREGIO II project, AdHopHTA project).

The found knowledge was weighted and evaluated according to evidence-based criteria in a multistep procedure (4-eyes-principle).

The findings had been integrated into a wide accepted model of decision making in hospitals.

**Results:** A systematic search in electronic databases identified 397 publications in total out of which five fulfilled all criteria during the critical appraisal. This knowledge and structured interview results were used to describe a model of using HTA in German hospitals.

**Conclusions:** Although there is low evidence with regard to the acceptance of HTA in hospitals there can be identified a positive tendency for the use of HTA in hospitals.

Statements of the participants with regard to a change-management relativize the lacking evidence with regard to the acceptance (caused by the insufficient scientific examinations).

Within the well described processes of decision making we could identify and describe a model in which HTA has a role, can be used to raise the knowledge and can help to moderate difficult decision processes within a high specific setting.

## PO.004

### Use of Mobile Phone for a Community Epidemiological System in Paraguay

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**Background:** Information and communication technologies (ICT) has taken a key role in countries with limited resources like Paraguay, especially in the epidemiological field. Health surveillance systems need to strengthen data collection to provide responses according to the International Regulations. In remote areas in Paraguay due to geographical isolation, staff training, etc. are an epidemiological silence. In Paraguay 85.6% of householders has a cell phone. In this context, the Ministry of Public Health together with the National University of Asunción has developed a simplified surveillance system for five syndromes based on mobile phones implemented in remote areas of the country.

**Objectives:** To describe implementation of the simplified community notification system.

**Methods:** The system consists of central telephone system, database and open source type web applications which allow the capture and display of data from weekly and alerts notifications of the syndromes under surveillance. Users access to the system via a phone call to an answering machine that asks questions about the number of cases.

**Results:** The system was implemented in December 2012 in five indigenous communities; syndromes under surveillance were: diarrhea, acute febrile syndrome (eg hantavirus, dengue), acute respiratory infections (e.g. influenza like infections), chronic respiratory infection (e.g. tuberculosis), febrile eruptive syndromes. Indigenous promoters were trained to use the system. Weekly notifications were made on Wednesdays, while alert notification at any time. Personnel in charge received hourly reminding messages until notification was effective, once occurs the system sent confirmation messages. From May 15 to November 20, 2013, 1048 cases were reported: 171 diarrhea, 850 acute respiratory syndromes and 27 chronic respiratory syndromes.

**Conclusions:** The system was recognized by the community as simple, easy to use and useful for prioritizing the type of care they needed. It has generated for the first time information on trends of these syndromes in these communities, consistent with the national situation.

## PO.005

### Systematic Review of [18F] FP-CIT Brain PET, PET-CT

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**Background:** [18F] FP-CIT Brain PET, PET-CT is a test for determination of diagnosis of Parkinson's diseases, screening diagnosis of Parkinson's syndrome and expecting treatment effect on Parkinson's disease after having performed imaging of the brain for patients suspected of Parkinson's disease.

**Objectives:** The [18F] FP-CIT Brain PET, PET-CT that test for Parkinson's disease was assessed to see if it was safe and effective.

**Methods:** The [18F] FP-CIT Brain PET, PET-CT was assessed using 8 domestic data-bases, Ovid-MEDLINE, Ovid-EMBASE and Cochrane Library. Through a search strategy, a total of 69 works were identified. Of them, animal study or studies not published in Korean or English were excluded. A total of 6 works were included in the final assessment. Two reviewers screened all references independently.

**Results:** Safety:[18F] FP-CIT Brain PET, PET-CT was assessed to be free of any safety problems in its application if implemented by abiding by the safety management rules on radiation since it dose not harm to human body.

**Effectiveness:**The effectiveness was assessed through a total of 6 works. Diagnostic accuracy was reported to have sensitivity of 94.0% and specificity of 92.0% Parkinson's disease in the case of distinction between Parkinson's disease patient and progressive supranuclear palsy patients, and sensitivity of 84.0% and specificity of 98.0% in the case of image analysis. Concordance rate between [18F] FP-CIT Brain PET, PET-CT and reference standard is 94.0% in the case of Parkinson's disease patients. Extent of severity of disease was measured with UPDRS and was significantly reversely correlated with the results of [18F] FP-CIT Brain PET, PET-CT( $p < .01 \sim .001$ ).

**Conclusions:** This could be a test with grounds for safety and effectiveness in distinguishing Parkinson's disease accompanied by damages to dopaminergic neuron and Parkinson's disease not accompanied by damages to dopaminergic neuron in patients that display symptoms of Parkinson's disease.

## PO.006

### Managing Access to Therapies for Rare Diseases: the International Landscape

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**Background:** Regardless of type of health system or payer, coverage decisions on orphan and ultra-orphan drugs are challenging. While these drugs typically represent the only active treatment option for a progressive and/or life-threatening condition, evidence of clinical benefit is often limited because of small patient populations and the costs are high. Thus, decisions come with considerable uncertainty and risk. In Canada, interest in developing a Pan-Canadian decision-making approach informed by international experiences exists.

**Objectives:** To develop an inventory of existing policies and processes for making coverage decisions on orphan and ultra-orphan drugs around the world

**Methods:** A systematic review of published and unpublished documents describing current policies and processes in the top 20 GDP countries was conducted. Bibliographic databases, the internet, and government/HTA organization websites in each country were searched. Two researchers independently extracted information and tabulated it to facilitate qualitative comparative analyses. Policy experts from each country were contacted and asked to review the information collected for accuracy and completeness.

**Results:** Almost all countries have multiple mechanisms through which coverage for an orphan or ultra-orphan drug may be sought. However, they typically begin with a review that follows the same process as drugs for more common conditions (i.e., the centralized review process (CDR)), although specific submission requirements could differ (e.g., no need to submit a cost-effectiveness analysis). When drugs fail to receive a positive recommendation/decision, they are reconsidered by 'safety-net' type programs. Eligibility criteria vary across countries, as do the decision options, which may be applied to individual patients or patient groups.

**Conclusions:** With few exceptions, countries have not created separate centralized review processes for orphan and ultra-orphan drugs.

Instead, they have modified components of existing mechanisms and added safety nets.

## PO.007

### gms-HTA – Technology Life-Cycle Information Publication Platform at German Medical Science

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**Background:** DIMDI and by this DAHTA is commissioned to host an information system on HTA related topics and data. One part of the system is the electronic journal gms Health Technology Assessment (gms-HTA), a bilingual journal within a group of open access journals hosted on the gms platform offered by a consortium of the a Association of the Scientific Medical Societies in Germany, the Leibniz Information Centre for Life Sciences and DIMDI.

There are 15 journals of medical associations and institutions. Six journals, among them gms-HTA, are even listed in PubMed.

**Objectives:** The primary aim of gms-HTA is to form a platform to publish experiences and methodological issues useful for daily life activities and open for discussion among the HTA community and the users of HTA. This includes information of the whole life-cycle of a technology.

**Methods:** N/A

**Results:** As long as an article topic is related to the aim of the journal, every article will be published. In case of a conflict with the reviewers, both, article and review are published together.

Every paper is published and up to now also translated into the second language without paying for it. gms-HTA has an international Editorial board with members from German speaking countries (Austria, and Germany), Australia, Netherlands, Norway and Spain.

Besides the regular publishing of different HTA papers received by authors, the journal will set some focus points on specific topics to raise the discussion among the HTA community. Due to the nature of an electronic journal, there will be limitations in publishing also original data.

**Conclusions:** One objective is to broaden the content of the journal. A sign for that are different document types.

The thematic openness of the journal is a characteristic for gms-HTA.

## PO.008

### A Budget Impact Analysis of the Inclusion of Abatacept and Rituximab in Brazilian' Public Health System

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**Background:** Abatacept and rituximab are biologic drugs used to treat rheumatoid arthritis (RA). The clinician' therapeutic choice between different drugs can always lead to a budget impact.

**Objectives:** The aim of this study was to perform a budget impact analysis of the inclusion of abatacept and rituximab in the Specialized Component of Pharmaceutical Assistance (SCPA) in Brazil for treating severe non-controlled RA.

**Methods:** The model was constructed and evaluated for most optimist and most pessimist scenarios. The representative fraction of abatacept and rituximab of this amount was determined. The total amount spent by the SUS with drugs in 30 days (US\$18,331,173) and the amount spent with SCPA (US\$11,269,353) were considered. In the same period, spending on anticytokines was US\$3,419,814.

To calculate the budget impact different scenarios were created based on the number of patients using abatacept or rituximab in Paraná.

- 1: patients using anticytokines were equally distributed between anticytokines, rituximab and abatacept.
- 2: only 10% of patients used rituximab and abatacept (5% each).
- 3: 50% of patients using anticytokines used rituximab or abatacept (25% each).
- 4: it was considered that 75% of patients using anticytokines used rituximab or abatacept (37.5% each).

**Results:** For budget impact, we reached the following values, comparing with current scenario. Analyzing the data it is possible to verify that occurs saving of resources in any hypothetical scenario (US\$3,294,335, 678,023, 3,371,786 and 5,034,549, for scenario 1,2,3 and 4 respectively).

**Conclusions:** Based on budget impact analysis, we verified that the inclusion of abatacept and rituximab for treatment of RA leads to a save of resources (Table 3). Thus, one should evaluate the cost-effectiveness ratio of the studied drugs for decision making, since the point of view of resource use, the inclusion of these drugs is favorable to the Brazilian public health system.

## PO.009

### Cost-Effectiveness Analysis of Introducing an HPV Vaccination Program in Uruguay

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**Background:** The HPV vaccine was recently licensed for use in Uruguay.

Beginning in March 2013, the Ministry of Health initiated a demand driven HPV vaccination program targeting girls aged 12. However, the decision to integrate the vaccination program into the routine immunization program has not been made yet.

**Objectives:** The aim of this study was to evaluate the health benefits, costs, and cost-effectiveness of adding the HPV vaccine to the routine immunization schedule

**Methods:** The integrated CERVIVAC cost-effectiveness model for cervical cancer prevention and control strategies (Version 1.1.11.) developed by the Pan American Health Organization's ProVac Initiative in collaboration with the London School of Hygiene and Tropical Medicine was used to assess the health outcomes and costs associated with vaccinating one cohort of 24738 girls aged 12 years. HPV vaccine was compared to a scenario assuming no HPV vaccination. The program and treatment costs were estimated for public and private institution for the entire country. A discount rate of 3% for costs and health benefits was used for the base case.

**Results:** Vaccinating against HPV in one cohort of girls would prevent 14 cervical cancer deaths in this population. The life years gained (LYG) in the base case were 305 years. From the health system perspective, the cost per DALY averted was US\$ 3419 and the cost per LYG was US\$ 4403 compared to no vaccination scenario. Taking into account the threshold who has recommended to cost effectiveness, the HPV vaccination represents a cost effective intervention for cervical cancer prevention and control in Uruguay

**Conclusions:** Routine vaccination against HPV in Uruguay would be cost-effective, would prevent a substantial number cases of HPV, and deaths by cervical cancer.

## PO.010

### Patient-Centered Care Effectiveness in Brazil: a Randomized Clinical Trial Protocol

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**Background:** There are many definitions for patient-centered care. Many definitions cover the patient participation importance in the decision-making process. For this to happen, it is necessary that the health professionals possesses accessible communication skills to inform patients with good evidence quality information. A Cochrane systematic review found several clinical trials evaluating the effectiveness of patient-centered care, but none conducted in low and/or middle income countries.

**Objectives:** To evaluate the effectiveness of the patient-centered care in a Brazilian hospital.

**Methods:** A randomized clinical trial will be conducted in the Department of Clinical Medicine of the Sao Paulo Hospital (from the Universidade Federal de São Paulo). Patients that are being taken care by the hospital with hypertension and diabetes will be included. A group of care providers will receive training and evidence-based information from Cochrane Systematic Reviews for the related topics while the other group will receive the conventional care. The patients will be randomized by the hospital screening sector that will maintain the allocation concealment and the evaluation team will be blinded to the intervention received by the patients. The primary outcome will be the patient satisfaction with the treatment. The secondary outcomes will be the professional ability to communicate, the adherence to the treatment and health status (physiological and clinical measures). The sample size was calculated, aiming 176 patients for each group (G1 74%, G2 60%, with 5% significance and 80% power). The analyses will be conducted with a Chi-squared test, NNT and 95% CI.

**Results:** The present trial will be implemented in the second semester of 2014.

**Conclusions:** It is expected that the cultural aspects from the Brazilian patients and the lack of structure from the health service will compromise the effectiveness of the patient-centered care. The protocol presentation allow us to take suggestions in consideration and to improve the research design.

## PO.011

### Exhaled Breath Test for Identifying Gastric Cancer from Benign Gastric Conditions

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**Background:** Upper digestive endoscopy with gastric biopsy is the standard method for diagnosing gastric cancer (GC). A nanomaterial-based breath test for identifying GC among patients with gastric complaints based in biomarkers derived from exhaled breath may provide a solution for GC screening.

**Objectives:** Synthesize current research evidence regarding a nanomaterial-based breath test for identifying gastric cancer among patients with gastric complaints

**Methods:** The use of a nanomaterial-based breath test for identifying GC was identified by the Early-Awareness and Alert-System, "SINTESIS-new technologies," of AETS-ISCIII. An early assessment of the technology was conducted. The searched databases were: MEDLINE

(PubMed), CRD, and Cochrane Library. Clinical studies using the nanomaterial-based breath test for identifying GC published in any language until 15 January 2014 were reviewed.

**Results:** We found only 1 cross-sectional comparative study (N=160) to distinguish GC patients from patients with benign gastric conditions (gastric ulcer or less severe gastric conditions such as endoscopic abnormalities without ulceration or no endoscopic abnormalities). Predictive models were built employing discriminant factor analysis. Results for accuracy, sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were determined using conventional diagnosis as reference standard. The results showed accuracy, sensitivity, specificity, PPV and NPV of 90%, 89%, 90%, 79% and 96% respectively to distinguish GC patients from patients with benign gastric conditions.

**Conclusions:** The initial experience of the breath test for identifying gastric cancer of 1 cross-sectional comparative study show that this test could be a promising procedure for gastric cancer screening. More studies, including large studies, are necessary to confirm these results.

## PO.012

### Effectiveness and Safety of Subcutaneous Implantable Cardioverter Defibrillator (S-ICD®) in Patients at Risk of Sudden Cardiac Death

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**Background:** The S-ICD® is a new medical device that is placed entirely under the skin of the chest. It detects and treats cardiac arrhythmias using electrical shocks to help control life-threatening arrhythmias, especially those that can cause sudden cardiac death (SCD).

**Objectives:** To study the effectiveness and safety of S-ICD® for detection and treatment of cardiac arrhythmias in patients at risk of SCD.

**Methods:** Early assessment of S-ICD® identified through the Early-Awareness and Alert-System, "SINTESIS-new technologies", of AETS-ISCIII. The searched databases were: MEDLINE (PubMed), EMBASE, CRD and Cochrane Library. Clinical studies using the S-ICD® published in English, French or Spanish until March 2013 were reviewed.

**Results:** We found 11 studies with 1337 patients: 8 case series, 2 comparative studies and 1 prospective control-case study. The quality of evidence was low. Case series show an appropriate detection of spontaneous arrhythmias in the 84-100% of episodes and conversion was successful in the 80-100%. The first comparative study analysing S-ICD® vs transvenous implantable cardioverter defibrillators found 100% appropriate conversion rate of arrhythmias in both devices; the second comparative study performed in children did not show information regarding S-ICD® because no arrhythmias occurred. In the case-control study more patients in the control group experienced appropriate episodes (p=0.05). Regarding safety, in case series studies inappropriate shocks delivery was found in 8-16% of patients. Other complications as infection or reintervention were infrequent (<10% and <17%, respectively). Any of the comparative studies detected infection, while rates of reinterventions (6 vs 19%, p=0.25) and inappropriate shock (6 vs 25%, p=0.14) were lower in the control group. In the case-control study, procedural complications were similar between the 2 groups.

**Conclusions:** Preliminary data shows that the S-ICD® seems to be an effective and safe device in patients at risk of SCD. The research continues running.

## PO.013

### A Systematic Review on the Efficacy and Safety of the O-ARM CT-Guided Navigation System in Spine Surgery

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**Background:** The O-arm surgical imaging system is a multi-dimensional surgical imaging device developed for orthopedic and neurological surgeries with emphasis on spine surgeries.

**Objectives:** o determine the benefits and safety of O-arm-guided spine surgeries compared to spine surgeries that are guided by a conventional fluoroscopy.

**Methods:** Literature searches were performed in Medline and Embase (from inception to 05/09/2013). Two independent reviewers screened citations and extracted data.

**Results:** Seven studies met the inclusion criteria. None was randomized. Of these, six were carried out in humans, whereas one investigation was performed in non-human (dummy) operators. Based on the available studies, we were able to investigate the following outcomes: operative time (one study) and risk of re-operation (six studies). No study investigated critical outcomes such as health-related quality of life (time until full return to work or daily activities), pain and chance of adjacent segment degeneration/adjacent segment disease. Overall, there is no evidence suggesting that the risk of re-operation/re-intervention will be different for O-arm-guided surgeries compared to C-arm guided surgeries (Tian's exact test: risk reduction = -1%; 95% confidence intervals = -2 to 1%); GRADE: low quality). Similarly, there is no evidence indicating that use of the O-arm device will produce a reduced operative time compared to the use of a traditional fluoroscopy (GRADE:very low quality). The study performed in non-humans (dummy) operators concluded that the O-arm device emits an ionizing radiation dose that might be five times higher than that observed with a traditional fluoroscopy.

**Conclusions:** Given the presence of sparse data, the putative low statistical power of the analyses and potential methodological biases, the current available evidence is still insufficient to support the hypothesis that the O-arm technology is superior to the traditional fluoroscopy for spine surgeries. Our review highlights the need for larger and well conducted studies.

## PO.014

### A Systematic Review on the effectiveness of Detection of M.tuberculosis and Rifampin Resistance[Real-time, Nested PCR]

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**Background:** Detection of M.tuberculosis and Rifampin Resistance [Real-time, Nested PCR] is a test for confirmation of presence of infection by M.tuberculosis pathogen and presence of Rifampin resistance simultaneously by using real-time nested PCR.

**Objectives:** The purpose of this study was to evaluate Detection of M.tuberculosis and Rifampin Resistance[Real-time, Nested PCR].

**Methods:** A systematic literature review was used to evaluate the effectiveness of Detection of M.tuberculosis and Rifampin Resistance [Real-time, Nested PCR]. The literature review covered from August 16, 2011 to October 1, 2011, and eight domestic databases including KoreaMed and foreign databases including Ovid-Medline, Embase,

and Cochrane Library were used. Key words, such as 'Rifampin', 'PCR', 'GeneXpert' and 'Xpert MTB-RIF', were used to search a total of 1,385 documents. The SIGN (Scottish Intercollegiate Guidelines Network) tool was used by two evaluators to independently evaluate the quality of the 20 selected studies.

**Results:** Firstly, test accuracy on detection of *M.tuberculosis* pathogen was assessed on the basis of 20 literatures with *M.tuberculosis* pathogen culture test as the reference standard. As the result of acid-fast bacteria smearing test and in the case of overall specimen that did not consider the types of specimen, sensitivity in the range of 0.69-1.00, specificity in the range of 0.72-1.00 and test accuracy in the range of 0.75-1.00 were reported. Secondly, test accuracy on Rifampin resistance was assessed on the basis of 17 literatures. When anti-tuberculosis agent sensitivity test is used as reference standard, the sensitivity, specificity and test accuracy of Real-time, nested PCR were in the ranges of 0.75-1.00, 0.96-1.00 and 0.95-1.00, respectively, and the rate of concordance with standard test was in the range of 0.95-1.00 for observed agreement.

**Conclusions:** Detection of *M.tuberculosis* and Rifampin Resistance [Real-time, Nested PCR] is a useful test on patients suspected of multiple drug resistant *M.tuberculosis* with at least grade C evidence based on existing positive studies.

## PO.015

### User Centered HTA Reporting and Scientific Correctness – Processes and Products to Increase Visibility and Usability

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**Background:** The German Agency for Health Technology Assessment (DAHTA@DIMDI) runs an information system for HTA based on a national law. The classical approach for HTA reports at DAHTA is the full HTA with all domains and all documentation within one book. This way of publication is a hurdle within the use of HTA reports.

**Objectives:** The starting point of every HTA project is the aim to help people within their decision process related to health technologies. By this DAHTA was looking for new approaches to fulfill the aim of transparent and legally correct documentation as well as easy to read and to understand publications. The new processes should help to identify special user groups related to a topic and based on this special kind of publication close to the normal environment of users.

**Methods:** N/A

**Results:** The processes in during priority setting and project description includes now a specific process of identifying the potential users. In addition, there are now new publication products and ways beside the scientific complete documentation report. All scientific HTA papers are published within a HTA journal (eGMS-HTA) or within the DAHTA database for HTA reports (full reports) while the additional user centered papers are published in those journals regularly read by specific users.

**Conclusions:** The new process during the HTA project to produce specific user centered publications and the new processes to identify the specific users of a HTA information in connection with a broad portfolio of publications products helps to focus on the users and to decrease of serving with one product all potential users. It is less time and resource consuming and increase the visibility by more user-friendly products.

## PO.016

### Assessment of Catheter-Free (Wireless) Ambulatory Oesophageal Ph Monitoring for Gastro- Oesophageal Reflux Disease (GORD)

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**Background:** When a trial of medication fails for patients with GORD symptoms, typically an endoscopy is undertaken. If this fails to show erosion, a 24 hour catheter-based pH monitoring test (CBPM) may be conducted. A new catheter-free pH monitoring test has become available in Australia for use when CBPM is not tolerated, is anatomically inappropriate, or has failed.

**Objectives:** To determine the safety and effectiveness of 48 hour catheter-free pH monitoring (CFPM) for GORD, compared to either no pH monitoring or CBPM. The evaluation was undertaken to inform a public funding decision.

**Methods:** The medical literature was systematically searched to identify relevant studies from 2001 to September 2013. Studies were screened according to predefined eligibility criteria. Direct evidence of the impact of CFPM on patient health outcomes was supplemented with evidence obtained using a linked evidence approach.

**Results:** Studies assessing the impact of CFPM vs no monitoring in the defined study population were not available. The study population had to be broadened to GORD-patients tolerating CBPM. Test accuracy depended on the monitoring time, cut-off value, capsule placement and the reference standard applied. Chest pain occurred more often with CFPM compared to CBPM; however, other adverse events were less common with CFPM. More technical failures occurred with CFPM, compared to CBPM. In general, studies were of poor to medium quality and there was a lack of good comparative evidence.

**Conclusions:** CFPM is usually better tolerated compared to CBPM. Most reported complications are mild and do not require medical therapy. However, some (rare) complications could become severe if left untreated. Using CFPM for GORD appears likely to be effective at benefiting the health of patients, compared to no monitoring, but due to applicability concerns regarding the patient populations used in the studies, there remains a large amount of uncertainty about this conclusion.

## PO.017

### Dietetic Treatment or Liver Transplantation? Which is the Best Treatment for MSUD?

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**Background:** Maple syrup urine disease (MSUD) is a metabolic disorder caused by a deficiency in the branched-chain  $\alpha$ -keto acid dehydrogenase complex, leading to the accumulation of branched-chain ketoacids and their corresponding branched-chain amino acids (BCAA) in patients. Treatment involves a protein-restricted diet and supplementation with a specific formula containing essential amino acids (except BCAA), and micronutrients. More recently, liver transplantation have been shown to be successful in treating this condition. The possibility of moving from a restricted diet to a free diet is contrasted by the risks associated with liver transplantation, such as immunosuppression. Damages caused by inappropriate treatment are irreversible and the consequences on the mental and motor development are severe, requiring a lifetime of rehabilitation.

**Objectives:** We sought to systematically evaluate the efficacy and the safety of dietary treatment and liver transplantation for MSUD

patients; and verify if there are significant benefits of liver transplantation in MSUD patients in relation to dietary treatment.

**Methods:** Systematic literature search and meta-analysis is being performed in Medline, Lilacs, Cochrane, EMBASE, and Scielo. Randomized controlled trials (RCTs) comparing liver transplantation with any other type of treatment or non-treatment will be included. With less than five studies meeting the previous criteria, studies with less power will be included (randomized open-label trials, non-randomized clinical trials and case studies).

**Results:** So far, we are selecting papers according to the proposed methodology. Our preliminary results suggested, as expected for rare disorders, that: 1) there are few studies on this issue published in the literature; 2) the studies are very heterogeneous preventing most variables to be meta-analysed.

**Conclusions:** New technologies come very fast and sometimes the evidence is quantitatively enough to sustain them. In this case, systematic reviews about the treatments of rare disease - which are expensive - are important to the process of clinical decision making.

## PO.018

### The Influence of Pediatric Palliative Care Program on Health Care Utilization and Costs: a Systematic Review

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**Background:** Pediatric palliative care (PPC) is an under studied yet critically important area of health care.

**Objectives:** To synthesize information on the effects of PPC on health care resource utilization and costs, in order to support informed decision-making around resource allocation.

**Methods:** A systematic review of Medline, EMBASE, CINAHL, LILACS and the grey literature was undertaken, according to PRISMA guidelines. Studies were eligible for inclusion if they evaluated any individual PPC program component. Both experimental and observational studies were considered. Outcomes of interest included hospital admissions (emergency, general ward or critical care), length of stay (LOS), and health care costs. Two reviewers conducted title and abstract screening, full text review, and data extraction independently.

**Results:** The search produced 5,193 references, 109 were full-text reviewed and 11 articles were included. No randomized clinical trials (RCT) were found. We observed mixed results of the effect of PPCP on all the outcomes. In terms of hospital admissions four studies found a decrease in the proportion of children admitted to the hospital, rates of planned hospital admissions, and admission rates to critical care. Yet, five studies found an increase or no difference in this outcome. In regards to effects on LOS, five studies found PPCP associated with a decrease in LOS. However these articles did not investigate the number of days spent in other facilities. The only study with a broader measure of inpatient days found an increase in the total LOS, demonstrating a shift in health care setting utilization. In terms of costs, four articles found PPCP associated with a decrease in costs. However, most studies did not account for shift in health care settings. Only two studies considered a broader perspective and found controversial results.

**Conclusions:** Although there is a paucity of research evaluating the effects of PPCP on health care system utilization and costs, some evidence suggests a decrease in utilization. The key challenge with the review was the considerable heterogeneity in outcome measurement and reporting of program components.

## PO.019

### HTA and the Ethical Domain Under Specific Hospital Settings

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**Background:** In Germany hospitals are owned by different groups. Beside public owned hospitals (city, state, federal), there are a many of private owned hospitals. Some of them are company owned but also there is a huge group of hospitals owned by communities of faith. Independent from the ownership mainly all of these hospitals have public duties and are included within health providing to the public. Out of the different role and functions, public hospital, persuasions of the hospital owner, patient requirements, there is a potentially conflicting situation.

**Objectives:** Is there an option for HTA to help to solve ethical and social issues on hospital level within a given health care system? Can HTA offer as well a model, a scientific and pragmatically approach to help within decision processes? Can a structured HTA approach help to identify areas of ethical conflicts and, in addition, include the patient's perspective?

**Methods:** Based on existing HTA reports and a given model of hospital based HTA in German hospitals different ethical problems are discussed. Hospital management from different kind of hospital owners are asked how to handle these topics within their setting (semi structured interview). The results are tested against the approach using HTA during the decision process on hospital level to describe needs and knowledge related to the management process.

**Results:** The detailed results and opinions of using HTA to solve ethical issues based on faith will be described.

**Conclusions:** The preliminary results show that ethical issues can be described much more structured, much more proactive and much more holistic and by this reduces discussion and misunderstanding and can be done by people within a hospital with the help of HTA expertise.

## PO.020

### Non-Invasive Prenatal Diagnostic Accuracy for Trisomy 21 in Maternal Plasma: a Systematic Review and Meta-Analysis

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**Background:** Trisomy 21, also known as Down's syndrome, is the most common human chromosome abnormality and the predominant reason for women seeking prenatal diagnosis. Recently, research on non-invasive prenatal diagnosis (NIPD) for fetal Trisomy 21 is developing fast. However, there is a lack of published meta-analysis that assesses the diagnostic accuracy of NIPD for Trisomy 21.

**Objectives:** To assess the diagnostic accuracy of NIPD for Trisomy 21 in maternal plasma.

**Methods:** Cochrane Library, PUBMED, EMBASE and clinical trials registries were searched in July 2013, using 'cffDNA' OR 'cffRNA' and terms for 'non-invasive prenatal diagnosis' and 'Trisomy 21'. Studies assessing the diagnostic accuracy of NIPD for trisomy 21 in maternal plasma were eligible for inclusion. QUADAS-2 was used to evaluate the quality of the included studies. A meta-analysis was performed with Meta Disk 1.4 to examine the accuracy (both sensitivity and specificity) of NIPD methods.

**Results:** 366 literatures were identified and 23 were included in the analysis. Most common NIPD methods used in included studies were



digital analysis of selected regions (DANSR), massively parallel sequencing (MPS), and single nucleotide polymorphism (SNP). Most studies had a high risk of bias in the domain of 'patient selection' and 'flow and timing'. Pooled sensitivity of NIPD was 0.982 (95%CI 0.973-0.989), and the pooled specificity was 0.998 (95%CI 0.997-0.998). Meta-regression showed a significant positive relation between the type of index test and results of analysis ( $P=0.0001$ ). Subgroup analysis indicated that the pooled sensitivity of DANSR was 0.995 (95%CI 0.973-1.000), and the pooled specificity was 0.999 (95%CI 0.998-1.000); the pooled sensitivity of MPS was 0.994 (95%CI 0.985-0.998), and the pooled specificity was 0.999 (95%CI 0.998-0.999); the pooled sensitivity of SNP was 0.956 (95%CI 0.890-0.988), and the pooled specificity was 0.978 (95%CI 0.961-0.989).

**Conclusions:** NIPD appears to have high diagnostic accuracy for the detection of Trisomy 21 in maternal plasma.

## PO.021

### A Systematic Review of Percutaneous Left Ventricular Assist Device

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**Background:** The percutaneous left ventricular assist device (pLVAD) was developed for short-term use in patients who require acute circulatory support. The TandemHeart system (CardiacAssist Inc., USA) can be inserted percutaneously in the catheterization laboratory through standard insertion techniques.

**Objectives:** The objective of this review is to evaluate the safety and effectiveness of pLVAD compared with intra-aortic balloon pump (IABP).

**Methods:** The searches were conducted via electronic databases including MEDLINE, EMBASE and the Cochrane Library and retrieved 942 non-duplicate citations. Total 20 studies (2 RCT, one cohort study, 17 case series) were included for this review. Two review authors independently applied the extracted data and assessed study quality.

**Results:** Two randomized controlled trials compared the TandemHeart device with IABP, 30-day all-cause mortality was not significantly different.

**Conclusions:** On the basis of current data, we recommend that pLVAD is possible treatments as the mechanical management of cardiogenic shock.

## PO.022

### Usefulness of Rapid Tests for Detecting Hepatitis B Virus Antibody (Anti-HBS)

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**Background:** Identification of susceptible individuals for hepatitis B virus (HBV) infection is quite difficult in remote areas where there is no infrastructure for blood testing.

**Objectives:** This study aims to evaluate a rapid test for detection of antibody against HBV (anti-HBs) in serum samples of general population from different regions of Brazil.

**Methods:** Sera samples were obtained from 2331 individuals (mean age  $\pm$  standard deviation of  $43.4 \pm 19.3$  years and 54.7% of female)

and divided in four groups: G1) high endemicity areas for HBV (HBsAg prevalence higher than 8%); G2) low endemicity areas for HBV (HBsAg prevalence lower than 2%); G3) risk behavior for HBV acquisition (drug users and beauty professionals); G4) All three groups. Samples were submitted to anti-HBs detection using a gold standard (enzyme immunoassay (ETI-AB-AK-3, Diasorin, Italy) and rapid test (Imuno-Rápido anti-HBsAg, Wama, Brazil). Both assays employ 100 microliters of sample and results are ready in approximately 4 hours in EIA and 15-20 minutes in RT.

**Results:** Sensitivities and specificities of rapid test for anti-HBs detection were as follows: G1: 50.3% (67/133) and 99.6% (289/290); G2: 51.0% (292/572) and 98.0% (935/954); G3: 46.7% (50/107) and 98.5% (270/274); G4: 50.3% (409/812) and 98.4% (1494/1518). Sensitivity of rapid test was improved when only anti-HBs reactive samples (titers higher than 100IU/mL) were included in the analysis [G1:73.2% (60/82); G2: 82.9% (252/304); G3: 72.7% (48/66); G4: 79.6% (360/452)].

**Conclusions:** Rapid test for anti-HBs detection presented high specificity, although sensitivity of the method was not efficient among individuals presenting low antibody titers. This assay could improve the access for a rapid of diagnosis to patients in remote areas or emergency situations.

## PO.023

### Diagnostic Accuracy of CT Coronary Angiography Versus Invasive Coronary Angiography in the Diagnosis of Coronary Heart Disease

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**Background:** Invasive coronary angiography (ICA) and non-invasive computed tomography coronary angiography (CT-CA) are used in the diagnosis of coronary heart disease (CHD).

**Objectives:** The evaluation addresses diagnostic accuracy of CT-CA vs. ICA in the diagnosis of CHD.

**Methods:** A systematic literature search was conducted in electronic data bases (MEDLINE, EMBASE etc.) in October 2010 and was completed with a manual search. Two independent reviewers selected the relevant publications.

The evaluation was based on systematic reviews of diagnostic studies with ICA as the reference standard (identification/exclusion of obstructive stenoses) and on diagnostic studies with intracoronary pressure measurement as the reference standard (identification/exclusion of functionally relevant stenoses). Study results were combined in a meta-analysis with 95 % confidence intervals (CI).

**Results:** 15 systematic reviews with data from 44 diagnostic studies using ICA as the reference standard and two diagnostic studies using intracoronary pressure measurement as the reference standard were included.

CT-CA with ICA as the reference standard had a sensitivity of 96% (95%-CI: 93-98%), specificity of 86% (95%-CI: 83-89%), positive likelihood ratio of 6.38 (95%-CI: 5.18-7.87) and negative likelihood ratio of 0.06 (95%-CI: 0.03-0.10), showing "high"/"persuasive" diagnostic evidence to identify patients with/without obstructive coronary stenosis.

Using intracoronary pressure measurement as the reference standard, CT-CA compared to ICA had a sensitivity of 80% (95%-CI: 61-92%) vs. 67% (95%-CI: 51-78%), a specificity of 67% (95%-CI: 47-83%) vs. 75% (95%-CI: 60-86%), an average positive likelihood ratio of 2.3 vs. 2.6, and an average negative likelihood ratio 0.3 vs. 0.4, respectively. Therefore, both types of coronary angiography showed „weak” diagnostic evidence to identify patients with/without functionally relevant coronary stenosis.

**Conclusions:** Based on diagnostic accuracy, CT-CA can be recommended to rule out obstructive coronary stenoses to avoid inappro-

prate ICA. Neither CT-CA nor ICA alone can be recommended for identifying or ruling out functionally relevant coronary stenoses.

## PO.025

### Association of Inosine Triphosphatase (ITPA) Polymorphisms with Treatment-Induced Reduction in Hemoglobin in Brazilian Patients During HCV Therapy and Allelic Distribution in Healthy Individuals

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**Background:** Treatment of patients with chronic hepatitis C virus infection (HCV) is a major challenge both in terms of clinical success and cost-effectiveness. Ribavirin-induced hemolytic anemia is the most important hematological adverse effects in treatment of hepatitis C (HCV). Recently, ITPA gene variants associated with protection against ribavirin-induced anemia were identified.

**Objectives:** Evaluate the association of SNPs rs7270101 and rs1127354 in ITPA gene with treatment-induced reduction in hemoglobin (Hg) and to evaluate the distribution in general population, considering the scarcity of studies in Brazil.

**Methods:** Real-time PCR (Roche) and direct nucleotide sequencing.

**Results:** In healthy individuals (n=100), the distribution of genotypes AA, AC, and CC of SNP rs7270101 was 87%, 11%, and 2%, respectively; and in rs1127354 genotype AA was found in 93% and AC in 7%. In HCV infected patients (n=194), genotypes AA, AC, and CC of rs7270101 were seen in 82.4%, 17%, and 0.6%, respectively; as to rs1127354 genotype CC was seen in 96% and genotype AC 4%. Among those who completed the treatment (n=61), the mean pre-treatment Hg was 14.0±1.7g/dL, but a progressive reduction in Hg levels was observed at weeks 4 (12.3±1.7), 8 (11.1±1.40), and 12 (10.6±1.5) after treatment beginning. The prevalence of anemia at week 12 was 83.6% (51/61), of which 70% (43/61) had AA genotype in rs7270101 and 100% had CC genotype in rs1127354.

**Conclusions:** These results demonstrate that AA genotype of rs7270101 SNP was associated with reduced levels of Hb for antiviral therapy. A relatively high proportion of healthy and HCV infected individuals harbor the unfavorable genetic variants of rs7270101 and rs1127354 which could explain the high rates of ribavirin-induced anemia observed during treatment of HCV in Brazilian population.

Key-words: Hepatitis C, ITPA, SNP, Brazil

Financial support: CAPES, CNPq, FAPERJ, IOC

## PO.026

### Deep-Brain Stimulation as a New Therapeutic Procedure for Anorexia Nervosa

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**Background:** Deep-brain stimulation (DBS) is a surgical procedure used to treat a variety of disabling neurological symptoms, and some psychiatric disorders too. DBS could be used in the treatment of refractory Anorexia Nervosa (AN).

**Objectives:** To study the efficacy and safety of DBS in patients affected of refractory AN.

**Methods:** Early assessment of this technology identified and prioritized by the early warning system "SINTESIS-new technologies" of AETS-ISCI. Medline (Pubmed), the Cochrane Library, CRD and Clinical Trial databases were searched. Studies published in any language until January 2014 was retrieved.

**Results:** Two retrieved case-studies analysed DBS for the treatment of refractory AN. The first study included 4 female aged 16-17 years. Patients were treated with bilateral DBS. The mean follow-up was 38 months (range, 9-50). Average baseline body mass index (BMI) was 11.9 Kg/m<sup>2</sup> (range, 10.0-13.3). Average BMI at last follow-up was 19.6 Kg/m<sup>2</sup> (range, 18.4-22.1). All patients recovered menstrual cycle in an average of 6.8 months. Side-effects were not studied. The second study a phase-1 trial included 6 female aged 24-57 years. Patients underwent bilateral DBS. Follow-up was at 1, 3, 6 and 9 months after treatment. Three patients gained weight compared with their baseline measurements (11.1 vs 21.0 kg/m<sup>2</sup>, 14.2 vs 16.0 kg/m<sup>2</sup>, and 15.1 vs 20.0 kg/m<sup>2</sup>) at 9 months follow-up. These patients at 6 months follow-up showed improvement in their quality of life (mean score: 43.0, SD: 20.1 vs 60.0, SD: 7.5). The remaining 3 patients showed no changes in the BMI or quality of life score. Severe side-effects such as pancreatitis, hypokalaemia, refeeding delirium, worsening mood, and QT-prolongation were described.

**Conclusions:** Deep-Brain Stimulation could be a promising technology to treat refractory Anorexia Nervosa. However, at present the treatment is still in an early stage of development. Further scientific research is necessary to better know the efficacy and safety of this procedure.

