

# 9<sup>th</sup> HTAi ANNUAL MEETING

## “HTA in Integrated Care for a Patient Centered System”

Bilbao, 23<sup>rd</sup>-27<sup>th</sup> June 2012

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### ORAL COMMUNICATIONS

Monday 25<sup>th</sup> June 2012. 14:30-16:00

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#### 107. CHALLENGES IN COMMISSIONING RESEARCH TO INFORM SERVICE DECISIONS ON WHAT WORKS IN INTEGRATED CARE

Tara Lamont and Steph Garfield-Birkbeck

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Most countries face similar challenges of providing coordinated, patient-centred care for a growing number of people with complex and chronic conditions at a time of severe economic constraint. Different forms of integration have been developed within and between countries to address these. These include models of joint services at an institutional (macro) or planning (meso) level, as well as initiatives at a patient (micro) level to provide multidisciplinary teams across health and social care. But there is little high quality research on which models are most cost-effective. In England, the National Institute for Health Research (NIHR) Health Services and Delivery Research (HS&DR) programme has funded a number of recent studies on integrated care, including: A study of ‘virtual wards’ (innovative form of multidisciplinary case management) and impact on reducing emergency hospital care and social care. Two projects reviewing different forms of interprofessional teamworking for stroke and frail elderly. A study of innovative models of integration for people with longterm neurological conditions. Our experience in commissioning this research has highlighted key challenges. These include difficulties in generalising from single-site studies of innovation. Case study research can generate rich information on context, but how do findings translate to other services? And how can such studies provide cumulative knowledge, outside traditional methods of systematic review? Many proposals struggle to provide rigorous evidence of costs and potential savings, with little data and problems in definition. There are also issues about the fidelity and reproducibility of service interventions, which have often developed locally under charismatic leaders. Overall, there is a tension between the pace of change and managers’ need for immediate answers against the time taken to commission and complete robust evaluations. These dilemmas will be explored and debated in this presentation, together with some practical tips for research funders and others on maximising impact.

#### 230. ORGANIZATIONAL READINESS FOR KNOWLEDGE TRANSLATION IN CHRONIC CARE: A SYSTEMATIC REVIEW OF THEORIES

Randa Attieh<sup>a</sup>, Marie-Pierre Gagnon<sup>b</sup>, Jenni Labarthe<sup>a</sup>, France Légaré<sup>c</sup>, Mathieu Ouimet<sup>c</sup>, Carole A. Estabrooks<sup>d</sup>, Geneviève Roch<sup>b</sup>, El Kebir Ghandour<sup>a</sup> and Jeremy Grimshaw<sup>e</sup>

<sup>a</sup>Research Center of the Centre Hospitalier Universitaire de Québec. Québec. Canada. <sup>b</sup>Research Center of the Centre Hospitalier Universitaire de Québec. Québec; Faculty of Nursing. Université Laval. Québec. Canada. <sup>c</sup>Research Center of the Centre Hospitalier Universitaire de Québec. Québec; Department of Family Medicine. Université Laval. Québec. Canada. <sup>d</sup>Faculty of Nursing. University of Alberta. Edmonton. Alberta. Canada. <sup>e</sup>Ottawa Hospital Research Institute. Ottawa; Faculty of Medicine. University of Ottawa. Ottawa. Ontario. Canada.

**Background:** Knowledge translation (KT) is an imperative in order to implement research-based and contextualized practices that can answer the numerous challenges of complex health problems. The Chronic Care Model (CCM) provides a conceptual framework to guide the implementation process in chronic care. Yet, organizations aiming to improve chronic care require an adequate level of organizational readiness (OR) for KT. Available instruments on organizational readiness for change (ORC) have shown limited validity, and are not tailored or adapted to specific phases of the knowledge-to-action process.

**Objective:** Our objective was to review and synthesize the existing evidence on theoretical foundations of ORC as the basis for the development of a comprehensive, bilingual OR for KT instrument in chronic care organizations.

**Methods:** A systematic review of the literature on conceptual frameworks and theoretical models of ORC in health care was conducted to document the core concepts to be operationalized for measuring KT in the context of chronic care.

**Results:** This systematic review found 59 articles describing how ORC has been used as a critical precursor to the successful implementation of complex changes in health care settings and measured in health services and in other fields. Ten theoretical models/conceptual frameworks of ORC in healthcare were identified. Preliminary findings suggest a lack of consensus on the theoretical domains involved in ORC.

**Discussion:** This systematic review provides a comprehensive synthesis of current knowledge on explanatory models assessing OR for KT. Moreover, it aims to create more consensus on the theoretical underpinnings of OR for KT in chronic care.

**Implications:** The literature findings will provide useful tools for stakeholders and decision makers in assessing their organizations’ readiness for successful knowledge implementation. The validation of OR for KT in a sample of chronic care organizations will promote the application of the research findings in various health services contexts.

## 264. IMPROVING THE EXPERIENCE OF CARE FOR PEOPLE USING ADULT HEALTH SERVICES: DEVELOPING THE NICE GUIDANCE AND QUALITY STANDARD

Liz Avital<sup>a</sup>, Sophie Staniszewska<sup>b</sup>, Ian Bullock<sup>a</sup> and Norma O'Flynn<sup>a</sup>

<sup>a</sup>National Clinical Guideline Centre. UK. <sup>b</sup>RCN Research Institute. UK.

**Background:** The National Clinical Guideline Centre was commissioned by the National Institute of Health and Clinical Excellence (NICE) in 2010 to develop guidance and quality standards to outline a level of service that people using adult national health services (excluding adult mental health services) should expect to receive.

**Objectives:** To develop guidance, recommendations and quality standards outlining a level of service that people using adult national health services should expect to receive. To develop guidance for all staff (including non-clinical staff) involved in providing health services, as all interactions can have a profound effect on patient experience of care.

**Methods:** A multidisciplinary Guideline Development Group (GDG) comprising of ten health care professionals and six patient representatives, supported by a technical team, developed this guidance. It was drafted on the basis of GDG interpretation and a synthesis of different forms of evidence, including the Warwick Patient Experiences Framework. The quality standards are based on key areas of priority as identified by the GDG.

**Results:** The following key themes were identified which underpinned recommendations: Knowing the patient as an individual. Essential requirements of care. Tailoring healthcare services for each patient. Continuity of care and relationships. Enabling patients to actively participate in their care. The resulting guidance and quality standard will be presented.

**Discussion:** This guidance provides the evidence and expert consensus base to create sustainable change in changing health care professionals' behaviours and directing commissioning to meet this challenge, resulting in the cultural shift required to produce care that is effective, acceptable and appropriate for patients.

**Implications for the health system/professionals/patients/society:** The generic nature of this guidance makes it internationally transferable and applicable to other healthcare environments.

## 536. THE HEALTH TECHNOLOGY ASSESSMENT PROGRAMME AT THE NHLS

Sarvashni Moodliar, P. Dabula, H.L. Miles and J. van Heerden

CMREC HTA Unit. Johannesburg. Quality Assurance Division. National Health Laboratory Services. South Africa.

**Background:** The National Health Laboratory Services offer laboratory services to 42 million people in South Africa and employ more than 7000 people across South Africa. The NHLS, Quality Assurance Division has initiated a programme to categorize all NHLS laboratories according to size and workload. This is the first step in preparing to establish standard criteria for laboratory instrumentation. Once this process has been completed the NHLS would be able to rationalize systems in order to achieve better standardization across all equivalent sites.

**Objective:** To utilise HTA for improvement of decision making within NHLS

**Methods:** A qualitative study design was used to interview key stakeholders.

**Results:** The participants mentioned that HTA program should provide the following benefits: Better health (patients and providers have access to a centralized location to learn about proven health care); Transparent (the technology selection, evaluation, and committee decisions follows a published process and are open to public input); Elimination of bias (neither the purchaser nor a company selling the

products are making the decision, however all can share information), Consistency (state agencies will be relying on a single, scientifically based source to inform coverage decisions on the selected technologies). In addition it should assist the NHLS in terms of *the proposed changes for Health Care Diagnostics in relevance to in-vitro diagnostic devices and products such as* level of standardization, flexibility of choice as per laboratory category. They mentioned the need for an evidence based selection process for procurement, maintenance and decommissioning of HT in the organisation.

**Conclusion:** The NHLS QA Division along with CMERC HTA Unit is currently working towards a model for standardization within the confines of National/Public sector regulations to develop a program to access efficiencies with the technologies utilized and to develop standardized equipment specifications.

## 134. IS PRIMARY CARE ACCESSIBLE FOR THE POOR IN MONGOLIA?

Oyun Chimeddamba<sup>a</sup>, Jargalsaikhan Dondog<sup>b</sup>, Munkhdelger Tsogbayar<sup>c</sup> and Enkhmaa Ulziikhutag<sup>d</sup>

<sup>a</sup>Team leader for the Consultancy services to Ministry of Health. Mongolia. <sup>b</sup>Ministry of Health. Mongolia. <sup>c</sup>ADB consultancy to Ministry of Health. Mongolia. <sup>d</sup>Department of Health. Mongolia.

**Background:** The Health Sector Master Plan for 2005-2015 stresses the need to provide essential health services to the people of Mongolia, with emphasis on the elderly, adolescents and the poor.

**Objective:** Exploring of potential factors encountered by disadvantaged groups when seeking primary care is increasingly needed.

**Methods:** 500 individuals were involved in the quantitative survey and 74 family doctors, nurses, social workers and heads of administrative units of the selected districts to participate in the qualitative surveys.

**Findings:** 55.6% of the respondents expressed that they are able to obtain health care services when required, 26.6% said sometimes they are not able to obtain it and 12.6% said no. The main reasons for not being able to obtain necessary health care services were poor living conditions, lack of money to get treated (20.4%), some tests and screening cannot be performed at family clinics (16.2%), poor service quality, insufficient family practitioners' knowledge and skills (8.6), family clinic is located far away (5.0%).

**Conclusions:** The majority of the respondents urge that skilled physicians and nurses, medical supplies and equipment, comfortable environment and friendly communication are very influential in family clinic health care and service. They were also pressed out ways to bring family clinic's service closer to the population by improving of quality of service at family clinics and involving of health volunteers in service provision.

## 224. USE OF WIRELESS - BASED ASSISTIVE TECHNOLOGY FOR CONTINENCE MANAGEMENT IN RESIDENTIAL AGED CARE

David Hailey, Ping Yu, Richard Fleming, Victoria Traynor and Zhenyu Zhang

University of Wollongong. Australia.

**Background:** Continence care of older persons residing in nursing homes is demanding on staff resources and ineffective; it is difficult to determine time to toileting and to keep residents dry.

**Objective:** To assess the impact of using a wireless - based monitoring system (SIM<sup>®</sup>. Simavita, Pty Ltd, Sydney) to manage urinary continence (UC) in a nursing home.

**Methods:** In SIM® a sensor is embedded in a disposable pad and activated by the wearer's urine. The sensor sends data to a computer which alerts care givers and records voiding pattern data. Voiding patterns of 32 older people in a Melbourne nursing home were recorded for 72 hours and the data used to inform a new UC care plan for each person. Their voiding patterns were re-assessed during weeks two to five of care plan implementation.

**Results:** When compared with baseline data there were significant increases in the number of times residents were provided with toileting assistance ( $p < 0.001$ ), and in the number of successful voiding events into the toilet ( $p = 0.016$ ). The volume of urine voided into incontinence pads was reduced during the follow up period ( $p = 0.013$ ).

**Discussion:** This short study suggests that application of a telemonitoring system for UC management is associated with more successful toileting and less inadvertent voiding. Care staff's awareness of residents' requirements and their contact with residents at appropriate times of need were increased.

**Implications:** Use of this new technology has the potential to significantly change continence management practice in aged care homes. Expected consequences are better health outcomes for residents (for example reduction in the number of falls and improvements in skin integrity) and better quality of life for both residents and care staff. These aspects, and economic costs and benefits of telemonitoring, require further study.

#### 474. STUDY ON THE CURRENT SITUATION, PROBLEMS AND COUNTERMEASURES OF COOPERATION OF PUBLIC HEALTH ITEMS IN RURAL MEDICAL INSTITUTIONS-BASED ON THE TOWNSHIP HOSPITAL EAGLE OF VIEW

Xiao-He Jiang and Li Kuang

*Health management. School of Public Health. Sun Yat-Sen University. Guangzhou. China.*

This paper is mainly based on the perspective of integrated services, aimed at understanding the status quo and problems of cooperation between the rural township hospitals and village clinics in China, to explore how to promote public health service integration between township hospitals and village clinics in the rural areas. According to the county economic conditions, population density and health management, etc., 149 public health managers of township hospitals from 15 counties of Guangdong province were selected and investigated with a self-designed questionnaire. We find that the public health items were mainly launched by the township hospitals, but the village clinics takes low responsibilities the role of the village clinics have not been effectively. The doctors of village clinics participate in public health services with high enthusiasm, but they are lack of knowledge, technology and equipment, no enough money to run. etc ; Township hospitals make a low satisfaction with village clinics for public health services (23% in total). We present that the infrastructure and skills are the cornerstones for village clinics, but the division of responsibilities and interests of the distribution rights are the keys for the integrated services.