## PO.027

### Robotically-Assisted Surgery for Mitral Valve Repair: a Systematic Review and Meta-Analysis

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**Background:** Despite the established benefits of sternotomy for repairing or replacing the mitral valve, it is an invasive procedure with a considerable recovery time and risk of complications. Robotic surgery has been proposed as a procedure that integrates its inherent advantages while not losing the advantages of open surgery.

**Objectives:** To assess the efficacy and safety of robotic valve mitral repair compared to non-robotic procedures.

**Methods:** Literature searches were performed in Medline, Embase, Lilacs, Cochrane registry of Controlled Trials and Google Scholar. Study eligibility was determined by two independent investigators who also extracted the data. Random-effects models were used to combine data, whereas the I<sup>2</sup> was used to quantify statistical heterogeneity.

**Results:** Nine studies met the inclusion criteria. None were randomized. All nine studies investigated the comparison "robot vs open surgery". We were able to investigate 12 outcomes, including reoperation, length of hospitalization, blood transfusions, post-operative complications, cross-clamp, and mortality. Only one study investigated important outcomes such as quality of life and time taken to return to work. While it suggests that quality of life of robotic surgery patients might be better in the short-term, quality of life at 12 months after surgery is identical. Robotic surgery seems to require fewer blood transfusions (OR=0.33, 95% CI: 0.12-0.91, I<sup>2</sup>=85%) and results in a shorter length of hospital stay (-1.25 days; 95% CI: -2.12 to -0.38, I<sup>2</sup>=0%). However, it showed inferiority regarding time of bypass (+52 minutes; 95%CI: 40-61, I<sup>2</sup>=81%) and cross-clamp (39.4 minutes; 95% CI: 33-45.7, I<sup>2</sup>=55%). Quality of the evidence was judged as either low or very low depending on the outcome.

**Conclusions:** There is no evidence that robotic surgery for mitral valve repair has either a higher or lower efficacy, nor that it increases survival. The current evidence would benefit from well conducted randomized controlled trials.

## PO.028

### The Effectiveness on Assessment of Endothelial Function Using Peripheral Artery Tonometry: a Systematic Review

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**Background:** 'Assessment of Endothelial Function using Peripheral Artery Tonometry' is a test for evaluation of endothelial dysfunction.

**Objectives:** The purpose of this study was to evaluate 'Assessment of Endothelial Function using Peripheral Artery Tonometry'.

**Methods:** A systematic literature review was used to evaluate the effectiveness of 'Assessment of Endothelial Function using Peripheral Artery Tonometry'. The literature review covered from April 2, 2012 to May 2, 2012, and eight domestic databases including KoreaMed and foreign databases including Ovid-Medline, Embase, and Cochrane Library were used. Key words, such as 'peripheral arterial tonometry' and 'Endo-PAT', were used to search a total of 1,157 documents. The SIGN (Scottish Intercollegiate Guidelines Network) tool was used by two evaluators to independently evaluate the quality of the 11 selected studies.

**Results:** A study is compared with 'coronary endothelial function testing' reported that the cut-point was 1.35 and sensitivity, specificity were 0.80, 0.85. A study is compared with 'computed tomography' reported that the cut-point was optimum and sensitivity, specificity were 0.62, 0.63. The area under the curve (AUC) was 0.613 ( $P=0.04$ ). Moreover, when the cut point was 0.52, the sensitivity, specificity were 0.76, 0.56 and AUC was 0.63 ( $p=0.015$ ). This test was not established test cut point yet and the correlation coefficient was 0.4~0.5. Therefore, it is a technology at a stage of needing long-term follow-up well designed researches.

**Conclusions:** 'Assessment of Endothelial Function using Peripheral Artery Tonometry' is not a useful test on patients suspected cardiovascular patients based on existing studies.

## PO.029

### An Empirical Evaluation of Funnel Plot Asymmetry in Meta-Analyses of Medical Interventions

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**Background:** An asymmetrical funnel plot does not necessarily mean that publication bias exists.

**Objectives:** To investigate characteristics of interventions that yielded asymmetrical funnel plots and to estimate how many of them suggest publication biases as the cause of the asymmetry.

**Methods:** Based on the Cochrane Database of Systematic Reviews (2010), we selected all binary-outcome forest plots amenable to statistical testing for funnel plot asymmetry. Eligible forest plots were those with (i) at least 10 studies (at least one showing a  $P<0.05$ ), (ii) lack of evidence for heterogeneity and (iii) ratio of the largest to smallest variance  $\geq 4$ . Asymmetrical funnel plots were those with a  $P<0.10$  in at least two out of three statistical tests: Harbord, Peters and Rücker. The types of technologies and outcomes were identified for each selected forest plot. We further classified the cause of the asymmetry for the statistically-defined asymmetrical funnel plots into one of two categor-

ies (visual inspection by two investigators): asymmetry with a high or low risk of being due to publication biases.

**Results:** Among 85,002 forest plots, only 1056 (1.2%) qualified for asymmetry tests. From these, 161 (15.2%) had statistical evidence for funnel plot asymmetry, with 54 (33.5%) suggesting dissemination biases as the cause of the asymmetry. In only 31 (57%) instances were readers warned about the possibility of publication bias. Meta-analyses with outcomes defined as a "clinically-defined benefit" were 12 times more likely to show funnel plot asymmetry with a high risk of being due to dissemination biases compared to those with "death" as outcome (odds ratio = 11.7; 95% CI=1.67-502.9). The corresponding results for "clinically-defined benefit" vs "harms" were: 4.8, 95% CI =1.00-45.2).

**Conclusions:** Dissemination biases might be more common in clinically-defined benefits than in mortality- or harm-related outcomes. Notification regarding the asymmetry in funnel plots may be suboptimal.

## PO.030

### Technology in Health for Membership of the Treatment Hypertensive Elderly

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**Background:** Demographic projections predict that by 2025 Brazil will occupy the sixth position worldwide, with about thirty-two million seniors. The age-related diseases lead to increased healthcare costs have a major impact on the economy of countries. It is estimated that at least 65 % of the Brazilian elderly are hypertensive. Non-adherence to treatment of systemic arterial hypertension (SAH) is considered a complex and multi particular phenomenon.

**Objectives:** Analyze the behavioral changes in elderly hypertensive with treatment adherence, through the application of a health technology (TS) grounded in the Health Belief Model (HBM).

**Methods:** Participatory research developed in a Reference Center for Social Assistance in Fortaleza - Ceará - Brazil. Twenty seniors participated. The TS was designed based on MCS, based on the assumptions of health education, and consisted of ten matches occurred for three months. We opted for the MCS as a theoretical and methodological framework, due to its relevance to explain the adoption of behaviors in the prevention and control of diseases.

**Results:** Most elderly showed knowledge about hypertension and on the conduct of control deficit. Eighteen elderly perceived their susceptibility to complications of SAH, and seriousness. The elderly feel after which returned the severity to the memory of daily facts. Fifteen perceived benefits to adhere to measures to control hypertension. Were numerous barriers encountered by the elderly to treatment adherence as inappropriate relationship with the healthcare team, high cost of medicines.

**Conclusions:** Seniors understand the application of TS as something positive for their lives and for the control of SAH, and realized the vulnerability, the severity of SAH, the benefits of treatment adherence, barriers impeding the behavioral changes, and incentives for strategies developed by them aiming at an adequate control of SAH.

**PO.031****Emergence of Real World Data in Reimbursement Decision Making**

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**Background:** There is a growing body of evidence related to real world data (RWD). RWD is an umbrella term and constitutes a variety of types of evidence, coming from observational studies, registries, pragmatic trials and surveys etc. All types of evidence have a place in the decision-making process and RWD is often used to fill in critical gaps in the evidence base. Healthcare costs have been rising consistently at a rate that cannot be sustained by most healthcare systems. This coupled with the increasing cohort of an ageing population and the financial crisis, appropriate resource allocation has become even more important.

**Objectives:** This paper considers the role of RWD in healthcare decisions and explores how best it can be used for health technology assessments (HTAs) more successfully going forward.

**Methods:** N/A

**Results:** Recently, it has become widely recognised that data from normal clinical practice gives a better reflection of healthcare delivery and should play a stronger role in healthcare decisions. Additionally, the long-term data on efficacy and adverse events (especially rare events) could be studied efficiently through well-designed registries. This is often necessary for rare diseases, where RCTs may not always be feasible. This has led to some initiatives being developed to explore these issues including the adaptive licensing project, the MIT NEWDIGS programme in the US and the European Commission funded IMI-GetReal projects in Europe.

**Conclusions:** Vast amount of data is collected through observational studies, registries, pragmatic trials, and surveys. Strategic and systematic efforts are required to ensure efficient use of existing RWD in HTA and reimbursement decisions. Further work is needed to validate and critically appraise different forms of RWD such that policy makers can use them more readily. This is a shared responsibility for all stakeholders to shape the future direction of this growing field.

**PO.032****The New Coverage with Evidence Development (CED) Regulation in Germany**

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**Background:** Funding of diagnostic and therapeutic methods in Germany's statutory health insurance follows a dichotomy: in ambulatory care, only methods with proven benefit are reimbursed while in inpatient care, all methods may be provided unless they are excluded due lack of evidence on benefit or because they cause harm. Until recently, the decision-making body (Federal Joint Committee) had no possibility to conduct or initiate clinical trials in order to overcome the lack of evidence.

**Objectives:** (1) Present the details of the new Coverage with Evidence Development (CED) regulation managed by the Federal Joint Committee (G-BA). (2) Compare the German approach with approaches from other countries.

**Methods:**

- (1) In January 2012, a new section 137e was added to the Social Code Book V (SGB V), allowing for the inclusion of innovative and potentially beneficial diagnostic or therapeutic methods in the SHI benefit basket, while additional evidence may be gathered.

In 2013, the G-BA has regulated the details of this new approach, which can be considered a version of CED.

- (2) Structured comparison according to the method of Walt and Gibson.

**Results:**

- (1) According to the new CED approach in Germany, manufacturers have the possibility to apply at the G-BA for conducting a clinical trial in order to generate evidence with the aim to prove a claim that a new diagnostic or therapeutic method, in which a medical device is an essential component, has an additional benefit in comparison to current standard procedures.
- (2) A comparison of the German approach with CED schemes in various other countries shows that current schemes do share certain key attributes and share the common goal of generating evidence to validate and support current decision-making. However, a common methodological approach or a standardised procedure cannot be identified yet.

**Conclusions:** The G-BA will possibly initiate a first wave of clinical trials during 2014.

**PO.033****A Rapid HTA on Implantable Devices for the Closure of Patent Foramen Ovale (PFO)**

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**Background:** Percutaneous closure of PFO is proposed to patients suffering from cryptogenic stroke, transient ischemic attack (TIA) or persistent migraine. Even though no PFO devices has been approved by the FDA, several are CE marked.

**Objectives:** To produce a rapid HTA report focused on the effectiveness and safety of PFO devices.

**Methods:** We performed searches on a national database to identify PFO devices on the market. We conducted a systematic review and meta-analysis of studies in which patients with PFO and TIAs, cryptogenic stroke or persistent migraine who underwent PFO closure were compared to patients treated by usual care. We performed searches on clinical trial databases to identify clinical trials on the identified PFO devices.

**Results:** We included 5 controlled clinical trials (CCT), and 1 randomised controlled trial (RCT). According to our meta-analysis, PFO closure significantly reduced the incidence of stroke in only one study and the incidence of TIA in two studies; PFO closure reduced the incidence of combined outcomes (stroke, TIA, mortality) in one study. However, all studies had poor methodological quality and heterogeneity made stratification of results per device not practicable. From the included RCT we extracted a safety profile of the procedure characterised by 4.7% of procedure-related serious adverse events.

From clinical trials databases we found just 4 PFO devices who have records (9 trials registered; status: 2 = unknown; 2 = terminated; 2 = ongoing; 1 = expanded access; 2 = recruiting). Trials results made available from two trials failed to show superiority of PFO closure compared to medical therapy in a significant reduction of the risk of recurrent embolic events or death.

**Conclusions:** According to the available evidence, PFO closure is not associated to significant benefits in adults who had had cryptogenic ischemic stroke. Results on the effects of PFO closure on migraine are expected in 2014.

**PO.034****Training to Achieve the Innovation**

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**Background:** The Brazilian National Commission for Health Technology Incorporation - CONITEC advises the Ministry of Health about new technologies adoption, exclusion or modification for the Unified Health System – SUS - Listings. The incorporation and management decisions are based on normative instruments presenting the quality of the scientific evidence according to the Methodological Guidelines for Technical - Scientific Appraisals. There are, thus, specialists' training requirements for systematic reviews and HTA presentations. The Library of the Faculty of Medicine, University of São Paulo - USP, has trained teams in the literature review and integrates the Board of Scientific Evidence of the Center for Health Technology Assessment - NATS, Hospital das Clínicas-USP- for the Brazilian Network - REBRATS .

**Objectives:** Aiming to prepare HTA specialists, this librarians team will be taught an intensive HTA course during the year 2014.

**Methods:** Indeed, it started October 2013, with Brazilian Cochrane team presenting the history and evidence-based medicine state of the art. During 2014, the course will be taught by a Cochrane member, with USP bond. The content emphasizes: systematic review, study types identification/differentiation, searching methods and strategies, always with directed exercises from the health literature.

**Results:** It is expected that the Librarians team will multiply acquired knowledge, to make it available for orientation/training of other professionals involved in the HTA Network, including other libraries to support HTA teams. This pilot project is the first step towards the creation of the formal specialization course for HTA Librarians proposed.

**Conclusions:** It is expected that the Librarians team will multiply acquired knowledge, to make it available for orientation/training of other professionals involved in the HTA Network, including other libraries to support HTA teams. This pilot project is the first step towards the creation of the formal specialization course for HTA Librarians proposed.

**PO.035****CT Colonography for Those at High Risk or Symptomatic for Colorectal Cancer**

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**Background:** Computed tomography colonography (CTC) is a less invasive investigative alternative to colonoscopy or double contrast barium enema (DCBE) for patients suspected of colorectal cancer (CRC). It can be conducted in radiology rooms and does not require a gastroenterologist.

**Objectives:** CTC was assessed to determine whether it should be publicly funded for patients who are contraindicated for colonoscopy, or who have limited access to colonoscopy. The comparators were, respectively, DCBE and delayed colonoscopy

**Methods:** Following a protocol, the medical literature was systematically searched to identify evidence of the safety and effectiveness of CTC. Studies were screened according to predefined eligibility criteria. Direct evidence of the impact of CTC on patient health outcomes was supplemented with evidence obtained using a linked evidence approach ie narrative synthesis of data on the accuracy of CTC, its impact on clinical decision making, and likely health impact of changes in patient management.

**Results:** One randomised controlled trial found that the 4-year mortality rates for patients undergoing CTC or DCBE were similar (15.7%

and 15.8%). CTC was found to be more sensitive than DCBE, but less specific. CTC is likely to result in more follow-up colonoscopies, but DCBE is more likely to produce false negative results, which could hypothetically lead to a delay in diagnosis. CTC is a safe procedure for which serious adverse events are rare. Patient acceptability of CTC is much greater than for DCBE. Repeat colonoscopies are very likely to be successful provided extra care and 'modifiable factors' are corrected. No evidence was found to compare CTC with 'delayed colonoscopy'. However, a systematic review found that even when CRC patients have diagnostic or therapeutic delays the health outcomes are unaffected; suggesting that appropriate triaging occurs.

**Conclusions:** CTC is a safe, accurate and effective alternative to DCBE in patients suspected of CRC and contraindicated for colonoscopy.

**PO.036****Advancements of Resolution n° 9, 28th Pan American Sanitary Conference in Brazil by Technical Cooperation Term with Ministry of Health and Pan American Health Organization**

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**Background:** In 2012, Brazilian's Ministry of Health (MoH) signed a Technical Cooperation Term (TCT) with PAHO to strength the actions in innovation and regulation in health on emphasis in the incorporation of health technology and research ethics based in the Resolution n°09, 28th Pan-American Sanitary Conference (CSP28.R9).

**Objectives:** Describes the results from the first year of the implementation of CSP28.R9 in Brazil by TCT between Brazil's MoH and PAHO.

**Methods:** Observational study that describes the results of TCT from April/2012 to December/2013 and described in three axes: The organization of MoH for HTA; The production and the dissemination of HTA; and The review and elaboration of the Clinical Protocol and Therapeutic Guidelines (CPTG).

**Results:** The main result of the cooperation to the implementation of the CSP28.R9 is the partnerships among specialists and Universities creating the opportunities for the discussion about HTA.

1staxis Publication of four legal acts: a federal law, a decree and two ordinances. They contributes to the structuration of the National Commission of Incorporation of Technology (CONITEC).

2ndaxis: 297 requests of HTA have been submitted to CONITEC. 50,1% of the requests were originated by an external demand and the other half were internal MoH demands and 21,9% of these requests had been incorporated by the MoH, 14,8% were unincorporated. Types of technologies analyzed: 192-medicines, 44-medical devices, 61-diagnostics. CONITEC created and publicized 84 public reports of recommendation with the results of process. 3rdaxis: 14 guidelines reviewed and 2 new elaborated.

**Conclusions:** This is the first study of implementation the CSP28.R9 by TCT that shows important results for organization, production and dissemination of HTA. The CONITEC Reports of Recommendation is an important strategy of dissemination and helps to improve a dynamic system of review and elaborations of CPTG. There are some challenges to implement the CSP28.R9 and this TCT is relevant to achieve the goals.

**PO.037****Defining a Comprehensive Model of Care for Hemophilia in Colombia**Ramon Abel Castaño<sup>2</sup> Diana Tellez<sup>1,3</sup> Luz Andrea Ramirez<sup>1</sup>

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**Background:** Hemophilia is a high cost chronic disease that has become relevant for many health systems around the world. Adopting a comprehensive care model in developing countries is necessary to tackle this challenge. In Colombia, access to medications is established via inclusion on the formularies or reimbursement measures. Nevertheless it is still undefined which components of a model of care are crucial to guarantee the best adherence to treatment and an optimal management of acute episodes of bleeding.

**Objectives:** Our aim is to understand the best structure and processes required to improve both clinical outcomes and the best use of resources.

**Methods:** A literature review regarding models of care for Hemophilia was undertaken after which visits to five best-practice care providers were completed. Two expert committees validated the findings according to local particularities.

**Results:** The elements of a model of care were classified as supply-side and demand-side. On the supply side the identified elements included health care team involved, electronic clinical records, planned medical visits, use of Tele-medicine and IT to speed access to patient in case of bleedings, use of clinical guidelines and process, output and outcome metrics. On the demand side the use of individual risk profiling, an individualized care plan, support for self-care and adherence to treatment, education on the adequate use of health care services and the use of community resources were tackled. Of particular importance for Colombia, it is key to overcome fragmentation of the cycle of care by integrating its components and designing adequate payment mechanisms with some degree of risk transfer to care providers.

**Conclusions:** Demand and supply elements of a model of care are vital in the delivery of comprehensive care for hemophilia. Individual services should be built and monitored around care cycle and innovative payment mechanisms need to be explored for the local context.

**PO.038****Systematic Review of the Efficacy of Platelet-Rich Plasma in the Treatment of Aseptic Non-Union**María Dolores Vega-Coca<sup>1</sup> Miguel Ángel Giráldez-Sanchez<sup>2</sup> María Teresa Nieto-Rodríguez<sup>3</sup> Rebeca Isabel-Gómez<sup>1</sup> Auxiliadora Castillo-Muñoz<sup>1</sup> Teresa Molina-López<sup>1</sup>

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**Background:** The gold standard for biological treatment of non-union is autologous bone grafting from the ileac crest. This technique is not effective in all cases, and has limitations such as morbidity of the donor site. Platelet-rich plasma (PRP) has been proposed as an alternative biological stimulus.

**Objectives:** To assess the efficacy of PRP in the treatment of aseptic non-union.

**Methods:** A systematic review of literature was performed (until December 2012).

Databases searched: MEDLINE, EMBASE, Web of Science, Cochrane Library, Centre for Reviews and Dissemination, Índice Bibliográfico Español en Ciencias de la Salud, and Índice Médico Español. Additionally, the Emergency Care Research Institute's website was searched.

Systematic reviews, meta-analysis, health technology assessment (HTA) reports, randomized controlled trials (RCTs), analytical observational studies and case series on patients with aseptic non-union, comparing PRP (alone or as an adjuvant treatment to conventional surgery) with conventional therapy or placebo (or in the absence of a comparator), in terms of union and time to union, were included.

Selection, critical review and data extraction were carried out by two researchers.

**Results:** 11 studies met the inclusion criteria: 1 brief HTA report, 1 RCT (results from one of the arms), and 9 case series with low-to-moderate methodological quality.

Union rates ranged from 64.7%-100%. The best outcomes were found in patients receiving PRP as adjuvant therapy to surgery, and in combination with bone graft or synthetic substitutes. The median time to union ranged from 2.8 to 9 months. When PRP-treated patients were compared with a historical control group, no significant differences were found in terms of union rate or time to union.

**Conclusions:** Overall, the majority of studies reported positive outcomes associated with the use of PRP. However, available evidence is insufficient and higher methodological quality studies are needed to confirm the efficacy of PRP in healing aseptic non-union.

**PO.039****The Influence of Recommendations Related to Antineoplastic Drugs Issued by Agency for Health Technology Assessment in Poland (AOTM) in 2013 for the Reimbursement Decisions**

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**Background:** The main task of AOTM, established in 2005, is to assess and appraise all medical technologies and services claiming public money funding. For all new health technologies entering market full pharmacoeconomic evaluations are required before the reimbursement decisions are taken by Minister of Health (MoH).

**Objectives:** The objective of this study is to assess scope and the influence of oncology drugs recommendations issued by AOTM in 2013 for the reimbursement decisions taken by MoH.

**Methods:** Among recommendations of AOTM issued in 2013 we analyzed all related to new oncology and hematology drugs. The recommendations were identified and categorized also into types of recommendations (positive or negative). We compared the outcomes with reimbursement list officially published by MoH (January 2014). Recommendations related to reassessment, off-label use drugs or individual treatment agreement were excluded

**Results:** Among 189 recommendations, issued by President of AOTM, 79 (42%) applied to innovative medical technology which were never reimbursed. In this group 26 of 79 (33%) was related to innovative antineoplastic drugs. AOTM issued positive recommendations for reimbursement to 16 of 26 of cancer drug submissions (62%). 10 of 26 (38%) were not approved and received negative recommendations. Having analyzed the reimbursement list we realized that only 6 of 26 (30%) assessed by AOTM drugs are occurred on the reimbursement list. All of them were positive recommended by AOTM.

**Conclusions:** The influence of recommendations issued by AOTM for anticancer drugs for reimbursement decisions taken by MOH were not significant with respect to place the drugs on the list. But we can realize that none oncology drug with negative AOTM recommendation appears on the list. The conclusion indicates that the medicine with negative recommendations probably will not be accepted for reimbursement from public sources. Contrarily, not every drug with positive recommendation issued by AOTM will be placed on the reimbursement list.

**PO.040****Accuracy of HTA Reports: a Survey of Ten-Year Activity of a Hospital-Based HTA Unit**

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**Background:** Created in 2002, the Lausanne University Hospital HTA unit performs hospital-based HTA (HB-HTA) reports to help hospital management in decision-making.

**Objectives:** We assessed (1) the acknowledgment of the HTA procedure's utility by relevant clinicians, (2) the compliance with indications for treatment defined by the HTA reports and (3) the accuracy of the expected medical impact of the new technology.

**Methods:** We retrieved all HB-HTA reports published during the period 2002-2011. For each technology accepted by the hospital management, a semi-structured interview with the relevant clinicians was conducted by an investigator not involved in the HTA process. We then compared the expected medical impact described in the report to real patient data for year 2012.

**Results:** During the ten-year period, 40 HB-HTA were carried out, of which 34 led to management's acceptance. Out of the 28 clinicians in charge of these 34 technologies, 27 accepted to be interviewed. Eighty-five percent of clinicians (23/27) acknowledged the utility and necessity of the HB-HTA process. Out of the 34 technologies adopted, 6 were no more in use in 2012. For the 28 remaining technologies, effective number of patients was higher than expected in 5 cases, lower in 15 cases, as expected in 5 cases, and not available in 2 cases. Average length of stay was longer in practice than expected (+61%). Two technologies had a higher complication rate, and 3 technologies had a lower success rate than expected. Initially, indications for treatment as defined in the HB-HTA reports were strictly followed. However, they evolved in 15/28 of them after a few years of practice (7 restrictions, 5 broadenings, and 3 other changes).

**Conclusions:** HB-HTA is acknowledged as a useful tool to improve quality in decision-making. A follow-up analysis should routinely be performed to adapt HB-HTA's conclusions to practical experience and new scientific evidence.

**PO.041****Understanding the Research Focus of HCV Health Technology Assessment**

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**Background:** With deeper understanding of the main classes of enzymes involved in viral replication, researchers, globally, are developing more direct-acting medications to treat Hepatitis C Virus (HCV). As new technologies proliferate, patient access to these products in many countries may be impacted by recommendations resulting from health technology assessments (HTAs).

**Objectives:** This analysis reports the evidentiary demands of key comparative effectiveness research (CER) and HTA organizations evaluating HCV treatments.

**Methods:** Using the Avalere EBM Navigator™, we reviewed final and "in progress" reports published by 18 U.S. and international CER and HTA organizations between January 2007 and January 2014 that assessed HCV treatments.

**Results:** We identified 32 reports from 7 organizations. Clinical outcomes of focus of the reports included adverse events (28 reports), sustained virological response (21), mortality (19), and biochemical response (8). Over half of the reports (18) assessed an economic endpoint, of which 14 reported incremental cost effectiveness ratios. 14 reports evaluated quality of life.

11 reports were still "in progress," of which 3 focus on recently approved or soon-to-be approved HCV therapies. HTA organizations whose decisions have been referenced in payer coverage policies (i.e., Canadian Agency for Drug and Technologies in Health, U.K.'s National Institute for Health and Care Excellence) were more likely to assess emerging therapies. Reviews that evaluated regimens involving pegylated interferon, ribavirin, and an additional drug in combination generally resulted in positive recommendations, while negative recommendations or inconclusive findings primarily occurred when the HTA organization had a narrow research question (i.e., effectiveness in a specific patient population).

**Conclusions:** Stakeholders are demanding evidence on cost-effectiveness and patient-centered outcomes which are becoming an integral pieces of the HCV evidence base, given the significant side effect profiles of current standards of care. An understanding of trends in evidentiary demands can inform decisions regarding future evidence generation that will ultimately meet public health needs.

**PO.042****A Strategy to Control Expenditure of Health Technology in Korea: Focused on Medical Devices**

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**Background:** Health expenditure on medical devices in National Health Insurance (NHI) has been increasing rapidly in Korea. Average increasing rate over the period 2006-2010 was 16%, which was much higher than the rate of procedures or pharmaceuticals. To challenge the medical device policy, the new system is needed to evaluate the more strict evaluation system: the decision making system of entering the expansive device and the regular reassessment system.

**Objectives:** This study aims to suggest the effective policy issue of medical device in NHI. Specifically, we analyzed the utilization and expenditure of medical device using NHI claiming data. As the result of the data, we evaluated the policy in the process of deciding coverage and price, utilization, and re-evaluation.

**Methods:** The NHI claiming data was used from 2006 to 2010 in Health Insurance Review & Assessment Service (HIRA). The categories in medical devices were defined into three groups (new, continued, obsolete) according to whether they were decided as coverage condition in that year. Then, annual share of them was analyzed.

**Results:** The share of continued devices was a great part of medical expenditure (94.6~96.6%) every year, 2006-2010. Only 0.1~2.3% of health expenditure were decreased due to obsolete devices. Health expenditure per device unit was gradually increasing because of expanding coverage for devices with high prices in 2006-2010. Average listing period of devices was 6.6 years and devices older than 6 years accounted for half of total expenditures. About 40% of devices were still in the NHI benefit lists although they never had been used in that year.

**Conclusions:** In the future, the policy of the medical device in the NHI should be strengthened in some issue. It is needed to 1) consider cost-effectiveness when deciding coverage or price, 2) monitor utilization, and 3) re-evaluate for de-listing or adjusting the price in medical device.

**PO.043****From Assessment to Health Care Decision Making: an Example from Real World in Lombardia Region**

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**Background:** HTA can be integrated into the healthcare planning activities at national, regional and local level, as well as into the investment management strategy. By applying HTA concepts to the controlled adoption of innovative technologies a better allocation of investments could be achieved. Such a framework should involve in practice all the stakeholders by using contextual priorities, assessment methods and decision making processes committed to transparency, measurability, sharing, non-redundancy, and multi-disciplinarity.

**Objectives:** To develop, to field test and to put in practice a regional framework for the integration of assessment and appraisal of emerging, new and established healthcare technologies.

**Methods:** A quantitative appraisal method based on a multi-criteria decision analysis (MCDA) was adapted, with modifications, from the EVIDEM framework ([www.evidem.org](http://www.evidem.org)) and implemented as a web-based tool. Starting from a submission from manufacturers, clinical experts or other decision-makers, the framework guide a pool of experts (selected according to expertise in the area and conflict of interests) into the contextualisation of third party HTA reports independent from the industry (e.g. the national horizon scanning report published by Agenas or the EUnetHTA Core Model pilots and reports). The framework then provide regional decision-making committees with all the tools to appraise whether there are the conditions for the technology to be rejected, further assessed or directly approved for reimbursement within the Region. The committees' judgement is then translated into a formal act, i.e. a decree of the General Directorate of Health.

**Results:** Fourteen technologies have been processed according to the presented framework and reimbursement decisions have been taken for all of them.

**Conclusions:** The new framework allowed to regulate the investments on those technologies that are linked to new costs for the healthcare system but not yet proved to be effective in comparison with the standard of care.

**PO.044****Systematic Review of Methods for CER of Medical Devices**

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**Background:** Most international guidelines for Health Technology Assessment (HTA) and Comparative Effectiveness Research (CER) have been written with the main focus on pharmaceuticals. CER of medical devices (MD) raises special challenges which require reflections on whether the current methods adequately take account of specific features of MD and whether the conceptual differences between pharmaceuticals and MD require different methods for CER of MD.

**Objectives:** We review the approaches currently used for CER and identify challenges and gaps in methodology related to specific issues for MD. Further, we develop a comprehensive framework for evaluating clinical effectiveness of MD including recommendations for analytic methods and data collection.

**Methods:** A systematic literature review on current CER methods and on specific features of MD was performed. We conducted an electronic database search and a systematic screening of tables of content of journals in the fields of epidemiology, HTA, statistics, and evidence-based medicine, which have a strong focus on methods. From the included papers, we identified important key papers and additionally screened their bibliographies.

**Results:** Nearly 200 papers that address either generally the assessment of clinical effectiveness of MD or particular methods that are important for CER of MD, were included.

We found that the physical mechanism of action, the dynamic development and the regulatory evidence requirements for MD warrant focusing certain CER methods for the evidence generation, finding of information for HTA, data analysis and synthesis, and interpretation of results. The consideration of observational data, operator characteristics, active control trials, and decision-analytic modeling are of special importance, as well as the application of Bayesian methods.

We design a comprehensive methodological framework of CER for MD with recommendations for data collection and analytic methods.

**Conclusions:** The assessment of the clinical effectiveness of MD does require specific, although not necessarily different methods.

**PO.045****Ablation with Cryotherapy, HIFU and Laser-Therapy in Organ-Confined Prostate Cancer: Systematic Review**

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**Background:** In order to reduce the co-morbidity of established therapies for localized prostate cancer, new less invasive therapeutic options have been developed based on local ablation, cryotherapy, high intensity focus ultrasound (HIFU) and laser-therapy.

**Objectives:** To assess the effectiveness and safety of prostate ablation with cryotherapy, HIFU and laser therapy compared to open radical and/or laparoscopic prostatectomy in organ-confined prostate cancer.

**Methods:** The following data sources were consulted: MedLine, EMBASE and Web of Knowledge, between others. The inclusion criteria were published studies about organ-confined prostate cancer treatment with cryotherapy, HIFU or laser-therapy, with or without open or laparoscopic prostatectomy comparison. Between the primary outcomes, studies included survival, quality of life and complications.

**Results:** We selected 1 synthesis report about cryotherapy and HIFU without direct comparison, 1 systematic review and 3 case-series about HIFU, 1 case-series about cryotherapy, and 1 cost-effectiveness study. None of the identified studies showed information about laser therapy and only one of the case-series included prostatectomy as compared treatment.

The global five-year survival rate for cryotherapy and HIFU ranged between 39-100% and 62-95%, respectively.

Quality of life scores (UCLA-PCI) were +10 and -6 points in urinary function domain for cryotherapy and prostatectomy, and +24 for both in the intestinal function. Non-significant clinical differences appeared in the sexual function domain.

All therapeutic modalities presented complications as urinary infections and incontinence (2,2-33% and 2-27% for cryotherapy versus 1,8-47,9% and 1,4-38% for HIFU). Impotence was especially observed in the cryotherapy group (40-100%).

**Conclusions:** Cryotherapy could be associated with higher five-year survival and greater results for urinary and intestinal function compared to prostatectomy and HIFU. However, this evidence is based on indirect comparisons limiting the applicability of these results.



**PO.046****Evipnet Brasil and the Experience of Evidence Center**

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**Background:** Evidence center is an innovative initiative of EVIPNet Brazil which aims to promote local use of scientific knowledge in the formulation and implementation of health policies in order to support decision-making informed by the best evidence and consequently produce better results.

**Objectives:** To report the Brazilian experience with the implementation of the Evidence Center and the Virtual Health Library Stations (NEV/EBVS) through the Evidence-Informed Policy Network and to present the standards to select the cities/institutions that are able to receive the center and how this deployment is made by EVIPNet Brazil in partnership with Bireme/OPAS/WHO.

**Methods:** N/A

**Results:** In 2013, four centers were already opened and more than 200 researchers, policymakers and health professionals were trained in the methodology EVIPNet and the SUPPORT tools. In 2014, five new NEV/EBVS are planned to be open. The EVIPNet Network uses its website as a tool to turn easier the exchange of information between the centers, in order to support the development of evidence brief for policy.

**Conclusions:** Strengthening the "Culture of use of the evidence" in management; increase the representativeness of the local context through the publications and the databases access; understanding that scientific knowledge is (part of and most important) component of the decision-making process; lack of syntheses and good quality of systematic reviews for many of the health problems facing the avalanche of information; and to move from Eminent or Belief informed decision to Evidence informed decision.

**PO.047****The Role and Trends Health Technology Assessment in the Future Development of the Kazakh Healthcare Sector**

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**Background:** Public expenditure on health in Kazakhstan low by international comparison, and are less than 4 percent of the gross domestic product (GDP). With rising incomes and a commitment from the Government of Kazakhstan to increase the proportion of gross domestic product spent on health, this is an opportune moment to consider how health technology assessment (HTA) might help to allocate healthcare spending in Kazakhstan, in an equitable and efficient manner.

**Objectives:** Study of the current status and how HTA can be used to inform several aspects of care delivery.

**Methods:** A review of relevant key documents regarding the HTA process was performed and we identified and collected relevant information to map the level of HTA in Kazakhstan.

**Results:** In Kazakhstan, the implementation of HTA was part of joint project of Government of Kazakhstan and World Bank. Despite the active government support and the establishment a special unit of HTA at the National Center for Health Development, implementation of HTA occurred formal. HTA results have limited impact on the decision making process, no guidelines for HTA, also noted a lack of capacity. Decentralization of HTA and related functions widens the expertise available to HTA and brings broader perspectives to the process and diminishes or balances potential conflicts of interest. Together, these generally add to the credibility of HTA processes and

findings, and lessen any charges that assessments reflect narrow or self-serving interests of closely related to the payer organizations.

**Conclusions:** Areas in which HTA could be applied in the Kazakh context include, drug pricing, development of clinical practice guidelines, and prioritizing interventions that represent the greatest value within a limited budget. If aligned with the prevailing cultural and ethical considerations, and with the necessary investment in expert staff and resources, HTA promises to be a valuable tool for development of the Kazakh healthcare sector.

**PO.048****The Use of Surface Support for Preventing and Treating Pressure Ulcers: a Rapid HTA by a Center of Health Technology Assessment (CHTA) in Ceara, Brazil**

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**Background:** The health technology assessment for surface support for preventing and treating pressure ulcers was demanded by the Centers of Health Technology Assessment (CHTA) in Hospitals of the Department of Health in the State of Ceara, northeast, Brazil. This technology consists a set of recommended devices for prevention and reduction pressure ulcers.

**Objectives:** To present a rapid HTA for the use of surface support for preventing and treating pressure ulcers conducted by Technology Assessment Center of the Department of Health in the State of Ceara, Brazil.

**Methods:** The project methodology utilised PICO criteria (population, intervention, comparator and outcome). The searches were conducted using Tripdatabase, Cochrane Library, CRD, CINAHL, EMBASE and PUBMED. We used the Mesh tool and there were found "ulcer"[MeSH Terms], Ulcer[Text Word]), "pressure"[MeSH Terms], Pressure[Text Word], "equipment and supplies"[MeSH Terms] and medical devices[Text Word]. We used emtree tool and there were found "Decubitus" and "Medical device".

**Results:** Three systematic reviews of randomized controlled trials were selected. There were not methodological rigor and consistency in these trials, without statistical significance.

**Conclusions:** There is no conclusive or reliable evidence to suggest that devices of alternating pressure and mattresses profiles are more effective than other existing surfaces for preventing and treating pressure ulcers, like as standard mattresses. Independent, well-designed, multicenter, randomized, controlled studies are needed to compare the clinical use and cost-effectiveness of different types of support surfaces devices to prevent and treat pressure ulcers in patients with different levels of risk in a variety of settings.

**PO.049****A Review of the Health Technology Assessment and the Coverage Decision Making in Korea**

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**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 and benefit appropriateness. From 2007 to 2010, a total of 691 applications were submitted and 304 applications (44.0%) were eligible to be assessed. Among 105 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 no 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 decision making. Firstly, we consider improving the participation of patients and citizen. Secondly, we need to develop the flexible process of the new medical procedures and devices reflected on the technology's characteristics. And lastly, we need to set the scanning 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 decision making, and setting the scanning system should be considered. Further study should work out a strategy in detail.

## PO.050

### Framework of a "Special Follow-Up" for the Introduction of a New Technology in the Galician Health Service

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**Background:** The requirement for early access to new techniques, technologies, and procedures insufficiently assessed need new tools and procedures that allow for coverage whilst collecting information keys for informing decision making regarding final approval. The "special-follow up" procedure is a legal tool designed to the introduction of new technologies that present evidence gaps in the Galician Health Care Service (Spain). Canaloplasty in open-angle glaucoma, that has been reimbursed under this procedure.

**Objectives:** Using canaloplasty as an example, we aim to present the framework and steps for incorporating new technologies with evidence uncertainties in the Galician Health Service

**Methods:** NA

**Results:** In accordance to binding law, a proposal for incorporation of canaloplasty was submitted from a health care centre, accompanied by a report memory with key information (indications, proposed benefits, technical, personnel requirements, etc). Once the proposal was validated and it was confirmed to be a truly new technology, a report was requested from the Galician Agency for Health Technology Assessment (avalia-t). Avaluia-t carried out the systematic review and delivered the conclusions and recommendations for additional data requirements to the Advisory Commission, responsible for the appraisal. The Commission reinforced the recommendation to carry a follow-up study to assess the learning curve. The Advisory Commission's proposal was approved by the General Technical Secretariat and ratified by the Healthcare Assistance Division. Avaluia-t, in collaboration with the authorized centres, has the responsibility of developing the protocol for data collection, designing the database, analysing the results and delivering a final report to the Advisory Committee. Canaloplasty is currently in the data collection phase.