#### 615. THE USE OF DELIBERATIVE INCLUSIVE METHODS TO ACCESS INFORMED COMMUNITY VIEWS ON HEALTH TECHNOLOGIES AND HEALTH SERVICES: A REVIEW

Jackie Street, Katherine Duszynski, Stephanie Krawczyk and Annette Braunack-Mayer

*University of Adelaide. Australia.*

**Background:** Deliberative inclusive methods permit the collection of public views through informed deliberative discussion.

**Objectives:** To ascertain how deliberative inclusive methods have been used to collect informed patient and citizen views on health technologies, health policy and health services.

**Methods:** We searched Medline, Cinahl and Scopus for the years 1995-2010 using search terms describing the use of deliberative inclusive methods for engaging patients and citizens on issues relevant to health technologies, services and policy. Inclusion and exclusion criteria were applied and data from included papers managed in MS Access.

**Results:** Approximately 15000 hits were obtained with 1071 retrieved for full text reading. Of these, 75 papers described 101 deliberative exercises. These included 67 forums in the tradition of citizen juries, 19 consensus conferences and 15 other deliberative inclusive methods. In the forum category, 20 different strategies were used for recruitment. Two juries recruited only patients and 5 recruited other specific groups e.g. caregivers. The review shows that recruitment through advertising is associated with skewed participant make-up. Most forums took place over 1-2 days, considerably less than the recommended 4-5 days and half were conducted in 4 Canadian exercises involving multiple forums around single questions.

**Discussion:** It is clear that deliberative inclusive methods have been adapted to the constraints of research, policy and HTA needs. Juries in the peer-reviewed literature appear to have limited direct influence on policy, although this finding may be associated with potential bias related to the types and sponsorship of juries that are reported in the peer reviewed literature.

**Implications:** Deliberative inclusive methods offer a viable means for engaging citizens and patients but care is essential in question development, recruitment, facilitation, and evaluation.

#### 802. EVALUATION OF EFFECTS ON PUBLIC HEALTH SERVICES IN RURAL AREA OF HAINAN PROVINCE

Hong Zhou, Qionghua Xu and Zhibin Chen

*Hainan Medical University. China.*

**Background:** To improve the essential public health services is one of the important goals of health care reform in China. As the "bottom" of the three-level health network, the village clinic is one of the main institutions for implementing public health services. Its performance is the key factor in the evaluation of effects on the equalization of public health services, which is significant for improving the health of rural residents.

**Objectives:** Based on the survey on effects on public health services in the rural area of Hainan Province, their effects were analyzed in depth, for the preparation of policy recommendations.

**Methods:** Stratified random sampling was adopted in the east, middle and west of Hainan Province. A survey was conducted for institutions and rural residents in 6 Counties, 464 questionnaires were collected; in-death interviewed with 49 Senior Health Administrators was carried out.

**Results:** 84% of rural residents perceived that disease prevention education was provided; 66% to 78% of them perceived village clinic could basically meet their need; Service attitudes were evaluated as "fair" to "good" and considered good in general, increasing with respondents' age and decreasing with their education levels. Most residents chose to seek care in township health centers; Public health services were conducted adequately in village clinics.

**Discussion:** After the establishment of New Health Care Reform, the government invested more in the construction of village clinics, but team building still remains as a major concern. Because of relatively low income and insufficient subsidies, the village doctors tend to prefer the paid health services instead of health prevention services.

**Implications:** Through multi-source investments schemes, establishing performance evaluations of village clinics, and improving the subsidy to stabilize the talent teams are effective measures to ensure the construction of “bottom” of the three-level network.

### 113. A SYSTEMATIC REVIEW OF PATIENT INITIATED CLINICS IN PATIENTS WITH CHRONIC OR RECURRENT CONDITIONS MANAGED IN THE SECONDARY CARE: PATIENT SATISFACTION, QOL, AND CLINICAL AND COST EFFECTIVENESS

Rebecca Whear<sup>a</sup>, Abdul-Kareem Abdul-Rahman<sup>a</sup>, Jo Thompson-Coon<sup>a</sup>, Kate Boddy<sup>a</sup>, Mark Perry<sup>b</sup> and Ken Stein<sup>a</sup>

<sup>a</sup>University of Exeter. UK. <sup>b</sup>Plymouth Hospital Trust. UK.

**Background:** Missed or inappropriate hospital appointments cost the NHS millions every year. This has provoked interest into alternative methods of appointment scheduling that might improve patient attendance, be more flexible to patients needs and be more cost effective.

**Objective:** To understand the effectiveness, cost effectiveness and acceptability of patient initiated clinics in managing long term care for people with chronic or recurrent conditions in secondary care.

**Methods:** *Search strategy:* Databases included: Medline, Embase and Psycinfo (using the OVID interface), the Cochrane Library of Systematic Reviews and CENTRAL, Science Citation Index Expanded, Social Sciences Citation Index, Conference Proceedings Citation Index (via the Web of Science interface) from inception to October 2011. References from the included studies were also hand searched. *Inclusion criteria:* Studies comparing patient initiated clinics with traditional consultant led clinics in secondary care for people with long term chronic or recurrent diseases, which report on clinical outcomes, cost effectiveness or patient satisfaction. *Data extraction and synthesis:* Data from 11 included studies were extracted and checked independently by two reviewers. The results were synthesised narratively.

**Results:** There are some benefits of PICs for the management of chronic or recurrent conditions in secondary care relating to time and cost savings, however the impact on patients' clinical symptoms and risk of harm is unclear. Patient and clinician confidence and satisfaction in the PIC system was positive but the quality of life and psychological outcomes showed little change and were sometimes negative.

**Conclusions:** The UK policy context is ripe for evidence-based, patient-centred services to be implemented and evaluated, especially where hospital professionals' wasted time and costs can be minimised without reducing the quality of health care and outcomes for patients. Implementation of patient initiated clinics should remain cautious with ongoing evaluation of a range long term outcomes including costs and patient satisfaction.

### 118. BUILDING A PORTFOLIO OF RESEARCH FINDINGS FOR USE BY HEALTHCARE MANAGERS AND DECISION-MAKERS USING INTEGRATED CARE AS A SAMPLE THEME

Steph Garfield-Birkbeck, Tara Lamont and Matthew Westmore

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The National Institute for Health Research (NIHR) Health Services and Delivery Research (HS&DR) programme is funded by the English Department of Health with specific contributions from the CSO in

Scotland and NISCHR in Wales. Its purpose is to commission research to produce evidence on the quality, access and organisation of health services including costs and outcomes, to assist decision-makers in the improvement of health services and patient outcomes. The ethos of the centre managing the programme is ‘needs-led, science-added’. This means that a lot of work goes into ensuring that research commissioned by the programme is on topics identified as being of most interest and importance to the research-using community.

The presentation will show how we ensure that research commissioned addresses the most pressing evidence gaps or uncertainties identified by research-users and researchers. Using integrated care as the topic, we discuss examples from the programme's research portfolio covering areas such as: Virtual wards; Self-care and case management in long term conditions; the effective management of critical interfaces; Assessing outcomes of integrated care for people with long-term conditions; Self-management support among older adults: the availability, impact and potential of locally based services and resources. We will also consider what is the critical mass of research required to provide a sufficient body of evidence for decision-makers (ie: how big a research portfolio is required); how a small-scale study can still provide impactful findings which could be applied beyond the immediate disease area or particular service studied; how can research findings be durable/future-proofed; the major methodological issues encountered when commissioning viable research; how to manage research so that it delivers to contract.

### 333. PATIENT ASPECTS: A REVIEW OF FIFTY-EIGHT DANISH HTA REPORTS

Helle Ploug Hansen, Anne Lee and Christian Balslev van Randwijk

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**Objectives:** The objective of this presentation is to present results from a review about how patient aspects have been assessed in Danish HTA reports. Furthermore it shall contribute to the ongoing international debates concerning about how to gather patient evidence and the impact this can have in HTAs.

**Methods:** We systematically read fifty-eight Danish HTA reports published 1999 to 2010 focusing on the inclusion of patient aspects, the methods used to generate data (systematic reviews, primary research, or both), and the impact on final conclusions and clinical recommendations.

**Results:** Most of the reports had a chapter about patient aspects. In some way or another all reports included a literature reviews for patient aspects. Medical and HTA databases were the most frequently used for the literature search. There was a considerable variation in relation to how the authors presented and discussed their review methods. More than half of the reports generated empirical data, using quantitative as well as qualitative methods. All reports included the patient assessment in the summary and more than half of them included patient aspects in the recommendations. Some reports mentioned the importance of including patient aspects in daily clinical practice, while others provided ideas on how to improve patient information or recommended changes in healthcare practices.

**Conclusions:** Danish HTA reports do, to a large extent, include patient aspects in the assessment and in the final conclusions of the reports. However, there is still room for improvement. Especially in relation to the scientific managing, reporting, and production of clear recommendations. This conclusion is similar to the one reached in a review on the inclusion of patient and/or organizational aspects in HTA reports published by INATHA members 2000-05. It is important

that HTAs in the future integrate patient aspects in the assessments and the recommendations of HTA.

#### 421. ACKNOWLEDGING PATIENT HETEROGENEITY IN ECONOMIC EVALUATION: A SYSTEMATIC REVIEW OF GUIDANCE FROM PHARMACOECONOMIC GUIDELINES

Bram Ramaekers<sup>a</sup>, Manuela Joore<sup>b</sup> and Janneke Grutters<sup>a</sup>

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<sup>b</sup>Department of Clinical Epidemiology and Medical Technology Assessment. Maastricht University Medical Center. Netherlands.

**Background and Objective:** Although methods to acknowledge patient heterogeneity in health technology assessment (HTA) are available, patient heterogeneity is frequently neglected. However, mean cost-effectiveness for a population may mask important variations in cost-effectiveness. Reflecting heterogeneity has the potential to increase population health gains through a more individualized approach to the allocation of resources. Our objective was to review recommendations in pharmacoeconomic guidelines, which indicate the methods and requirements for economic evaluations in a particular country, with regard to the acknowledgment of heterogeneity and analyze their differences.

**Methods:** Pharmacoeconomic guidelines were obtained from the ISPOR website. Guidance on the identification of heterogeneity and methods to acknowledge heterogeneity was extracted from all guidelines. To compare guidance from different guidelines, extracted data were divided into subcategories based on consensus meetings.

**Results:** Of the 25 included guidelines, 20 (80%) advised to identify patient heterogeneity while 7 guidelines (28%) further specified whether to identify patient heterogeneity in relative treatment effects and/or baseline risks. Most guidelines (80%) provided some general methodological advice to acknowledge heterogeneity; including justifications for distinguishing subgroups (68%), prespecification of subgroups (44%) or methodology to acknowledge heterogeneity (80%). Subgroup analysis was most commonly advised (20 guidelines; 80%), however, guidance on specific methods to apply subgroup analyses was scarce (7 guidelines; 28%) and generally limited if provided.

**Conclusions:** The majority of pharmacoeconomic guidelines provide guidance on acknowledging heterogeneity in HTA. However, since guidance is mostly not specific, its usefulness is questionable. This may reflect that the importance of acknowledging heterogeneity is usually recognized while there is a lack of consensus on specific methods to acknowledge heterogeneity. We advise the further development of pharmacoeconomic guidelines to provide specific guidance on both the identification of heterogeneity and methods to acknowledge heterogeneity. This would facilitate the systematic and transparent handling of heterogeneity in economic evaluations worldwide.

#### 775. ECONOMIC IMPACT OF A HOUSING FIRST INTERVENTION FOR HOMELESS PEOPLE WITH MENTAL ILLNESS: PRELIMINARY ONE-YEAR RESULTS OF THE AT HOME/CHEZ SOI STUDY IN MONTREAL

Angela Ly<sup>a</sup>, Daniel Rabouin<sup>b</sup> and Eric Latimer<sup>c</sup>

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**Background:** Current health, social and justice services to homeless people have low levels of integration and many are not specialized in

dealing with homeless people with mental illness. More integrated patient-centered services may be more efficient.

**Objectives:** We report on the efficacy of 3 inter-related patient-centered Housing First interventions to improve housing outcomes for homeless people with mental illness, and evaluate their overall costs in comparison with usual services.

**Methods:** As part of a 5-year, pan-Canadian At Home/Chez Soi study, 302 participants with moderate needs (MN) entered a randomized trial of Housing First (HF) compared to treatment as usual (TAU), while 161 with high needs (HN) entered a parallel trial. The interventions integrate rehabilitation services with rent subsidies for private-market apartments. Service use and residential data were obtained through questionnaires administered at 6- and 3- month intervals. Costs from a healthcare perspective were estimated for three consecutive six-month periods.

**Results:** By the 6-12 month period, both HN and MN participants receiving HF were spending significantly more time in apartments, and less in shelters, compared to TAU (baseline differences n.s.). HN participants receiving HF also spent less time in hospitals: from 14.7% of days at baseline to 4.2% one year later, compared to 9.6% and 10.1% for TAU. For both HF and MN, no changes in costs of non-overnight services were observed. However, reductions in costs of shelters and hospitalizations more than offset costs of subsidized apartments for HN participants receiving HF: pre-baseline, overnight costs were \$18,145 for HF and \$14,826 for TAU (n.s.), vs. \$9,345 and \$16,749 one year later (p = 0.04).