**Conclusions:** The framework used in Galician Health Service can serve as a reference for other institutions that aim to effectively implement strategies for additional data collection.

## PO.051

### Profile of Demands for Technology Incorporation in the Brazilian Public Health System Between the Years 2012 and 2013

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**Background:** The National Committee for Health Technology Incorporation – CONITEC, created by the federal law 12,401/2011, advises the Ministry of Health (MoH) of Brazil in the process of modifying, excluding and including health technologies in the Brazilian public health system (SUS). Its assignments guide the evaluation of health and social benefit, as well as, economic consequences of the use of these technologies.

**Objectives:** To describe the profile of demands for technology incorporation in SUS between the years 2012 and 2013.

**Methods:** Retrospective, descriptive study, based on records available in the CONITEC database. The database permitted to classify the demands by origin (internal: claims from MoH's Departments; external: pharmaceutical industries, state's governments, health professionals or general population) and by technology: in type of technology and health subjects.

**Results:** In 2012, CONITEC received 161 demands for technology evaluation, being most of them externals (n=109). Of these, 70% were medicines (n=113), 15% health products (n=24) and 15% procedures (n=24). In 2013, the majority of demands was internal (90/126), with a similar profile to former year, except for an enhancement of claims for procedures, being 57% medicines (n=72), 29% procedures (n=36) and 14% health products (n=18). The most demanded health subject in 2012 was oncology (14%), followed by pneumology (12%), infectology (12%) and rheumatology (11%); in 2013, the profile was 17% in the rheumatology area, followed by cardiology (14%), genetic (14%) and oncology (10%).

**Conclusions:** During 2012-2013, CONITEC received a large number of demands. Thus, many companies saw an opportunity to incorporate their innovative products in SUS, in addition, CONITEC gained the confidence of the technical areas of MoH. The type of technology most demanded didn't vary among the years, although the health subject was modified, reflecting potential relations with social needs in health and improvement of the SUS management.

## PO.052

### Therapeutic Vaccines in Lung Cancer as an Emerging Technology: Systematic Review

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**Background:** Lung cancer is one of the pathologies with the most increased mortality despite the established treatments. Active immunotherapy is a therapeutic approach aimed at inducing an immune response to be specifically and selectively against cancer cells.

**Objectives:** To assess the effectiveness in terms of survival and safety of therapeutic vaccines against lung cancer in advanced stages (III-IV).

**Methods:** A Systematic review was performed in accordance to the PRISMA statement. MedLine, EMBASE, The Cochrane Library were

consulted (until October 2013), and in several information sources. The inclusion criteria were published systematic reviews and primary studies that included patients with lung cancer, stage IIIb and IV, with administration of active immunotherapy in the experimental group. The risk of bias was assessed using The Cochrane Collaboration's tool. The level of evidence was determined in accordance with the SIGN guideline criteria.

**Results:** 278 citations were retrieved after eliminating duplicates. Finally, 6 randomized clinical trials and 1 cohort study were selected with a moderate risk of bias. In all, therapeutic vaccines were compared to the administration of palliative treatment (chemotherapy and/or radiotherapy). None of them showed significant improvement in time to progression and overall survival. The differences appeared with the subgroup analysis: survival improved in patients with stage IIIb (median 30,6 vs 13,3 months,  $p=0,007$ ), in patients younger than 60 years compared with older (median 11,57 vs 5,3,  $p=0,0124$ ) and in patients with good immune response (1:4000) compared with a low one (median 11,7 vs 3,6,  $p=0,002$ ). No serious adverse events were found and the most frequent were related to the injection site, fever and flu-like syndrome.

**Conclusions:** Therapeutic vaccines could increase time to progression in lung cancer patients in specific situations (stage IIIb, younger than 60 years and with good immune responses) compared to conventional palliative treatment.

#### PO.053

##### The Use of Information Technology and Communication in Health at the Federal District of Brazil

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**Background:** The Information and Communication Technologies ( ICT ) are present in everyone's life : users , technology professionals , health , education , researchers , among others . In 2011 the Brazilian Institute of Geography and Statistics ( IBGE ) showed that in the first quarter of this year 77.7 million people 10 years and older accessed the Internet . Regarding Primary Care , ICT use is still very recent , since few health facilities in the Federal District have network system , electronic medical records , televisions and totems .

**Objectives:** In this sense, the present study aimed to analyze access ICT for Health ( ICT ) for health professionals from the Regional Health Paranoá , located in the Federal District , Brazil .

**Methods:** The qualitative research was initially developed with 39 Community Health Administrative Region Paranoá , Federal District . Data were collected from a questionnaire previously developed with objective questions , open questions , applied to health professionals and included the observation unit .

**Results:** Partial results show that 95 % reported having a computer at home and, of these , less than half , ie , 48 % said they also have access to a computer at work, another 23 % reported computer access in Internet cafes . However , the ability to access both the computer and the internet does not mean the guarantee of effective digital inclusion and , therefore , the improvement in the working process of the professionals within the health unit .

**Conclusions:** Thus concludes - that access to information and communication technologies by health professionals can lead to empowerment of information in order to strengthen both work processes , such as service users and ways of socializing health information and quality life along to individuals, families and communities .

#### PO.054

##### HTA in the Era of Personalised Medicine: a Methods Comparison

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**Background:** Genomic research is advancing at rapid pace, however the translation of genetic findings into clinical pathways remains difficult. Health technology assessments (HTA) are often produced to determine whether a new technology should be implemented into clinical practice. At present the implementation of diagnostic or prognostic gene expression markers is impeded by a lack of robust evidence as requested by current HTA standards, but a feedback loop between assessors and evidence generators is often missing and is not adapted to the highly dynamic field of genomic research.

**Objectives:** We will explore the evidence requirements for genomic technologies based on a comparison of HTAs for selected, widely assessed gene expression markers (Mammaprint, Oncotype DX). We will further analyse alternative methods such as constructive technology assessment with regards to their capacity to fill in evidence gaps.

**Methods:** Based on existing guidelines for assessment of diagnostics, we will investigate in a systematic review published and unpublished reports on technology assessment for selected genomic technologies.

**Results:** Expected results will allow to identify clinical, economical, patient-related and organisational aspects that can be studied as part of a CTA (or other alternative methods) and as such could complement HTA decisions.

**Conclusions:** Our study will inform HTA producers if and how evidence gaps on genomic technologies can be filled by alternative technology assessment methods and provide directions on how to possibly integrate them in conditional coverage decisions.

#### PO.055

##### Leading Hospital Based HTA initiatives: an Analysis of Organisational Models across Europe

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**Background:** Health Technology Assessment (HTA) has been widely recognized as methodological approach aimed at informing on the impact of health technologies (HTs) and supporting decision-making at different levels. Hospitals still remain the main entry level for innovative HTs. Thus, the role of Hospital- Based HTA (HB-HTA) became a central topic in healthcare management, since the understanding of organizational features and arrangements characterizing HB-HTA are crucial in orienting the introduction of good innovations.

**Objectives:** The aim of this study is to explore how different organizational models accommodate to strengthen the impact of desirable and amend undesirable uptakes of innovative technologies.

**Methods:** Data used in this study are gathered within the European Project AdHopHTA, granted under the 7th Framework Research Programme and aimed at strengthening the use and impact of HTA in hospital settings. Supported by previous research on this topic, we will carry out a survey among hospitals participating in the Project and having a HB-HTA programme. The survey will be aimed at investigate: (i) hospital's organizational attributes; (ii) the main mission of HTA activities; (iii) competences involved in the programme; (iv) final outputs and principal users; (v) further organizational arrangements.

**Results:** Expected results will allow to identify and define organizational models applied in European hospital settings and those organizational characteristics affecting the adoption of HTs. Moreover, our results will give the opportunity to understand and critically appraise

how organizational models could facilitate or hinder the introduction of innovative HTs.

**Conclusions:** Our study will provide useful information for hospital administrators and decision makers. First, the awareness of the several organizational solutions in approaching HB-HTA would be of helpful in managing the complexity of hospitals and encouraging the adoption of good innovations. Moreover, this information would be useful for those who are willing to implement HB-HTA programs within their own contexts.

## PO.056

### Virtual Learning Object focusing on Family Health Strategy

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**Background:** Given the intense transformations related to education, it is necessary to take into account that practices involving health education transform and are transformed by the actions of other areas. The objects of virtual learning can be defined as digital tools whose constant updating as well as the combination with other tools mark the dynamism of such resources.

**Objectives:** The objective is to describe an experience report on the development of a learning object virtual blog on health in 2013.

**Methods:** The educational blog aimed to share information through videos, chargetexts and discussions of primary healthcare for students and professionals working Basic Health Unit Jander Antônio Pereira Machado, in Ceara-BR.

**Results:** The topics covered in the blog were: dental care during pregnancy, the importance of prenatal care, diabetes, among others.

**Conclusions:** In order to evaluate user satisfaction in relation to the available material, we created a poll. When we make a blog structured to provide meaningful content, activities and moments of interaction, we can consider it as a learning object .

## PO.057

### Step Up HTA Toolbox: a Way to Enhance Innovation

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**Background:** Health technology development is crucial to promote patient's safety and a better organisation of care delivery. However, HTA can sometimes be viewed as a barrier to the integration of new promising technologies. This is especially true for technologies developed in small and local companies and they do not perform clinical studies. As a matter of fact, given the short period of time allowed to make a contextualised informed decision and the lack of scientific evidence, traditional HTA-based literature reviews may not be suitable to appraise the evidence.

**Objectives:** To estimate field evaluation process through the assessment of a new technology on the organisation of delivery care in the context of poor evidence and high incertitude present in the literature

**Methods:** HTA process was initiated in order to assess if the actual manual system used to manage narcotics should be replaced by an automated dispenser (NarcoMedic<sup>®</sup>) developed by a small company in the province of Quebec. Nurse and pharmacy assistant productivity as well as enhancement of narcotics management in our hospital were

the critical outcomes analysed. Because no evidence was published in Quebec, it would have been difficult to assess the performance of such a technology in the context of our hospital and a literature review would have brought little pertinent information to help decision-making. As a consequence, we conducted a field evaluation to address this point. We performed a longitudinal observational descriptive study to compare preparation and distribution of narcotics between the manual system and the automated dispenser.

**Results:** HTA unit and agencies are faced with rapid development of new technologies that are not supported by pertinent published evidence, which represents an important issue to help decision makers in their policy statements.

**Conclusions:** In this context, we showed that field evaluation can provide useful information directed towards an informed decision.

## PO.058

### HTA Network of the Americas (RedETSA)

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**Background:** Growing interest for HTA and EE in the Region of the Americas and a consensus of their importance for supporting decision making brought important achievements at National level in the last 10 years.

**Objectives:** Presented the HTA Network of the Americas – RedETSA.

**Methods:** N/A

**Results:** RedETSA was launched in June 2011, Representatives with 14 countries and a total of 26 institutions, including Ministries of Health.

Ever since, PAHO acts as the Secretariat of RedETSA and proposal of the network is to promote and strengthen HTA, through regional exchange as a tool to support decision-making on the introduction, dissemination and use of technologies; advance the adoption of common methodologies; and establish joint working priorities for capacity building.

Main activities of RedETSA: Monthly virtual meetings, annual meeting with the participation of the members and invited institutions; Development of a Community of Practices for the Network within the Regional Platform of Access and Innovation for Health Technologies; Mapping of the situation of HTA\EE and decision making.

The mapping of the situation of HTA\EE has two components:

- Capacity to perform HTA/EE: a questionnaire was developed based on the mapping exercise made by MERCOSUR countries and will be applied in all countries participating in the network
- Decision-making processes: a template was adapted from one developed by NICE (UK), which was used in a similar mapping exercise performed in a few countries by IDB, NICE, IECS, MoH Colombia.

**Conclusions:** After three years, the recognition by the Member States of the legitimacy of RedETSA as the Regional HTA network and also of the role of PAHO was achieved. Now, it's time show some results. The network's website is under development and together with the community of practice, will serve for sharing experiences and problem-solving together. The biggest challenge is to pursue sustainability network, funding sources and dynamic communication.

**PO.059****The Importance of the Colaborative Networks to the HTA Development in Developing Countries**

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**Background:** The evaluation of health technologies assessment (HTA) is essential in the management and incorporation of new technologies in Brazil Public Health System (Sistema Único de Saúde - SUS), which must evolve to guarantee that only the relevant technologies to the performance of the system and process that prove to be effective, safe and cost-effective are incorporated. This is a major challenge for developing countries where public health systems are struggling to offer basic health care for the entire population.

**Objectives:** To analyze the Brazilian HTA model and contribute to the improvement of HTA in Latin America.

**Methods:** Descriptive evaluation of the Brazilian HTA model focusing on the communication between institutions and nations.

**Results:** The Brazilian model is based on a restricted group of evaluators of the Ministry of Health public policies. It keeps partnerships with universities (REBRATS) and teaching hospitals (NATS Network) to develop dissemination of information studies in HTA. The Ministry of Health articulates with States and municipalities by SUS tripartite management and with Latin American countries cooperation (REDETSA). Communication and transparency are central parts of the HTA process, helping relationships with partners and stakeholders with regulated sector, media, proposal of law and society. The exchange of experiences on HTA between institutions and countries is important to the development of skills to interpret local reality and make the best choices of technology.

**Conclusions:** The HTA is science that needs to be translated into the universe of every country and culture. It depends on network information and local expertise. This new paradigm of the necessity and contrasts of the people's health scenarios, will favor the spread of the model to countries and institutions, thereby strengthening its implementation and effective development.

**PO.060****How to Enhance the Use of Evidence in Decision-Making? Evidence-Informed Options for Health Policies**

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**Background:** The use of scientific evidence is considered an important factor for the development of efficient policies and one of the main challenges of health systems. This challenge is especially relevant for developing countries such as Brazil, in which public health investment is insufficient and the available resource is not always allocated efficiently.

**Objectives:** The objective of this policy brief was to identify and evaluate options to stimulate the use of research evidence in the process of health policy-making.

**Methods:** Evidence search was conducted at different databases. Seven systematic reviews were used for the elaboration of options based on the SUPPORT tools.

**Results:** We proposed four options: 1) Produce policy briefs with adapted language for different audiences; 2) Implement an online platform for dissemination of scientific knowledge; 3) Stimulate the use of journalism for dissemination of scientific knowledge, and; 4)

Promote the dialogue between researchers and policymakers. All options seem to stimulate the use of evidence in decision-making process. The way scientific information is presented may influence the decision maker, as do the use of online platforms and information systems. Similarly, the use of journalism seems to provide positive effects for the dissemination of scientific knowledge, although the data are insufficient to demonstrate significant changes in the behavior of decision makers.

**Conclusions:** Despite political uncertainties and the lack of consensus among the involved actors, we believe that better access to research information and greater interaction between researchers and decision makers may increase the use of research in the process of formulation and implementation of public policies. Nevertheless, studies that aim to analyze the impact of evidence-informed decisions in local context are still necessary. Despite the complexity of the variables and the possible scenarios involved in decision-making process, different strategies seem to be essential to improve the use of research evidence in health policy making.

**PO.061****Economic Evaluation of Sevelamer for the Treatment of Hyperphosphatemia in End-Stage Renal Disease Patients**

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**Background:** Calcium-based phosphate binders may not be perceived as suitable for controlling hyperphosphatemia in all patients because of theoretical concerns about their use, and dose-limiting hypercalcemia. Sevelamer is the first non-calcium-based phosphate binder to receive approval in Kazakhstan Healthcare system. Given a large differential cost between this new agent and traditional therapies, the appropriate use of this new therapy requires examination.

**Objectives:** To assess the cost-effectiveness of sevelamer versus calcium carbonate as a treatment for hyperphosphatemia in end-stage renal disease (ESRD) patients.

**Methods:** We conducted a cost-effectiveness analysis to compare costs and clinical outcomes of sevelamer versus calcium carbonate for treatment for hyperphosphatemia in ESRD patients. Efficacy and adverse event rates for each regimen were obtained from published clinical trials. Drug costs were based on average wholesale prices; monitoring costs were based on budgetary reimbursement rates in Kazakhstan. A Markov decision analytic model was developed to estimate total life years, quality-adjusted life years (QALYs), and costs for patients treated with sevelamer or calcium carbonate.

**Results:** Over a lifetime horizon, sevelamer treatment led to an increase in QALYs per patient. Results were robust to alternative assumptions in key parameters; results were most sensitive to alternative assumptions regarding the mean daily dose of sevelamer, impact of sevelamer on dialysis initiation, cost of dialysis, and health utility estimates. The probabilistic sensitivity analysis showed that sevelamer was cost-effective vs calcium carbonate in 90% of simulations. Possible that sevelamer use, restricted to patients  $\geq 65$  years old, might be more economically efficient.

**Conclusions:** Sevelamer therapy results in a smaller decrease in phosphate levels, and fewer episodes of hypercalcemia of unknown clinical significance, compared with calcium-based phosphate binders. Sevelamer hydrochloride is a cost-effective strategy compared with calcium carbonate in the treatment of ESRD patients with hyperphosphatemia who were previously treated with calcium-based binders. Sensitivity analyses demonstrated the robustness of the pharmacoeconomic model.

**PO.062****Experience with the Collection and Use of Real World Evidence in Asia**

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**Background:** Health Technology Assessment (HTA) systems are being implemented or considered in many countries in Asia. However the availability, accessibility and quality of real world evidence (RWE) to use in conjunction with data from randomised controlled trials to inform HTA decisions is highly variable across the Asian region.

**Objectives:** To describe our experience with a range of sources of RWE in China, Japan and Taiwan.

**Methods:** In-house studies using primary and secondary sources of RWE used to generate information on the cost/burden of illness, current treatment patterns, epidemiological data, use of medicines and treatment effectiveness and cost-effectiveness were reviewed.

**Results:** RWE is available from a range of commercial and non-commercial sources across Asia. In China administrative claims data are available from the Urban Basic Medical Insurance system in some cities, and from the Electronic Medical Records systems used in some large teaching hospitals in major cities. In Japan, most data sources are commercial. In Taiwan, comprehensive longitudinal national data are available from the National Health Insurance Research Database. General issues common to many of these sources include: that the sample of patients in many of the RWE sources may not be representative of the broader population; limited access for non-academic researchers; quality of data in newly established data collection systems; and a lack of outcomes data. Hybrid study designs that supplement claims/electronic data with information from medical chart reviews have been adopted to address some of these limitations.

**Conclusions:** A range of sources of RWE within Asia were identified, however issues relating to availability, accessibility, affordability and quality of data limit the overall ability to access and use RWE for HTA purposes. Despite these limitations, matching the right study design to the available data sources has been a successful approach to address specific research questions.

**PO.063****Deep Brain Stimulation in Parkinson's Disease: Meta-Analysis of Randomized Controlled Trials**

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**Background:** Until recent years there has been no evidence from randomized controlled trials (RCTs) on the efficacy of deep brain stimulation (DBS) for Parkinson's disease (PD).

**Objectives:** This review and meta-analysis of RCTs describes the efficacy of DBS in improving motor signs, functionality and quality of life of PD patients.

**Methods:** Systematic review and meta-analysis. Several electronic databases were consulted until April 2013. RCTs that compared DBS plus medication versus medication (alone or plus sham DBS) in PD patients were included. Outcome measures were: motor function, waking time on good functioning without troublesome dyskinesias, levodopa-equivalent dose reduction, medication-induced complica-

tions, activities of daily living, health-related quality of life, and neuro-cognitive and psychiatric effects.

**Results:** Six RCTs (n=1184) that compared DBS plus medication versus medication alone were included. The results show that DBS significantly improves patients' symptoms, functionality and quality of life. Effects sizes are intense for the reduction of motor signs and improvement of functionality in the off-medication phase, in addition to the reduction of the required medication dose and its associated complications. Moderate effects were observed in the case of motor signs and time in good functionality in the on-medication phase, in addition to the quality of life.

**Conclusions:** Although the number of RCTs obtained is small, the total sample size is relatively large, confirming the efficacy of DBS in the control of motor signs and improvement of patients' functionality and quality of life. More controlled research is required on the neurocognitive and psychiatric effects of DBS.

**PO.064****The Clinical and Economic Burden of Infectious-Related Hospitalizations Among Solid-Organ Transplant Recipients: a Single Centre Study**

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**Background:** There has been a paucity of data on the healthcare resource utilization and economic burden of infectious-related (IR) complications in solid-organ transplant (SOT) recipients.

**Objectives:** The aims of this study were to describe and report the associated clinical and economic burden of SOT recipients hospitalized for IR complications, along with the impact of an infectious disease (ID) specialist consultation.

**Methods:** This cohort study evaluated all SOT recipients requiring admission to a tertiary-care centre during 2007, 2008, and 2011. Propensity-score (PS) matching and generalized linear regression methods were used to estimate the effects of patient demographics, co-morbidities, transplant- and infection-related factors on 28-day hospital survival, hospital length-of-stay (LOS) and direct medical costs.

**Results:** Infectious-related complications occurred in 603/1414 (43%) readmissions in 306/531 (58%) patients. The most frequent IR complications were: respiratory, sepsis, and liver infections. Overall, the mean LOS and hospitalization cost were 10.8d and \$21,365, respectively. Using the PS-matched cohort, the median LOS and hospitalization costs were significantly increased for patients receiving an ID consultation than in those managed by the attending team alone (7.0d vs. 5.0d, P=0.002, and \$19,619 vs. \$13,923, P=0.003). However, the median LOS (5.5d vs. 5.1d, P=0.31) and hospitalization costs (\$8106 vs. \$6912, P=0.63) did not differ significantly among those receiving an early ID consult (<48h) versus no ID consult, respectively. Patients receiving an ID consult had significantly longer 28-day survival estimates (HR=0.33, log-rank P=0.026), and were less likely to be readmitted within 30-days of their hospital discharge (17% vs. 24%, P=0.036).

**Conclusions:** Infections appear to cause significant morbidity in the transplant population, posing a significant burden on acute healthcare resource utilization. Enhanced patient risk assessment along with prompt and appropriate treatment for infectious episodes through the use of an ID specialist may decrease IR mortality.

**PO.065****Cost-Effectiveness of Treatment with Peginterferon alpha 2a Plus Ribavirin for Slow Virologic Responders Coinfected with HCV/HIV**

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**Background:** Hepatitis C virus (HCV) infection alone is responsible for the morbidity and mortality of an expressive portion of the world population. In co-infection with human immunodeficiency virus (HIV) can cause individuals' death in less than one decade. Few innovations regarding treatment technologies have been observed in recent years. One significant innovation was the availability of antiviral treatment for slow virologic responders.

**Objectives:** Considering the divergence between the latest Brazilian guidelines, this study assessed the cost-effectiveness of treatment at genotype 1 HCV/HIV co-infected individuals, treatment naïve and non-cirrhotic, examining the inclusion and non-inclusion of slow virologic responders.

**Methods:** A mathematical decision model, based on Markov chains, simulated the progression of liver disease through treatment and no treatment, from the perspective of the Brazilian Public health care system. The lifetime horizon was 30 years and discounted rate (5%) utilized for costs and clinical outcomes.

**Results:** The extent of treatment for slow virologic responders provided an extension of 3% in the cohort's survival and improvement of 0.28 QALY, when compared to the non-inclusion strategy. The treatment of slow virologic responders has an incremental cost-effectiveness ratio of 44,171 BRL/QALY, below the acceptability threshold recommended by the World Health Organization (63,756 (BRL/QALY)). In sensitivity analysis, the treatment of slow virologic responders was also the preferred option and not change the final results.

**Conclusions:** The inclusion of individuals co-infected HCV/HIV slow virologic responders in treatment guidelines presents a favorable cost-effectiveness ratio under the Brazilian Health Care System perspective. Its adoption could avoid, in a greater extent, deaths, complications and unnecessary hospitalizations.

**PO.066****Timely and Accessible Information to Optimise Regulatory Decisions**

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**Background:** Every year over 250 million prescriptions are subsidised by the Australian Pharmaceutical Benefits Scheme (PBS) and 80-100 new drugs are added each year to the PBS. To practice effectively, clinicians need access to timely, independent, evidence-based information about new PBS listed medicines. We fulfil this need via NPS RADAR.

**Objectives:** To provide health professionals with information about new medicines at the time they are making decisions to prescribe, dispense or use those medicines, to support appropriate decisions.

**Methods:** NPS RADAR is published three times per year, in line with major updates to the PBS. It is provided free of charge to health professionals in Australia and is available in print and online formats with or without opt-in electronic updates. It is also integrated into primary care clinical software systems. When a prescriber selects a newly listed medicine during the prescribing process, a pop up alert links to relevant NPS RADAR information. The information includes:

- how a new medicine might (or might not) fit with current treatment
- why a medicine has a particular PBS listing — if restricted, it describes the evidence for benefit and harm behind these restrictions
- recent published clinical research
- information about cost-effectiveness.

Monographs are independently reviewed by experts in clinical medicine, academics, consumers, pharmaceutical industry representatives and government. Comment is also sought from the pharmaceutical company sponsor who made the submission for PBS listing.

**Results:** Each issue of NPS RADAR is distributed in print format to over 75,000 health professionals including general practitioners, pharmacists, medical specialists and medical students and 20,765 health professionals subscribe to electronic updates. In a 2012 national survey, 40% of GPs reported using NPS RADAR when looking for information about prescribing medicines.

**Conclusions:** NPS RADAR is a unique and trusted service which assists in optimising the implementation of public subsidy decisions.

**PO.068****The Cost-Effectiveness of CT Coronary Angiography Versus Invasive Coronary Angiography in the Diagnosis of Coronary Heart Disease**

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**Background:** Conventional invasive coronary angiography (ICA) and non-invasive computed tomography coronary angiography (CT-CA) are used in the diagnosis of coronary heart disease (CHD).

**Objectives:** The evaluation addresses cost-effectiveness in the use of CT-CA versus ICA in the diagnosis of CHD.

**Methods:** The cost-effectiveness was evaluated through modelling from the societal perspective. The clinical assumptions in the model to identify/exclude obstructive stenoses were derived from the conducted meta-analysis of the diagnostic studies with ICA as the reference standard, in the model to identify/exclude functionally relevant stenoses from diagnostic studies with reference standard intracoronary pressure measurement. The economic assumptions were based on contemporary German sources.

**Results:** The modelling using ICA as the reference standard showed that at a pretest probability of CHD of 50% or lower CT-CA resulted in lower cost per patient with true positive diagnosis. At a pretest probability of CHD of 70% or higher ICA was associated with lower cost per patient with true positive diagnosis. Therefore, for identifying or excluding obstructive coronary stenosis, CT-CA was found to be more cost-saving at a pretest probability of CHD of 50% or lower and ICA at a pretest probability of CHD of 70% or higher.

Using intracoronary pressure measurement as the reference standard, both types of coronary angiographies resulted in substantially higher cost per patient with true positive diagnosis. Therefore, the use of both types of coronary angiography to identify or to exclude functionally relevant coronary stenosis should be regarded as highly cost-consuming.

**Conclusions:** Based on cost-effectiveness, CT-CA can be recommended as a test to rule out obstructive coronary stenoses to avoid inappropriate ICA in patients with a pretest probability of CHD of 50% or lower. Neither CT-CA nor ICA alone can be recommended as a single diagnostic test for identifying or ruling out functionally relevant coronary stenoses.

**PO.069****Procedure (Implantation) Cost and Total Hospitalization Cost of Patients Subjected to Cardiac Rhythm Management Devices Implantation: Results from a Single Tertiary Centre**

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**Background:** Nothing is known about the procedure (implantation) cost and total hospitalization cost of patients subjected to CRMD in Greece.

**Objectives:** The objective of the present study is to estimate the procedure cost, which includes: the human resources cost, the implant and the supplies cost and the total hospitalization cost which includes: the procedure cost, the hospitalization cost, the laboratory and imaging diagnostic examination cost and the indirect cost, in patients subjected to pacemaker (PM) and implantable cardioverter-defibrillator (ICD) implantation.

**Methods:** A single-centre, prospective study was conducted for one year's period. In total, 464 consecutive patients were recruited (370 were subjected to PM implantation initial or replacement and 94 to ICD implantation initial or replacement). Resource data were assessed at patients' enrolment in the study as well as during the procedure of implantation. Then, the components of the procedure cost and total hospitalization cost were calculated using the bottom-up approach.

**Results:** The mean (95% confidence interval) procedure cost of PM and ICD implantation (including the costs of devices, electrodes, other supplies, and personnel's time) was calculated to be €1.803 (€ 1.758–€1.858) and € 13.521 (€ 13.153–€ 13.892), respectively. The mean total hospitalization cost (including procedure cost, hospitalization cost, cost of laboratory and imaging diagnostic examinations and the indirect cost attributed to productivity lost due to patient's hospitalization) was €3.926 (€3.711–€4.167) for PM and €17.764 (€16.852–€18.692) for ICD.

**Conclusions:** These data revealed that although these devices are associated with a relatively high upfront cost, the total implantation cost for the society is relatively low compared with other countries. Therefore, implantation of such devices should be encouraged since these devices reduce the morbidity and mortality without a high economic burden to society.

**PO.070****The Health and Economics Bulletin - Publications in 2013**

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**Background:** The Health and Economics Bulletin is an electronic periodic of Brazilian Health Surveillance Agency (ANVISA). It aims to provide information to healthcare decision-makers and patients when there is more than one pharmaceutical option to treat the same disease and there is no scientific evidence of superiority among them, considering the safety and efficacy profile.

**Objectives:** The objective of this study is to analyze the published editions of the Health and Economics Bulletin on ANVISA website in 2013.

**Methods:** The data were collected from 9th and 10th editions of Health and Economics Bulletin published in 2013. Diseases, thera-

peutic classes, active substance, drugs and treatment costs were the variables that were analyzed.

**Results:** The iron deficiency anemia and anxiety disorders were the themes addressed in 9th and 10th editions. Two therapeutic classes were evaluated: ferric compounds in 9th Edition and benzodiazepines in 10th Edition. A total of 10 active substances and 40 drugs were evaluated, including generic, similar and brand drugs. Forty costs of treatment were performed, which demonstrated considerable differences between drugs prescribed for the same disease. For example, on the iron deficiency anemia edition, it was found 1329% of difference on treatment costs between the most expensive and the lowest cost drugs although they have similar safety and efficacy levels, based on scientific evidences. For the anxiety disorders edition, this difference was 680%.

**Conclusions:** The Health and Economics Bulletin is an important source of information and it was conceived for improvement of the critical view of healthcare decision-makers and patients. Considering differences of treatment costs, that have the same safety and efficacy profile, they can select the pharmaceutical options available on the Brazilian market more efficiently. The year of 2013 was very relevant to the Bulletin, because the diseases, that were addressed, considered serious problems for Brazilian public health.

**PO.071****Optimal Use of Self-Monitoring of Blood Glucose: Evaluation and Recommendations to Support Prac**

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**Background:** Self-monitoring of blood glucose is an approach used by people with diabetes, in the context of disease self-management, to measure their capillary blood glucose using test strips and a blood glucose meter, in order to adjust medication and lifestyle or to check their effects on diabetes control. Although the approach is widely used by people with type 2 diabetes not treated with insulin, there is controversy regarding its real benefits. We have opted for the promotion of optimal use of self-monitoring of blood glucose on the part of health professionals and patients rather than placing administrative restrictions.

**Objectives:** To formulate recommendations that provide guidance and support to health care professionals for the optimal use of self-monitoring of blood glucose by adults with type 2 diabetes not treated with insulin.

**Methods:** The process of formulating the recommendations took into account scientific evidence as well as the perspectives of patients and providers. We thus integrated the results arising from four methods of synthesis: a quantitative systematic review of clinical aspects, a narrative qualitative review of social considerations, a pharmaco-epidemiological assessment of the use of test strips, and an analysis of contextual and experiential data from health care professionals and patients.

**Results:** Despite inconsistencies in the scientific evidence regarding the risks and benefits of self-monitoring of blood glucose, the analysis of experiential data allowed us to establish that certain sub-groups of the target population can benefit from this approach. These are adults with poor control of their blood glucose, recently diagnosed patients and those treated with antidiabetic medication with the potential to cause hypoglycaemia.

**Conclusions:** Our multidimensional evaluation led us to recommend an individualized approach to using self-monitoring of blood glucose for people with type 2 diabetes not treated with insulin, which takes into account the clinical situation and the values and preferences of patients.



**PO.072****Iodine 125 Brachytherapy for Intraocular Tumors**

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**Background:** Uveal melanoma is the most common primary intraocular malignant tumor in adults. Enucleation is the standard treatment for choroidal melanoma, but the desire to improve survival and to preserve the eye has stimulated the development of other therapies.

**Objectives:** - To evaluate the efficacy, safety, and cost-effectiveness of iodine 125 plaque brachytherapy in the treatment of primary malignant medium-sized choroidal melanoma.

- To estimate the budget impact of adopting this treatment in the Canary Islands.

**Methods:** A systematic review consulting PreMedline and Medline, Embase, Cochrane Central, Cochrane Systematic Reviews, Cinahl, and CRD (until January 2013) was performed. The quality of included studies was assessed using the Oxman and Jadad scales. An estimate of the current cost was carried out establishing the number of patients who are referred to another Spanish regions to be treated with brachytherapy. The average annual cost of continue with the current situation was calculated, and the average annual cost to establish a regional referral center was estimated.

**Results:** The systematic review included 12 studies: 3 randomized clinical trials, 3 comparative studies, 1 observational study, and 5 case series. No differences in effectiveness and safety were found in enucleation vs. brachytherapy, so that the choice of treatment should include the values and preferences of patients. No economic evaluations on cost-effectiveness were found. To establish a reference center in the Canary Islands about iodine 125 brachytherapy is necessary an initial investment of approximately € 21,316 for the equipment and material required. The budget impact of treating new cases of uveal melanoma would be approximately € 20,062.40 as additional cost.

**Conclusions:** No significant differences were found in the medium to long-term survival of patients treated with ophthalmic brachytherapy. Moreover, the introduction of this treatment in the Canary Islands would be an additional cost to the regional health authorities.

**PO.073****Handling Censored Data to Estimate Cost**

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**Background:** The collection of cost data attached to randomized clinical trials has become a common practice with the increasing use of economic evaluation for decision making. As a result, cost data is observed longitudinally and some individuals will have informative censoring since there is a positive correlation between costs accumulated to, for example, death and costs accumulated to censoring. The inverse probability weighted (IPW) least squares regression is one of the methodologies proposed to analyze this kind of data. However, common assumptions of linear regression such as normality and homoscedasticity are, usually violated, since the distribution of health care costs can be heavily right skewed.

**Objectives:** To present how to use generalized linear regressions (with IPW) to estimate mean total cost from longitudinal censored data.

**Methods:** Cost data were simulated from a real case scenario with no censor (complete data). Some data were randomly deleted in order to have censor. Total cost was estimated considering the complete data. To handle with the censored data three methods was applied:

IPW, linear regression with IPW and generalized linear regression with IPW. Practical guidelines of how to fit generalized linear regressions with IPW are addressed with particular attention to interpretation of the results.

**Results:** The total cost estimated were: \$27,925; \$26,662; \$27,305 e \$27,403 using the methods cited above, respectively.

**Conclusions:** Generalized linear regression is a flexible model to fit cost longitudinal censored data since it can accommodate the skewed characteristic of most data sets.

**PO.074****DAHTA's KoWi - Cooperation, Communication, Knowledge and Information Exchange – a Modern, Lean and Simple Working Platform for HTA Agencies**

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**Background:** DAHTA, the national HTA Agency of DIMDI, is developing classical HTA products beyond the reimbursement topic. Together with cooperation partners from Germany and Austria, around 150 scientific people are working together, to produce up HTA. To enable the agency to have an efficient working environment there was the need to establish a cooperation and communication infrastructure to easy up the exchange of knowledge and information.

**Objectives:** There was the need of a system that is a transparent, reliable and sustainable platform for cooperation, communication and exchange. It has to support the option that people can work from everywhere together without the need to be physically at the agency. By this, the platform has to offer, beside these classical knowledge system functions, an ontology repository, a knowledge integration and management platform, library services and a business intelligence center. In addition, modern communication via video conferencing is needed to support easy communication and to reduce to hidden walls of communication failures.

**Methods:** N/A

**Results:** Since 2012, the agency has developed a list of requirements regarding data protection and security infrastructure needs as well as working needs. Out of this the DAHTA knowledge and working environment has been set up which is now the basis of the development platform for national HTA products. This platform is now also used for other projects and networks related to HTA as the eGMS journal editorial office and projects as the German edition of the HTAi/INAHTA glossary group.

**Conclusions:** With the new platform, DAHTA is enabled to offer an easy to use all inclusive working and knowledge sharing platform for an integrative approach for those people who are sitting at their desk and want to work together.

**PO.075****Validation of the "NOTing OUT" Corrao Filter Strategy in Medline with Studies Included in Systematic Reviews**

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**Background:** In 2012 Corrao tested an optimized search strategy using the Boolean "NOT" (also called NOTing OUT) to examine the effectiveness for detecting RCTs through PubMed. The results of the application of the Corrao filter showed a reduction in retrieved citations of up to -24 to -35%, without loss of information.

Corrao's research provides important empirical evidence on the use of NOTing OUT. However, the gold standard was not based on data from real systematic reviews. Therefore we intended to validate Corrao's

results using studies included in systematic reviews (SRs) prepared by the German Institute for Quality and Efficiency in Health Care (IQWiG). Our main focus was on whether recall is negatively affected.

**Objectives:** To validate the recall of studies in MEDLINE by applying the Corrao filter strategy (not ((exp animals/ not exp humans)/ or review.pt. or meta-analysis.pt.).

**Methods:** We validated the application of the Corrao filter on the basis of citations included as relevant in SRs prepared by IQWiG between 2005 and October 2013. These SRs included mainly RCTs, but also other study types. We determined the proportion of relevant citations identified by the Corrao filter. We then performed an evaluation of the citations not identified.

**Results:** 71 SRs contained 2094 citations in MEDLINE of which we identified 2067 via the Corrao filter. This led to an overall recall of 98.7%. The 27 remaining citations mainly represented follow-up studies, retrospective or pooled analyses. We will provide further information on these 27 citations and will also discuss the potential consequences of the application.

**Conclusions:** Our analysis indicates that the Corrao filter strategy yields sufficient results on recall for the detection of studies in MEDLINE.

**Reference:** Corrao S, Colomba D, Argano C, Calvo L, Scaglione R, Licata G. Optimized search strategy for detecting scientifically strong studies on treatment through PubMed. *Intern Emerg Med* 2012; 7(3): 283-287.

## PO.076

### Multielectrode Ablation Versus Conventional Point-By-Point Ablation in Atrial Fibrillation: a Bayesian Meta-Analysis

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**Background:** For patients with atrial fibrillation (AF), pulmonary vein isolation using radiofrequency catheter ablation has been widely implemented and the success rate of the ablation procedure was improved as the 3-dimensional (3D) mapping systems has shown considerable advancement. Unfortunately, the procedure remains complex, time-consuming, and highly dependent on operator competency. Multielectrode catheters which enable mapping and ablation with one single catheter were developed to address these technical difficulties. However, the efficacy and safety of this approach has not been compared with conventional pulmonary vein isolation systematically.

**Objectives:** Objective was to compare the effects and safety of multielectrode catheter ablation (MEA) and conventional pulmonary vein isolation (CPVI) in patients with atrial fibrillation.