**Discussion:** Preliminary results suggest that HF significantly increased time stably housed, while reductions in costs of shelter and hospital for HN participants, largely offset intervention costs. More complete results under a societal perspective are under preparation.

**Implications:** Client-centered care combining housing and rehabilitation services may be cost-efficient and improve outcomes for homeless people with mental illness.

#### 886. THE EVALUATION OF CHRONIC CARE PROGRAMMES IN CATALONIA: A CONCEPTUAL FRAMEWORK PROPOSAL

Mireia Espallargues<sup>a</sup>, Joan Escarrabill<sup>b</sup> and Dolors Ramírez<sup>c</sup>

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**Background:** The chronically ill and their caregivers have a high mortality & morbidity and quality of life impact and they represent a significant cost of care. Healthcare programs addressed to chronic care usually consist of complex interventions with the participation of multiple actors and levels of care and with difficulties when evaluating their results and impact or no evaluation at all.

**Objective:** To describe existing chronic care programmes in Catalonia (Spain) and propose a conceptual framework for their evaluation.

**Methods:** An operational definition of program has been proposed. Ongoing programs have been identified and described from various sources of information: data available from health authorities (Catalan Health Service, Catalan Health Service), interviews with key experts, repositories of organizational innovations (Health ICT Foundation, Observatory of innovation in health management in Catalonia), data/information supplied by the own programmes and review of the literature.

A conceptual model was defined based on domains emerging during the content analysis of included documents/data sources. Consensus meetings with different stakeholders will be carried out applying focus and nominal group techniques.

## 222. SERVICE UTILIZATION, PREDICTORS AND COSTS AMONG HIGH-RISK PATIENTS WITH CARDIOVASCULAR DISEASE: USING REAL WORLD DATA FROM THE AUSTRALIAN REACH REGISTRY

Zanfina Ademi<sup>a</sup>, Christopher Reid<sup>b</sup>, Deepak Bhatt<sup>c</sup>, Philippe Gabriel Steg<sup>d</sup> and Danny Liew<sup>a</sup>

<sup>a</sup>University of Melbourne. Australia. <sup>b</sup>Monash University. Australia. <sup>c</sup>Harvard University. USA. <sup>d</sup>Hôpitaux Universitaires Paris Nord Val de Seine. France.

**Background:** Cardiovascular disease remains one of the most common health problems in the world, both in terms of morbidity and mortality. Very few studies have reported follow-up data on costs and disease predictors.

**Objectives:** This study aims to quantify the resource utilization predictors and cost of cardiovascular disease using the Australian Reduction of Atherothrombosis for Continued Health (REACH) registry.

**Methods:** This study describes two-year cost data estimated using a bottom-up costing approach, and presents patterns of resource utilization based on types of vascular disease. The multivariate predictors of number of hospitalization, medication and other health services used per patient and related costs at two-year follow-up were examined using generalized linear models (GLM). Government reimbursement data from 2011 was used to calculate direct health care costs.

**Results:** Overall 2873 of the total 68 236 patients in the REACH registry cohort were enrolled from Australia. The two-year follow-up data was available for 2856 (99.4%) patients with or at high risk of atherothrombosis. Overall, the mean (SD) direct expenditure over 24 months of follow-up per person was \$7544 (\$10 758). In the adjusted model, patients with CAD and PAD incurred +A\$1255 (95% CI \$199 to \$2310) and +A\$4942 (95% CI \$3509 to \$6375) more in mean total costs compared to CerVD patients respectively. A history of atrial fibrillation (AF), peripheral arterial disease (PAD) and diabetes was associated with higher resource utilization.

**Discussion:** Our analysis has found that significant predictors of resource utilization and medical costs were PAD, AF, and diabetes. The results highlight the need for policies that target reducing the number of co-morbidities, which will decrease the incidence of PAD, AF and diabetes in population, given current and projected burden. This data provide the necessary framework for economic evaluations of health interventions.

## 424. RELATIVE EFFECTIVENESS OF PHARMACEUTICALS

Sarah Kleijnen and Wim Goettsch

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**Introduction:** Assessment of the effectiveness compared with alternative treatment(s) plays an important role in many jurisdictions in determining the reimbursement status of pharmaceuticals. This type of assessment is often referred to as a relative effectiveness assessment (REA) and is carried out by many jurisdictions at more or less the same time. Increased sharing of information across jurisdictions may save costs and reduce duplication. The objective of this study is to explore the main similarities and differences in the major methodological aspects of REA in multiple jurisdictions.

**Methods:** Thirty-five jurisdictions were included in the analysis. Data were gathered with a standardised data extraction form by searching publicly available information and by eliciting information from representatives at relevant organisations.

**Results:** Of the initially included 35 jurisdictions, data was gathered for 29 jurisdictions (26 European and three English speaking non-

European jurisdictions). There seem to be substantial similarities on the choice of comparator, the role of indirect comparisons and preferred endpoints in REAs (except for the use of utility values). However, jurisdictions differ in whether effectiveness (usual circumstances of health care practice) is estimated in case no (comparative) effectiveness data are available and how this done. National methodological guidelines on REA vary across jurisdictions in the level of detail provided.

**Discussion:** Some important methodological aspects for REA are approached in a similar way in many jurisdictions, indicating that collaboration on assessments may be feasible. Enhanced collaboration in the development of methods and best practices for REA between jurisdictions will be a necessary first step. Important topics for developing best practice are indirect comparisons and how to handle the gap between efficacy and effectiveness data in case good quality comparative effectiveness data is not yet available at the time of reimbursement decisions.

## 575. HORIZON SCANNING FOR HTA METHODOLOGICAL PRIORITIES: INTERNATIONAL CO-OPERATION NEEDED

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**Background:** The methodology for HTA has evolved rapidly over the last decade. Whilst the basic methodology is well established, there is still controversy about 'best practice' and challenges frequently arise in the context of specific technologies. Inadequacies in the evidence base have required the exploration of new methods such as indirect comparisons/network meta-analysis.

**Priorities for Research:** NICE, in collaboration with the UK's Medical Research Council have developed a formal framework for prioritising methodological uncertainties on an annual basis. An internal methods advisory group with support from a network of external research experts identified 45 key methodological uncertainties. These were clarified and prioritised into themes that included modelling service delivery, using qualitative evidence to capture patients experience, extrapolating data for co-morbid and paediatric populations and using observational data from large datasets for decision-making. The prioritisation framework and the final list of research priorities will be presented for consideration and comment.

**Need for co-operation:** It is becoming increasingly competitive to obtain research funding, particularly with the current economic climate. It is therefore essential that a formal process of prioritisation of methods research be established within organisations. Many HTA organisations do not have access to funding to enable in-house methodological development. International collaboration would help identify priorities and potential funding routes. There should be shared responsibility to ensure that key research is undertaken and co-operation to allow sharing of information to avoid duplication and improve efficiency.