**Methods:** To identify and retrieve all relevant literature, PubMed, EMBASE, Cochrane and 4 Korean domestic databases were searched. Search terms included 'atrial fibrillation' AND 'multielectrode radiofrequency ablation (MEA)' AND 'conventional pulmonary vein isolation (CPVI)'. Pooled estimates were calculated by using bayesian fixed-effect model or bayesian random-effects model where significant heterogeneity was found. The outcomes included procedure time, AF recurrence and complications.

**Results:** Finally 11 studies comparing MEA with CPVI were selected according to predefined inclusion/exclusion criteria. Bayesian meta-analysis results showed that procedure time (SMD=-1.06, 95% CrI: -1.59, -0.52) were shorter significantly in MEA. The risk of AF recurrence (OR=0.82, 95% CrI: 0.59, 1.09) tended to be lower in MEA, but was not statistically significant. No significant difference in complications was evident with a trend toward higher complication rate in MEA (OR=1.61, 95% CrI: 0.96, 2.70).

**Conclusions:** In patients undergoing catheter ablation for atrial fibrillation, the efficacy of MEA is comparable to CPVI with respect AF recurrence while providing the benefit of drop of procedure time. In spite of thromboembolism risk in 1~2 days, MEA can provide health benefit to the patients with AF when skilled physicians perform the procedure carefully. Long-term thromboembolism risk of MEA is comparable to CPVI.

## PO.077

### National Health Insurance Budget Impact Analysis for Three vs. Twelve Months Dual Antiplatelet Therapy after Use of Zotalolimus-Eluting Stent

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**Background:** The potential benefits and risks of the use of long-term dual antiplatelet therapy in patients receiving drug-eluting stents have not been clearly established. The over prescription of dual antiplatelet therapy is costly malady to the National Health Insurance and the under prescription is a serious concern of late-stent thrombosis. The OPTIMIZER trial was a multicenter, randomized clinical trial including patients undergoing percutaneous coronary intervention with the Endeavor Zotarolimus-eluting stent. Through the study, short-term dual antiplatelet therapy was non-inferior to long-term dual antiplatelet therapy for occurrence of death, myocardial infarction, stroke or major bleeding, without significantly increasing the risk of stent thrombosis.

**Objectives:** To assess the National Health Insurance budget saving effect of 3 months (short-term) versus 12 months (long-term) of dual antiplatelet therapy in patients receiving Zotalolimus-eluting stent.

**Methods:** The budget impact analysis was applied comparing 3 months (short-term) versus 12 months (long-term) dual antiplatelet therapy in patients receiving Zotalolimus-eluting stent. Budget impact analytic framework included the dual antiplatelet drug cost, adverse event treatment cost and Zotalolimus-eluting stent. Baseline cost data and resource utilization came from Health Insurance Review & Assessment Service (HIRA) and National Health Insurance System (NHIS) statistics. One-way sensitivity analysis conducted for analysis results using the base-case with respective range.

**Results:** Under base-case conditions, 3 months dual antiplatelet therapy was more cost-effectiveness therapy. The total National Health Insurance budget impact difference for short and long-term therapy was 14.4M (short-term therapy was \$118M and long-term therapy was \$132M respectively) With the sensitivity analysis, the budget impact analysis result was robust.

**Conclusions:** The budget impact analysis showed that short-term dual antiplatelet therapy after use of Zotalolimus-eluting stent is a cost-saving and safety therapy for the patients undergoing percutaneous coronary intervention.

## PO.078

### RENEM – Brazilian National List of Equipment and Materials

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**Background:** To ensure the actions of the Brazilian Unified Health System can be achieved with universality and integrality, the Ministry of Health (MH) provides investment programs for institutions to acquire equipment and materials for the operation of its services.

**Objectives:** Create an essential list of equipment and materials with an effective management process

**Methods:** As the budget is limited, the MH implemented a methodology to make improvements in their processes of adoption and investment, divided into four fronts: (1)-Adoption of a National List of Equipment and Materials (RENEM); (2)-Regulatory processes for incorporation and management of RENEM; (3)- Creation a bench of prices; and, (4)-Automation of investment analysis.

**Results:** RENEM was adopted after systematic standardization of nomenclatures culminating in the preparation of equipment combos distributed according to the complexity of healthcare environments, eliminating issues of requests not according to their profile service. A computerized system was developed to manage RENEM and the entire process of investment analysis, streamlining routines and paper elimination. Regulating incorporation of RENEM established the minimum requirements of scientific evidence and optimized technical specifications. A cooperation program was created to capture economic and technic information and a function was introduced into the system that provides the technical features of the equipment in multiple choices. Each technical feature has a monetary value associated that represents the impact on the final price. Thus, the system performs a dynamic price setting which automatically adjusts to the selected specification. A tool that performs the historical search of the quantity and value of equipment financed by state, city and institution allowed the creation of ABC curves and Pareto analysis, identifying the key items of RENEM that require further attention.

**Conclusions:** The number of investments approved in 2012 and 2013 was almost four times higher than the previous years with significant improvement in projects quality.

## PO.079

### Global Price System - Project to Collaboration About Medical Devices

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**Background:** One of the biggest challenges in HTA analysis in supporting the decision making process for the adoption of new technologies is to obtain reliable information about the real prices in different markets to set the fairest price in order to obtain a good cost-effectiveness ratio. In the pharmaceutical market, agencies and ministries of health make use of instruments and legislation to assure an adoption with a fair price. However, when it comes to medical devices, the difficulty in promoting these same practices is complicated as there isn't a standardized nomenclature, with names being different in different countries.

**Objectives:** Reduce the information asymmetry with a web registration system for medical devices prices.

**Methods:** DGITS-CONITEC within the Ministry of Health of Brazil, is launching an initiative to facilitate the exchange of prices. The project involves the development of a web registration system for price information based on the brand/ model of each device which is an almost unalterable standard in any country. The system will provide management units in each partner (Government Institutions) so they can register local users such as universities and hospitals who constantly purchase these technologies and can feed the system.

**Results:** The system will have a structure based in separate device groups, such as cardiology, orthopedics, neurology, and sub-groups, such as stents, catheters, valves, which will expand itself, according to the needs. English will be the default language, but the system will allow each country to work with their own language. The default currency will be the American Dollar and will also allow each country register in their local currency.

**Conclusions:** This tool will be developed and made freely available to partners allowing the establishment of a network of very significant economic information to support the decision-making process for the

adoption of technologies and negotiation process with the medical device industry.

## PO.080

### Protease Inhibitors (PIs) for Chronic Hepatitis C (CHC): Patients and Adverse Events Profile in Brazil

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**Background:** Since April 2013, the Protease Inhibitors (PIs) boceprevir and telaprevir are available in the Brazilian public health system (SUS) for patients with Chronic Hepatitis C (CHC), according to National Guidelines. These drugs can increase the likelihood of cure, but are also associated with anemia and neutropenia. To manage these adverse events, the SUS offers epoetin-alfa and filgrastim, respectively.

**Objectives:** To describe the profile of patients with CHC treated with PIs, their adverse events and expenses with epoetin-alfa and filgrastim expenses in the SUS.

**Methods:** Descriptive analysis of patients treated with PIs in 2013, based on records available in the database of Ministry of Health (MoH). The variables evaluated included demographics, medicines, adverse events frequency and its annual costs (current values; exchange rate: US\$ 1 = R\$ 2.36). MoH reimbursement values were assumed as the drug acquisition costs of epoetin-alfa and filgrastim.

**Results:** In 2013, 1,234 patients with CHC used PIs in the SUS. The mean age of this population was 55.70 years (SD: 9.52; Median: 56) and 63.70% (n=786) were male. Most of the patients (82.50%, n = 1,018) used telaprevir. Of these, 27.50% (n=280) developed anemia and 13.06% (n=133) neutropenia. In the boceprevir arm (n = 216), 19.44% (n = 42) developed anemia and 19.91% (n = 43) developed neutropenia. The annual budget with drugs to treat these adverse events reached to a total of US\$604,355.80 with epoetin-alfa, and US\$48,432.82 with filgrastim.

**Conclusions:** During 2013, telaprevir was the main PI chosen to compose the triple therapy in patients with CHC in the SUS. Both telaprevir as boceprevir led to adverse reactions consistent with the literature findings. The treatment of these adverse reactions has significant financial consequences for the SUS.

## PO.081

### Cost-Effectiveness of Peginterferon $\alpha$ -2a Plus Ribavirin vs. Peginterferon $\alpha$ -2b Plus Ribavirin for Patients Chronically Infected with HCV of Genotype 1 in Japan

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**Background:** Peginterferon  $\alpha$ -2a with ribavirin treatment ( $\alpha$ -2aT) has been shown to be more effective than peginterferon  $\alpha$ -2b with ribavirin treatment ( $\alpha$ -2bT) in patients with chronic hepatitis C virus infection.

**Objectives:** The purpose of this study was to evaluate the cost-effectiveness of  $\alpha$ -2aT compared with  $\alpha$ -2bT for patients chronically infected with HCV of genotype 1 in Japan.

**Methods:** We created a Markov decision model of HCV's natural history and progression toward advanced liver disease to evaluate the

cost-effectiveness of alternative treatment strategies, in a cohort consisting of patients with genotype 1 chronic hepatitis using a lifetime time horizon. We compared 3 strategies: no treatment, standard 48-week peginterferon  $\alpha$ -2a plus ribavirin therapy with further 24-week extended treatment for late virological responders ( $\alpha$ -2aT; total 72 weeks) and 72-week  $\alpha$ -2bT treatment. The data for the natural history model were mainly derived from Japanese epidemiological studies. The data for the effectiveness of  $\alpha$ -2aT and  $\alpha$ -2bT in chronic hepatitis C genotype 1 patients were derived from results of a Japanese randomized control trial comparing  $\alpha$ -2aT with  $\alpha$ -2bT.

**Results:** Our model estimated that  $\alpha$ -2aT and  $\alpha$ -2bT strategies yielded sustained virological responses of 0.66 and 0.51, respectively. In the base case analysis, treatment with  $\alpha$ -2aT was more effective than that by  $\alpha$ -2bT and no treatment strategies, and could increase by 0.6 and 2.9 the quality-adjusted life years and reduce the lifetime cost by 0.8 and 0.6 million Japanese yen, respectively. This dominance of  $\alpha$ -2aT over  $\alpha$ -2bT was robust to sensitivity analysis.

**Conclusions:** Although our results depended on data from a single Japanese trial and further trials are needed to evaluate the effectiveness of both agents, they do suggest that  $\alpha$ -2aT may be more effective and cost-saving than  $\alpha$ -2bT for Japanese patients chronically infected with genotype-1 HCV.

## PO.083

### Impact of HTA Regulation on Federal Spending on Health Technologies Supply Through Lawsuits

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**Background:** Escalating lawsuits over the last decade in Brazil led to several initiatives and to the publication of law 12,401/2011 that created the National Committee for Health Technology Incorporation (CONITEC) to advise the Ministry of Health in the incorporation of new technologies in Brazil's healthcare system.

**Objectives:** To analyze the impact of changes in Brazil's healthcare system legislation from 2009 and after 2011 on lawsuits for health technologies supply and federal spending.

**Methods:** Survey of federal spending in health technologies supply through lawsuits.

**Results:** Lawsuits with the federal government as a defendant for health technologies supply started in 2002. Ten years later there were 3,205 individual lawsuits for which the government spent US\$ 131.19 million. The number of lawsuits continued to grow, reaching 2,273 in 2008. Since 2009, the growth rate slowed, reaching the annual average of 1,579, showing a stabilizing trend over the last 3 years. Federal spending grew at an average rate of 150% per year: 221% per year until 2008, decelerating to 60% per year since 2008. The impact of these lawsuits creates a cumulative effect in federal spending because the technologies provided are for chronic diseases and continuous use. In 2012 and 2013, 5 medicines alone, all of them indicated for the treatment of rare diseases (e.g. idursulfase, galsulfase and eculizumab) represent more than 80% of the federal spending.

**Conclusions:** The law established a deadline of 180 days for a decision to be made, based on scientific evidence of efficiency, accuracy, effectiveness and security, and on a comparative cost-benefit evaluation in relation to the technologies already incorporated. Decision must consider social participation, be clear and comprehensible. The deceleration in the annual rates of new lawsuits and the decrease in federal spending demonstrate that HTA applied to regulation may play a critical role in this context.

## PO.084

### Comparative Efficacy of Tumor Necrosis Factor Alpha Blockers in Ulcerative Colitis: An Indirect Comparison

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**Background:** Infliximab, adalimumab and golimumab are approved by the European Medicines Agency (EMA) for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine or azathioprine, or who are intolerant to or have medical contraindications for such therapies.

**Objectives:** To compare the relative efficacy of infliximab, adalimumab and golimumab through adjusted indirect comparisons.

**Methods:** An exhaustive search was performed until October 2013. Databases consulted were MEDLINE (through OVID), EMBASE, the Cochrane Library, databases from the Center for Reviews and Dissemination and the Web of Science. We included RCT comparing the efficacy of these drugs versus a common comparator, in terms clinical remission, clinical response and mucosal healing. In those cases that more than one RCT were identified for the same drug, a metaanalysis was performed (fixed effect model). Indirect treatment comparisons were carried out using the method proposed by Bucher et al.

**Results:** 6 RCT published in 5 papers were included: two for infliximab (ACT 1 and ACT 2), two for adalimumab (ULTRA 1 y ULTRA 2) and two for golimumab (PURSUIT-SC y PURSUIT-M). Each biological agent was superior in efficacy to placebo.

In relation to the most important outcome, clinical remission, in the induction period, there were no statistically significant differences between infliximab and golimumab, and between adalimumab and golimumab. Nevertheless, clinical remission was statistically significantly higher for infliximab-treated patients compared with adalimumab. However, in the maintenance period there were no statistically significant differences between the three drugs.

**Conclusions:** There is not enough evidence to suggest differences in efficacy between the three anti-TNF drugs. Therefore, infliximab, adalimumab and golimumab could be considered equally valid alternatives to treat adult patients with moderate to severe ulcerative colitis.

## PO.085

### Effectiveness of Catheter-Based Renal Denervation for Treatment Resistant Hypertension – Results of a Systematic Review and Meta-Analysis

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**Background:** Catheter-based renal denervation (RDN) is a promising therapy option for patients with treatment resistant hypertension (TR-HTN) who, despite optimised medical management, experience uncontrolled blood pressure and remain at significantly increased risk of cardiovascular and renal morbidity and mortality.

The RDN evidence base currently consists of several studies with limited sample size and variations in design, follow-up duration and catheter, so uncertainty may exist regarding overall therapy effectiveness. A direct meta-analysis of relevant trials can provide the more powerful

estimate of true effect size required to inform clinical decisions and economic evaluations.

**Objectives:** Conduct a systematic review and meta-analysis of RDN studies to determine the overall treatment effect of RDN for patients with TR-HTN.

**Methods:** RDN publications were identified through MEDLINE, EMBASE and Cochrane databases and manual searching (June 2013). Pre-specified inclusion criteria identified all studies (regardless of catheter used) enrolling TR-HTN patients (SBP  $\geq$  160 mmHg despite  $>3$  anti-hypertensive drugs including a diuretic). Results were presented as weighted mean decrease (WMD) in office-based SBP over 6 months.

**Results:** A total of 57 trials were identified (1 RCT, 11 case control, 16 single arm, 29 case series), yielding 28 studies (n=896) for meta-analysis. All were open label and reported significant reductions in systolic and diastolic blood pressure. The overall WMD in SBP from all studies was -28.1 mmHg (95% CI: -24.5 to -31.6). Analysis of only comparative trials produced a reduction from baseline SBP ranging from -31.7 mmHg (95% CI: -25.26 to -38.14) in the RCT (n=49) to -26.75 mmHg (95% CI: -22.19 to -31.31) for the pooled case control trials (n=56).

**Conclusions:** Over 6 months, RDN was associated with substantial SBP reductions in patients with TR-HTN. However, the majority of eligible trials were non-randomised, unblinded and used the Symplicity catheter. This may have influenced the magnitude of the treatment effect observed.

## PO.086

### Technology Assessment in the Membership of the Treatment Hypertensive Person - a Systematic Review

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**Background:** Adherence to the treatment of systemic arterial hypertension (SAH) is the degree of matching between user behavior and the prescription of health professionals that involves pharmacological and non-pharmacological measures. Measure the lack of adherence to treatment of hypertension remains a challenge for the health care team, due to the multifactorial treatment adherence promotes, besides the absence of a gold standard to measure it.

**Objectives:** Evaluate the effectiveness of technologies available in the literature for the measurement of adherence to treatment of hypertension.

**Methods:** Systematic review of 35 articles in the languages - Portuguese, English and Spanish, between 2005-2012, in databases - LILACS, PUBMED, EBSCO and TRIP DATABASE. Registered information in bibliographic record, and organized the data in the program Statistical Package for Social Sciences (version 18.0), and then proceeded to statistical analysis - Testing of variance with Tukey and Bonferroni.

**Results:** Identified the technologies in articles - Method belief in Health, Medication Event Management Systems, Association between the Morisky Medication Adherence Scale Item 4 (MMAS - 4), Association between the Morisky Medication Adherence Scale Item 8 (MMAS - 8) Count Tablets Manual (CCM), Haynes - Sackett Test, Questionnaire for Adherence to Medications - Qualioids (QAM - Q), Batalla Test, the Self - Reported and Method of bromide. The results show difference: MMAS - 4 x HAYNES and HAYNES/MMAS-4 ( $p < 0.010$ ) for the membership criteria and MMAS-4/HAYNES and HAYNES / MMAS - 4 ( $p < 0.012$ ) for non-compliance.

**Conclusions:** The data reveal that is evident that there are different instruments that can be used to measure adherence and non-adherence to treatment of hypertension, and that there seems to be an instrument that suits all the studies and the results of evaluation membership and non-membership can be compared.

## PO.087

### Outcomes of Aortic Valve Replacement Surgery Using Mechanical or Biological Prostheses

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**Background:** Aortic valve replacement is a recommended standard surgical procedure for patients with symptomatic valve disease. More than 30 years after the introduction of modern prostheses, the choice between biological and mechanical for the aortic position remains controversial. The clinical decision becomes increasingly challenging with the increase in life expectancy and the presence of comorbidities.

**Objectives:** Assess mortality, bleeding events and reoperation in patients subjected to surgery for replacement of the aortic valve using a biological or mechanical substitute in a reference cardiac surgery tertiary hospital in the south of Brazil, where selection of the type of prosthesis is relevant.

**Methods:** Study design was historic cohort type. 301 patients subjected to aortic valve replacement surgery between 1990 and 2005, with a maximum follow-up period of 20 years. Level of significance was 5%. Mechanical prostheses used were of the bileaflet type and biological prostheses were made in Brazil.

**Results:** Survival at 5, 10 and 15 years using mechanical substitute was 83.9%, 75.4% and 60.2%; for biological substitute, was 89.3%, 70.4% and 58.4% ( $p=0.939$ ). Factors associated with death: age, obesity, pulmonary disease, arrhythmia, bleeding and aortic valve failure. Probability free of reoperation at 5, 10 and 15 years using a mechanical substitute was 97.9%, 95.8% and 95.8%; for those using bioprostheses, was 94.6%, 91.0% and 83.3% ( $p=0.057$ ). Factors associated with reoperation: renal failure, prosthesis endocarditis and age. Probability free of bleeding events at 5, 10 and 15 years after surgery using the mechanical substitute was 94.5%, 91.7% and 91.7%; for bioprostheses, was 98.6%, 97.8% and 97.8% ( $p=0.047$ ). Factors associated with bleeding events: renal failure and mechanical prostheses.

**Conclusions:** Mortality was statistically similar in the groups. Patient characteristics at baseline were a major determinant of late mortality after surgery. There was a tendency toward reoperation in the bioprostheses group. Patients using mechanical prosthesis had more bleeding events.

## PO.088

### Temozolomide in Pediatric Patients with Recurrent Brain Tumors: Rapid HTA

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**Background:** Temozolomide in pediatric patients with recurrent brain tumors was Demanded by the Centers for Health Technology Assessment (CHTA) and a Pediatric Hospital of the Department of Health in the State of Ceara, northeast, Brazil. This technology is an alkylating agent with antitumor activity, which undergoes rapid chemical conversion at physiologic pH in systemic circulation. It is indicated in the treatment of newly diagnosed glioblastoma multiforme concomitantly

with radiotherapy and subsequent adjuvant. In the treatment of patients with malignant glioma, glioblastoma multiforme or anaplastic, recurrent or progressive astrocytomas after standard therapy.

**Objectives:** To present a Rapid HTA Temozolomide in pediatric patients with recurrent brain tumors, conducted by Technology Assessment Center of the Department of Health in the State of Ceara and a Health technology assessment center of a Pediatric Hospital.

**Methods:** The project methodology utilised PICO criteria (population, intervention, comparator and outcome). The searches were conducted using Cochrane Library, CRD and PubMed. We used the Mesh tool and there were found "temozolomide" [Supplementary Concept]; "Brain Neoplasms" [Mesh], and "Pediatrics" [Mesh] and "Children" [Mesh].

**Results:** One systematic review of randomized controlled trials were selected and one Health Technology Assessment. The outcomes were about the effectiveness, cost-effectiveness, efficacy and toxicity.

**Conclusions:** There is conclusive evidence to suggest that temozolomide in pediatric patients with recurrent brain tumors has effectiveness, cost-effectiveness, efficacy and toxicity. Unfortunately in clinical RCTs have examined the efficacy of the various regimens TMZ. For pediatric use, in glioblastoma multiforme do not have clinical experience with use of TMZ in children under 3 years old. There are few studies of glioma in children above 3 years old. There is a lack of transparency in the estimation of both costs and effectiveness and cost-utility is not estimated. Results are restricted to cost per life-year gained.

## PO.089

### Budget Impact Projection for Incorporation of Analogue Insulin in the Brazilian Public Health System (SUS)

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**Background:** Brazil is the only country in the world with more than 100 million inhabitants with a universal, public and free of charge health system in the world. With an estimated 11.9 million people suffering from diabetes in 2013, insulin is one of the most essential medicines.

**Objectives:** The objective of this study is to estimate the budget impact to the Brazilian Public Health System (SUS) to providing analogue insulin to diabetics.

**Methods:** A budget impact for providing analogue insulin was estimated based on the overall consumption of NPH insulin in the insulin dependent diabetic population (types 1 and 2) between the years of 2004-2012. A simple regression line was used to estimate the consumption for the next ten years. The market share of analogue insulin was based on the study of Holden, 2011, where it was reported a steep rise in the consumption of analogue insulin after the NHS began analogue insulin prescription, even under some restrictions. The prices of analogue insulin considered was the average price of all brands found, while the price for NPH insulin was obtained from the last purchase by the Brazilian Ministry of Health. Quantity adjustments were made per IU on a 1:1 basis as this is the recommended dosage when switching for NPH to analogue.

**Results:** According to our findings the Brazilian Ministry of Health would have to spend around US\$ 78.9 million for the first year and US\$ 5.8 billion over the course of the next ten years, which represents an increase of almost 10 times the estimated amount spent over the same time period.

**Conclusions:** The study concludes that there would be a considerable budget impact in switching from NPH to analogue insulin, although it does not take into account possible price reductions if analogue insulin were to be incorporated in SUS.

## PO.090

### Cataract Surgery in Austria: Budget Impact Analysis Day Care Versus Inpatient Care

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**Background:** In Austrian public hospitals the most frequently performed surgical procedure is cataract surgery. The majority of cataract surgeries are still carried out as inpatient cases with an average length of stay of 2.3 days.

Under the current Austrian health reform inpatient services, if medically reasonable, shall be substituted by day care to reduce health care expenditures.

**Objectives:** Primary goal of the study is to identify and evaluate the economic effects of reallocating even more cataract patients to day care.

The main research questions are:

- Is it possible to reduce health care expenditures by transferring the treatment of cataract in adult patients from inpatient to day care and if yes, by how much?
- Does the organizational structure of the day care has any influence on costs?

**Methods:** To evaluate the effect of a shift from inpatient to day care a budget impact analysis (perspective hospital) was conducted. The calculations are based on administrative data from public hospitals (costs), demographic projections and incidence rates. To back up the economic analysis international benchmarks, systematic reviews and medical guidelines were consulted.

**Results:** Preliminary results show that increasing the share of day cases in a hospital-setting has a considerable cost reduction potential. If cataract surgery is carried out in a dislocated day clinic cost reductions of almost 50 % per case are feasible. However, results are subject to significant variations in public hospitals regarding costs and service provision.

**Conclusions:** Increasing the share of cataract day cases has a high potential of reducing financial expenditures of hospitals without compromising the service quality. On the contrary, more patients could benefit from a cataract surgery because the frequency of the surgery could be increased and hence waiting times could be reduced. To tap the full cost reduction potential a restructuring of the inpatient sector for day care is essential.

## PO.091

### Efficacy/Effectiveness of Different Schemes of Triple Antiviral Therapy in Patients with Chronic Hepatitis C Genotype 1

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**Background:** Chances of successful treatment of this group of patients by the standard scheme of dual therapy using pegylated interferon (Peg-IFN) and ribavirin (RBV) were limited by its low efficiency, as the stage of fibrosis is an independent predictor of decreased rate of achieving of sustained virologic response (SVR). With the advent of telaprevir (TPV) - HCV protease inhibitors, on the market of Kazakhstan, the treatment options for patients with chronic hepatitis C (CHC) infected with genotype 1 significantly enhanced.

**Objectives:** Assessment of the application of TPV therapy in different schemes in patients with CHC infected with genotype 1, with marked fibrosis or the liver cirrhosis (LC) in the compensation stage.

**Methods:** We have performed a systematic review of studies. The economic feasibility of triple therapy in patients with CHC is estimated by modeling with the construction of a decision tree and the use of a cost-effectiveness (CE) method.

**Results:** The results of CE analysis strongly suggest that in patients with CHC genotype 1 with liver fibrosis F3 and LC previously untreated with antiviral therapy the use of single-stage therapies in combination TPV, Peg-IFN and RBV at standard dosages more cost-effective compared with the use of a two-stage approach in which patients are treated with combination of Peg-IFN and RBV, and then, in the event of failure to reach an SVR they receive triple therapy with the addition of TPV to this combination.

**Conclusions:** Clinically and economically more profitable strategy than a two-stage approach in which therapy is started with use of a combination with Peg-IFN and RBV, and when its failure the therapy continues using triple therapy as repeated course. Moreover, the cured patients can stop the progression of the pathological process in the liver, that will prevent the annual cost of health care for patients with decompensated LC and HCC.

## PO.092

### Optimal Usage of Spinal Cord Stimulators and Intrathecal Pumps for the Treatment of Chronic Non-Cancer Pain

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**Background:** Spinal cord stimulators (SCS) and intrathecal pumps (ITP) that deliver medications are neuromodulatory devices used in the treatment of chronic non-cancer pain (CNC) that is refractory to all conventional medical therapy. These devices are costly and demand very careful selection of patients and the expertise of many professionals for implantation and follow-up of implanted patients.

**Objectives:** To formulate recommendations that provide a framework for optimal usage of SCS and ITP.

**Methods:** The formulation of recommendations was carried out by integrating results arising from diverse sources: a systematic review of clinical aspects, a narrative review of organizational issues, a budget impact assessment, and an analysis of contextual and experiential data from patients and health care professionals.

**Results:** Based on weak to moderate evidence, the use of these devices is recommended for patients with CNC that is neuropathic, nociceptive (especially ITP) or ischemic (mainly NSM). It is also recommended that patients follow a standard pathway for the use of neuromodulation. Patients should be selected on the basis of precise, well-established criteria and the process should include both a psychological assessment and a trial test. Implantation and patient follow-up should only be carried out within an appropriate environment by a multidisciplinary team of qualified professionals. The diverse health care centres involved in implantation and patient follow-up should possess or be linked to an optimal management framework serving the catchment population of patients eligible for neuromodulation, notably through the creation of a single access entry point and a central registry. Such a framework should permit reduction of waiting list time before implantation and an evaluation of the quality of neuromodulation care and services.

**Conclusions:** Our multifaceted-integrated methods allowed the development of recommendations addressing, particularly, treatment effectiveness, selection of patients and the organization of care to serve the needs of persons suffering from CNC refractory to more conservative treatments.

## PO.093

### Optimization Model of Using Mobile Mammography

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**Background:** In Brazil, about 57,000 new breast cancer cases were estimated of being the tumor, which will cause more women's death in 2014. The use of mobile mammography seems to be as an alternative to attend the target people in regions with low population density, where the acquisition of a fixed device may be economically and technically unviable.

**Objectives:** The purpose of this work is to increase the availability of diagnostic breast cancer tests in Rio de Janeiro State by allocating the mobile mammography devices in conjunction with the existing system of the fixed mammography.

**Methods:** The process of data collection involves different sources of information. The target population data are obtained from the 2010 Brazilian Census with women's group recommended age between 50-69 years old; The data about mammography fixed network devices are collected from the National Registry of Health Devices; The information about the mobile mammography devices and population rate of coverage are defined by the Ministry of Health of Brazil; The distances among countries are taken from Geographic Information Systems. Optimal solutions to routing problems are computationally exponential, so Genetic Algorithms Heuristics were used to optimize the results. The use of agent-based models, using the AnyLogic software optimizer tool was also implemented for comparison of obtained results.

**Results:** The results are the optimized schedules of each mobile mammography device. All entries of the solution were parameterized, allowing the simulation in different scenarios, providing thus, important information for decision-making.

**Conclusions:** The analyze of the obtained results, using Genetic Algorithms as well Agent-Based Models in AnyLogic, provide the number of mobile devices needed to cover the people demand. The models also allow determining when the acquisition of mobile devices is no longer economically efficient. Actually, the models may be adapted for many applications in health public politic programs.

## PO.094

### Effectiveness and Cost-Effectiveness of Different Immunization Strategies Against Whooping Cough to Reduce Child Morbidity and Mortality

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**Background:** In the last years there has been a significant increase in reported cases of pertussis in developed countries, in spite of high rates of childhood immunization. Health institutions have recommended different vaccination strategies to reduce child morbidity and mortality: vaccination of adolescents and adults, pregnant women, people in contact with the newborn (cocoon strategy) and health care workers.

**Objectives:** The aim of this paper is to review the scientific evidence supporting these recommendations.

**Methods:** Systematic review on the effectiveness and cost-effectiveness of the above strategies for the reduction of morbidity and mortality from pertussis in infants under 12 months. The electronic data-

bases Medline, PreMedline, Embase, CRD, Cochrane Central, and Trip Database were consulted from 1990 to October 2012. The evidence was assessed using the GRADE system.

**Results:** There were eight studies on the efficacy or safety of the strategies analyzed, and 18 economic evaluations. Direct evidence on the efficacy of these strategies is scarce. Economic evaluations suggest that vaccination of adolescents and adults would be cost-effective, although there is major uncertainty over the parameters used.

**Conclusions:** From the perspective of health technology assessment, there is insufficient evidence to recommend the vaccination strategies evaluated.

## PO.095

### Real World Data and Formal Decision Making for Appropriate Use of TAVI in Lombardia Region

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**Background:** Transcatheter Aortic Valve Implantation (TAVI) was introduced in 2008 when two devices (Medtronic's CoreValve and Edwards' Sapien) obtained CE mark in Europe. In 2010 an RCT found a mortality benefit with TAVI for patients with severe stenosis not suitable for surgery when compared with medical therapy, and non-inferiority for high risk patients but suitable for surgery. In 2012 a professionally-driven registry extended indications to high-risk patients.

**Objectives:** To verify outcomes associated with TAVI in a real-world population, and to revise requirements for hospitals and reimbursement regimens.

**Methods:** We performed a non-systematic literature review, a retrospective analysis of claims data, an experts consensus (surgeons, cardiologists, anaesthesiologists, internists, gerontologists, nurses, clinical engineers), and a Multiple Criteria Decision Analysis (MCDA) for decision making in the perspective of the health care programme.

**Results:** Hospital admissions, ambulatory care, and drugs data from the timeframe 2009-2012 were analysed for all patients with aortic stenosis received open surgery (n=4.650) or TAVI (n=908) and a non-paired control group treated with medical therapy (n=1.363) in 20 hospitals across Lombardia region. Data were analysed according to age and a co-morbidity index built using hospital admission data from the previous 10 years. Intra-hospital and longitudinal mortality, stroke episodes, and readmission rates were calculated. Survival data analysis showed, with high statistical significance (p<0.001), that surgery is more appropriate than TAVI in patients younger than 81 years with high co-morbidity, while confirmed similar outcomes for TAVI and surgery for patients older than 80 years independently of co-morbidity. Appropriateness Indexes calculated with MCDA were 0.60 for inoperable and 0.51 for high-risk patients. An analysis of 504 comments from experts helped to prepare a robust real data-driven revision of criteria for appropriate use of TAVI.

**Conclusions:** Real world data analysis and MCDA are feasible for policy making in the cardiovascular area in Lombardia region.

## PO.096

### Bargaining Power and Access to Drugs: the Case of Pulmonary Arterial Hypertension in Brazil

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**Background:** In 2013, the Brazilian Ministry of Health (MoH) included bosentan and ambrisentan in the treatments available for pulmonary arterial hypertension (PAH). This inclusion was conditioned to price reduction at a threshold compatible with the financial sustainability of the public health system (SUS). In 2014, these medicines will be available along with sildenafil and iloprost.

**Objectives:** Describe the scheme accesses adopted by the MoH to allow the inclusion of ambrisentan and bosentan to treat PAH in the SUS.

**Methods:** Descriptive analysis of the drug acquisition costs of sildenafil, ambrisentan and bosentan in the MoH perspective, based on the agreement between MoH, producers and Regulatory agency (current values; exchange rate: US\$ 1 = R\$ 2.36). The number of patients on sildenafil was estimated through the amount dispensed, available in the SUS database (Datusus), and its recommended dosage. For ambrisentan and bosentan, label dosage were considered.

**Results:** It is estimated that in 2013, 2,075 patients with PAH used sildenafil, with federal investment of US\$ 9,137,571.08. With the generic sildenafil approval in 2013, the annual cost of treatment per patient was reduced by 50% approximately (from US\$ 4,403.65 to US\$ 2,691.51). In that year, the annual cost of treatment per patient using bosentan and ambrisentan was US\$ 9,126.25 and 8,636.29, respectively, invalidating its inclusion in the SUS. Then, the MoH signed an agreement with the producers, limiting to the same annual cost of treatment per patient of sildenafil, aiming to enable the offer of these drugs. With this strategy, the treatment algorithm was defined in the National Guidelines of PAH, including sildenafil, bosentan and ambrisentan as options.

**Conclusions:** Scheme accesses conditioned to price reduction are valuable strategies to expand access to new therapeutic options. The case of ambrisentan and bosentan for PAH is a practical example in the SUS, maintaining its financial sustainability.

## PO.097

### Application of Health Technology Assessment to Obtain Indicators on Priority Incorporation of Medical Equipment

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**Background:** Changes in the economic environment in recent years have been striking in many segments, not unlike in the management of public health, thus requiring health managers a larger grounding in their decisions. In this situation, the Health Technology Assessment (HTA) promotes the strengthening of investigations of health technologies. Clinical engineering must use the methods of scientific investigation of HTA to potentiate the actions of health technology management, in particular, on medical equipment (ME). This is especially appropriate in the presence of economic uncertainty. Estimates of the total cost of ownership (TCO) and the application of stochastic models can bring satisfactory results, thus, supporting decision-making on the incorporation of ME.

**Objectives:** Develop a model to support the incorporation process of ME, contemplate on multi-criteria, and use the HTA as an investigation tool.



**Methods:** The model contemplates five stages: health problem, eligibility assessment, life cycle, health technology assessment, and indicator of priority incorporation. The innovation of the proposal is in the adaptation of HTA focused on ME, using clinical evidence and technological process evidence. A summary of evaluation is possible by obtaining indicators using the approach, multi-criteria decision aid (MCDA).

**Results:** A case study was conducted in the context of the State Department of Health of Santa Catarina (SDH-SC), Brazil. Essential criteria, namely, safety, efficacy, TCO, ease of maintenance, ease of installation, learning curve, and usability were evaluated as part of the challenging ME incorporation process. The indicators obtained within the scope of SDH-SC for the thyroidectomy procedure express were 78.92%, 49.82%, and 36.19% for the priority incorporation of the harmonic scalpel, the electric scalpel with function of sealing vessels, and the electric scalpel for coagulation and cutting, respectively.

**Conclusions:** The model developed can direct new health policies, given the identification of alternatives that are technologically safe, effective, and affordable to the health system.

### PO.098

#### Fractional Exhaled Nitrogen Oxide for the Management of Asthma in Adults – a Systematic Review

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**Background:** Fractional exhaled nitric oxide (FeNO) is a marker of airway inflammation. It is unclear whether its measurement can enhance asthma management in adults.

**Objectives:** To assess the clinical effectiveness of FeNO for asthma management in adults.

**Methods:** To update a previous high quality review, several electronic databases were searched from 2009 to September 2013. Searches were supplemented by hand searching relevant articles and contact with experts. Randomised control trials (RCT) comparing FeNO-guided management (measured in a clinical setting) with any other monitoring strategy were included. Methodological quality was assessed using an established checklist.

**Results:** Seven studies were included. Despite high levels of heterogeneity in study and patient characteristic, outcome definitions, FeNO cut-off points and in management protocols, class-effect meta-analyses were conducted (low heterogeneity scores ( $I^2 = 0\%$ ) in all cases). Three studies reported exacerbation rates (any severity), with a statistically significant pooled rate ratio of 0.58 (95% CI 0.43 to 0.77) in favour of FeNO management. Four studies reported major or severe exacerbation rates with a pooled ratio of 0.87 (95% CI 0.64 to 1.19). Inclusion of an additional large study (unreported error imputed conservatively based on previous studies) gave a pooled ratio of 0.83 (95% CI 0.83 to 1.09). Inhaled corticosteroid (ICS) use was reported by four studies, with a pooled standardised mean difference of -0.24 (95% CI -0.56 to 0.07) in favour of FeNO. One study in pregnant women reported statistically significantly better exacerbation rates and lower ICS use in the intervention arm.

**Conclusions:** As a class, FeNO guided management appears to reduce exacerbations (any severity) in adults. The effect on major or severe exacerbations and ICS use is less clear. There was no evidence relating to effects beyond one year. No firm conclusions could be drawn on which management protocols or cut-off points offer the best efficacy.

### PO.099

#### Variability in Evidence for Clinical Effectiveness on Multidisciplinary Osteoporosis Management System

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**Background:** Osteoporosis as a global health issue affecting millions of men and women places medical and economic burden across the globe. Although clinical effectiveness is one of the key areas providing evidence and information for HTA in making reimbursement decisions, very few studies are available to provide information for reimbursement recommendations on multidisciplinary osteoporosis management programs.

**Objectives:** To provide a systematic evaluation of clinical effectiveness of a seamless osteoporosis care model in detection, prevention, and treatment

**Methods:** A systematic review was conducted to summarize clinical effectiveness of multidisciplinary osteoporosis management systems using published articles from 2000 to 2011 in English. Each article was reviewed and summarized by the type, scope, and clinical outcomes of the multidisciplinary collaborations.

**Results:** A total of 39 published articles were identified for further review. Various healthcare professionals including geriatricians, orthopedic surgeons, endocrinologists, dentists, pharmacists, nurses, and allied health professionals were involved in the collaborative osteoporosis care models with different clinical goals ranging from reduction of osteoporosis related fracture to improvement of quality of life. Although majority of the research studies reported improvements in clinical or humanistic outcomes, variability in elements of the health technology system, outcome indicators, and success definition was detected.