## 692. PARAMETRIC SURVIVAL ANALYSIS IN HEALTH ECONOMICS

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**Background:** A large number of economic evaluations have life survival as a primary endpoint and clinical trials data are common used

to estimate the life survival. However, the clinical trials follow-up lengths are usually short and extrapolation techniques must be used to estimate the full survival. In this regard, parametric survival analysis has been largely used. Those models are built upon the supposition of a parametric function for the survival time. Different functions are available producing survival estimates with potentially large differences. It is therefore necessary to choose the parametric function on the light of the trial data available. That is, alternative models should be considered and its results formally compared. Also, Health Economics reviews that make use of parametric survival estimates should report the methodological process conducted in order to be transparent and justify their results.

**Objectives:** To present a systematic approach to parametric survival analysis (following the ideas of a technical report recently published by NICE) and how it can be performed using the software STATA.

**Methods:** This work shows a step by step practical example of parametric survival analysis using a real set of data from cardiac patients and the software Stata. It is shown how alternative parametric models (Exponential, Weibull, Log-Normal and Gompertz) can be fitted with particular attention to interpretation. Comparison among the alternative models are performed using graphical approaches (Log cumulative hazard plots and parametric versus Kaplan-Meier estimates plots), nested models and AIC/BIC tests. Practical guidelines of how to use and interpret these methods are addressed. Regression parametric models are also discussed.

## 722. UTILISING THE WARWICK PATIENT EXPERIENCES FRAMEWORK (WAPF) IN DEVELOPING NICE PATIENT EXPERIENCES GUIDANCE

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**Background:** The Warwick Patient Experiences Framework (WaPEF) was developed to inform and shape the NICE guidance and quality standard on patient experiences of health services.

**Objectives:** To identify generic themes and sub-themes of patient experience in three clinical areas: cardiovascular disease, diabetes and cancer. To use the themes and sub-themes identified in the three clinical areas to develop the Warwick Patient Experiences Framework (WaPEF) as an overall generic patient experiences framework that has potential relevance for all patients using adult health services. To utilise the WaPEF in the development of NICE Guidance on patient experience in the NHS.

**Methods:** Systematic review principles were used in the development of search strategies, inclusion and exclusion criteria and in the extraction of data from papers. An experiences framework was developed in each clinical area. The qualitative themes from each clinical area were synthesised to develop the WaPEF.

**Results:** The WaPEF identifies seven key generic themes that characterise patient experience: patient as active participant; responsiveness of services; an individualised approach; lived experience; continuity of care and the importance of relationships; communication; information, and support.

**Discussion:** The WaPEF is the first multidimensional framework for patient experiences with a robust underpinning, based on research evidence of what constitutes a good patient experience. The WaPEF informed the structure and content of the NICE guideline. The guideline is due for publication shortly and will form a key part of the NHS Outcomes Framework in England and Wales.

**Implications for health systems, professionals, patients and society:** The WaPEF could be adapted for use internationally in shaping the development of Patient Experiences Guidance which

aims to enhance the quality of the patient experience in international settings.

## 765. HOW GLAUCOMA PATIENTS ASSESS DIFFERENT ASPECTS 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. There is a need to prioritize these endpoints according to patients' preferences.

**Objectives:** To investigate how glaucoma patients prioritize different aspects of their treatment.

**Methods:** The study included a feasibility test and the complement of a specific questionnaire at the ophthalmology clinic of Bonn. Patients rated their preferences with respect to the importance of different aspects of glaucoma treatment by a pairwise comparison. These comparisons were performed by AHP, a multi-criteria decision analysis method using matrix algebra and relative weights were generated for each aspect. Additionally the EQ-5D was applied to stratify the patients into subgroups according to their stated utility.

**Results:** The AHP yielded the following results (weight, mean, sd, CI) by downwards order: 1. Autonomy (0.394, 0.371 ± 0.145, 0.311 - 0.431), subdivided in household chores (0.239, 0.275 ± 0.258, 0.168 - 0.381) and outdoor mobility (0.761, 0.725 ± 0.258, 0.619 - 0.832), 2. reading and seeing detail (0.229, 0.212 ± 0.123, 0.161 - 0.263), 3. darkness and glare (0.153, 0.165 ± 0.111, 0.119 - 0.211), 4. peripheral vision (0.089, 0.085 ± 0.058, 0.061 - 0.109), 5. side effects (0.088, 0.115 ± 0.131, 0.060 - 0.168) and 6. treatment-related burden (0.047, 0.052 ± 0.06, 0.027-0.076). The observed inconsistency reached a consistency ratio of 0.04 and did not exceed the limit of 0.1. Subgroup analyses of stratified patients showed adaptation effects and loss aversion.

**Discussion:** AHP can be used in HTA to give a quantitative dimension to patients' preferences for treatment aspects. Preference elicitation could provide important information at various stages of HTA and challenge opinions on the importance of treatment aspects or endpoints.

Implications for patients: Preference elicitation could provide important information at various stages of HTA and challenge opinions on the importance of treatment aspects.

## 847. MEASURING PUBLIC PREFERENCES FOR COLORECTAL CANCER SCREENING USING NEW GENOME-BASED NANOTECHNOLOGIES

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**Background:** Emerging developments in nanomedicine allow the development of genome-based technologies for unobtrusive and individualised screening for diseases such as colorectal cancer. An example is the nanopill that collects gastrointestinal fluid and screens DNA for tumour markers. The main objectives of this study were to explore if the inclusion of user preferences in early stage product development would be valuable and measure expected screening uptake compared to standard colorectal cancer screening.

**Methods:** Data was collected through a discrete choice experiment among individuals aged between 50 and 74 years living in the

Netherlands and the United Kingdom. A full-profile fractional factorial design with a balanced overlap was implemented. Fourteen random and two fixed choice-tasks with triplets and dual-none response were used. Through an extensive literature search following attributes were included: preparation, technique, sensitivity, specificity, complication rate, and testing frequency. Data were analysed using Hierarchical Bayes analysis and a Multinomial Logit model.

**Results:** Data was collected from 1356 respondents (56952 observations) who completed the questionnaire. Most preferred attributes were: technique (pill), sensitivity (100%), preparation (none), frequency (biennial), specificity (100%), and complication rate (none). Nanopill was with an expected screening uptake of 47% the most preferred screening modality, followed by iFOBT (35%), sigmoidoscopy (5%) and colonoscopy (3%). Eleven percent would choose not to be screened. Sensitivity analysis showed that the nanopill should be at least 90% sensitive, 95% specific and have an interval of two years to be equally attractive as biennial iFOBT.