**Conclusions:** A few reports are available documenting comprehensive collaborative care models for osteoporosis detection, prevention, and treatment. The variability in the HTA elements, clinical effectiveness, and benefits requires harmonization activities to produce objective assessment of the benefits and to generate explicit recommendations for reimbursement decision making.

### PO.100

#### Efficacy and Safety of Perioperative Thromboprophylaxis in Adults Undergoing Abdominal or Pelvic Surgery

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**Background:** Major abdominal or pelvic surgery, especially malignant tumours, is associated with high risk of developing venous thromboembolism (VTE). Despite the availability of preventive treatments, use of anticoagulants and mechanical thromboprophylaxis (TBP) methods seems inconsistent in clinical practice.

**Objectives:** To assess the clinical effectiveness and safety of mechanical and pharmacological TBP administered to adults undergoing abdominal or pelvic surgery for cancer.

**Methods:** A search was performed in Pubmed, Embase and the Cochrane Library to retrieve systematic reviews, clinical practice guidelines or primary studies. Governmental databases on safety issues were also reviewed. Main outcomes included incidence of deep vein thrombosis (DVT), pulmonary embolism (PE), major bleeding complications, and compartment syndrome. Two reviewers independently performed article selection, quality assessment and data extraction. Disagree-

ments were resolved with a third reviewer. Synthesis review was shared with an interdisciplinary group of experts.

**Results:** Eleven studies were included on both efficacy and safety issues. Data suggest that unfractionated heparin (UFH), or low molecular weight heparin (LMWH) in patient with low risk of bleeding is better than no treatment to prevent VTE. However, no clear evidence of superiority of one agent over the other has been established. Available evidence does not support prolonged LMWH up to 28 days to reduce VTE after abdominal or pelvic surgery for cancer. Pharmacological TBP combined to mechanical methods could be more effective to prevent DVT than another method alone. Additional studies are required to determine the efficacy in monotherapy of mechanical TBP. TBP measures appear to be safe in patients with low risk of bleeding.

**Conclusions:** Pharmacological and mechanical TBP methods are indicated for patient undergoing abdominal or pelvic surgery when risk assessment shows a low bleeding risk. According to the available evidence, prolonged pharmacological TBP after surgery should not be systematically introduced as a standard of care.

## PO.101

### Endobronchial Valves: Effectiveness, Safety and Cost-Effectiveness

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**Background:** There are published studies indicating that endobronchial valves (EBV) represent a safe procedure that offers a moderate improvement in lung function and exercise tolerance, but a significant number of patients do not respond to treatment, and only those in which collapse of the treated area is achieved exhibit a clear clinical and functional improvement

**Objectives:** To conduct a systematic review of the literature on the efficacy, safety, and cost-effectiveness of EBV.

**Methods:** A literature search was carried out in Medline and PreMedline, Embase, CINAHL, PsycINFO, Cochrane Library Plus, and CRD until November 2013. Systematic reviews, randomized and nonrandomized controlled trials (RCTs, NRCTs), observational studies and case series were selected.

**Results:** Seventy three references were selected by title and abstract, including finally 6 of them by full text: 3 secondary studies, and 3 RCTs. Evidence from RCTs on the treatment of advanced emphysema by EBV show that it is a technique with acceptable safety, except for a higher probability of hemoptysis and exacerbation of Chronic Obstructive Lung Disease in the short-term. However, its efficacy is modest when compared with standard therapy. Although there have been significant differences or bordering the limit of statistical significance in some variables, the effects sizes obtained are not considered clinically relevant in any case. In the treatment of persistent air leaks, evidence obtained is limited to some case series and single case studies, so it is not possible to draw valid conclusions about the effectiveness of EBV.

**Conclusions:** Based on the available scientific evidence, it is not currently possible to recommend the use of EBV for the treatment of advanced emphysema or persistent air leak. People with greater heterogeneity of emphysema or greater integrity of the interlobular fissure could benefit more from the procedure. To develop an evaluation record is recommended.

## PO.102

### Estimation of the Cost of Complications Related to Glycated Hemoglobin in the Italian Diabetes Type 1 Population

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**Background:** Patient with Type 1 diabetic (T1D) and high values of glycated hemoglobin (HbA1c) have a higher risk of experiencing complications leading to additional costs to the National Health Care System (NHS).

**Objectives:** This analysis aims at evaluating the economic impact of poor glycemic control, and the potential savings associated with better glycemic control in the Italian T1D population.

**Methods:** Published risk-curves were used to populate a probabilistic model to project incidence and progression of diabetes-related complications associated with different HbA1c levels over 1-year and 5-year time-horizon in T1D patients. Associated cost of retinopathy, nephropathy, neuropathy, cardiovascular disease, diabetic ketoacidosis and severe hypoglycemia in the Italian setting were used to estimate the economic impact of complications in each HbA1c interval from the NHS perspective. Subsequently the results of the simulation were translated to the entire Italian T1D population stratified by HbA1c level accordingly to published 2012 data.

**Results:** The estimated cost per patient due to diabetes-related complications in the first year of occurrence, stratified by HbA1c intervals, were ranging from 4,463€ for HbA1c  $\geq 10\%$  to 2,006€ for HbA1c between 7% and 8%. A 5 year follow up analysis was also conducted. A treatment strategy able to reduce HbA1c level from  $\geq 10\%$  to 9% could lead to potential savings of 1,342€ per patients in the first year of occurrence. Considering the total T1D Italian population, improving HbA1c to  $< 8\%$  in the first year would allow potential savings of about 17 million euros.

**Conclusions:** It has been shown that the economic impact of diabetes-related complications in the Italian setting is significant. Consequently the potential savings for the NHS derived from the implementation of strategies aimed at improving HbA1c in T1 should be considered. Moreover, greater reduction of HbA1c allowed greater associated savings.

## PO.103

### The German HTAi/INAHTA Glossary Group – Transnational Activity to Support a Common HTA Wording for the German Speaking Area

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**Background:** Some years ago, a glossary for the HTA world was developed and implemented. At his time HTA was still, more or less, an insider knowledge and English was the overall accepted and used working language. Nevertheless, French and Spanish versions had been added soon.

The increasing implementation of HTA in health care systems has increased the need for translation of English terms into the health environments of German speaking countries, Austria, Switzerland and Germany.

**Objectives:** Public funded HTA agencies of Austria (GÖGmbH), Switzerland (BAG) and Germany (DAHTA@DIMDI) have agreed to implement a process of developing and maintaining a German version of the HTAi/INAHTA glossary. This process should include:

Quality aspects, support for translation, integration of HTA experts and feedback to the international steering committee responsible for the glossary.

**Methods:** N/A

**Results:** The public agencies were immediately supported by national scientific associations and HTA networks to run this process. In a transparent process, all institutions and networks are included during the translation process to include the specific knowledge and to raise a broad acceptance of the glossary terms. In addition, there is the willingness of all integrated partners to raise the quality of the international glossary by offering specific knowledge into the process of the maintenance of the English repository.

**Conclusions:** The new activity established in 2013 showed that there is an easy way of international cooperation if the project is focused. By this also scientific networks can easily work together to improve the quality of eg. the glossary. The combination of public funded institutions and scientific networks ensures a sustainable and scientific correct approach.

## PO.105

### Cost Model Analysis of GORE® PROPATEN® Vascular Graft vs. Standard ePTFE Vascular Graft for Infrapopliteal Bypass in Peripheral Arterial Disease (PAD) Management: Italian Scenario

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**Background:** Vascular bypass is used in patients with PAD to treat ischemic rest pain, to improve walking distance in patients with severe life-limiting claudication, and to save limbs that might otherwise require amputation. When patients presenting for peripheral artery reconstruction have absent or inadequate saphenous veins due to prior use, small size, or poor quality, vascular surgeons may choose a prosthetic bypass graft. The GORE® PROPATEN® Vascular Graft features a proprietary end-point covalent linkage of heparin molecules to the luminal surface of the graft that provides sustained resistance to thrombosis.

**Objectives:** Demonstrate the cost savings of using the GORE® PROPATEN® Vascular Graft compared to standard ePTFE vascular grafts in the management of PAD patients. Superior clinical outcomes in terms of primary/secondary patency and limb salvage rates result in lower average per-patient treatment costs.

**Methods:** A cost model analysis was developed to represent hospital treatment costs. A typical PAD patient's treatment pathway in Italian clinical practice was identified by a survey involving Italian vascular surgeons. A literature review was conducted to determine patency and limb salvage rates. Italian MD18ottobre 2012 DRG tariffs were used as hospital cost of treatment inputs. A three-year patient management cycle was considered.

**Results:** Better patency and limb salvage rates obtained using the GORE® PROPATEN® Vascular Graft result in fewer reinterventions and amputations, corresponding to lower per-patient treatment costs. The cost model demonstrates an overall cost saving for PAD patient management using the GORE® PROPATEN® Vascular Graft for infrapopliteal bypass. The cumulative cost savings at 3 years is estimated to be 10.704€ per patient.

**Conclusions:** The use of the GORE® PROPATEN® Vascular Graft for infrapopliteal bypass in the PAD patient population represents a safe, clinically effective, and cost-saving alternative to standard ePTFE vascular grafts.

## PO.106

### Cost-Effectiveness Analysis of 10-Valent Pneumococcal Conjugate Vaccine After Its Introduction in Brazil

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**Background:** Traditionally, childhood vaccines are considered the most efficient investment in public health. Brazil has decided to incorporate 10-valent conjugate pneumococcal vaccine (PCV10) into its routine National Immunization Program in 2010, targeting children 2-23 months of age. Cost effectiveness analyses (CEA) of PCV10 introduction were conducted prior to its introduction.

**Objectives:** To assess CEA after PCV10 introduction, considering the pneumococcal burden and cost data contrasting methods, models, and results with those from previous CEA studies.

**Methods:** We used a publicly available and validated model - Interactive Pneumococcal Vaccination Model (PneuModel), considering the Brazilian public health system (SUS) perspective. PCV10 vaccination was compared with no vaccination. Disease costs were estimated using micro-costing approach. Disease burden data was obtained from prospective population-based surveillance conducted in Goiânia, Brazil. Vaccine coverage data and vaccine costs were obtained from the Ministry of Health. Immunization program costs were obtained from the literature. The analytic horizon was 5 years and costs and benefits were discounted at 5%. All costs are reported in \$ international. Univariate sensitivity analysis was performed from key model parameters.

**Results:** Each year, PCV10 vaccination would avert 3,942 cases, 16,514 years of life lost (YLL) and 16,759 averted DALY due to pneumococcal diseases in one cohort of children < 1 year. The average annual costs of disease avoided would be \$ 2,830,784. The estimated CE ratio was \$ 485,360 per life saved and \$ 14,230 per DALY averted. In the sensitivity analysis of the incidence and mortality from meningitis were the variables with the greatest impact.

**Conclusions:** Unlike previous studies, we consider the incidence of pneumococcal pneumonia. The introduction PCV10 is a highly cost effective intervention. More studies are needed to document further the impact of PCV10 in Brazil. However, our results are useful to enhance the impact of CEA and PCV10 initially estimated from previous studies.

## PO.107

### An Adjusted Indirect Comparison for Everolimus-Eluting Bio-absorbable Vascular Scaffold versus Zotalolimus-Eluting Metallic Stent

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**Background:** Everolimus-eluting bio-absorbable vascular scaffold has theoretical advantages as the stent body disappears after vascular constrictive remodeling. Currently, no data are available on the direct or indirect comparison between the Everolimus-eluting bio-absorbable vascular scaffold and Zotalolimus-eluting metallic stent.

**Objectives:** The objective of the present study is to assess the safety and effectiveness between Everolimus-eluting bio-absorbable vascular scaffold versus Zotalolimus-eluting stent using the adjusted indirect comparison method.

**Methods:** An adjusted indirect comparison of Zotalolimus-eluting Stent versus Everolimus-eluting bio-absorbable vascular scaffold with Everolimus-eluting metallic stent common comparator was performed. The direct data between Zotalolimus stent and Everolimus stent was came from RESOLUTE All Comers trial and the data between

Everolimus stent and Everolimus bio-absorbable vascular scaffold was utilized from ABSORB Extent and Cohort B trial with propensity score adjustment. The safety outcomes were cardiac death, myocardial infarction and stent thrombosis; effectiveness outcomes were target lesion revascularization (TLR), target vessel failure (TVF) and target lesion failure (TLF).

**Results:** In total, 3,480 patients were assigned to the adjusted-indirect comparison with Zotalolimus stent versus Everolimus stent (n=2,250) and Everolimus stent versus Bio-absorbable vascular scaffold (n=1,230). Treatment with Zotalolimus stent versus Everolimus stent slightly reduced TVF (odds ratio =0.95), TLF (0.98) and have comparable clinical outcomes for cardiac death (1.21), myocardial infarction (1.07), ischemia TLR (1.03) and stent thrombosis (1.63). Treatment with Everolimus stent versus Bio-absorbable vascular scaffold reduced cardiac death (odds ratio =0.605), ischemia TLR (0.48), TVF (0.62) and have comparable clinical outcomes for myocardial infarction (1.93), TLF (1.03) and stent thrombosis (1.21). The indirect comparison found no difference with Zotalolimus stent versus Bio-absorbable vascular scaffold in the risk of TVR (odds ratio=1.54), TLF(0.95), stent thrombosis(1.35), myocardial infarction(0.55).

**Conclusions:** In patients with symptomatic coronary artery disease treatment, Everolimus-Eluting Bio-absorbable Vascular Scaffold and Zotalolimus-Eluting Metallic Stent have comparable effectiveness and safety.

## PO.108

### PROCOT – Cooperation Program to Captation of Technical and Economic Information

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**Background:** The Brazilian Ministry of Health (MH) offers a list of medical equipment to hospitals and health centers across the country to apply for funding of new acquisitions. The request occurs through project proposals containing the identification of the equipment with technical specifications and required values, with the MH being responsible for the analysis, price compatibility and specification of each device and then to authorize financial transfers. The information needed to support these analyses were collected through the internet and specific contacts with suppliers who sent price quotations upon request of an individual technical analyst. Due to the high number of project proposals increasing each year, this process has become unproductive due to excessive time needed.

**Objectives:** Create a bench of prices and a cooperation program.

**Methods:** In order to receive such information in advance and a spontaneous way from suppliers, the MH has released a Technical Cooperation Programme called PROCOT, establishing as incentive to the participating companies the possibility of conducting technical presentations to MH technicians, monitored technical visits to reference hospitals and disclosure of their names and contact information in the medical equipment system called SIGEM, with free access on the internet. PROCOT also consists of a centralized system with specific repositories of information, such as prices, brochures, studies and data of supplier companies, separated by year and linked to nomenclature of equipment.

**Results:** The information began being received continuously, and after validation, are archived in a central database where all technical analysts have access to the same specifications and reference prices, increasing the speed of the analysis and reducing the subjective factor which was a critical point when a lot of information existed scattered in several computers.

**Conclusions:** The number of investment proposals approved increased significantly, as well as the speed of issuing the authorization for release of funds.

## PO.109

### Cost Analysis of Lung Cancer Screening with Low-Dose Computed Tomography in Switzerland

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**Background:** Based on the 2011 National Lung Screening Trial (NLST), the U.S. Preventive Services Task Force recommended annual lung cancer screening with low-dose computed tomography (LDCT) in current and former smokers 55-80 years of age with  $\geq 30$  pack-years smoking.

**Objectives:** We aimed to estimate the prevalence of persons eligible for LDCT screening for lung cancer in Switzerland and the economic impact of a national screening.

**Methods:** The 2007 prevalence of smokers and tobacco exposure were assessed using data from the population-based CoLaus Study and the Swiss Health Survey. The annual rate of positive screening test (28%), the health care resource use for participants with a positive screening test, the confirmed diagnosis rate (1%), and the number needed to screen to avoid one death over 3 years (320) was based on the NLST. Cost analysis adopted the 3-party payer perspective. Costs in Swiss Francs (CHF) of LDCT and workup investigations were based on Swiss Tarmed fee-for-service reimbursement system.

**Results:** Overall, 11% of the Swiss population aged 55-75 years had 30 pack-year of smoking history and would be eligible for LDCT screening, out of which 22% are former smokers. Using a 75% screening participation rate, 148'000 Swiss adults per year would have a LDCT for an annual cost of CHF 59 million. Of those, 41'000 (28%) per year would need additional investigations, including approximately 2'000 mediastinoscopies or thoraco-scopies/tomies, for an extra annual cost of CHF 27 million. Over 3 years of screening, 4'440 confirmed lung cancer diagnosis would be made and 463 deaths would be avoided, for a diagnosis cost of CHF 564'000 per death avoided.

**Conclusions:** Implementation of LDCT screening in Switzerland would have large benefit on lung cancer mortality, but also substantial cost. Further comprehensive economic evaluation including treatment costs is needed to assess the efficiency of this screening program.

## PO.110

### The Challenges Turkey Faces Regarding Pharmacoeconomic Studies

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**Background:** Pharmacoeconomic studies are considered as essential tools evaluating the value of a pharmaceutical compared to another, generally the standard therapy. As cost-containment measures are increasingly applied in the healthcare sector, pharmacoeconomics continue to gain significance on decision-making as the major HTA instrument. In Turkey clinical-effectiveness, cost-effectiveness (CEA) and budget impact analyses (BIA) are provided by the companies

mandatorily within the reimbursement dossiers and the reimbursement decision is made mainly based on BIA.

**Objectives:** The aim of this study is to bring forward the latent limitations behind the production and assessment of pharmacoeconomic studies in Turkey.

**Methods:** Current practice of pharmacoeconomic studies and their use in pharmaceutical reimbursement process in Turkey's are examined.

**Results:** Pharmacoeconomics and HTA are still at their infancy state in Turkey; absence of local data, qualified personnel and pharmacoeconomic study guidelines being the main underlying reasons.

Social Security Institution (SSI), the payer, has a comprehensive database (MEDULA) containing crucial patient level prescription and utilization data. There is not much local real-life-data available besides MEDULA, which the companies conducting pharmacoeconomic studies have no access.

Quality-of-life (QoL) data, considered as essential in global pharmacoeconomics guidelines, are factored out from the evaluation in Turkey due to the insufficient local HR QoL research providing utility values for QALYs.

Moreover, there are no comprehensive guidelines for pharmacoeconomic studies required for the reimbursement submission, such as ICER thresholds, time horizon, discount rates and type of sensitivity analyses.

**Conclusions:** Pharmacoeconomic studies in Turkey are still limited in their function as HTA instrument, while the most emphasis is placed on BIA in the reimbursement process. Recent organizational changes in both SSI and Ministry of Health (MoH) regarding HTA are in development to address this issue.

In essence, the improvement of pharmacoeconomics in Turkey depends on generating local data and having complete guidelines to ensure a transparent reimbursement process.

## PO.111

### Safety, Efficacy and Budget Impact of Idursulfase for Mucopolysaccharidosis Type II in the Brazilian Public Health System's Perspective

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**Background:** Enzyme replacement therapy with idursulfase has emerged as a treatment for mucopolysaccharidosis type II (MPSII). In Brazil, this drug is not available in the public health system. Thus, it has increased the judicialization against the Ministry of Health (MoH) to ensure the public provision.

**Objectives:** To evaluate the safety, efficacy and the budget impact of idursulfase.

**Methods:** A rapid HTA was carried out to assess the safety and efficacy of idursulfase. We also estimate the incremental budget impact of incorporating idursulfase in the public health system compared to current expenditure with judicialization of idursulfase, as there is no drug comparator available to idursulfase. Costs related to idursulfase and to its infusion were calculated considering the public health system's perspective. We have also adjusted the patient's weight to the Brazilian context. We followed the methodological recommendations set in the national and international guidelines.

**Results:** Rapid HTA showed that idursulfase 0.5 mg/kg weekly (53 weeks) has improvement two outcomes compared to placebo: six minute walk test [37.0 (6.52;67.48)] and absolute forced vital capacity [0.16 (0.005;0.27)]. There was no evidence that idursulfase modified final outcomes, as quality of life or mortality. The total annual expenditure of judicialization in Brazil was R\$ 73.71 million and the estimated cost related to treatment of 100 patients (estimated target population with MPSII) was R\$ 87.45 million, having an incremental

budget impact of R\$ 13.74 million each year. In the sensitive analysis, the incremental cost ranged from – R\$ 24.49 million (saving) to R\$ 59.9 million per year.

**Conclusions:** The evidence available in terms of safety and efficacy of idursulfase is still scarce and weak. The incremental budget impact is relatively low due to high cost of judicialization of idursulfase. Based on this context, the MoH shall consider the possibility to incorporate idursulfase into public system.

## PO.112

### Comparative Safety of Tumor Necrosis Factor Alpha Blockers in Ulcerative Colitis

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**Background:** Infliximab, adalimumab and golimumab are approved by the European Medicines Agency (EMA) for the treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine or azathioprine, or who are intolerant to or have medical contraindications for such therapies.

**Objectives:** To compare the relative safety of infliximab, adalimumab and golimumab.

**Methods:** An exhaustive search was performed until October 2013. Databases consulted were MEDLINE (through OVID), EMBASE, the Cochrane Library, databases from the Center for Reviews and Dissemination and the Web of Science. We included randomized controlled trials (RCT) comparing the long-term safety of these drugs versus a common comparator, in terms of adverse events (AE).

Quality of included studies was assessed through the checklist proposed by the Critical Appraisal Skills Programme, in its spanish version (CASPe).

For safety assessment, unadjusted indirect comparisons were performed.

**Results:** Three RCTs were included: ACT 1 for infliximab, ULTRA 2 for adalimumab and PURSUIT-M for golimumab. They had a high quality (score 6 of 6).

Infliximab (5mg/kg at weeks 0, 2, 6 and then every 8 weeks), adalimumab (160mg at week 0, 80 mg at week 2 and then 40mg every 2 weeks), and golimumab (200mg at week 0, 100mg at week 2 and then 50 or 100mg every 4 weeks) were well tolerated and had a safety profile similar to placebo.

Based on unadjusted indirect comparisons:

- The three biological agents have a similar percentage of AE (72,7-87,6%), AE involving discontinuation (5,2-9,1%) and infectious AE (39-41,5%).
- Infliximab is the biological agent that higher percentage of severe AE presents (21,5%).

**Conclusions:** Infliximab, adalimumab and golimumab are well tolerated and have a similar safety profile to placebo. There is insufficient evidence to suggest differences between them.

**PO.113****Cost Effectiveness of Catheter-Based Renal Denervation for Treatment Resistant Hypertension – an Australian Payer Perspective**

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**Background:** Catheter-based renal denervation (RDN) is an effective and durable therapy option for patients with treatment resistant hypertension (TR-HTN). Consideration of both clinical and economic evaluations may be necessary to inform reimbursement decision making.

Based on results of the Symplicity HTN-2 trial (NCT00888433), Geisler et al. (2012) developed a Markov model to quantify the cost effectiveness of RDN plus standard of care (SOC) vs SOC alone in the US healthcare setting.

**Objectives:** Assess the cost-effectiveness of RDN in patients with TR-HTN from the Australian payer perspective.

**Methods:** Geisler methods were largely retained but life tables, resource use, costs and discount rates were revised to reflect Australian parameters. Importantly, the treatment effect of RDN was based on a meta-analysis of all studies (regardless of catheter used) enrolling TR-HTN patients (SBP  $\geq$  160 mmHg despite  $>3$  anti-hypertensive drugs including a diuretic).

The model consisted of 30 health states and employed multivariate risk equations from large-scale cohort studies to calculate transition probabilities of events and event mortality. Discounted (5%) costs and outcomes were calculated over a lifetime horizon.

**Results:** The weighted mean decrease in office-based SBP over 6 months was -28.1 mmHg (95% CI: -24.5 to -31.6). The RDN procedure cost (\$10,724.22) was partially offset by lower event costs – primarily through a reduced incidence of stroke (-0.0559) and MI (-0.0524).

RDN was associated with higher incremental costs (\$5,951.04) and additional QALYs (0.4296) resulting in an incremental cost per QALY of \$13,852. Sensitivity analyses demonstrated reliability of the base case results across a wide range of assumptions.

**Conclusions:** Based upon this analysis, RDN is a cost effective treatment option for patients with rHTN in Australia. However, this conclusion is dependent upon the magnitude of SBP reduction with RDN and assumptions related to long term patient outcomes.

**PO.114****Transparency in Medical Devices Pricing: Information that Helps Different Stakeholders in Decision Making**

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**Background:** The Brazilian Health Surveillance Agency (Anvisa) approved in October 2006 a specific legislation, the Resolution RDC 185/2006, which obliges the suppliers of medical devices to send economic information of their products to Anvisa. In order to reduce the information asymmetry in this market, the Economic Regulation Office (NUREM/ANVISA) has developed the database of economic information of medical devices and has published on Anvisa's website a list of prices of some cardiologic and orthopedic devices. The list compares the supplier economic information to the data provided by different sources, such as specific medical devices journals, marketing authorization and research on international and Brazilian market.

**Objectives:** The aim of this study is to present an assessment of economic information of medical devices based on the ANVISA database.

**Methods:** The data of medical devices were collected from Anvisa's database of economic information from 2007 to 2013. The price from different regions (Brazilian, American and European) and the classes of medical devices (cardiologic and orthopedic devices) were compared.

**Results:** The prices in Brazil are far superior to American and European countries. In 2013, considering different regions of Brazil, the prices can vary about 15%; the most expensive cardiologic product identified was Implantable Cardioverter/Defibrillator, whilst the most expensive orthopedic one was the Intervertebral Prosthesis (cage).

**Conclusions:** These analyses allow the healthcare professionals and payers know the medical device pricing behavior regarding to the internal and international market. In summary, the free access of economic data of medical devices can increase the transparency, which can be helpful to support decisions of different stakeholders, who can distribute healthcare resources more efficiently in order to improve the health care conditions and to develop health public policies.

**PO.115****Cost Analysis of Cervical Cancer Relevant Diseases**

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**Background:** Prevalence of HPV infection in Korea is estimated to be approximately 10 to 15% and the figure was typically high among young ages. Supposing that the average life span of Korean women is 84, the chance of incidence of cervical cancer in a life time will be 1.4%.

**Objectives:** The purpose of this study is to estimate the number of patients and the medical costs of HPV-related diseases by analyzing the claims data of NHI from 2007 to 2011.

**Methods:** We included the patients with primary disease or first subordinate disease related HPV infection, as classified by ICD-10 code. We defined new patients as those who did not utilized medical services with CIN 1, CIN 2/3, or cervical cancer for the previous two years, and we used data from 2007 and 2008 as a wash-out period. Cervical cancer was analyzed with more specific health condition separating following up of stable condition and suffering a recurrent/persistent condition in next year after initial cervical cancer diagnosis.

**Results:** The estimated range of incidence rate per 100,000 women was CIN1 104.4-187.0, CIN2/3 97.8-175.1, cervical cancer 22.5 in 2009, changing to CIN1 139.9-277.4, CIN2/3 88.1-174.8, cervical cancer 19.8 in 2011. The incidence rate of cervical cancer increased with age, peaking at 70 years of age.

We estimated that in 2009 the average treatment cost per new patient with CIN 1 was KRW 209,979, CIN 2/3 was more than three times higher at KRW 679,291. The average treatment cost per patient in the first year following diagnosis of cervical cancer was KRW 6,570,000 while the average cost per follow-up patient without recurrence was KRW 1,000,000 and that per patient with recurrence was KRW 16,220,000.

**Conclusions:** The incidence rate of cervical cancer is decreasing annually, the average cost per follow-up patient with recurrence was 16 times higher than patient without recurrence.

**PO.116****Economic Impact and Optimization of Surgical Intervention with a New and Innovative Surgery System in Patients with Pacemaker and Defibrillator Replacements**

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**Background:** Intraoperative complications like mechanical lead damage, infections and hematomas during replacement of implantable pacemaker and defibrillators contribute to additional costs for hospitals.

**Objectives:** This analysis aimed to evaluate the economic consequences and operation room use if the traditional surgical approach (TS) by using scissors and scalpels is replaced by a new radiofrequency energy (RF) based surgical system, called PEAK PlasmaBlade™.

**Methods:** A retrospective analysis examined 509 patients with TS and 102 patients with RF, who underwent generator replacement at the general hospital in Linz, Austria. Intraoperative complications (lead damages, infections, hematomas) and duration of operating time for TS and RF were analyzed. Economic analysis included the costs for resource use.

**Results:** Proportion of males (TS = 59.5%; RF = 63.7%), mean age (TS = 74.2±12.6, RF = 75.1±12.8 years), mean ejection fraction (TS=50,0±14,5; RF=52,2±13,5) and type of implanted generator were not significantly different between the two groups. Lead damage occurred significantly more often with TS than with RF (5.7% and 0.0%; p= 0.0084) and operating time with TS was significantly longer than with RF (47.5±24.0 and 28.4±8.97 minutes; p<0.001). The outcomes were not associated with type of implanted device. Cost savings due to shorter operation time and replacement of damaged leads resulted in a cost saving of € 120 per patient when using RF instead of TS. Based on estimated 2,600 patients annually undergoing generator replacement in Austria, the use of RF may result in savings of € 311,000 and 828 hours of operation time.

**Conclusions:** New surgical techniques by using PEAK PlasmaBlade™ has the potential to minimize the risk of expensive complications (e.g. lead damage) while decreasing surgery time, resulting in a more efficient utilization of the operation room. Along with cost savings and improved quality of care hospitals may increase the number of daily surgeries.

**PO.117****Minimization Strategy of Antiretroviral Drug Costs Implemented by the Ministry of Health of Argentina**

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**Background:** In Argentina, antiretroviral treatment (ART) is fully covered by the government for all persons who do not have health insurances, who represent 69% of all HIV-infected patients in the country. The Direction of Aids (Ministry of Health) acquires and delivers ART, treatment for opportunistic infections and reagents to diagnose and follow-up HIV infection since 1990.

Up to date, there are approximately 36000 HIV(+) patients who receive treatment from the public system (MoH) in Argentina.

Total expenditure on antiretrovirals for the MoH was 80.277.480.u\$ in 2013. During 2010, the Ministry incorporated the drug darunavir, which is used in the treatment of patients with multiple failures, which

require the use of more specific drugs, associated with higher costs than therapies for first and second line. Currently, 4% of the patients are treated with therapies that include at least some of these drugs, representing 18.2% of the total expenditure. Darunavir represents 34% of this share.

**Objectives:** Explain how the appeared of a generic drug in the market in Argentina. allows to the Ministry of Health to purchase more efficiently.

**Methods:** N/A

**Results:** In the public tender launched in 2014, the original's pharmaceutical company decreased by 20% the price of the drug compared to 2013, and the price offered by the national companies represented a decrease of 27% and 38%. This decline in the price of the drug translates in savings of 2.639.980 u\$ and represents a decrease of x% of the total budget for 2014

**Conclusions:** The appearance of generic formulations produced an improvement in the price of darunavir. This strategy allows the Ministry of Health to improve access to treatment with darunavir for larger number of patients and/or to use the money for other interventions that can improve the quality of life of patients with HIV/Aids.

**PO.119****Designing Fair Scales of Fees for Ambulatory Nursing Services – Proof from Empirical Evidence Wanted! a Case Study From Luxembourg**

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**Background:** Luxembourg's fee-for-service scheme for extramural nursing care composes of 40 items. It assumes that the overall workload per patient equals the sum of the standard time-values of services performed.

**Objectives:** The study seeks to prove empirical evidence of different proposals as regards the change of specifications and standard times.

**Methods:** Time has been reported for the execution of services and the period for the home-care visit. Recording is limited to six single specifications. The study involves a random sample of 20 home-care services and includes 313 outpatients. To seek out the relevant attributes that determine a detected time-variance for the execution, a total of 300 variables are additionally collected.

For analysis, we used (1) methods of inference statistics, (2) a qualitative evaluation of annotations and (3) an explorative data analysis by the calculation of multivariate adaptive regression splines (MARS) to identify relevant patient- and organisation-related variables.

**Results:** There is no proof from empirical evidence for any pre-determined default time for the provision of an individual nursing act. The time for delivery varies so strongly with the setting and the performance profile that values for individual performances can by no means be stabilized scientifically.

Nurses' home visits are often used to compensate within the limits of available time for non-prescribed and non-remunerated activities attributable to the personnel demand and social setting of the patient. Such implicit supplementary performance of social care beyond any official mission conveys a perceived huge benefit for the general public.

**Conclusions:** For patients and the public, a fair design of a fee-schedule for ambulatory care requires a shift towards the remuneration of the "total workload" per home visit. For the introduction of such a system, organizational and client variables will have to be taken into account, as large differences between providers of care exist.

**PO.120****Effect of Catch-Up HPV Vaccination of Young Women**

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**Background:** While prophylactic HPV vaccination is considered effective and cost-effective in young girls, it is unclear whether a catch-up vaccination of older girls would be beneficial

**Objectives:** We aimed to examine the potential impact of a catch-up vaccination of young women aged 16 and older.

**Methods:** We systematically searched the literature for randomized clinical trials (RCTs) that examined the effect of HPV vaccines on overall mortality, cancer mortality and incidence, high-grade cervical intraepithelial neoplasia grades 2 and 3 (CIN2+), vulvar intraepithelial neoplasia (VIN) and vaginal intraepithelial neoplasia (VaIN) grade 2 and higher lesions (VIN2+ and VaIN2+, respectively) genital warts (condyloma) (considering all lesions and those associated with HPV type(s)). RCTs reporting on serious adverse events were also eligible. Selected publications were assessed for potential risk of bias and we ascertained the overall quality of the evidence for each outcome using GRADE. Meta-analyses were performed, assuming both random and fixed effects, to estimate risk ratios and corresponding 95% confidence intervals, using intention-to-treat and per-protocol populations.

**Results:** We included 46 publications reporting on 13 RCTs. Most of the RCTs had a maximum follow-up period of four years. We found a borderline protective effect of a HPV catch-up vaccination on all CIN2+, with a pooled risk ratio (RR) of 0.80 (95% CI: 0.62-1.02) for a follow-up period of 4 years. A HPV catch-up vaccination was associated with a reduction in VIN2+ and VaIN2+ lesions, and condyloma. No difference in risk of serious adverse events was seen in vaccinated participants versus controls (pooled RR of 0.99 (0.91-1.08)).

**Conclusions:** This systematic review indicates that a HPV catch-up vaccination could be beneficial, however the long-term effect of such a vaccination, and its effect on cervical cancer incidence and mortality is still unclear.

**PO.121****Health Policy for Fetal Alcohol Spectrum Disorders in Japan**

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**Background:** Internationally, fetal alcohol spectrum disorder (FASD) has received a substantial concern. However, FASD is not well known or understood in Japan, since most research and work in this field have been undertaken overseas. It is important to examine present situation and identify critical issues for reducing this gap between evidence and health policy.

**Objectives:** To examine the number and characteristics of studies related to FASD in Japan, and evaluate the present health policy for FASD, a systematic review was carried out.

**Methods:** A literature search was done using the Japan Medical Abstract Society database and MEDLINE in 2013. All studies conducted in Japan, and published as original articles related to FASD were included. Data were independently assessed and abstracted by two reviewers. Among 629 studies located by searching databases, excluding unrelated studies, duplication and reviews, 109 studies were included for the review.

**Results:** A total of 109 studies conducted in Japan were published from 1980 to 2012. The majority (66, 61%) was non-human studies. Nineteen (or 44%) among 43 human studies were case studies. The incidence rate of FAS and FAE was roughly estimated to be 0.05 ~ 0.1 per 1,000 birth. However, there was no study for FASD prevalence.

Only 4 (8%) studies were related to prevention. On the contrary, there has been no systemic policy for FASD in Japan, and only a program for education and check for alcohol consumption at antenatal care or checkup was implemented under the broad umbrella for alcohol policy and/or the general health policy. The drinking rate during pregnancy was changing from 18% in 2000 to 8% in 2009.

**Conclusions:** In Japan, studies related to FASD are greatly lacking. To address key issues for FASD, the development of a comprehensive and integrated health policy is urgently needed.

**PO.122****Equity in Incorporating Technologies in Brazilian Unified Health System (SUS)**

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**Background:** In 2011 was published 12.401 Law establishing the National Committee for Technologies Incorporation in SUS (CONITEC) and defining the criteria and deadlines for the analysis and adoption of technologies. According to the law, CONITEC's assessment must consider necessarily scientific evidences about efficacy, accuracy, effectiveness and safety of technologies and economic evaluation studies of benefits and costs in relation to the technologies already incorporated in SUS. Studies of economic evaluation traditionally ignore equity in health, and because this gap, researches have been undertaken to develop methods to incorporate equity into economic evaluation in health.

**Objectives:** This work aims to analyze the viability of using an economic evaluation framework in the decision making process about incorporating technologies so that the equity is maximized within the Brazilian Unified Health System.

**Methods:** To fulfill this goal, review the scientific literature for methods to incorporate equity into cost-effectiveness was conducted with subsequent discussion how the methods found can be applied in the context of SUS, a system that offers universal coverage to approximately 201 million citizens.

**Results:** Until end of 2013, CONITEC recommended the incorporation of 64 technologies for diagnosis, prevention and treatment of various diseases, and no study of economic evaluation submitted addressed the issue of equity. By the research found a systematic review conducted by Johri & Norheim (2012) having found three distinct approaches: integration of distributional concerns through equity weights and social welfare functions, exploration of the opportunity costs of alternative policy options, through mathematical programming and multi-criteria decision analysis.

**Conclusions:** These and other methods may be used by CONITEC's assessment, approaching the issues of efficiency and equity in decision making. Thus, is expected to contribute to the development and application of these decision-support tools and to improve the criteria of Ministry of Health for deciding which technologies to fund.



**PO.123****How to Improve the Management of Depression? Contributions of Qualitative Research with Patients, Caregivers and Professionals**

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**Background:** The incorporation of patients and caregivers values and preferences is crucial in clinical practice guidelines (CPGs) and has an important role in promoting implementation and patient-centered care. Also, due to the potential role of CPGs in clinical decisions, and in a broader manner in health policy and organization of resources, the implication of professionals views is a key aspect. In this work we summarize the main results of a systematic review of qualitative evidence and a qualitative study carried out for the updated edition of the CPG on adult depression, included in the Spanish National CPG Development Program.

**Objectives:** To capture patients, caregivers and clinicians experience and attitudes about depression care and to use the themes and subthemes identified to formulate specific evidence based recommendations for clinical practice.

**Methods:** We carried out a systematic review with thematic analysis of qualitative studies and narrative synthesis of data. In a second phase we carried out 2 focus groups with patients, 1 with caregivers and 1 with professionals. Patients and caregivers were recruited from mental health services and a patient association. The clinicians group (general practitioners, psychiatrists, clinical psychologists, nurse and social worker) were recruited through Galician Health Service. Transcripts were analyzed using content analysis.

**Results:** Data analysis revealed a range of clinically relevant themes that characterize patient and caregivers experience and professionals views, principally related to: impact of depression, diagnosis, management strategies, course and recovery and Primary vs. Secondary Care. This information allowed to the guideline group to formulate 14 evidence base recommendations for a total of 57 included in CPG.

**Conclusions:** Qualitative approach could help bridge the gap between scientific evidence, routine and optimal care and evidence. For this reason its implication in CPGs and HTA is crucial.

**PO.124****Methodological Issues in Systematic Reviews on Alcohol and Cardiovascular Diseases. How Do We Deal with Missing Information Essential to Judge Internal Validity and the Confidence in the Effect Estimates Using GRADE?**

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**Background:** In our overview of systematic reviews (SRs) about the relationship between alcohol consumption and the risk of CVD, we assessed our confidence in effect estimates for outcomes using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) method. Four of five included SRs included observational studies only. These mainly lacked description of study participants including age, sex, pattern and time of exposure to alcohol consumption, cardiovascular status, or other CVD risk factors.

**Objectives:** To discuss the impact on conclusions resulting from the difference in judgements made when in lack of essential information.

**Methods:** Uncomfortable with making judgments in lack of participant information, we read full text of the 130 studies included in the four SRs. Unfortunately, we did not gain much more information on participants. Using GRADE we make judgments about risk of bias in studies reporting the relevant outcome, consistency, directness, precision, reporting bias, large effect, dose responses and plausible confounding. With little information about participants, judgments about similarities between comparison groups in the studies needed for risk of bias, and judgment about directness of the population, is fraught with uncertainty. Should we downgrade for uncertainty?

**Results:** Alcohol consumption (100 g/day) increase risk of hemorrhagic stroke (RR 4.7; CI 3.35 to 6.59) and hypertension (RR 4.15; CI 3.13 to 5.52). According to GRADE, observational studies start at low. If downgrading for uncertainty, we end up with very low confidence in the effect estimate. If we do not downgrade, we can upgrade for large effect and dose-response relationship resulting in high confidence in the effect estimates!

**Conclusions:** We are still uncertain and wish to discuss issues on downgrading and upgrading. We also wish to make a plea to authors of primary research (and SRs) to include essential information about the participants of the studies in their publications.

**PO.125****Reduced Fluoroscopy Time Using Tridimensional Electroanatomical Mapping with the Carto System®: Mith or Reality? Literature Review**

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**Background:** Radiofrequency catheter ablation is considered one option for tachyarrhythmia treatment. During the interventionist procedures for complex tachyarrhythmia the prolonged use of fluoroscopy can cause acute and sub acute skin lesions, cancer induced by radiation and genetic abnormalities to both patient and healthcare professionals involved in these procedures.

**Objectives:** The primary objective of this study was to perform a literature review comparing the fluoroscopy time during the treatment of tachyarrhythmia using the conventional mapping (CM) vs. 3D electroanatomic mapping (EAM) with the CARTO® System. The secondary objectives were to evaluate the procedure total time and the radiation dose rate comparing these two treatment modalities.

**Methods:** It was utilized the "PICO" methodology (Centre of Evidence-Based Medicine – Oxford, UK) to generate the following equation for the literature search: (((((((arrhythm\*) OR (atrial fibrillation)) OR (ablation\*)) AND ((((((map\*) OR (impedance)) OR (electric\*)) OR (3D)) OR (CARTO)) OR (electromagnetic))) AND (((fluoroscopic) OR (2D)) OR (conventional))) AND (((clinical\*) OR (radiation exposure)) (Figure 1). The classification of level of evidence for the studies included into this review was according to the Centre of Evidence-Based Medicine – Oxford, UK.

**Results:** Eleven clinical trials, published up to 2012, demonstrated, with statistical significance, reduced fluoroscopic time for the EAM group. 1/3 of the studies analyzed the procedure total time, which was significant lower in the EAM group (p<0.005). 100% of the studies that evaluated the radiation dose rate demonstrated a statistically significant reduction in the EAM group (p<0.005).

**Conclusions:** This literature review shows that there is an important reduction on the fluoroscopy time and the radiation dose rate utilizing the 3D electroanatomic mapping with the Carto® System, which reduces the exposure of patients and healthcare professionals to radiation, and therefore, its somatic (stochastic and deterministic) and hereditary side effects.

**PO.126****Putting Patients and Public at the Centre of Health Care**

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**Background:** A model of partnership exhibited by Patient Organizations, through their expertise and experience while dealing with key healthcare stakeholders results into multisector knowledge for contributing and strengthening patient centered health care and healthcare systems. Patient organizations are empowered to communicate with a strong unified voice on shared agendas and patient issues that bring together patient groups so as to build an active network. Both Communicable and Non-communicable diseases form a complex of disease burden among patients represented and require strong partnership.

**Objectives:** Forming an alliance of Patient organizations representing multiple disease areas in Uganda will promote patient entered healthcare. The alliance aims at diversifying the IAPO strategy of 'strengthening the patients' voice in Africa' and contribute to the global patients' voice. Ensures it accurately reflects the diverse needs and experiences of patients globally and that it is well communicated. Promoting meaningful involvement and engagement of patients and other key stakeholders to improve quality health service delivery, create awareness and bring out the plight of patients in Uganda for inclusion in decision making.

**Methods:** Engaging various healthcare institutions, professionals, Associations and organizations policy makers to discuss access and availability of health care; observing patient solidarity are part of strategies for improving health care. Monitoring of health service delivery, health literacy and education, organizing public events are formulated to contribute to healthcare decision making processes.

**Results:** 10 patient groups represent over 20000 patients of different diseases enabling them to demand for quality and adequate health services.

**Conclusions:** Effective health care Policies need to engage patients at all levels of healthcare decision-making in order to meet the needs of patients. Through Patient groups, efforts are galvanized towards patient-centered healthcare as it brings together patients with common issues and concerns, to make their collective voice stronger and sharing best practices. improving lives.

**PO.127****Insulin Analogues**

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**Background:** The goal of diabetic treatment is to achieve tight glucose control, avoid chronic complications and limit hypoglycaemic episodes frequency in everyday life with minimal weight gain. It is claimed that the new insulin analogues have been designed to more closely mimic physiologic insulin profiles through improved pharmacokinetic characteristics, which result in either more rapid or prolonged pharmacodynamic effects. However, the cost of insulin analogues is more expensive than conventional human insulin, hence, limiting the use in the public hospitals in Malaysia.

**Objectives:** To assess the safety, efficacy or effectiveness and economic implications of using rapid-acting, long-acting or premixed insulin analogues compared with conventional human insulin for treatment of type 1, type 2, or gestational diabetes mellitus.

**Methods:** Studies were identified by searching electronic databases through the Ovid interface, PubMed and FDA. The last search was run on 7 March 2012. Relevant literature was appraised using the Critical

Appraisal Skills Programme (CASP) or Jadad scale and graded based on guidelines from the U.S./Canadian Preventive Services Task Force. Forty-five full text articles were included in the review.

**Results:** Treatment with insulin analogues compared with conventional human insulin appeared to offer minor benefit in terms of glycaemic control as reflected in HbA1c level, postprandial blood glucose and fasting blood glucose but have advantages in terms of reduced occurrence of hypoglycaemia, particularly nocturnal hypoglycaemia and severe hypoglycaemia as reported in some studies. While the adverse events (excluding hypoglycaemia episodes) were found to be similar in both treatment groups, patients treated with insulin analogues showed greater treatment satisfaction and less weight gain.

**Conclusions:** It is recommended that insulin analogues should be made available for treatment of all type 1 diabetes mellitus and for type 2 diabetes mellitus who have recurrent hypoglycaemia. Local economic studies including societal perspective are encouraged.

**PO.128****Engaging Patients/Clients in the Development of Interprofessional Education to Improve Outcomes**

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**Background:** Chronic health conditions pose a significant challenge for North American health care systems. An estimated 65,000 Canadians and approximately 1.4 million Americans live with the sequelae of HIV infection (PHAC, 2010; CDC, 2009). Quality health care of these individuals and significant others/family members involves a collaborative approach to the management of the complexity of disease and resulting challenges. Interprofessional learning activities are an ideal learning strategy for students to work collaboratively to consider presenting challenges. Although faculty may work collaboratively to create learning opportunities, they do not necessarily focus on the informed voice of the patient/client. This presentation will highlight an example of benefits of engaging the client/patient in the development and evaluation process.

**Objectives:** To consider how the patient/client can be more fully integrated in education of health science students

To discuss how the patient/client voice can inform development of learning activities

To review how health science student development of underlying values and ethics, as well as communication and collaboration skills are developed through the described HIV educational learning opportunity

**Methods:** An elective learning activity that focuses on the facilitation of patient/client empowerment within the context of HIV/AIDS was developed for students from the health science professions. The interprofessional session engaged students in the lived experiences of patients/clients through the use of Reader's Theatre and case-based discussions.

**Results:** Global rating scales reflecting student self-assessment of achievement of IPE core competencies, evaluation data, as well as student and facilitator focus group results will be highlighted. The presentation will also focus on how the engagement of the patient/client affected the process.

**Conclusions:** The involvement of consumers of the healthcare system in the planning process of interprofessional learning activities results in a more patient/client-centred educational process.

**PO.129****The Effects of Patient Involvement in the Assessment of Alternatives Measures to Restraint and Seclusion**

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**Background:** Patient involvement in HTA should contribute to care that is responsive to their needs and values. This research was part of a larger project aiming to implement and evaluate patient involvement strategies in the assessment of alternatives measures to restraint and seclusion among adults in short-term hospital wards and long-term care facilities for the elderly.

**Objectives:** Evaluate the effects of patient involvement in the assessment of alternatives to restraint and seclusion.

**Methods:** A descriptive design was used to explore the effects of patient involvement, based on thirteen semi-structured interviews with caregivers, healthcare managers, patient representatives, HTA unit members, researchers and members of the local HTA scientific committee. Document analysis of HTA reports and presentations was also performed. Data analysis was based on a framework developed to assess patient involvement in HTA.

**Results:** The majority of interviewees consider that patient consultation had enriched the content of the HTA report by improving the understanding of the real-life experience of people who had been under restraint or in seclusion. It also revealed new alternatives to reduce the use of restraint and seclusion. The patients' views also confirmed some views and comments from healthcare professionals consulted in this HTA. According to a local HTA unit member, the direct participation of patient representatives allowed rephrasing some findings so as to bring their perspective.

**Conclusions:** Patient involvement could help the integration of the patients' perspective in HTA. Patient consultation seems to have directly influenced the content of the HTA report while direct participation allowed rephrasing some findings. However, the real effect of direct participation was difficult to grasp because patient representatives were only involved in one of the three meetings of the HTA working group. It would be therefore important to make sure that the patient representatives' voice is captured early in the HTA process.

**PO.130****Patient Outcomes of Hip Resurfacing Compared to Total Hip Arthroplasty: a Systematic Review**

Deborah A Marshall<sup>1,2</sup> Karen V MacDonald<sup>1</sup> Tom Noseworthy<sup>1,3</sup> Diane L Lorenzetti<sup>1</sup> Jason Werle<sup>1</sup> Tracy Wasylak<sup>3</sup> Donald Dick<sup>3</sup> Greg O'Connor<sup>4</sup> Cy Frank<sup>1,5</sup>

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**Background:** Hip resurfacing (HR) was developed for younger, active patients as an alternative to total hip arthroplasty (THA), but remains controversial. Inconsistent definitions, and non-standardized outcome measures challenge arthroplasty outcome comparisons.

**Objectives:** Systematic review of HR and THA outcomes in patients with hip osteoarthritis (OA).

**Methods:** We included English language studies published after 1996 reporting adverse events (early failure, time to revision, reoperation, dislocation, infection/sepsis, femoral neck fracture), complications, safety issues or revision rates in adults with primary hip OA, who underwent HR or THA. Revision rates were compared with four

national joint replacement registries (JRRs). Results were reported as adverse event rates per 1000 person-years with 95% confidence intervals (CI), stratified by device market status (in-use and discontinued). Comparisons between event rates are made using quasi-likelihood generalized linear model. We identified 7421 abstracts, reviewed 384 full-text papers, and included 236 studies.

**Results:** Average time to revision was 3.0 years for HR (95% CI: 2.95-3.1) versus 7.8 for THA (95% CI: 7.2-8.3). Revisions and reoperations were more frequent in HR than THA based on point estimates and CIs: 10.7 (95% CI: 10.1-11.3) versus 7.1 (95% CI: 6.7-7.6;  $p=0.068$ ) and 7.9 (95% CI: 5.4-11.3) versus 1.8 (95% CI: 1.3-2.2;  $p=0.084$ ) per 1000 person-years, respectively. This difference was consistent with three of four JRRs, but overall JRR revision rates were lower than those reported in the literature. Dislocations were more frequent in THA than HR: 4.4 (95% CI: 4.2-4.6) versus 0.9 (95% CI: 0.6-1.2;  $p=0.008$ ) per 1000 person-years, respectively. Adverse event rates change when discontinued devices were included.

**Conclusions:** Revisions and reoperations are more frequent and occur earlier in HR, except when discontinued devices are removed from the analyses. Standardized comparative outcomes for HR and THA should be considered when selecting which device is most appropriate for individual patients.

**PO.131****Detecting a Heterozygosis Result Following the Sickle Cell Disease Neonatal Screening: What Impact Has Information for the Newborn and His Family in 2013? Literature Review and Interviews of Experts and Patient Advocates in France**

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**Background:** Sickle cell anemia, is linked to the production of abnormal hemoglobin, and is more prevalent among populations coming from certain regions of sub-Saharan Africa. Following migrations, sickle cell disease (SCD) has spread to the Americas, the Caribbean, the Mediterranean and Europe. The discovery of a heterozygous newborn is a possible result of neonatal screening for SCD and raises questions about the provision of information related to this condition. An analysis of the impact of this information for the newborn and his family was carried out in the context of a referral of the French National Authority for Health by the Department of Health on current SCD targeted screening in France.

**Objectives:** To achieve a synthesis of knowledge and debates related to the detection of a heterozygosis in the newborn, in terms of impact on health and in terms of familial projects

**Methods:** Literature review: qualitative studies, systematic reviews and health agencies reports, 2000-2013 Analysis of debates related to the detection of a heterozygosis in the newborn was conducted according to the criteria of Beauchamp and Childress for the newborn and his family.

Interviews: patient representatives (4), medical experts (4), anthropologists (2) experts in charge of neonatal screening program in France.

**Results:** This complex information on a condition that generally has no effect on health may generate misunderstandings and raise questions about family projects. Difficulties concerning the systematic revelation of this information with heterogeneous practices are reported in the literature and by health professionals and representatives of patient associations interviewed in France.

**Conclusions:** Representatives of patients interviewed emphasize the complexity of the information on heterozygosis and suggest for improvement related to its provision. The use of Beauchamp and Childress criteria may help identify some questions and dilemmas faced

by both parents and health professionals. These elements should be taken into account to public decision making.

## PO.132

### Descemet Stripping Automated Endothelial Keratoplasty for Corneal Endothelial Dysfunction

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**Background:** The main causes of corneal endothelial failure are Fuchs' endothelial dystrophy and aphakic or pseudophakic bullous keratopathy. In the severest cases, the only treatment is corneal transplantation, with penetrating keratoplasty (PK). With the aim of reducing complications arising from this intervention, Descemet's stripping automated endothelial keratoplasty (DSAEK) is a novel technique with promising results.

**Objectives:** To assess the efficacy/effectiveness, safety and cost of the DSAEK technique per se or in comparison with PK, in patients with corneal endothelial failure.

**Methods:** A bibliographic search stipulating no time limit was made in the principal biomedical databases specialising in systematic reviews and in general databases such as Medline and Embase in January 2013.

**Results:** Of a total of 583 papers retrieved, 20 case series and 2 economic evaluation studies fulfilled the inclusion criteria. Best-corrected visual acuity (BCVA) improved after treatment with DSAEK, with statistically significant results vis-à-vis pre-intervention figures, attaining values of 0.6 to 0.8. Studies which compared DSAEK to PK reported values of 0.45-0.56 and 0.125-0.38 respectively, with differences that were not always significant. The degree of post-DSAEK astigmatism was not significant and appeared to be better than that achieved with PK. In terms of effectiveness and safety, outcomes were better in patients having no severe ocular comorbidities.

**Conclusions:** In Fuchs' dystrophy and bullous keratopathy, data on the effectiveness of DSAEK indicate post-intervention improvement in uncorrected and BCVA in relation to baseline values registered prior to the procedure. According to the studies located, post-DSAEK outcomes for BCVA and degree of astigmatism are similar to or even better than those achieved with PK.

The most important post-DSAEK complications are linked to the viability of the graft. In PK, rejection is the most frequent complication.

Economic evaluation data show that as compared to PK, DSAEK could be a cost-effective technique.

## PO.133

### The Cost-Effectiveness of the Retinal Prosthesis in Retinitis Pigmentosa Patients

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**Background:** Retinitis Pigmentosa (RP) is a hereditary genetic disease causing bilateral retinal degeneration. RP is a leading cause of blindness resulting in incurable visual impairment and drastic reduction in the Quality of life of the patients. Although the condition is at present incurable, advances in the field of retinal implants demonstrate the progress now being made in combating the condition and restoring a measure of sight to those afflicted.

**Objectives:** The objective of this study was to assess the cost-effectiveness of first ever-commercial implant intended to restore some vision in the Retinitis Pigmentosa (RP) patients.

**Methods:** A multi-state transition Markov model was developed to determine the cost-effectiveness of retinal transplant versus usual care in RP from the perspective of healthcare payer. A hypothetical cohort of 1000 RP patients aged 46 years followed up over a (lifetime) 25-year time horizon. Health outcomes were expressed as quality adjusted life years (QALYs) and direct healthcare costs expressed in 2012 €. Results are reported as incremental cost per ratios (ICERs) with outcomes and costs discounted at an annual rate of 3.5%.

**Results:** The ICER for the retinal implant was €14,603 /QALY. Taking into account the uncertainty in model inputs the ICER was €14,482/QALY in the probabilistic analysis. In the scenarios of an assumption of no reduction on cost across model visual acuity states or a model time horizon as short as 10 years the ICER increased to €31,890/QALY and €49,769/QALY respectively.

**Conclusions:** This economic evaluation shows that the retinal implant is a cost-effective intervention compared to usual care of the RP patients. The ICER for retinal implant falls below the published societal willingness to pay of EuroZone countries. Retinal implants could eventually change the lives of up to 200,000 people worldwide who suffer from blindness due to Retinitis Pigmentosa.

## PO.134

### Scientific Evidence Closer to Health Consumers: How Can We Make Health Technology Assessment Reports Understandable?

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**Background:** Health Technology Assessment (HTA) represents a scientific method -based tool to help decision making in Health. Technical pieces of information are usually not very easy to find nor to interpret. HTA can potentially be used by several organizations to make decisions: it can be used to advise regulatory agencies, payers of health services, and to guide health care providers as well as health care consumers about the proper use of a technology.

**Objectives:** Our objective is to incorporate a tool which helps HTA results become accessible to patients and professionals not related to medical areas, using plain and understandable language, based in the

fact that usually technical scientific words can represent a barrier to the complete comprehension of the information.

**Methods:** This patient centered approach is in consonance with current international trends, mainly represented by the International Patient Decision Aid Standards (IPDAS) Collaboration, which constitutes a group of researchers, practitioners and stakeholders from 14 countries worldwide.

**Results:** Today, in our public health setting we use HTA Quick Reports, which are standardized documents adopted by the Mercosur, the National Agency of Health Technology Assessment (UCEETS) and the Argentinean Public HTA network, RedARETS.

This standardized model includes a non technical summary. Nevertheless its complete comprehension still requires a high literacy level and familiarity with technical health related terminology.

**Conclusions:** We suggest that HTA elaborating organisms and agencies incorporate a plain language section in every HTA report, with participation of specialized professionals skilled in social communication, to cooperate with informed patient choice. We trust that this action will be an important step towards the development of new standards of patient care at a policy making level.

### PO.135

#### A Systematic Review of the Clinical Effectiveness of Music as an Aid for Post Operative Recovery

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**Background:** Music has long been used as an adjunct to pain and mood (it was used by Florence Nightingale), has been investigated in the context of recovery from operative procedures but results not synthesised and disseminated. Music is a non-invasive, safe and inexpensive intervention that can be delivered easily and successfully in a hospital setting.

**Objectives:** To evaluate music to improve postoperative recovery after surgical procedures.

**Methods:** A protocol was registered with Prospero. Randomised controlled trials (RCTs) in any language of adult patients undergoing surgical procedures to any part of the body excluding the central nervous system or head and neck were included. Any form of music initiated before, during or after surgery was compared to standard care or other non-drug interventions such as massage, bed rest or relaxation. Outcomes up to six weeks postoperatively were pain, analgesia requirement, anxiety, infection rates, wound healing, length of stay, costs and satisfaction with care. Databases were searched to October 2013: Medline, Embase, CINAHL, and Cochrane Central, using search MESH terms and keywords. Inclusions, data extraction and quality assessment were in duplicate. Meta-analysis with RevMan (version 5.2), was with random effects models because of heterogeneity of participants and interventions. Standardised mean differences (SMD) were used where continuous outcomes had differing measurement scales.

**Results:** Of 3876 titles and abstracts, full papers were sought for 260 references (238 from database searches, 22 from reference lists). Included in meta-analyses were 71 RCTs. There were significant improvements with music on pain (SMD -0.73 [-1.01, -0.44]), analgesia use (SMD -0.44 [-0.62, -0.25]) and anxiety (SMD -0.33 [-0.53, -0.12]). Subgroup analyses suggested that patient choice of music improved outcomes irrespective of whether anaesthesia was used.

**Conclusions:** Music is beneficial following surgical procedures. As asking patients to provide their own music on portable devices is of minimal cost, this intervention should have widespread adoption.

### PO.136

#### Comparison of Survival Between Patients with Screen-Detected and Interval Gastric Cancer Related to Endoscopic Screening

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**Background:** The effectiveness of endoscopic screening for gastric cancer has been continually evaluated; however, only a few studies have reported its effectiveness.

**Objectives:** Since an important requirement for cancer screening is improving survival, we compared the survival of patients with either screen-detected or interval cancer who underwent endoscopic screening with that of patients who underwent radiographic screening.

**Methods:** Survival analysis was performed using the Kaplan-Meier method. Each type of screening was conducted once a year; therefore, interval cancer was defined as cancer detected within one year after a negative result on cancer screening. The subjects of the study were selected from gastric cancer cases registered in the Tottori Cancer Registry. The target age group was defined as the age at which gastric cancer was diagnosed from 40 to 79 years. Follow-up was continued from the date of diagnosis to the time of death due to gastric cancer or up to December 31, 2011.

**Results:** Endoscopic screening detected a total of 324 cases of gastric cancer, 23 of whom with interval cancer, whereas radiographic screening detected 143 cases, also finding 23 with interval cancer. The 5-year survival rates were as follows: concerning endoscopic screening, 91.9±1.6% (95% CI: 87.5-93.8) for patients with screen-detected cancer, and 91.3±5.9% (69.5-97.8) for those with interval cancer; concerning radiographic screening, 86.8±2.9% (79.9-91.5) for patients with screen-detected cancer and 68.7±2.9% (45.2-83.7) for those with interval cancer.

**Conclusions:** With endoscopic screening, survival rate of patients screen-detected and interval cancers was equal; therefore, the screening interval of endoscopic screening could be extended to more than one year and thus enable easier access to gastric cancer screening for the target population. However, since a high survival rate is mainly affected by lead-time bias, the effectiveness of endoscopic screening should be evaluated in terms of mortality reduction in future studies.

### PO.137

#### Pharmaceutical Industry Alignment to Meet Health Consumer Needs for a Greater Opportunity to Provide Input to HTA Process in Australia

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**Background:** Patients and consumers are encouraged to provide comments to the HTA process for reimbursing medicines in Australia i.e. Pharmaceutical Benefits Scheme. This process allowed consumers to make comments via an online form during a two week window prior to the meeting of the Pharmaceutical Benefits Advisory Committee (PBAC). HTA\_Aus\* worked with a number of patient groups to identify barriers and facilitators, identifying that two weeks is not an appropriate timeline for relevant consumers to be informed and provide effective comments.

\*(D Grainger et al, Bilbao June 2012. Facilitation of patient-centred HTA by an independent multistakeholder HTA working group in Australia, a community view pilot project).

**Objectives:** - Gain agreement from the Pharmaceutical Industry to extend the timeline for consumer comments

- Encourage discussion regarding more effective consumer participation in the PBAC process

**Methods:** Through the HTA\_Aus Think Tank we identified that the limited window of opportunity was initially established in 2004 by Medicines Australia (MA), the Australian pharmaceutical industry association. While consumers and the PBAC were agreeable to a change, a consultation with MA was required in order to approve any change in the timeline. HTA\_Aus approached MA asking that it review its policy. MA then engaged their members asking whether they agreed to increase the window. Member companies were asked to make submissions to MA stating their position.

**Results:** MA members unanimously agreed to extend the window for consumer comments from two weeks to six weeks. In addition the process was helpful to identify a number of other suggestions from industry that may improve consumer participation in the process, such as greater promotion of the PBAC agenda and increased HTA education for consumers.

**Conclusions:** The Pharmaceutical industry is supportive of consumer participation in the HTA process and should be considered a key stakeholder in discussions between payers, clinicians and patients.

## PO.138

### Disease Burden and Economic Impact of Tobacco Use in Argentina, Chile, Colombia and Mexico

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**Background:** Tobacco use is the leading cause of preventable illness and death in the world and imposes a large economic burden.

**Objectives:** To estimate the burden of disease and health care costs attributable to tobacco use in Argentina, Chile, Colombia and Mexico.

**Methods:** A validated microsimulation model was used. It estimates the probability of illness or death by 17 conditions associated with smoking. The event costs were estimated using a micro or macrocosting approach based on availability and quality of information and validated among events and countries. Results are expressed in current U.S. dollars/December 2013.

**Results:** The model estimated that 111 people die per day in Argentina, 45 in Chile, 72 in Colombia and 118 in Mexico due to smoking. 8.4% of all deaths in Mexico, 13.6% in Argentina, 15.9 in Colombia and 18.5% in Chile can be attributed to tobacco use, and 126,791 deaths per year could be avoided in these countries; 24% due to heart disease, 23% to COPD (chronic obstructive pulmonary disease), 15% to lung cancer and 11.5% to passive smoking. More than three million of years lost due to premature death and disability can be attributed to tobacco. 53,858 cancer diagnoses and 291,578 hospitalizations for heart disease could be avoided annually.

Tobacco use generates an annual direct cost of U.S. \$ 34 billion mainly due to cardiovascular disease, COPD and cancer, accounting for between 0.4% (Mexico) and 1% (Argentina) of GDP. Revenue from cigarette taxes in these countries accounts for 46% of attributable costs in Argentina, 86% in Chile, 11% in Colombia and 52% in Mexico.

**Conclusions:** The burden of disease (mortality and morbidity) and costs associated with tobacco use is high in Argentina, Chile, Colombia and Mexico. Although tax revenues from cigarettes were heterogeneous, there is a clear opportunity to promote increases in them.

## PO.139

### Pooling Outcome Data Across Generic Utility Measures of Health Related Quality of Life (HRQL): a Case Study in Rheumatoid Arthritis

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**Background:** The importance of evaluating treatment efficacy from the patient perspective is increasingly recognized in the evaluation of health technologies. Pooling data across patient reported outcomes is challenging when the construct is measured with instruments that have underlying differences. Generic utility measures of HRQL, for example, differ in the attributes of HRQL captured, attribute weighting, recall period, and range of scores.

**Objectives:** To evaluate feasibility of pooling HRQL data across different generic utility measures of HRQL using different methods of pooling.

**Methods:** RCTs that compared standard dose biologic DMARD with methotrexate (MTX) to MTX alone in MTX-experienced patients with rheumatoid arthritis were identified by searching bibliographic databases, clinicaltrials.gov, and the grey literature. Data were pooled using random effects models with inverse variance weighting. Treatment effects were estimated using the standardized mean difference (SMD), minimally importance difference units (MIDs) and by converting to the EQ-5D by re-scaling and using crosswalk formulas. MIDs for the measures were obtained from the published literature.

**Results:** In the included studies, HRQL was measured with HUI3 (n=2), SF-6D (n=2) and EQ-5D (n=1). The SMDs between biologic DMARD with MTX versus MTX alone ranged from 0.36 (SF-6D) to 0.57 (HUI3), with a pooled SMD of 0.52 [95% CI: 0.31, 0.52]. Differences expressed in MID units ranged from 1.3 (SF-6D) to 3.0 (HUI3) in the individual studies, with a pooled estimate of 1.98 [95% CI: 1.85, 2.11] MIDs. The pooled estimates of treatment effects were 0.10 [95% CI: 0.07, 0.13] and 0.09 [95% CI: 0.06, 0.12] rescaled and cross-walked to the EQ-5D scale, respectively.

**Conclusions:** Based on limited data, preliminary results suggest that despite differences in the utility measures, it may be feasible to pool outcome data across these measures in rheumatoid arthritis. Expressing differences in MID units or in units of a common instrument may facilitate interpretation.

## PO.140

### Does Therapeutic Writing Help People with Long Term Conditions? Systematic Review, Realist Synthesis and Economic Modelling

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**Background:** Long-term medical conditions (LTCs) cause reduced health-related quality of life (HRQoL) and considerable health service expenditure. Therapeutic writing (TW) may improve physical and mental health in people with LTCs, but its effectiveness is not established.

**Objectives:** This project establishes the clinical and cost-effectiveness of therapeutic writing (TW) in LTCs by systematic review, realist review and economic evaluation.

**Methods:** Any comparative study of TW in patients with any diagnosed LTCs reporting any relevant clinical outcomes was included. Searches were in Medline, Embase, PsychInfo, Cochrane Library and Science Citation Index to March 2013, no language restrictions. Synthesis: narrative and tabular with meta-analysis where appropriate. De-novo economic modelling will be attempted in one clinical area if sufficient evidence available.

**Results:** We included 62 clinical trials and one observational study. Most were conducted in USA (n= 42) and assessed adults patients (n= 39). Studies reported mainly psychological (n= 49), physiological (n= 31), general HRQoL (n= 20) and pain (n= 10) outcomes. Resource use outcomes was described in 13 studies. More than 240 different outcome measures were used. Many studies used the Pennebaker type of writing model, but also positive writing, enhanced meaning writing, diary writing and Internet chat forums were found. Study sizes were mostly small (n<100). Follow-up was between one week and one year after the writing intervention, but mostly between one and three months. Review results suggest that TW might be effective for one or more outcomes in approximately half of the studies (n= 31).

**Conclusions:** The effectiveness of Pennebaker-style TW interventions in LTCs is not so clear as would have been expected from textbooks. Interventions evaluated in included studies do not mirror those used by professional TW practitioners in clinical practice. Further research is needed that evaluates interventions employed in clinical settings. The project finishes in June 2014 when full results will be presented.

## PO.141

### New and Emerging Technologies for Urinary and Faecal Incontinence: a Horizon Scanning Review

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**Background:** Urinary and faecal incontinence have wide ranging impacts on quality of life. Incontinence is managed using a range of therapies, procedures, devices and drugs, depending on the cause, severity and impact of the condition. However, many patients still suffer significant morbidity despite optimal management and there is a need for more effective and less invasive treatment options.

**Objectives:** To identify emerging technologies for the diagnosis and management of urinary and faecal incontinence in both sexes, using experts and patient representatives to select those most likely to offer significant patient benefit.

**Methods:** Emerging technologies were identified by systematically searching bibliographic and commercial databases, trial registries, and media websites. Commercial developers were contacted to exclude technologies no longer in active development or already marketed in the UK. Finally, technologies were reviewed by a panel of experts and a patient organisation to determine novelty, potential impacts, and barriers to adoption.

**Results:** Twenty-three technologies were identified (two diagnostic, six pharmaceutical, fifteen other technologies), most of which represented incremental developments. Drugs in development focused mainly on increasing selectivity of existing agents, though a small number of novel agents were identified.

Procedures currently available to treat incontinence include injectable bulking agents, synthetic slings and artificial sphincters; incremental developments in these were identified. Experts were particularly interested in regenerative medicine technologies, including autologous muscle cell derived cells for stress and faecal incontinence, which may advance on current bulking agents and sling repairs. Finally, several novel but unproven outpatient procedures were also identified (e.g.

intra-bladder balloon system and non-ablative radiofrequency heat system).

**Conclusions:** Most technologies currently in development for incontinence represent incremental developments, though these may still improve patient outcomes. Few novel technologies were identified; most of these were in early development and several years from launch, requiring further well-designed trials and cost-effectiveness data before adoption into routine clinical practice.

## PO.142

### Is the Normalization of Bariatric Surgery in the Interest of Public Health? Can HTA Inform the Discussion?

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**Background:** Obesity constitutes a major public health challenge. The use of bariatric surgery to decrease obesity and obesity related diseases in individual patients has increased strongly in Norway, as in many other countries in the latest decade.

The National Council for priority setting in health care (NC) provides recommendations on priority setting and quality issues to the Ministry of Health in Norway. The NC is an interdisciplinary arena for comprehensive discussions on current health care issues. The NC has commissioned a HTA report to assess the long-term effects of bariatric surgery, and will discuss these issues in February 2014.

**Objectives:** The public debate in Norway has so far mainly focused on demand for increased capacity. There is a need for a broader discussion that also address long-term results, side effects as well as alternative approaches and prevention of obesity.

**Methods:** N/A

**Results:** The HTA report confirmed the effects on weight loss on short terms, but also concluded that adverse events are neither systematically evaluated nor reported. There was limited information about negative long-term outcome measures. The report also addresses serious ethical issues related to the intervention.

**Conclusions:** Obesity will continue to constitute a major public health challenge in the years to come. The role and tasks of the health care service still need to be discussed. HTA reports are useful in these discussions, also to detect knowledge gaps and highlight ethical issues. However, the strong increase in bariatric surgery calls for close surveillance, and data from clinical practice and patient experiences provide useful supplement to HTA.

## PO.143

### Optimal Search Strategies for Identifying Moderators of Treatment Outcome in Pubmed

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**Background:** Treatments are becoming increasingly personalized in recognition that treatment effects differ from individual to individual. Implementing personalized care may have significant benefits for the individual patient and society as a whole. Retrieving existing evidence on moderators of treatment effects may be a first step towards personalized care but is a daunting task without a specialized search strategy.

**Objectives:** To generate and evaluate a search query in PubMed to find articles identifying moderators of treatment effects.

**Methods:** Four top-ranked journals from the field of rheumatology and two general medicine journals were hand-searched for articles reporting on moderators of treatment effects yielding a 'gold standard' (limits: published in 2011, English language). Selected articles were randomly allocated to a development and a validation set. PubMed was used to retrieve keywords and MeSH-terms linked with the 'gold standard' articles in the development set. Terms were tested for retrieval accuracy (e.g. sensitivity (Se) and specificity (Sp)) within the development set. Preselected 'core terms' and de novo single terms that yielded  $Se > 25\%$  and  $Sp > 75\%$  were used to generate combined search queries. The best search queries were tested in the validation set.

**Results:** Of 4407 articles, 198 were considered to report on moderators of treatment effects. The 97 articles in the development set yielded 1231 keywords and 1253 MeSH-terms. The most sensitive query is: '(("Epidemiologic Methods"[MeSH] OR ASSIGN\* OR CONTROL\*[tiab] OR TRIAL\*[tiab]) AND THERAPY\*[sh])' (Se 100%, Sp 79%), the most specific query is: 'GROUP\*[tw] AND THERAPY\*' (Se 75%, Sp 95%). In the validation set these queries yielded values of (Se 89%, Sp 80%) and (Se 58%, Sp 95%), respectively.

**Conclusions:** We developed narrow and broad search queries to be used according to search requirements. These preliminary queries represent the first step in making it easier to retrieve evidence on moderators of treatment effect on the road towards implementing personalized care.

## PO.144

### Telemonitoring Multi-Pathological Chronic Patients from Primary Care: Effect on Healthcare Resource Use (The TELBIL-A Study)

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**Background:** In an environment with limited healthcare resources, home-telemonitoring could offer a promising alternative for the care of the increasing number of chronic patients.

**Objectives:** To evaluate the effect of a home-telemonitoring intervention on the number of hospital admissions, length of hospital stay and emergency department visits.

**Methods:** We are conducting a primary care-based study with a before-and-after design and a 12-month follow-up. Forty-two patients participated in the study. Patients, diagnosed with heart failure and/or COPD or multiple-pathologies and with difficulty to leave the home, aged  $\geq 14$  and with  $\geq 2$  admissions in the previous year were eligible. Telemonitoring consisted of daily transmissions of a number of selected self-measured clinical parameters (i.e., respiratory/heart-rate, blood-pressure, oxygen-saturation, weight and temperature) and a brief clinical, medication and dietary questionnaire. Alerts were triggered when recorded values fell outside established limits. The primary outcome measure was the number of hospital admissions (total and specific) that occurred 12-months before and after the start of the study. Outcomes on length of stay and emergency department visits are also presented.

**Results:** Twenty-eight patients completed the study. There were  $2.64 \pm 1.63$  total hospitalisations in the previous year compared to  $1.08 \pm 1.55$  during the 12-months of telemonitorization, being the difference statistically significant ( $p$ -value=0.001). Specific hospitalisations ( $1.92 \pm 1.25$  before versus  $0.60 \pm 1.26$  after;  $p$ -value<0.001). Length of stay ( $11.82 \pm 7.26$  days before vs.  $7.47 \pm 2.94$  days after;  $p$ -value=0.027). Emergency department visits resolved without hospitalisation ( $1.72 \pm 1.88$  before vs.  $1.16 \pm 1.49$  after;  $p$ -value=0.057).

**Conclusions:** This study shows a statistically significant reduction in hospitalisations (both, total and specific) and length of hospital stay when patients were telemonitored during 12-months compared to the previous year. Emergency department visits were also reduced although the difference was not significant. Home-telemonitoring could constitute a beneficial alternative mode of healthcare provision for medically unstable chronic patients, leading to a decrease in the use of secondary care.

## PO.145

### Is FDA's Breakthrough Therapy Designation a Game-Changing Trend for Patients and Payers?

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**Background:** In 2012 United States Food and Drug Administration (FDA) created a new expedited pathway of 'Breakthrough Therapy Designation' (BTD) to enable early approval of therapies, which have shown substantial activity in early trials.

**Objectives:** The objective of this study was to understand the impact on BTD on patients and payers.

**Methods:** The data for number of granted BTDs was obtained from FDA.gov. The data for publically disclosed BTDs was obtained from sponsor's press releases. For all products the information for their mechanism of action, type of molecule, trial design, clinical efficacy and safety, and pricing and time to approval (for approved products) were obtained from peer-reviewed publications, conference abstracts, FDA and sponsor websites.

**Results:** Since the establishment of the BTD pathway, 37 products have been granted breakthrough therapy designations (2012-2013), of which, 28 have been publically disclosed by the manufacturers and 3 have been approved by the FDA. In terms of indications, 12 (43%) are for cancer, 5 (18%) are for genetic diseases and 4 (14%) are for Hepatitis C Genotype 1. The three approved drugs with BTD are Gazyva, Imbruvica and Sovaldi. The median time to approval for these three drug was ~5 years, significantly shorter than the 2012 median time to approval for priority review applications (6 years). However, the price premium was 30-50% compared to other drugs in the same category. Two of the drugs with BTD did not meet primary endpoint in their pivotal trial. While the BTD pathway promises to reduce development time, the high price is a major concern for payers and patients.

**Conclusions:** BTD is a promising pathway to shorten development time and provides early access, however, high price could pose challenges for payers and patients.