**Conclusions:** Expected benefits of genome-based nanotechnologies are improved screening adherence, earlier diagnosis and more accurate test results. Study findings adhere to the outcomes of previous studies, and suggest the nanopill to be accepted by the public, which does support further development.

**Implications:** Early stage preference assessment in new product development is beneficial and may offer several advantages such as a better understanding of consumer needs, estimate preference for a technology that is not yet available and inform R&D to make timely adjustments if needed.

#### 946. TELEASSISTANCE AND HEALTH RELATED QUALITY OF LIFE IN PEOPLE WITH NEUROMUSCULAR DISEASES

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Neuromuscular diseases are a group of pathologies characterized by the progressive loss of muscular strength, atrophy or hypertrophy, fatigue, muscle pain and degeneration of the muscles and the nerves controlling them (The French Muscular Dystrophy Association, 2004). Perceived isolation and health related quality of life are affected in the majority of cases due to the illness chronicity. Internet, and in this way, the use of chat and videoconferencing programs, is an alternative option to mitigate the mentioned variables. Thus, the aim of the study is to assess the effectiveness of teleassistance on reducing isolation and improving health related quality of life in adults with neuromuscular diseases. The sample is composed of 60 participants randomly selected and affected by different neuromuscular diseases (e.g. Myasthenia Gravis, Becker Muscular Dystrophy, Facioescaapulohumeral Muscular Dystrophy, etc.). Thirty patients were assigned to the experimental group, which participated in the chat and videoconferencing sessions, and the other thirty to the control group, which did not participate. The inclusion criteria for both groups were: medical confirmed diagnosis (CIE-10) of one of the diseases mentioned above, age  $\geq 18$  years, agreeing to participate in the study by signing an informed consent, and finally, ability to manipulate a computer (just for the experimental group). The exclusion criteria for both groups were to have a psychiatric disorder (DSM-IV-TR), head trauma or severe visual limitations. All the patients were recruited from neuromuscular disorders associations and Hospitals of The

Basque Country. Effectiveness were assessed by a pre-post design in which questionnaires and interviews were administrated (e.g. Disability Assessment Schedule – WHO-DAS II, Sickness Impact Profile, The MOS Social Support Survey, etc.). The online support entails different activities developed during three months in once a week sessions: a) Group videoconference sessions with a Psychologist, b) Individual videoconference sessions with a Neurologist, and c) Forum discussion groups about biopsychosocial issues. The psychologist counseling consists on a psychosocial program about general topics such as illness information, emotional reactions to the disease, the most frequently automatic thoughts, etc. A web site was developed to carry out the intervention: <http://neuromusculares.deusto.es/>. An exhaustive preliminary analysis of this pre-post assessment was necessary in order to know if the psychosocial programme is effective and if it could be a helpful tool for this type of population. Preliminary results revealed that health-related quality of life improved after the teleassistance and feelings of isolation were reduced in patients with mobility problems due to teleassistance. High levels of satisfaction are reported by the participants. Teleassistance is an effective alternative way of advising people with neuromuscular disorders.

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#### 866. DESIGN OF IMPLEMENTATION MEASURES ARE EXTREMELY IMPORTANT TO INCREASE THE PARTICIPATION RATES AND SUCCESS OF A POPULATION-BASED SCREENING FOR COLORECTAL CANCER

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**Background:** Cancer is the first cause of mortality in the Basque Country (ACBC). Colorectal cancer (CRC) is the second cancer in women and men, after breast and lung cancers, respectively. The European Code Against Cancer (2003) includes among its recommendations that “men and women aged 50 years or over should participate in colorectal cancer screening programs” and “these programs should incorporate quality assurance procedures”. European Union and Spanish Ministry of Health support similar measures.

**Objectives:** To detect early lesions, high-risk adenomas and malignancies in the first phase and to eliminate its influence and reduce mortality rates.

**Methods:** The CRC screening programme of the ACBC, includes people aged 50–69 years in a biennial iFOBT screening. Individuals collect the sample and deliver them at a health care centre and then to laboratory. The final result is communicated to the individual at home and his/her primary care physician. In case of a positive diagnosis, primary care physician requests colonoscopy. Data from 2009–2010 were collected and analysed.

**Results:** 111,047 individuals aged 50 to 69 out of 116,948 were invited. The overall participation rate was 65% and positive results 6.9%. Colonoscopy was performed to 90.84% of the positive cases. Female participation rate was 67.20% and male 61.79%. Positive rate was 4.25% for females and 8.60% for males. Complication rate of colonoscopies was 1.09%. The positive predictive value for cancer was 6.28% and for high risk adenomas 42.72%. The detection rate for advanced stage cancer was 0.12 per 1,000.

**Discussion:** Possible reasons that could explain high participation rates could be the involvement of primary care and the submission of

the kits to the homes of patients. The identification of factors influencing partaking of CRC screening can be used to increase participation and the health benefits for the population.

#### 294. PUBLIC INVOLVEMENT IN THE SYSTEMATIC REVIEW PROCESS IN HEALTH AND SOCIAL CARE: A NARRATIVE REVIEW OF CASE EXAMPLES

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**Background:** It is good practice for the public to be actively involved in systematic reviews. Objectives: To review examples of public involvement in the review process; to examine the different methods and stages of involving the public; to synthesise their contributions, and to identify tensions, facilitating strategies and recommendations for good practice.

**Methods:** Systematic literature search and narrative review.

**Results:** Seven examples were found covering the following review topics: patients' perspectives on electro-convulsive therapy; user involvement in nursing, midwifery and health visiting research; treatments for degenerative ataxias; teaching, learning and assessment of law in social work education; HIV health promotion for men who have sex with men; the conceptualisation, measurement, impact and outcomes of public involvement in health research; methods of consumer involvement in developing healthcare policy and research, clinical practice guidelines and patient information material. The public was found to contribute to reviews by: refining the scope; suggesting and locating relevant literature; appraising the literature; interpreting review findings; writing up the review. No evidence was found of public involvement in meta-analysis. Involvement methods included consultation workshops, membership of review advisory groups, membership of the review team, email discussion lists, and the Delphi process.

**Discussion:** Concerns raised by researchers about involving the public in the review process included: funding and time pressures, confusion over whether ethical approval is required, and the representativeness of the public. Good practice recommendations included offering payment for the public, identifying a lead for involvement among the research team, training and information provision for the public, and using structured methods of involvement.

**Implications:** Review commissioners need to be aware that public involvement, if undertaken meaningfully, may mean that reviews take longer to deliver whilst being more expensive, compared to reviews that do not involve the public. Published examples are needed of public involvement in meta-analysis.