## PO.146

### Determining Patients Preferences for Use in a Multi-Criteria Decision Analysis Aid for Osteoarthritis

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**Background:** Osteoarthritis is a highly prevalent and disabling disease. Various treatments are available but differ in respect to the benefits and risks they confer to patients. This has led to an interest in the use of decision aids as a means to facilitate patient engagement on treatment preferences. Annalisa® (AL) is a web-based decision-support aid grounded in multi-criteria decision analysis (MCDA). In using AL, the patient indicates the relative importance of different preferences. These weights are then combined with effectiveness data to calculate a score for each treatment option.



**Objectives:** To generate a list of potential attributes for use in a MCDA decision support aid for osteoarthritis.

**Methods:** A systematic review of the literature was undertaken to identify both qualitative and quantitative studies reporting on treatment preferences of patients with osteoarthritis. Online databases including Medline, Embase, PsychInfo were searched along with Google scholar. Data from included studies was then extracted.

**Results:** The literature search identified 386 studies, with 20 studies reporting on relevant outcomes. Eleven studies were qualitative studies, with the rest reporting quantitative outcomes. The majority of studies focused on preferences of individuals undergoing or contemplating joint replacement surgery. Almost all of the 22 studies noted the importance of improvement in clinical outcomes such as pain and function. Other considerations such as ability to participate in family life, out of pockets costs, impact on body image were also reported.

**Conclusions:** Clinical outcomes such as pain reduction and improved function are not the only factors that patients with osteoarthritis consider when making trade-offs between different treatments. While effectiveness data is easier to obtain on clinical outcomes; the challenge is to obtain estimates of effectiveness for other attributes that fall outside the traditional clinical realm but are considered important to patients. In doing so, this will improve the quality of the decision for patients.

## PO.147

### Are Drug-Eluting Stents More Effective and Safe Than Bare Metal Stents for Coronary Artery Disease Treatment? an Updated Systematic Review

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**Background:** Percutaneous Coronary Intervention with stenting is one of the main strategies for Coronary Artery Disease treatment (CAD). Stents are tubular metal structures that can be metallic (Bare Metal Stents-BMS) or drug-coated (Drug Eluting Stents-DES).

**Objectives:** We aimed to evaluate if DES are safer and more effective than BMS and if there are differences between the various DES.

**Methods:** We searched for systematic reviews (SR) of randomized controlled trials comparing DES with each other or to BMS in Medline and EMBASE databases until May 18, 2013. We also searched for observational and Health Technology Assessments (HTA) studies. Quality of evidence was evaluated according to the GRADE system.

**Results:** We included 28 SR; 14 had moderate to high quality that lead to a weak recommendation in favor of the technology for most studies. The use of DES was associated with a significant reduction of revascularization and major adverse cardiac events compared to BMS. There was no difference in the mortality risk, myocardial infarction and intrastent thrombosis. DES were associated with a higher risk of thrombosis. Among DES, sirolimus and everolimus eluting stents showed better results. The efficacy and safety profile for diabetic patients was similar to that observed for other patients. We included 34 observational studies which results agreed with those of the SR. We selected four HTA that recommended the use of DES when cost is considered acceptable and for patients considered at high risk of restenosis.

**Conclusions:** There was consistency between studies regarding the efficacy of DES compared to BMS in revascularization rate reduction. However, in robust outcomes there was no difference between the various technologies compared. Therefore, DES may be superior than BMS only for patients at high risk of being subjected to reintervention, such as diabetics, and further studies in this subpopulation are needed to support this statement.

## PO.148

### The Cost-Utility of Exercises in the Management of Osteoarthritis of the Knee and Hip: a Systematic Review

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**Background:** Osteoarthritis (OA) is a chronic progressive disease of the joint, characterized by the loss of articular cartilage, appositional new bone formation in the subchondral trabeculae and the formation of osteophytes. The effectiveness of exercises to treat OA is well documented in the literature but little is known about their cost-utility.

**Objectives:** To evaluate the cost-utility of exercises in treating patients with hip and knee OA.

**Methods:** The search was carried out by a specialist librarian in the following databases (initiated – January 2014): Embase, Medline, Web of Science, Scopus, Cinahl and PubMed as supplied by the publishers and Cochrane economic evaluations. No language restrictions were applied. Studies were eligible if they were randomized controlled trials that reported an economic evaluation concerning exercises to treat patients with hip and/or knee OA. Two independent authors reviewed the selected trials, performed data extraction and assessed the risk of bias using the Cochrane Back Review Group and The Consensus on Health Economic Criteria (CHEC) scales. Disagreement was resolved by consensus and by third party adjudication. Publications related to the included studies were used to assist these processes.

**Results:** The database searches identified 2,553 articles. After removing the duplicates 1,491 references (title and abstract) were examined by two independent authors, followed by the full text of 55 references. Ultimately we included 10 studies in this review. Six of these studies included only patients with knee OA; one study included only participants with hip OA and the other 4 included mixed hip and knee OA patients. The exercise therapy (on land and in water) was compared with exercises or with a control group (usual care, no intervention, telephone contacts, educational groups). The results will be presented at the Conference.

**Conclusions:** These will be presented at the Conference. Acknowledgements: Grants MCTI/CNPq/MS- SCTIE- Decit # 06/2013 and PhD sandwich scholarship from CAPES.

## PO.149

### Breast Cancer Screening in Estonia: Effectiveness and Costs

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**Background:** Mammography screening is a commonly used breast cancer screening method worldwide. In Estonia mammography screening programme started in 2002 and women in the age group of 50–62 years, covered by health insurance are invited to get screened every two years. However, until now, the effectiveness and costs of the national screening programme are not known.

**Objectives:** To evaluate the effectiveness and costs of existing breast cancer screening programme in Estonia.

**Methods:** The data from Estonian Health Insurance Fund and Estonian Cancer Registry was linked to assess the effectiveness and costs

related to breast cancer screening and additional testing in Estonia in 2008.

**Results:** 30,114 women who participated in mammography screening in 2008 were identified, meaning that only 32% of women targeted attended the screening programme. In total 3.3% (964) of the women screened were invited to have additional tests and 807 of them (83.7%) were false-positives. As a result of screening 157 breast tumours were diagnosed, out of which 38 were benign and cancer treatment was started in 119 women. In 2008 667 new cases of breast cancer were reported in Estonia, thus 17.8% originated from screening. The total cost of mammography screening in 2008 was 1,217,000 euros, including screening mammograms (802,000 euros), follow-up tests to rule out false-positive result (305,000 euros) and programme management costs (110,000 euros), which on average makes 40 euros per woman screened.

**Conclusions:** Only 18% of the breast cancer cases diagnosed in Estonia in 2008 were identified by the screening programme. To diagnose one case of breast cancer, 250 women had to be screened. The total cost of the screening programme was 1,217,000 euros and an average cost of detecting one cancer was 10,227 euros. Based on the analysis conducted, recommendations were given to improve the organization of the national screening programme.

## PO.150

### A Systematic Review About Use of ICD-10 Codes to Identify Adverse Drug Events in Inpatients

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**Background:** The occurrence of adverse drug events (ADE) is associated with increased morbidity, mortality and higher costs. The use of ICD 10 codes can contribute to the launch of monitoring events particularly when used together with others identification methods like voluntary reporting.

**Objectives:** To review literature to build a comprehensive list of ICD 10 codes used to identify ADE of hospital admissions from national administrative databases.

**Methods:** A search was conducted on Medline, Embase and Lilacs, until October 2013. There were no language restrictions. Studies were included that identified ADE by ICD 10 codes using hospital administrative databases and displayed their set of codes. We excluded studies where population was selected for specific drugs or diseases. ADE was defined as any injury occurring during the patient's drug therapy and include adverse drug reactions during normal use of the medicine, and any harm secondary to a medication error. Two independent reviewers made the selection, critical assessment and data collection. Codes were grouped as follows: poisoning, general codes, vaccines, transfusion blood and external cause.

**Results:** We found four articles that presented their list of codes. Reviewing these lists yielded 856 codes related with ADE, 495 were included at least in two studies, but only 72 in all four studies. The remaining 361 were included in only one study. There is a large variability between studies in the inclusion criteria and in the set of codes used. All studies included some codes about complications from transfusion blood, two included poisoning, three external cause (y40-59.9) and three vaccine-associated codes.

**Conclusions:** The compiled list of codes can be a point of consensus to define a list for national application, but it is necessary to consider differences in national databases, adaptations and versions of ICD 10 codes.

## PO.151

### Insulin Pumps for the Treatment of Type 1 Diabetes Mellitus: why is Uptake So Low in the UK?

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**Background:** NICE technology appraisal TA151 (Continuous subcutaneous insulin infusion [CSII] for the treatment of diabetes mellitus) was issued in July 2008, replacing TA57 from February 2003 and recommending uptake of CSII pumps in (1) adults with type 1 diabetes mellitus (T1DM) who fail to reduce HbA1c <8.5%, or disabling hypoglycaemia using multiple daily injections (MDI), (2) and children without requiring previous MDI-failure. CSII uptake in the UK rose to 4% between 2003–2008 and to 6% between 2008–2013. It still lags behind NICE's 2008 benchmark of 12%, in addition to uptake in other Western countries.

**Objectives:** We aimed to understand why the UK has comparatively low pump uptake.

**Methods:** We performed a structured PubMed literature review using search terms "Continuous subcutaneous insulin infusion" AND glycaemi\* OR hypoglycaemi\* OR "costs and cost analysis[MeSH]"; published after 01/01/2008. Captured articles were sifted; excluding irrelevant articles, or those not in English. Other relevant reports were captured by horizon scanning.

**Results:** Our search terms captured 113 articles. Reviewing reports meeting the inclusion criteria revealed that since 2008, additional studies contribute evidence supporting CSII efficacy in improving HbA1c, glycaemic variability and incidence of hypoglycaemia compared to MDI; in addition to being well-tolerated by patients. Recent cost-analyses suggest that CSII remains cost-effective, especially when increasing baseline HbA1c, hypoglycaemia avoidance, or pump life expectancy. Furthermore, there may be a low availability of specialised nurses, dietitians and other clinicians that NICE recommends are required to form part of a CSII-specialised multi-disciplinary team.

**Conclusions:** It is surprising that given the amount of evidence supporting the efficacy, safety and cost-effectiveness of CSII, uptake of pumps by T1DM patients remains low in the UK. It is interesting that current evidence may be undermined by poor availability of clinical staff specialised in CSII, thus preventing new patients from effectively managing their condition.

## PO.152

### Direct and Indirect Costs of Diabetes and Its Related Complications – Data from Poland

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**Background:** An estimated 3.1 million Polish adults had diabetes in 2012, whereas at least 19% of the total population are at high risk of developing diabetes. The national healthcare burden of diabetes is a growing problem in Poland.

**Objectives:** The aim of this study was to access direct and indirect costs attributable to the treatment of diabetes and its related complications in Polish settings in years 2009-2012.

**Methods:** Direct costs were estimated based on data provided by public payer in Poland (National Health Fund). Indirect costs resulting from productivity loss were calculated using records obtained from Social Insurance Institute in Poland. An average salary approach was used to value productivity loss due to work absenteeism. Transfer payments were not added to productivity loss calculations. The impact of diabetes complications on health care system was assessed based on attributable risk methodology.

**Results:** In 2012 the total costs of diabetes and its complications treatment - both direct and indirect - accounted for 5.6 billion PLN (1.34 billion €). Over a half of those costs were driven by diabetes complications. Hospitalization and outpatient care expenses spend on complications management were 3.5 times higher than expenses spend on diabetes treatment itself. Similar dependence was observed for indirect costs. Costs of antidiabetic drugs reimbursement were 740 million PLN (176.8 million €) in 2012 which was approximately 13% of total costs. Time trend analysis showed that over the period of 2009-2012 the highest increase was reported for diabetes complications (~20%), whereas diabetes treatment expenses grew only by 7%.

**Conclusions:** Diabetes imposes a large economic burden in Poland, yet most of total costs are driven by diabetes complications, which could be somewhat controlled by better allocating resources to diabetes prevention and treatment.

## PO.153

### James Lind Alliance Priority Setting Partnerships: a Unique Forum for Identifying Potential Questions for Comparative Effectiveness Research

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**Background:** Since 2004 the James Lind Alliance Priority Setting Partnership (PSPs) have provided a method for patients and clinicians to work together on equal terms to identify and prioritise treatment uncertainties concerning specific conditions. The patient's understanding and experience is central to this process and many patients and clinicians attest to its uniquely positive value.

**Objectives:** PSPs bring together patients, carers and clinicians to explore treatment uncertainties within a specified condition or disease area. A rigorous prioritisation process results in a 'top ten' list of treatment uncertainties. This list informs the research priorities of interested parties - including academia and research funders - and often leads to comparative effectiveness research studies.

**Methods:** Organisations and individuals participating in a PSP ask their members and those they represent to submit uncertainties via a survey; these are then checked and verified as true uncertainties. The final stage is a face-to-face priority setting workshop where a top ten list of uncertainties is agreed.

**Results:** 18 PSPs have been completed in a wide range of conditions. The majority of PSPs result in funded research, including a joint international research call in the area of schizophrenia.

**Conclusions:** Patients and clinicians working together on equal terms and using a stringently controlled, transparent process produce research questions that cannot be identified in other ways. The strengths of this unique model provide opportunities for all who define and fund health research.

## PO.154

### Giving Patients a Voice: the Use of Patient-Reported Outcomes in Research with Patients with Rare Diseases

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**Background:** Patient-reported outcomes (PROs) report the status of a patient's health condition directly from the patient. PROs enable the patient to provide information about the impact of health technologies, and are often the outcomes of most significance to patients.

**Objectives:** To explore the experiences of researchers and health technology assessment (HTA) experts regarding the use of PROs in studies

investigating the effectiveness of new health technologies for patients with rare diseases including lysosomal storage diseases (LSDs).

**Methods:** International researchers and HTA experts were invited to participate in a telephone interview conducted in English. A semi-structured questionnaire was used to explore the opportunities and challenges arising with the use of PROs. Interviews were audio-taped and transcribed verbatim. The research team employed thematic analysis to identify recurrent themes in the anonymized transcripts.

**Results:** Seven researchers and four HTA experts representing seven countries in Europe and North American participated. This sample was comprised of four women and seven men. Researchers and HTA experts acknowledged the importance of using PROs for which there was evidence of validity and responsiveness when evaluating quality of life or other outcomes. The participants indicated that often the data is incomplete for PROs. Researchers indicated that this may occur because the study questionnaires that include the PROs were long and time consuming, or because many PROs do not specifically address the patient's outcomes of interest or concern. Researchers and HTA experts outlined several suggestions regarding the development of new PROs for rare diseases. These included ensuring patients are involved in the development of a concise, valid and responsive PRO, and offering the PRO online.

**Conclusions:** Researchers and HTA experts acknowledge the importance of using PROs but describe challenges to the use of PROs available for research with patients with rare diseases. Further research to develop new PROs with patient input appears indicated.

## PO.155

### Center for Technology Assessment in Health in Hospital of Sao Paulo/Brazil: an Experience Report

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**Background:** The Health Technology Assessment (HTA) is a process that evaluates and regulates the use of technologies in health (since innovation, diffusion, incorporation, and until the abandonment), offering technical grants based on the best scientific evidence and contributing to decisions on health. It is a multidisciplinary research, which has as a fundamental tool to critical assessment of the validity of the clinical research carried out with the new technology. To do this, managers need to use instruments that produce reliable information for decision-making.

**Objectives:** The study aimed to report the experience of the Center for Technology Assessment in Health in hospital of Sao Paulo/Brazil.

**Methods:** The NATS/HCFMB was deployed in January 2010. For your deployment featured resources from the public call for deployment of Center for Technology Assessment in Health (NATS) in teaching hospitals offered by the Ministry of health of Brazil, in the year 2009.

**Results:** The construction of the NATS allowed a preparation of the input stream of demands of HTA and the production of scientific and technical advice; initiation of the preparation of the team of NATS to development activities of HTA; beginning of the creation of an internal information network involving all professionals of health HCFMB aimed at identification of researchers and teachers who perform or have an interest in developing research in HTA and HTA tool use in managerial practice; beginning of realization of educational activities for students and health professionals; and techniques for developing research activities focused on evaluation of health technologies.

**Conclusions:** The deployment of NATS contributes to the dissemination and knowledge of the activities developed in HTA in the institution and in Brazil as well as for the decision-making of managers of health services.

**PO.156****Public Input for Supporting Policy Development for Pharmacogenomics - a Scoping Review**

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**Background:** Pharmacogenomic (PGx) technology – offering the right drug to the right person at the right time - holds the promise of reducing health care costs, avoiding unnecessary or ineffective therapy, and increasing patient adherence to drug therapy. Potential downfalls of PGx related to social and policy challenges include: preparing clinicians and healthcare institutions to manage genomic results, additional costs for testing, expanded patient populations for some drugs, increased diagnostic budgets, enforcement of privacy safeguards, and extended patent protection for secondary tests not co-developed with drugs. The extent to which these factors affect the social value proposition of PGx is unclear.

**Objectives:** To determine what is known about the public sentiment around these potential downfalls of PGx in order to support policy development in the area.

**Methods:** A scoping review was conducted using widely accepted methodology. A comprehensive search was conducted via the OVID platform for MEDLINE, EMBASE, EBM HTA and CINAHL databases. Grey literature was sought through internet searches and reference lists of all screened articles were reviewed. Title and abstract screening and selection of literature were performed independently by two reviewers. A structured data extraction form was developed and suitable quality assessment completed. Data was analyzed using standard qualitative techniques including thematic analysis.

**Results:** Through surveys, interviews, and focus groups, public attitudes and views surrounding issues of costs of tests, inequities in access, and the privacy and use of genomic test results beyond their intended purpose have been examined. Surveys indicated limited awareness and knowledge about PGx. There is no information on the public's views about several of the potential downfalls representing social and policy challenges of PGx.

**Conclusions:** In order to support policy development, studies eliciting views of the public on a wider range of issues are required. Methods designed to elicit an informed public view are recommended.

**PO.157****Systematic Review and Mixed Treatment Comparison of Lithium or an Atypical Anti-Psychotic Used to Augment a Selective Serotonin Reuptake Inhibitor (SSRI) in Treatment Resistant Depression**

Victoria Wakefield; Steven J Edwards; Leo Nherera; Nicola Trevor

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**Background:** Pharmacological treatment options for patients with treatment resistant depression (TRD) include use of an augmenting agent, such as lithium or an atypical anti-psychotic (AAP). However, there is limited evidence available on the effectiveness of these strategies in TRD.

**Objectives:** To estimate the clinical effectiveness of augmentation of SSRI antidepressant therapy with either lithium or an AAP in TRD, defined as failure to respond to two or more antidepressants in the current episode of depression.

**Methods:** Systematic review of CENTRAL, EMBASE, MEDLINE, and PsycINFO was completed in August 2011. Additional data were obtained from manufacturers. Studies were assessed for quality using the Cochrane Risk of Bias Tool. Pairwise meta-analysis and mixed treatment comparison (MTC) were undertaken based on intention-to-treat analyses.

**Results:** Of the 3,721 papers found in the literature search, 12 randomised controlled trials (RCTs) were identified; 10 (SSRI + AAP vs SSRI + placebo/no treatment); 1 (SSRI + AAP vs SSRI + lithium); 1 (SSRI + lithium vs SSRI + placebo). The RCTs included in the primary analyses used fluoxetine as the SSRI and olanzapine as the AAP. Results of the MTC showed a non-significant trend in favour of lithium augmentation for response [lithium odds ratio (OR) 1.29; 95% credible interval (95% CrI): 0.11 to 5.32], mean change in Montgomery-Åsberg Depression Rating Scale (MADRS) score from baseline (mean difference -1.47; 95% CrI: -9.10 to 6.41) and all-cause withdrawals (OR 0.74; 95% CrI: 0.10 to 2.66).

**Conclusions:** In patients with TRD, there is a lack of direct evidence comparing the clinical effectiveness of augmenting an SSRI with an AAP compared with augmenting with lithium. Augmentation of SSRIs with lithium or AAP is likely to be beneficial in people with TRD. The limited evidence indicates no statistically significant difference between the two augmentation strategies.

**PO.158****Fecal Microbiota Transplantation (FMT) for the Treatment of Recurrent Clostridium Difficile-Associated Diarrhea (CDAD) why Renewed Interest in an Old Technology?**

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**Background:** Clostridium difficile is the leading cause of healthcare-associated infectious diarrhea. Recurrent CDAD places a high burden on our health-care system and significantly affects the morbidity and quality-of-life in elderly patients. Management of this debilitating and potentially fatal disease remains clinically challenging as some patients repeatedly fail standard antibiotic treatment.

FMT, a process of delivering a liquid suspension of feces from a healthy donor into a patient's gastrointestinal tract through a nasoduodenal catheter, colonoscope, or enema catheter, was first introduced in 1958 but has only gained popularity in recent years.

FMT has not followed the usual technology diffusion curve with a bolus of research being published over the last three years.

**Objectives:** To determine the clinical status of FMT.

**Methods:** A systematic review of the research evidence was conducted and published in 2011. An updated search in January 2014 indicated the need for a reassessment.

**Results:** Our 2011 systematic review showed that FMT was a promising but not yet an established technology due to low level of evidence. The updated search revealed more than 60 relevant abstracts, including several systematic reviews/ meta-analyses, one long-awaited randomized controlled trial, and numerous case series and case report studies.

FMT has been used increasingly by healthcare professionals and accepted by patients, reflecting a rapid transition from being a promising to an accepted clinical intervention over a 2-year span.

**Conclusions:** Several explanations are proposed for the rapid change in clinical status of an old, low profile, and inexpensive technology: (1) severe CDAD epidemic in North America and Europe in recent years; (2) patient resistance to antibiotics against CD; (3) new concept of "intestinal microbiota as a dynamic human organ" with increased research in this area; (4) recent publication of a randomized controlled trial; (5) high patient acceptance of FMT. Information about patients' perspectives and preferences should be integrated into reassessment.

**PO.159****Capturing the Patient Voice in the Scottish Medicines Consortium's Advice**

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**Background:** The Scottish Medicines Consortium strives to ensure that the patient/carer perspective on new medicines is always taken into consideration in its decision making. Written submissions of evidence are actively sought from Patient Interest Groups and these are presented to the Committee by a member of the SMC Patient and Public Involvement Group (PAPIG). The submissions from the Patient Interest Groups are an important part of the discussion and decision making, but to date they have not been reflected in the SMC advice, known as detailed advice documents (DADs). Patient groups were not clear that their view had been recognised.

**Objectives:** A pilot study was designed with the aim of condensing the Patient Interest Group submissions into a bullet point summary to capture this perspective in the DAD.

**Methods:** The pilot was carried out for a 6 month period. Clearly laid out standard principles ensuring a consistent style were developed. One of three members of PAPIG, known as a 'public partner', prepared a summary of the Patient Interest Group submission. These draft summaries were then tabled at SMC meetings for consideration and comment by members. After 6 months, feedback on the principle and content of the summaries was requested both from the submitting Patient Interest Group (via emailed questions) and SMC members (via an online survey).

**Results:** The principles regarding the content of the summaries were accepted. It was challenging to develop a system in which observational data and personal testimony in submissions could be described in a document based on assessment of scientific evidence. The feedback both from the Patient Interest Groups and SMC members was extremely positive and supportive of the summaries being published in the DADs.

**Conclusions:** From March 2014 SMC published advice will include a summary of the Patient Interest Group's view on the patient experience with the medicine under review, where this is submitted. This will ensure that this vital perspective as considered by SMC is now a component of the advice.

**PO.160****Localized Prostate Cancer: an Interdisciplinary Collaboration to Improve Treatment Pathway**

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**Background:** Several therapeutic options are available for localized prostate cancer (PCa) including radical prostatectomy (RP), external beam radiation therapy (EBRT), brachytherapy (BT), and active surveillance (AS). However, divergence exists among experts about which option should be preferred and how to support patients' choice.

**Objectives:** To integrate health technology assessment (HTA) approach for localized PCa treatment into the development of an informed-decision making process.

**Methods:** A systematic review (SR) the effectiveness and harms associated to options for localized PCa was performed in Medline, Embase, Cochrane Library and grey literature. Outcomes included PCa-specific and all-cause mortality, general and specific health-related quality of life (urinary, sexual intestinal functions), and adverse effects (secondary cancer, radiation toxicity, inguinal hernia, urethral stricture). An interdisciplinary group of experts (IGE) including specialists in uro-

oncology, radiation therapy and HTA was created to develop the HTA protocol and share the results and recommendations.

**Results:** According to the balance between benefits and harms, results from the SR suggest that EBRT, RP, BT and AS remain acceptable options for localized PCa (low and intermediate-risk).

In addition to patient preferences, the IGE considered that clinical effectiveness and adverse effects specific to each treatment option should be presented to patients. A subset of information to support patients' treatment choice was then developed and shared within the IGE in order to reach a consensus on what information should be given to patients.

**Conclusions:** Collaboration with an IGE within an HTA approach may contribute to support best clinical practices. In this project, integration of evidence-based knowledge was intended to improve informed-decision making process and could ultimately lead to a patient-centered PCa treatment pathway. The next step will focus on how and by whom this information regarding the localized PCa options should be communicated to patients.

**PO.161****The Role of HTA in Quality Improvement: Preventing Healthcare Associated Infections in Different Regions Around the World**

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**Background:** The World Health Organization (WHO) has identified Healthcare Associated Infections (HAIs) as a leading cause of preventable morbidity and mortality. The cost of treating avoidable HAIs is substantial and could be significantly reduced with the implementation of evidence-based guidelines targeting effective infection control. In light of the global impact of HAIs, we propose a panel to discuss the unique ways that HTA is informing clinical practice and policies in the prevention of HAIs across the world.

**Description/Objectives:** The objective of the panel is to identify mechanisms where HTAs inform clinical guidelines, translate policy mandates into practical recommendations and improve the overall quality and efficiency of health systems. Independent hospital-based HTA: Showcase hospitals in the UK that undertook local reviews of infection related technologies that have helped hospital administrators make decisions on infection prevention programs. Government agency-based HTA: The Canadian Agency for Drugs and Technologies in Health (CADTH) has issued many HTAs and rapid reviews on diverse infection-related areas. Showcase how these reviews have informed clinical practice. Emerging markets: Showcase examples of how government entities in emerging markets use HTA to inform clinical practice around HAI infection and prevention. The Brazilian Ministry of Health released their first centralized regulation around endoscopy clinics to bring smaller ambulatory centers to a higher standard. China has finalized its first flexible endoscope reprocessing guidelines which include recommendations on hospital processes and purchasing.

**PO.162****Patients/Users and Citizens Consultation in Evaluating Technology and Social Care Intervention or in Developing Social Care Guidelines: the Inesss Collaborative Approach**

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INESSS, Montréal, Canada

**Background:** The mission of the Institut national d'excellence en santé et en services sociaux (INESSS) is to promote clinical excellence and

the efficient use of resources in the health and social services sector. INESSS assesses the clinical advantages, cost-effectiveness, as well as the social, ethical, organizational and economic implications of technologies, drugs and interventions in health care and social services. It makes recommendations and develops guidelines to support decision-making. In order to do so, it relies on knowledge coming from various sources of information including patients/users and citizens' point of view.

**Objectives:** Patients/users and citizens are affected by the questions being evaluated by INESSS, and they will have to live with the results. Our challenge was to find an approach that would take their perspective into consideration and support their involvement. There so, we developed a collaborative approach, that aims to recognize and reflect the views of patients/users and citizens, value their participation and encourage their mobilization while keeping the entire evaluation process open, transparent, inclusive, ethical and democratic. We will demonstrate the strengths and limits of this approach, central to the scientific evaluation process at INESSS.

**Methods:** We will illustrate how the collaborative approach was integrated into the scientific evaluation process through examples of patients/users and citizens' consultation and strategies implemented to support their involvement.

**Results:** Our observations of the implementation of the collaborative approach revealed that various aspects of the patients/users and citizens' participation need to be considered, e.g. selection and recruitment, type of involvement (committee, focus group, interview), demographic characteristics and representativeness. Perceptions of patients/users and citizens with regard to their experience and their motivation should also be examined.

**Conclusions:** Examples and solutions will be presented and discussed pertaining participants' roles and expectations, and the optimal use of their knowledge.

### PO.163

#### Intraoperative Radiation Therapy in the Treatment of Breast Cancer

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**Background:** IORT enhance local control of disease by administering a single radiation directly to the tumour bed, thereby enabling dosages to be increased and toxicity decreased through less irradiation of healthy tissue.

**Objectives:** To assess safety and effectiveness of IORT as adjuvant or replacement treatment for the standard treatment of breast cancer.

**Methods:** We conducted a systematic review with a search of the scientific literature from 2000 to 2013 in the main biomedical databases.

**Results:** 44 reports met the inclusion criteria, with 2310 patients included in booster and 5494 in monotherapy. IORT booster recurrence was 6.5% at 5 years and survival around 91% at 5-7 years. The cosmetic results were good in 90% of patients and the toxicity was moderate. The most frequent complications were fat necrosis, seroma and skin toxicity, with worse results after IORT. The recurrence of IORT ranging from 1.22%-7% at 4-10 years, higher than conventional treatment, though without statistical significance. Overall survival was close to 90% at 10 years, with good cosmetic results in 90% of patients. The complications indicated that IORT patients presented a higher incidence of ulceration, fat necrosis, infections, seromas and haematomas than conventionally treated patients, with a lower incidence of pain, fibrosis and oedema, though in most cases without statistically significant. IORT seemed to improve certain aspects of quality of life, pain, as compared to patients treated with an IORT booster or conventionally, though these differences failed to prove statistically significant.

**Conclusions:** IORT booster does not increase the effectiveness and overall survival, nor does it entail a significant reduction in terms of safety with respect to conventional treatment. IORT single dose is associated with a comparable effectiveness to the conventional treatment and, despite low toxicity, does not improve the safety of conventional treatment to any significant degree.

### PO.164

#### Intraoperative Radiation Therapy in the Treatment of Colorectal Cancer

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**Background:** IORT enhance local control of the disease by administering a single dose of radiation directly to the tumour bed, thereby enabling dosages to be raised without increasing related toxicity, and thus constituting a complement to current treatment of locally advanced and recurrent colorectal cancer.

**Objectives:** To assess the effectiveness and safety of IORT boost for the current standard treatment of colorectal cancer.

**Methods:** We conducted a systematic review with a search of the scientific literature from 2000 to 2013 in the main biomedical databases.

**Results:** 23 reports met the inclusion criteria with 3155 patients included, recruited from 1990s to 2010-2011. In locally advanced disease, clinical trials did not show significant improvement in efficacy and survival over controls, with local control (LC) and overall survival (OS) of 90%-92% and 64%-70% at 5 years. Systematic reviews indicated that IORT treatment reduced LC and helped improve LC and OS, without increasing complications. In recurrent disease recurrence was 30%-46% and LC 41%-68% at 5 years. OS did not exceed 43% at 5 years, with results being broken down by margin status (R0:46%-63%, R1:26% and R2:0%-24%). Safety did not improve in either locally advanced or recurrent disease. None of the clinical trials detected significant differences between the two types of treatment. The most frequent complications were surgical wounds, gastrointestinal complications, urethral obstructions and peripheral neuropathies.

**Conclusions:** IORT treatment of locally advanced disease achieves good results, but it does not amount to an increase in effectiveness and OS, or to a significant reduction in complications regard to conventional treatment. IORT does not increase the complication rate, displaying comparable short- and long-term complications. In the recurrent disease, the available evidence is, not only of low quality, but is far less abundant.

### PO.165

#### Regulatory Agency in Health: a Judicialization Analysis

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**Background:** The creation of the Agência Nacional de Saúde (ANS) meant a large regulatory event to increase the quality of health insurance providers. It meant the expansion, regulation and control in Brazilian health insurance system, with an impact on public health in our country. Because of the number of beneficiaries and the impact that supplementary health system in health care system, the studies in this area are important to the improvement of health services.

**Objectives:** The aim of this study is to provide a quantitative analysis of the questions from beneficiaries received by Agência Nacional de Saúde (ANS) in the Gerência de Atenção à Saúde in 2012 and 2013. We classify the data according to State, relevance of fate and questions destination

**Methods:** According with these data, we received 175 and 190 questions in 2012 and 2013, respectively. The states of southeastern and southern ranked at the top in two consecutive years, São Paulo was leading with 24 % in 2012 and 22.6 % in 2013. We can associate this result to larger amount of beneficiaries in the region and discuss the quality of care provided to the beneficiaries, because 47 % of the health procedures that are coverage were denied in 2012 and 45 % in 2013.

**Results:** To improve the quality of this service, ANS can be closer to the judiciary to establish a permanent channel of communication and provide a technical documents on the agency website for consultation, especially in health events that generate more questions, such as: Pet-Scan, IMRT Radiotherapy and appointments with health professionals

**Conclusions:** These measures can disseminate the information on health care coverage according to the year of consultation and increase the quality of health services in the Brazilian supplementary health system

## PO.166

### Cost-Effectiveness of Lithium Versus an Atypical Anti-Psychotic (Aap) Used to Augment Treatment with a Selective Serotonin Reuptake Inhibitor (Ssri) in Treatment Resistant Depression (TRD)

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**Background:** Pharmacological treatment options for patients with TRD include use of an augmenting agent, such as lithium or an AAP. However, there is limited evidence available on the cost-effectiveness of these strategies.

**Objectives:** To estimate the cost-effectiveness of augmentation of SSRI antidepressant therapy with either lithium or an AAP in TRD, defined as failure to respond to two or more antidepressants.

**Methods:** CENTRAL, EMBASE, MEDLINE, PsycINFO and NHS Economic Evaluation Database (NHS EED) were searched from inception to August 2011. Additional data were obtained from manufacturers.

Systematic reviews of the economic and quality of life (QoL) literature were executed. Studies were assessed, independently by two reviewers, for quality against predefined criteria. A de novo probabilistic economic model was developed to synthesise the available data on costs and clinical effectiveness from UK NHS perspective; time horizon 1-year (8 weeks of acute treatment and 10 months of maintenance treatment).

**Results:** Four economic evaluations (none directly addressing the review question) and 17 QoL studies were identified and summarised in narrative reviews. Model results indicate that augmentation of an SSRI with lithium dominates augmentation with AAP (i.e. results in cost savings of £905 per person per year and generates more health benefits, estimated to be 0.03 quality-adjusted life-years). However, sensitivity analyses showed that the model was highly sensitive to changes in acute treatment efficacy (response and remission) or discontinuation. The model was not sensitive to changes in other parameters.

**Conclusions:** Cost-effectiveness analyses suggest that augmentation with lithium is less expensive and more effective than augmentation with AAP. However, the uncertainty in the clinical estimates of discontinuation and treatment response is reflected in the model results. An RCT comparing the two augmentation strategies, reporting relevant outcomes, including QoL, is needed.

## PO.167

### Treatment Patterns and Health Outcomes Among Patients in the Waiting List of Bariatric Surgery: a Non-Interventional Single-Site Retrospective Longitudinal Survey – Preliminary Results

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**Background:** Obesity is a chronic condition that leads to an increased risk of death and other chronic debilitating conditions. Obesity and its related co-morbidities were associated with USD 270 million annually as direct costs at SUS in 2013. In Brazil, according to data from 2013 nearly half of the population has overweight and/or obesity.

**Objectives:** To describe treatment patterns, epidemiology, resource use of morbid obese patients eligible to bariatric surgery in the waiting list for surgery, in order to identify the clinic burden of not providing surgical treatment to eligible patients.

**Methods:** Non-interventional, single center, retrospective cohort with medical chart review of patients. The study revised data from a single reference bariatric site. Three hundred patients who met eligibility criteria had their registry data extracted and the patient outcomes were followed for up to 12-months post-bariatric-surgery. Study population was adult patients eligible to bariatric surgery, according to the Brazilian government criteria undergoing gastric bypass Roux-en-Y covered by SUS in 2010.

**Results:** Data was summarized descriptively; 217(90%) of patients were female, 238(79%) were Caucasian, 57(19%) Black and 6(2%) Asian. 181(60,1%) patients were 20-39 years-old at surgery, 116(38,6%) were 40-59 and 4(1,3%) were >60 years-old. The mean time in the waiting list was 749 days (2,05 years). 196(64,9%) of patients presented hypertension at baseline, which 92,8% presented improvement/resolution 6-months after surgery. 70(23,2%) presented dyslipidemia, with resolution of 91,43% after 6-months. 56(18,5%) presented diabetes, with resolution of 91% after 6-months.

**Conclusions:** Additional analysis is needed mainly to determine the clinic and economic burden of not providing surgical treatment to patients eligible to bariatric surgery, to measure the effect on the medication use for obesity related co-morbidities, its associated costs and the complication rate of open surgery. The preliminary analysis demonstrated a tendency that bariatric surgery might be associated with co-morbidity improvement/resolution.

## PO.168

### Inter-Temporal Change of Body Mass Index in Brazil: What is the Role of Food Prices?

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**Background:** Obesity can be understood as a problem resulting from the imbalance between the intake and the individual caloric expenditure, which has sparked concern among researchers and policymakers in public health. The alert comes up with the fast growth in the prevalence of obesity in adults and children in Brazil.

**Objectives:** The challenge of this essay is to estimate the relationship between food prices and obesity, in order to check how the pricing impact on nutrition and health conditions of individuals between 2002 and 2009. The questions to be answered in this essay are: 1) what is the effect of food prices on change of BMI in Brazil? 2) this effect changes over time?

**Methods:** To assess the changes in BMI over time, first of all, we analyze its distribution using the relative distribution method proposed by Handcock and Morris (1998). Then, recentered influence function (RIF) regressions were applied to decompose the changes in the BMI distribution into composition and structure effects and identify the specific contribution of food prices.

Empirical estimates needed to carry out this work are based on micro-data from household budget survey-POF in two points of time: 2002-2003 and 2008-2009. The POF is accomplished by the Brazilian Institute of geography (IBGE) and investigates information about characteristics of households, families, residents and their respective budgets. Were considered only the information regarding the adult population aged less than 20 years.

**Results:** The main changes in BMI distribution showed that the density has moved to the right over the time and there were increases in the right hand tail.

**Conclusions:** The results show an increase in weight in at the top of the distribution and higher levels of obesity between the years of 2002-2009 in Brazil.

## PO.170

### Mobil Crisis Home Treatment an Alternative to Hospitalization

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**Background:** In order to meet the challenges of the welfare state in the 21st century, countries across Europe have made efforts to reorganize healthcare services. A central trend in the reorganizations process is less hospital admissions and more outpatient treatments. In 2009 psychiatric care in Silkeborg went through a reorganization process with that ambition. From a political point of view the criteria for success was financial savings. Inspired by the community-based treatment model Mobile Crisis Home Treatment (MCHT), established in the U.S., Canada and UK MCHT was established

**Objectives:** The basic idea of MCHT is to offer an alternative to hospitalization. Psychiatric treatment proceeds as home treatments based on the patient's daily life, where relatives are involved in an ongoing collaboration. The focus is on building, or restoring, the patient's ability to cope in a process of recovery and empowerment.

Based on organizational, patient- and relatives-related analyzes the treatment is documented, and the quality of MCHT is assessed.

**Methods:** A literature review. Furthermore, qualitative interviews with managers, staff, patients and relatives at MCHT have been conducted. In addition, a questionnaire survey has been done among acute psychiatric patients admitted to hospital and MCHT.

**Results:** The literature review concludes that MCHT is cheaper, is relevant in 80% of the cases where a patient could have been admitted to a psychiatric hospital. Based on the qualitative interviews several points of interest arise. One is how the patient thinks of himself when treated. When hospitalized the patient regards himself as precisely that, a patient. Patients in MCHT regards himself as a citizen, a part of a family, a provider etc. This point towards MCHT being a form of treatment that contributes to the empowerment of patients.

**Conclusions:** MCHT is a model suited for acute psychiatric treatment in Denmark and it contributes to the empowerment of patients.

## PO.171

### The Economic Burden of Newly Diagnosed Atrial Fibrillation in China

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1. Fudan University, Shanghai, China; 2. Laurentian University, Sudbury, Canada

**Background:** The prevalence of atrial fibrillation (AF) is increasing, but there is almost no study of the economic burden of AF in China.

**Objectives:** To estimate the economic burden of AF in China during the first year after initial diagnosis.

**Methods:** A prospective survey was conducted to collect information of newly diagnosed AF patients in 10 provinces throughout China. Patients were recruited and surveyed from February to November, 2010, and two follow-up visits were carried out semiannually. A human capital approach was used to calculate the indirect cost.

**Results:** The study recruited 590 newly diagnosed AF patients, of which 559 cases were qualified for baseline analysis, and 492 cases completed follow-up visits.

Direct cost per case in the first year after diagnosis was US \$1318, of which, outpatient costs accounted for \$545 and hospitalization costs were \$773. The indirect cost was \$525 per case in the first year after diagnosis, according to calculations based on per capita GDP, of which, the loss of income was \$254 and \$271 for the patient and his/her family, respectively. Therefore, the total AF-related costs per case during the first year following diagnosis were \$1843.

The prevalence rate of AF in China is about 0.61%, according to an epidemiological survey. Projecting the estimated costs nation-wide, we estimated the hospitalization and outpatient costs of all patients were about \$4.9 billion and \$3.5 billion, respectively, in the first year. The indirect costs were about \$4.3 billion. Thus, nationally, the total cost of patients with newly diagnosed AF was about \$12.7 billion during the first year after AF diagnosis.

**Conclusions:** AF poses a heavy economic burden in China, but the economic burden of AF could be reduced if patients receive early and effective treatments, maintain a stable condition, and avoid deterioration, hospitalization and surgery.

## PO.172

### Spatial Distribution of Records of Patients and Apparatus Glucometers: a Description of the Public Health System

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**Background:** In front of the current economic conditions in Brazil, in which technological innovation has an important role in the dynamics of economic growth, we intend to analyze the access to Glucose device used to control diabetes. The approach of this study is delimited to the following question: what are the factors that influence the insulin-dependent patients' access to glucometer?

**Objectives:** Therefore, the aim of this study is to evaluate the pattern of obtaining by glucometer -insulin dependent patients in the public health system in the city of Salvador state of Bahia, Brazil In period between 1998 and 2012.

**Methods:** Was performed Exploratory Spatial Data Analysis (ESDA) using the Index of Global Spatial Autocorrelation Moran (Moran's I). After the specification of the regression model econometric estimations and analysis of results were made.

**Results:** Initial results showed that there is a considerable concentration of patients in a few neighborhoods in the city of Salvador and



that this concentration does not have a very clear relationship with the socioeconomic conditions of these neighborhoods.

**Conclusions:** The final results showed that there was initially a great randomness in the distribution of glucometers. Random factors determine the probability of obtaining the blood glucose meter. The characteristics of the individuals themselves were not decisive in the probability of obtaining a glucometer, but the characteristics of the type of diabetes and the type of treatment. At the same time, patients who last entered in the system were less likely to receive the device. This suggests that there were changes in the distribution or availability of devices to be distributed in a more recent period.

## PO.173

### Health-Related Quality of Life (HRQoL) of Adults in Brazil: a Population-Based Cross-Sectional Study

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**Background:** Indicators of Health-related quality of life (HRQoL) can guide actions aimed to improve the quality of life. However, population-based studies are scarce in this field.

**Objectives:** To describe the HRQoL indicators, according to demographic, social and economic factors in a sample of adults living in the Federal District, Brazil.

**Methods:** Based on a representative sample of adults living in the Federal District, Brazil, each person was interviewed with questionnaires, including the EQ-5D-3L domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The collected health states were linked by the Brazilian EQ-5D index tariff. Data were analyzed with SPSS Statistics software (version 21) complex sample methods, adopting 0.05 alpha errors. The project was approved by the local ethical committee and the EuroQol Group.

**Results:** During the first semester of 2012, 1,852 individuals were interviewed and 1,820 (98.3%) were included. Female gender represented 59.8% (n = 1,089), with a mean age of 38.36 years (SD: 12.57), comparable to male (38.40 years, SD: 12.61). The mean EQ-5D-3L score was 0.906 (95%CI: 0.898 to 0.913). According to gender, the mean score was 0.892 (95%CI: 0.882 to 0.902) for female and 0.925 (95%CI: 0.914 to 0.935) for male. Individuals with higher qualifications, including respondents with a degree (n = 316), showed higher scores when compared to respondents without a degree: 0.938 (95%CI: 0.927 to 0.949) versus 0.899 (95%CI: 0.890 to 0.907). Unemployed individuals (n = 247) referred a mean utility of 0.878 (95%CI: 0.858 to 0.899), while the others, 0.910 (95%CI: 0.902 to 0.918). Finally, the score of lower social classes respondents (n = 166) was 0.852 (95%CI: 0.824 to 0.880) against 0.911 (95%CI: 0.904 to 0.919) for upper classes.

**Conclusions:** Our sample revealed an elevated HRQoL, which seems to vary according to demographic, social and economic factors. This variation needs better investigation, including confounding analysis.

## PO.174

### Clinical and economical evaluation of Trastuzumab for Metastatic Breast Cancer in Brazil: a Public Health System perspective

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**Background:** Trastuzumab is a recombinant humanized monoclonal antibody that selectively targets the extra-cellular domain of the HER2 receptor, and has significantly improved outcomes for women with both early and metastatic HER2-positive breast cancer. In 2013,

Brazilian National Sanitary Vigilance Agency (ANVISA) approved trastuzumab only for adjuvant treatment in patients with early breast cancer.

**Objectives:** To critically review the efficacy of the combination of trastuzumab to first-line chemotherapy in patients with HER-positive metastatic breast cancer, and evaluate the cost-effectiveness and budgetary impact in Brazil, using a Public Health System perspective.

**Methods:** A systematic review was conducted, with meta-analysis of all randomized clinical trials (RCTs) that evaluated chemotherapy with or without trastuzumab in patients with advanced breast cancer. Incremental cost per life-year (LY) gained with the combination treatment was evaluated using a Markov modeling approach, and real-world cost data. Costs and outcomes were discounted at 5% annually, for a life-time horizon. Budgetary impact was estimated using epidemiologic and economic data from the Brazilian Public Health System.

**Results:** We included results reported from four RCTs, with a total of 864 patients included in the meta-analyses. Compared to chemotherapy alone, the addition of trastuzumab to chemotherapy enhanced both Overall Survival (HR 0.81, CI95% 0.66-0.99, P 0.04) and Progression-Free Survival (HR 0.51, CI95% 0.43-0.61, P <0,001). Trastuzumab combined to chemotherapy, versus chemotherapy alone, resulted in a gain of 0.44 LY, with an incremental cost of \$17,500 per patient. Thus, the cost per LY gained was \$39,750. The net budgetary impact was estimated to be \$26,530,680 in the first year of incorporation.

**Conclusions:** The addition of trastuzumab to chemotherapy in patients with advanced breast cancer prolongs OS and PFS. Due to its high unit price, this strategy has a cost-effectiveness ratio slightly above the threshold usually recommended for incorporation, and a high net budgetary impact.

## PO.175

### Guiding Criteria for Decision-Making on the Incorporation of a Magnetic Resonance Imaging Equipment in a Public Pediatric Hospital, in Santa Catarina State, Brazil

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**Background:** Continuous changes occur in the health system and hospital medical technology is recognized as an important element of this transformation, but it is also recognized their contribution to the increased costs resulting from its use.

**Objectives:** To develop a decision matrix, using costs and factors related to quality on public health

services as an aid in the analysis of incorporation of an MRI.

**Methods:** The calculations were carried out by means of the Life Cycle Cost Analysis and the current hospital costs, for two scenarios: acquisition of equipment or outsourcing service. The life cycle of the equipment was stipulated in ten years, the annual depreciation at 10%, the discount factor at 10% per year and an annual increase of 10% of examinations.

**Results:** For the state manager, practicing outsourced service, annual cost of 1440 tests was estimated at R\$1,211,040, and the average unit cost per test in R\$841.00 Considering the acquisition and deployment of service itself, and the calculations made by the Life Cycle Cost Analysis, the total annual cost was estimated at R\$1,169,280.00 and the average unit cost per test in R\$812. For the first scenario the Net Present Value was estimated at R\$ -7,586,892.00 and the second scenario at R\$ -8,675,617.00. The difference between the two scenarios was at R\$ -1.088.725.00. Other criteria as technical, interpersonal and environmental factors, were included in a questionnaire to be applied

to other stakeholders and companions, whose results might compose the decision process.

**Conclusions:** At the time the own service is the most feasible from the economic and financial

standpoint, with the Financial Breakeven Point reached at the fifth year of the cycle. To complete the Decision Matrix, a questionnaire on Service Quality (perceptions and satisfactions domains) will be applied to internal (servers) and external (companions) clients, whose results should be considered when making any decision.

## PO.176

### Complications Related to Cardiac Rhythm Management Devices (CRMD's) Therapy and Their Financial Implication: A Prospective Single-Center Two Years Survey

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**Background:** Limited information exists about the complications related to cardiac rhythm management devices implantation and their financial implication.

**Objectives:** Cardiac rhythm management devices (CRMD's) have proven their clinical effectiveness for patients with heart rhythm disorders. Little is known about safety and complication rates during implantations of these devices. This study demonstrated the complications rates related to implantations of CRMD's, and estimated the additional hospital stay and cost associated with managing these complications.

**Methods:** During a period of one year in total 464 consecutive recipients were subjected to CRMD's implantation and furthermore were recruited and followed up for 2 years. Finally, data were analyzed for 398 patients who completed the two year's follow up, resulting in a total of 796 patient-years.

**Results:** From the 201 patients with initial pacemaker (PM) implantations, 6 (2,99 %) patients had seven complications (5 patients had lead's dislodgement, 1 of them twice and 1 patient developed pocket infection), while from the 117 PMs replacements 1 (0,85 %) patient developed a complication (pocket erosion). 2 patients with complication (1 with an initial PM and 1 with replacement) died before they complete the follow up from reasons unrelated to cardiac causes. There weren't any complications neither in initial implantations (69 patients) nor in replacements (11 patients) of implantable cardioverter defibrillator (ICD). The average prolongation of the hospital stay was 7 days ranging from 1 to 35 days, resulting in 17.411 € of total additional direct hospital cost.

**Conclusions:** This study provides relatively low rates of complications in patients subjected to PMs implantation, initial or replacement, in our center compared with others studies. The additional hospitalization days and cost attributed to these complications depends on the nature of complication.

## PO.177

### Access to Treatment for Phenylketonuria by Judicial Means in Rio Grande Do Sul, Brazil

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**Background:** The judicialization of health for obtaining medicines, including those which are on the lists or clinical guidelines developed by the public health system, is considered common in Brazil. Treatment of Phenylketonuria (PKU), a genetic disease detected by the Brazilian National Neonatal Screening Program, includes the use of a Phenylalanine (Phe)-free formula, which should be provided at no cost by the Brazilian public Unified Health System. There are no studies on the use of judicial means for access to treatment of PKU in this country.

**Objectives:** To characterize the use of the judicial means to obtain treatment for PKU in the State of Rio Grande do Sul (RS), Brazil.

**Methods:** A retrospective, observational study, based on analysis of judicial lawsuits. To be included in the study, the lawsuits must have initiated between 2001 and 2010, having as beneficiaries individuals with PKU requesting some form of treatment for this disease.

**Results:** Twenty cases that met the inclusion criteria, were analyzed, but only 19 of these were fully obtained for analysis. In 17/17 cases it was reported that there had been prior request of the treatment granted by the Department of Health of the State of RS. Figured as defendants the State of RS (n=19), the Union (n=1), and municipalities (n=4). In all cases applications for advance relief were granted. Court ruling occurred in 18/19 cases. Data indicate the violation of the right to health and the interruption of treatment supplied by the State as the main reasons for the use of the judicial process.

**Conclusions:** Our data suggest that patients with PKU face difficulties in accessing their treatment in the RS, Brazil. The search for judicial means to obtain a product that is already included in the national pharmaceutical assistance suggests that management failures are one of the factors triggering judicialization in the country.

## PO.178

### Systematic Review of the Clinical Effectiveness of Biomarkers as Cancer Screening Test offered as Self-Pay Healthcare Service

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**Background:** Individual health services (IGeL) are medical self-pay services that are not under the liability of the German statutory health insurance. Up to 14% of IGeL are blood or laboratory and cancer screening tests, which are offered to asymptomatic individuals.

**Objectives:** The aim was to investigate the clinical effectiveness of eleven biomarkers that are offered for cancer screening on the internet in Germany (i.e., AFP, CA125, CA15-3, CA19-9, CEA, Cyfra21-1,  $\beta$ -HCG, NMP22, M2-PK, NSE, PCA3).

What is the benefit-harm-balance regarding patient relevant outcomes (mortality, morbidity, quality of life) for using these biomarkers as cancer screening test in comparison to usual care?

**Methods:** Firstly, searches for systematic reviews (SR) and Health Technology Assessments (HTA) were performed in three databases in 2012. Secondly, randomized controlled trials (RCT) that were published after the end of the research period of the most recent included secondary study were searched. We included publications in English or German which analyzed these biomarkers as cancer screening test in an asymptomatic intervention group compared to an unscreened control. This review was performed according to the methods of evidence-based medicine.

**Results:** Five HTA or SR dealing with CA125 (4) or NMP22 (1) and 2 RCTs (CA125) were included. Only one RCT which simultaneously uses CA125 and vaginal ultrasound for ovarian cancer screening provided the outcome data of interest. Screening compared to usual care did not reduce ovarian cancer mortality. Harm occurred through overdiagnosis and false-positive results. Up to 4.5 surgeries were performed to identify one invasive cancer through CA125 screening.

**Conclusions:** While ovarian cancer screening with CA125 showed no survival benefit, false-positive tests, overdiagnosis and -treatment resulted in harm. For ten biomarkers no sufficient evidence was available. When IGeL are offered, patients should get comprehensive information about the lack of evidence on patient-relevant outcomes and potential harm caused by biomarker screening.

## PO.179

### NICE Moves to Even Greater Transparency in Handling (Trial) Information

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**Background:** The guides to the Technology Appraisal process describe the key process components that both NICE and stakeholders should consider and adhere to whilst developing recommendations for use of health technologies in the NHS in England. The guides are subject to periodic review, the most recent of which has recently completed. Emphasis has been given to describing more clearly NICE's expectations regarding the handling of clinical trial data for health technology assessment and appraisal; in line with other initiatives such as those of the European Medicines Agency, AllTrials, and the UK parliament.

**Objectives:** NICE seeks to create an opportunity to increase transparency, reduce the amount of redacted information and improve information sharing with stakeholders. It is anticipated that this will ultimately ensure availability of all clinical trial data relevant for decision making in the context of health technology assessment.

**Methods:** N/A

**Results:** NICE will ask companies to consent to NICE approaching regulators directly for access to data from the regulatory submission dossier. Furthermore, medical directors of companies are asked to sign a statement confirming that all data relevant to the remit and scope of the technology appraisal in its possession have been disclosed to NICE. All stakeholders that have signed a confidentiality acknowledgement and undertaking agreement with NICE will be able to receive all information marked as confidential, be it commercial or academic. Documents intended for public consideration will still be redacted from confidential information where companies insist on confidentiality.

**Conclusions:** Moving to even greater transparency reinforces NICE's ambition to put all stakeholders, including the patient and public, into the centre of our work. Public consultation on the updated process closed at the end of March. A preview of the comments received will be given at the conference in advance of formal consideration by the NICE Board in July 2014.

## PO.180

### Economic Impact Among Caregivers of Patients with Mood Disorder

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**Background:** Mood disorders (MD) are prevalent chronic diseases, entailing impairment on individuals' functioning, as well as in family. Data on economic impact of MD patients in caregivers are scarce in Brazil.

**Objectives:** Evaluate the impact on productivity of caregivers of patients with MD through the assessment of indirect costs measures.

**Methods:** A cross-over study, in a specialized outpatient service, with a preliminary sample of 80 caregivers of patients with MD. Caregiver is the relative considered by patients who cares/attends whenever necessary. Questions about indirect costs were applied.

**Results:** Preliminary data show that 68,8% of the caregivers are female, 51,3% spouses or parents, 44% are employed, with a mean age of 41,1 (sd=15,2) years. In the previous three months, 56,3% missed until one week to work due the patient, and 41,3% missed more than 30 days; 57,5% are involved in caring more than four shifts (six hours each) per week; 43,8% had a reduction of more than 24 hours in the workweek due care with the patient.

**Conclusions:** In addition to the patients' life impairment, this study suggests that MD caregivers are as well negatively affected by the patient disorder, also provoking a burden on the economic perspective. Further studies are required to clarify and quantify this type of outcome.

## PO.181

### Evaluation of impact of the Complete Denture Program for Elderly Poor People

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**Background:** The Complete Denture Program for Elderly Poor People (CDPPEP) is a free service program conducting from 2011 to 2013, by which elderly poor edentulous people living in Shanghai were provided complete denture. CDPPEP was funded by the Shanghai government and aimed to improve the oral health and the quality of life in Elderly Poor People.

**Objectives:** This study evaluated the impact of CDPPEP on oral health-related quality of life for participants.

**Methods:** This evaluation was conducted after the program. 282 individuals aged 51-94 years were selected through random sampling from all participants of CDPPEP. Data were collected through a questionnaire, in which the information of (1) satisfaction with denture provision (2) self-reported oral health status before program and the improvement in self-perceived oral health after program were investigated, and the Chinese version of the Oral Health Impact Profile (OHIP-14) was used to assess the participants' oral health-related quality of life (OHRQOL) before and after the program. The change in the score of OHIP-14 was calculated. The association between OHIP-14 score's change and the relevant factors was analysed by Poisson Regression using multiple backward methods.

**Results:** The mean OHIP-14 scores is respectively 21.48 and 4.17 before and after the program, and there was a decrease in the OHIP-14 scores to  $17.31 \pm 13.03$  ( $p < 0.01$ ). The multiple linear correlation analysis showed that the improvement in OHRQOL was associated with the self-reported oral health status before program, the satisfaction with denture provision, follow-up times after provision of dentures.

**Conclusions:** The elderly poor people's OHRQOL was improved after CDPPEP. Primary oral health status, satisfaction with denture provision and follow-up times were associated with the improvement.

## PO.182

### Compliance with Clinical Guidelines and Pathways for Inpatient Care in General Public Hospitals of Pudong New Area

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**Background:** With the reform of public hospitals in China, more than 400 clinical practice guidelines and pathways are issued by National Health and Family Planning Commission of China to improve the effectiveness and efficiency in medical care.

**Objectives:** The aim of our study is to measure the physician compliance with national clinical guidelines and pathways in public general hospitals of Pudong New Area in Shanghai and to analyze the effect of hospital quality control on physician compliance with national clinical guidelines and pathways.

**Methods:** We studied physician compliance with the national clinical guidelines and pathways in all 7 public general hospitals of Pudong New Area in Shanghai by chart audit of inpatient care of 5 common diseases or conditions (pneumonia, AMI, heart failure, cesarean section, type-2 diabetes). The other related data (such as patient demographic, illness, hospital quality control) were collected from the surveyed hospitals. When analyses of the effect of hospital quality control on compliance rate, the  $\chi^2$  tests and multivariate logistic regression were adopted.

**Results:** The compliance rates for all requirements of key process variables for five selected diseases or conditions in our study were low and varied from 7.06% to 38.67%. Comparisons with previously published studies in other countries revealed the deficiencies in clinical compliance with national clinical guidelines and pathways in secondary general hospitals of Pudong new area. In addition, hospital quality control may not be an only important factor that affects clinical compliance.

**Conclusions:** More specific reasons of low compliance with national clinical guidelines and pathways in public hospitals of China need to be explored and to be strategically acted upon.

## PO.183

### A Cost-Utility Analysis of Microprocessor Knee Technologies Versus Mechanical Knees from a Healthcare and a Societal Perspective in England

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**Background:** Every year, approximately 2,200 people in England undergo a trans-femoral limb amputation. Currently, the NHS supports the provision of mechanical legs to any above-knee amputees registered with the NHS.

**Objectives:** To identify the cost-utility of microprocessor knee technologies versus mechanical knee technologies in England.

**Methods:** Primary data have been collected from interviews and surveys, and secondary data from public databases and published literature. 40 patients have been recruited, 20 for each study arm. The economic evaluation has been conducted from the NHS and societal perspective. Differential effectiveness has been assessed by measuring

utility scores with the EQ-5D-3L questionnaire, and costs have been calculated based on responses to a detailed questionnaire. These have been utilised as inputs to a Markov model to calculate the incremental cost-effectiveness ratio (ICER) (in 2013 £ per quality-adjusted life-years [QALY] gained). The time horizon was set at 5 years. A secondary analysis has been performed using utilities based on the Visual Analogue Scale (VAS).

**Results:** Microprocessor knees are dominated in the reference case under the NHS perspective, whereas the societal case is associated with lower costs but worse outcomes (ICER=£25,500/QALY). The use of the VAS scale to calculate QALYs leads to different conclusions: from the NHS perspective, microprocessor knees are associated with higher costs and higher QALYs (ICER=£7,900/QALY), whereas it dominates from the societal perspective. Sensitivity analyses showed that utility values and productivity loss are the variables with the greatest effects on the ICER.

**Conclusions:** Cost-utility results depend on the perspective adopted, as amputees incur high productivity costs. The methodology used to obtain QALYs has a significant impact on the final ICER value, meaning that EQ-5D-3L and VAS captured different aspects of the condition. The small sample size and assignment of constant costs and QALYs to the consecutive tunnel states in the Markov model are the main limitations.

## PO.184

### A Qualitative Systematic Review of the Clinical Effectiveness of Art Therapy Among People with Non-Psychotic Mental Disorders

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**Background:** Mental health problems account for almost half of all ill health in people under 65 years. The majority are non-psychotic (e.g., depression, anxiety, and phobias). For some people, art therapies may provide more profound and long-lasting healing than more standard forms of treatment, possibly because they provide an alternative means of expression and release from trauma.

**Objectives:** This systematic review aimed to synthesise qualitative evidence relating to user and service provider perspective on the acceptability and relative benefits and potential harms of art therapy for people with non-psychotic mental disorders. This review was part of a larger project and was complementary to a quantitative review of clinical effectiveness and cost-effectiveness model.

**Methods:** A comprehensive literature search was conducted in 13 major bibliographic databases from May-July 2013. A qualitative evidence synthesis is proposed using thematic framework synthesis.

**Results:** The searches identified 10,270 citations from which 11 studies were included. 10 studies included data from 183 service users, and two studies included data from 16 service providers. Major themes relating to benefits of art therapy for service users were: increased understanding of self, and expression of feelings. Potential harms related to the activation of emotions which were then unresolved, lack of skill of the art therapist, and sudden termination of art therapy. Service providers reported benefits such as the promotion of communication, anger management, and expression of emotions, and highlighted the importance of AT's and other health professionals working together and if they did not this was a barrier to service users participation in art therapy.

**Conclusions:** The qualitative synthesis provides added value to the quantitative analysis of the clinical effectiveness of art therapy for non-psychotic disorders. The project will provide evidence to commissioners and providers of mental health services about the value of future art therapy services.

**PO.185****Measuring Public Preferences for Reimbursement Decisions: Protocol for an Empirical Study in Belgium**

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**Background:** Health care policy makers usually get the remit to decide 'on behalf of the general public'. However, they often do not know what the general public prefers.

**Objectives:** The aim of our study is to measure public preferences with respect to reimbursement criteria for medical treatments in Belgium and to create a decision making tool to help making the decision making more transparent and consistent.

**Methods:** A longlist of criteria was reduced to a manageable short-list that satisfied the conditions for multi-criteria decision analysis. A survey was created, pre-tested in 12 people and revised after an extensive pilot-test in 219 people. A test-retest of the survey was organised in 60 people. An invitation to participate in the actual population survey will be sent to a sample of 20,000 citizens in Februari 2014. Citizens will be drawn at random by the national registry, stratified by age and sex. The discrete choice method was selected for deriving the relative importance of the criteria. The results will be available in May 2014 and be presented at the meeting if the abstract is selected.

**Results:** The survey was prepared across three main blocks with a limited number of criteria per block: therapeutic need (impact of disease on quality of life and life expectancy, given current treatment), societal need (frequency of disease and societal cost per patient) and new treatment characteristics (impact of new treatment on previous criteria and comfort as compared to the current treatment). Several rounds of expert consultation and pilot-testing were needed to arrive at the final version of the questionnaire. The pilot study showed that the discrete choice exercise is difficult but manageable.

**Conclusions:** Developing a national survey on preferences for reimbursement criteria requires the involvement of different types of expertise. Although discrete choice exercises are difficult, they are feasible for the general public.

**PO.186****Physical Design Strategies to Increase the Time of Clinical Staff with the Patients in Psychiatric Hospital Units**

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**Background:** Recent studies have shown that increasing the time of interaction between caregivers and patients is beneficial for the health and wellbeing of patients. Renovations of the hospital units at Institut universitaire en santé mentale de Montréal imposed a decision-making process on the type of architectural design to choose in order to meet patients' needs of interaction with the clinical staff.

**Objectives:** An evaluation was conducted to identify the physical design and other strategies that could increase the time spent by clinical staff with patients.

**Methods:** One systematic review was conducted in PubMed, CINAHL, PsycINFO, Web of Science and several sources of grey literature. The information from the literature was supplemented with interviews with Institute's stakeholders. Data was examined by thematic content analysis and presented as a narrative synthesis.

**Results:** The systematic search yielded 990 results of which, only ten studies met the inclusion criteria. Most of them had a qualitative or mixed methods design, and an average quality. These studies showed

that decentralized units, units of certain types and sizes, and the presence of activity rooms may increase the time nurses spend with patients. Organizational factors also play an important role on this time of interaction. The consultations with Institute's managers revealed possible elements to promote the interaction between clinical staff and patients, such as location of office spaces, alcoves, and meeting rooms around the unit, and changes at the organizational level.

**Conclusions:** Our results show that the physical design of hospital units could be a factor that influences the amount of time spent by the clinical staff with patients, but it is not the only one. Other factors are related to clinical practices, work organization and the organizational culture. Therefore, any redesign of the hospital units should be accompanied by a precise clinical programming and an adapted work organization to the local context.

**PO.187****Identifying Priority Needs and Gaps for Medical and Assistive Devices for Older People in Six Asian Countries**

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**Background:** Earlier work by the WHO has highlighted the importance of assessing the availability of medical devices (MDs) and assistive devices (ADs) in several Asia Pacific region countries including China, Japan, Malaysia, Philippines, Republic of Korea, Viet Nam. Further information was required to better define options for improving access in these countries.

**Objectives:** To identify devices required to support healthy ageing for older people in the six countries, factors contributing to their availability, and approaches to improve availability.

**Methods:** Lists of key MDs and ADs were developed for an electronic survey that was sent to contacts in the six countries, including health professionals, administrators, engineers, device suppliers and carers. ADs were linked to functions which are priorities for older people to undertake independently. Respondents were asked to rate relative importance of functional areas, and priority ADs for each of these. MDs were grouped by areas of disease or by types of function if they had broad applications. For both types of device, respondents were asked for details on the extent of current use, aspects that would influence their use, reasons why they are or are not widely used, and approaches that would improve availability.

**Results:** Earlier data had indicated a wide variation in device use between the countries, and in device availability between regions. Issues affecting availability include affordability to potential users, suitability for current practice, device quality, and acceptability to health professionals. Approaches to improving access may include increased local production of devices, upgrading infrastructure, regulatory changes, and negotiations to reduce costs to older people.

**Conclusions:** Equitable provision of effective MDs and ADs remains a challenge. Details on the extent of use, needs and options for change such as those from this survey will provide input to future policy and administrative developments to meet the needs of older people in the region.

**PO.189****Patient Involvement in Clinical Practice Guidelines in Argentina**Analia Amarilla<sup>2</sup> Victoria Wurcel<sup>1</sup> Verónica Sanguine<sup>2</sup>

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**Background:** Clinical guidelines are being promoted and developed at many levels of argentinian's complex health system, but they present variations in overall quality and stakeholder's involvement.

**Objectives:** To review experiences of patient or public involvement in the development and implementation of standards of care such as clinical practice guidelines in Argentina.

**Methods:** We conducted a cross-sectional study to identify models of patient and community involvement in guidelines in Argentina between 2009 and 2014. Experiences were identified through electronic databases such as MEDLINE, LILACS and EBSCO, HTA agencies sites, and Internet search engines. Inclusion and exclusion criteria were independently assessed by two reviewers. Exploratory statistical analysis was performed for association factors of patient involvement.

**Results:** A total of 1,150 potentially relevant papers were identified by the main search strategy. Among these, 34 papers met the inclusion criteria. Patient involvement was found in 47% of them, all from central public level. The findings revealed that patient or public involvement was reported in two domains: consensus panel (grading of recommendations) (24%) and external review stage (76%). In the domain of external review the participation of patients was done by "pull strategy" through internet communication but not directly with patient interviews or face to face public consultation. A positive association was found between patient involvement and higher scores in the rigour of development domain of AGREE II quality instrument (Mean score 5.50 ;SD 1.29 in patient involvement group vs 2.77 SD; 1.69, P value < 0.0001).

**Conclusions:** Almost half of published guidelines in these past five years in Argentina involved patients in some way. We found none which included them in the implementation or monitoring stages. Better quality guidelines could be associated with more patient involvement.

**PO.190****Corruption in Health Care**

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**Background:** The fight against corruption is a priority across the world. The health care sector is one of the areas that is particularly vulnerable to corruption, but relatively little is known about this subject. We focused on medical service delivery, procurement and certification of medical devices, and procurement and authorisation of pharmaceuticals.

**Objectives:** To assess 1) the capacity of the Member States (MS) of the European Union (n=28) to prevent and control corruption in health care and 2) the effectiveness of these measures.

**Methods:** The methods used were desk research, interviews with EC officials and representatives of health professional's organisations, medical device industry, pharmaceutical industry and health insurers, and field research in the 28 MS. The field research included, per MS, 3-4 interviews with stakeholders, 3-6 descriptions of corruption in health care cases and a description of policies and practices in place to prevent and control corruption in health care.

**Results:** Corruption in health care occurs in all countries studied. We identified three categories of policies and practices: generic anti-corruption policies and practices, e.g. procurement policies and forceful

anti-bribery legislation; generic health care policies and practices, e.g. health care supervision and reforms to address structural health care system weaknesses; and corruption-in-health policies, e.g. health specific anti-corruption strategies and self-regulation.

**Conclusions:** There is no single policy to successfully fight corruption in health care. Policies and practices that work in one country do not necessarily work in another country. A general rejection of corruption by society, as well as clear and effectively enforced general anti-corruption legislation, independent and effective judicial follow up on corruption cases, and sound general procurement systems, are necessary preconditions for success. This will make the health care system more transparent and robust and will eventually benefit all stakeholders, including patients and citizens.

**PO.191****Inequalities of Hemodynamic Services Supply in Rio de Janeiro State, Brazil.**Marco Antonio Ratzsch de Andrauzzi<sup>1</sup> Maria de Fatima Siliansky deAndrauzzi<sup>2</sup> Leyla Sancho<sup>2</sup> Heitor Alarico Gonçalves de Freitas<sup>2</sup>

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**Background:** The universal health care system Brazil adopted in 1988 has not presented yet significant results in the reduction of the inequalities in supply and utilization of health care. Voluntary health insurance (VHI) is maintained around 25% of the total population and 40% of the population of Rio de Janeiro(RJ) state. The demographic and epidemiological transition that has happened in Brazil since the 1960's transformed the obstructive coronary disease in an expressive cause of morbimortality. Consequently, Interventional Cardiology procedures have become a frequent motive of health care utilization

**Objectives:** To analyze the inequality in supply and utilization of hemodynamic equipment and Interventional cardiology procedures at Rio de Janeiro state, Brazil.

**Methods:** Exploratory and comparative quantitative study using secondary data of Minister of Health's statistic databases, referred to equipment supply and Interventional Cardiology procedures between 1999 and 2012.

**Results:** An increase in the hemodynamic equipment quantity has been evidenced between 1999 and 2009, resulting in 4,1 equipment per 1 million inhabitants, in a contrast with 1,5 offered to the public system. 78% of this equipment was private, in 2009, but only 36% of the total was accessible through public financing. In 2011 the crude rate of Interventional Cardiology procedures was 106, 2 by 100.000 inhabitants. Procedures performed at public hospitals have diminished after 2010 simultaneously with their growth at contracted private hospitals.

**Conclusions:** We could verify a maintained growth of hemodynamic equipment supply in the state, especially in the private sector. There was an accentuated inequality in the supply of this equipment considering the total population and the VHI beneficiaries, where the rate of supply overreached the industrialized rich countries rates. Data suggested underutilization of Interventional Cardiology procedures in public sector. Recent government policy has resulted in the dismantling of public services and an increase in contracted private services.

**PO.192****Involvement of Stakeholders in Health Technology Assessment in Colombia**

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**Background:** Until 2012, HTA had a limited role in Colombia in terms of generating information to set priorities, allocating resources or formulating evidence-based policy. Although the country struggles to set priorities and allocate resources for its citizens in an efficient, equitable and sustainable manner, decision making in Colombia as happens in many other contexts occurred ad-hoc, without the explicit consideration or incorporation of societal values and preferences into the process.

The Colombian Institute of Health Technology Assessment (IETS) was founded in 2012, IETS is an advisor agency to the Ministry of Health and other national authorities but has no legal authority to make decisions. The quality, effectiveness and efficiency of HTA can be enhanced by open and consultative processes. HTA processes involve multiple stakeholders including the government, industry, providers, patients and members of the public.

**Objectives:** To explain how the topic of stakeholder involvement was proposed by IETS

**Methods:** We performed a systematic literature review of participation methods in HTA agencies and designed a range of measures to constructively engage multiple stakeholders throughout the HTA process in Colombia.

**Results:** Participative processes were designed to consolidate the legitimacy of IETS and its products and encourage the representation of interests, thus contributing to promoting the utilization of HTA in national policy making. The manual of participation includes key strategies as: 1) ensuring that stakeholder groups are properly represented; 2) enabling a flow of input from all groups; 3) communicating HTA evidence appropriately across diverse audiences.

**Conclusions:** It is important to fully appreciate the role of the different stakeholders involved in the process and promote and ensure that their evidence and values are considered in the HTA process and maintain constant communication with them. It is expected that these strategies bringing together: a strong commitment to clear and transparent processes.

**PO.193****The Contribution of National Committee of Health Technology Incorporation (CONITEC) to the Brazilian Public Health System, Face the Challenge to Harmonize the Needs of Population Aging with the Financing of the Sector**

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**Background:** Life expectancy at birth of the Brazilian population has increased in recent years, from 66 years in 1991 to 74.6 years in 2012, demonstrating that the Brazilian population is aging. In addition to the population changes, there has been an epidemiological transition in Brazil, with significant changes in terms of morbidity and mortality. The infectious diseases, which accounted for 40% of deaths in Brazil

in 1950, today represent less than 10%. The opposite occurred in relation to cardiovascular disease, which in 1950 were the cause of 12% of deaths, and currently represent more than 40%. In a few decades, Brazil passed from a mortality profile typical of young population to a profile characterized by complex and burdensome illnesses typical of older ages. Thus, the challenge of the public health sector is to harmonize the needs of an aging with the financing of the sector.

**Objectives:** To identify the contribution of Conitec to the Brazilian public health system, face the challenge of epidemiologic transition.

**Methods:** Qualitative analysis of Conitec contribution for that the Brazilian Health Care System can accompany population aging.

**Results:** The incorporation of new health technologies is achieved by Conitec advice. Were analyzed 122 proposals in 2012 and 2013, based on studies of efficacy, safety, effectiveness, cost-effectiveness and impact on the health care system that led to the improvement and modernization of the Brazilian Health Care System. Related to innovation in health, Conitec ever examined drugs and technologies for Chronic Degenerative Diseases such as cancer, diabetes, cardiovascular, rheumatologic, neurological, psychiatric, AIDS and Hepatitis C.

**Conclusions:** The advice of Conitec contributes to inclusion of technologies that demonstrates greater benefit with acceptable safety and sustainable cost, which are provided to the population by compliance with the use of protocols, essential for regulates supply, ensuring effectiveness and safety in treatment.

**PO.194****Cochrane Reviews' Abstracts Translations to Brazilian Portuguese to Stimulate the Patient Participation in the Decision Making**

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**Background:** The Cochrane Library has more than 5,000 systematic reviews and it is one of the main information sources for evidence in health worldwide. In Brazil and Latin America, the access to the Cochrane Library is free, but the language it is still a barrier. The Cochrane Collaboration and the Brazilian Cochrane Center (BCC) are compromised to promote the access to information through the translations of the Cochrane reviews' abstracts for the health professionals and patients. For that matter, we intended to expose how it is done by the Brazilian Cochrane Center to promote the access to information as a stimulus to promote incentives for the patient participation in the process of decision making.

**Objectives:** To promote the access to information to patients as a stimulus for the participation in the decision making for Brazilian Portuguese speakers patients and professionals.

**Methods:** The process consists of: Abstract and plain language summary translation for each systematic review; translation published in the Cochrane Library; translation dissemination. The team consists of a coordinator, two translators and a technician. The translations are revised and once they are approved, they are published at the Cochrane Library. The dissemination is done through the website Cochrane Summaries, at the workshops promoted by the BCC and by the BCC webpage and Facebook page.

**Results:** The Brazilian Cochrane Center translated a total of 101 abstracts and 54 abstracts publications from Cochrane reviews from May to December 2013 with an average of four translations per month.

**Conclusions:** The abstract production is growing and constant. The abstracts visibility and acceptability by the website users from the BCC seems to be high although not quantified. It is still needed to evaluate the impact of this production in the decision making process by the patients and the health professionals.

**PO.195****Stress During Prenatal and Effects in Fetal, Neonatal or Child Development: a Systematic Review**

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**Background:** The prenatal stress has been associated with alterations in the fetal's and child's behavior and development.

**Objectives:** To evaluate whether there is a relationship between maternal psychological or environmental stress exposure and fetal, neonatal or child development outcomes through a systematic review and meta-analysis of observational studies.

**Methods:** Search strategy: With PUBMED, EMBASE and LILACS, a literature search was conducted to identify studies evaluating the relationship between fetal development and stress maternal during pregnancy with a minimum time of follow-up of one month.

Selection criteria: Studies were included if the participants were mothers subjected to any form of psychological or environmental stress during an uncomplicated pregnancy, regardless of age and the cause of the stress.

Data collection and analysis: Two reviewers independently screened the studies identified by the literature search and extracted data. Using the available data reported, we calculated 95% confidential intervals (CI) around the odds ratios and used RevMan software to combine results in a forest plot using a random-effect model.

**Results:** There was a statistically significant difference favoring the non-exposure group compared to the prenatal stress exposure group with regards to the overweight and obesity and regarding the language ability.

**Conclusions:** Based on the data presented, we can infer that prenatal stress negatively influences fetal life and infants. However, we also suggest further well-conducted studies with adequate sample size and longer follow-up time to confirm or refute our findings.



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