#### 440. HANDLING SURROGATE OUTCOMES BASED EVIDENCE IN HTA: A FRAMEWORK FOR THE NICE METHODS GUIDE UPDATE

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Current methods guidance of international HTA agencies, including the National Institute for Clinical and Health Excellence (NICE), have been shown to contain almost no detailed methodological advice on the handling and validation of surrogate outcomes (Elston et al. *Int J Technol Assess Health Care*. 2009;25:6-13; Velasco Garrido et al. *Surrogate outcomes in health technology assessment: an international comparison*. *Int J Technol Assess Health Care*. 2009;25:315-22), with the exception of the Australian

Pharmaceutical Benefits Committee (PBAC), yet this advice has not been formally incorporated into PBAC's submission guidance for industry. This gap is in sharp contrast to controversy that surrounds the use of the surrogate outcomes (Yudkin et al. *BMJ*. 2011;343:d7995-d) and their increasing use in clinical trials with the desire of driving faster market access in terms of both licensing and reimbursement. In 2012, the NICE Methods Guide is being updated on the basis of a number of specific aspects, one of which is handling of surrogate outcomes in appraisals. This presentation will discuss a framework proposed for the NICE methods guidance update based on the three following issues: 1) the appropriate definition of surrogate outcomes to use within the HTA context, i.e. whether the definition should be limited to include not only biomarkers but a wider category of intermediate health outcomes (e.g. fracture rate, progression free survival); 2) the assessment of the validity of the surrogate outcome, i.e. what evidence should be provided to assess whether a proposed outcome can be reasonably accepted as a surrogate outcome; 3) the prediction and quantification of the surrogate-final outcome relationship to input in the cost-effectiveness analysis, i.e. how the treatment effect on the surrogate outcome can be used to predict the final outcome and, thus, assess the incremental cost per QALY. We will also discuss the implications of the updated guidance on the use surrogate outcomes for stakeholders and future technology appraisals.

#### 718. SAFEGUARDING PATIENTS' INTERESTS THROUGH DECLARATIONS OF CONFLICTS OF INTEREST IN CLINICAL PRACTICE GUIDELINE DEVELOPMENT

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There is a conflict of interests (COI) whenever the professional judgement about a primary interest (i.e: patient welfare or validity of research results) of a member of a panel can be affected by a secondary interest (financial compensation, personal rivalry, etc.). Members of a Clinical Practice Guideline Panel have the responsibility of acknowledging every personal and economical relationship that could influence their opinion. In the case of the National Guideline for Tobacco Cessation for Argentina we asked for potential COIs using a questionnaire involving the previous five years and including reimbursement by scientific talks or events, honoraria for conferences or presentations on the guideline topics, research grants, advisory boards, consulting, financial interests, and other COIs. We asked about close relationships with persons with interests in the publication of the guideline, personal or academic rivalries or personal convictions that could bias the opinions on the guideline topics. Nineteen members of the panel had nothing to disclose. Two members had previously been involved in clinical trials. Three members had received honoraria for talks. Most of the COIs were related with the sponsor of an specific smoking-cessation drug. COIs were classified as potential and actual. While the final version of the Guideline was being prepared, two meta-analysis questioning the safety of this drug were published. This evidence affected the strength of recommendations for the drug. In two cases, members of the panel with actual COIs related to the sponsor of the drug chose not to participate in a plenary session after discussing the situation with the steering group and were excluded from the panel. The issue was of such importance that a plenary panel session was summoned out of schedule to rediscuss several recommendations of the GPC which ended up in the change of the strength of several recommendations. In order to minimize the impact of not acknowledged potential biased

opinions, members with potential COIs were placed in different groups in the moment of formal consensus. Declaration of COIs kept patients' best interests safe from potential influences on the decision-making process.

#### 745. INTERVENTIONS TO INCREASE PARTICIPATION IN ORGANISED SCREENING PROGRAMS: A SYSTEMATIC REVIEW

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**Background:** European Union Guidelines recommend the implementation of population-based organised screening programmes for breast cervical and colorectal cancer in order to obtain high coverage of the target population and equity of access. The Italian Ministry of Health sponsored an HTA report on methods to increase uptake to oncologic screening.

**Objective:** To assess the effectiveness of intervention to increase participation in organised screening programmes.

**Methods:** We updated the systematic review conducted by Jespon et al. (2000). Literature search was made on electronic databases as well as retrieving grey literature on national and regional websites. We included all studies on interventions, strategies or programmes aimed at increasing screening participation published between 1999-2009. Only studies comparing interventions vs. a standard invitation letter were included. Relative risk for participation in breast ( $RR_M$ ), cervical ( $RR_M$ ) and colorectal ( $RR_M$ ) screening are reported.

**Results:** We identified 5900 of which 900 were relevant. Among these 51 reported quantitative, other 70 studies were included from the previous review (Jepson, 2000). The following interventions showed a relevant effect: a mail ( $RR_M = 1,37$  CI95%: 1,25-1,51;  $RR_C = 2,46$  CI95%: 2,15-2,81;  $RR_{CR} = 1,33$  CI95%: 1,17-1,51) or phone recall ( $RR_M = 1,58$  CI95%: 1,20-2,07;  $RR_C = 2,52$  CI95%: 1,44-4,41;  $RR_{CR} = 1,35$  CI95%: 0,96-1,98) after the invitation letter; the GP's sign on the letter ( $RR_M = 1,13$  CI95%: 1,11-1,16;  $RR_C = 1,20$  CI95%: 1,10-1,30;  $RR_{CR} = 1,19$  CI95%: 1,06-1,34); individual educational interventions ( $RR_M = 1,24$  CI95%: 1,01-1,52;  $RR_C = 1,23$  CI95%: 1,04-1,45;  $RR_{CR} = 1,28$  CI95%: 1,00-1,64); a pre-fixed compared to an open appointment ( $RR_M = 1,26$  CI95%: 1,20-1,33;  $RR_C = 1,20$  CI95%: 1,16-1,25;  $RR_{CR} = 1,42$  CI95%: 1,36-1,48); a reminder to the GP for overdue people ( $RR_M = 1,08$  CI95%: 1,03-1,14;  $RR_C = 1,14$  CI95%: 1,03-1,26). Generally, many interventions aimed at removing logistical barriers were effective, particularly for colorectal screening. Few evidences were available for mass campaigns and for face to face recall. Mailing informational material is not effective.

**Implications for the health system:** There are several evidence-based interventions, even if many cultural and social factors may be relevant effect modifier. Some interventions can be implemented with very few adjunctive resources.

#### 937. DEVELOPING METHODOLOGICAL STANDARDS FOR SEARCHING FOR STUDIES: EXPERIENCES FROM THE COCHRANE COLLABORATION

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Searching for studies is a key element of evidence synthesis (systematic reviews, HTAs and guidelines). As part of the ongoing

work to improve the quality of Cochrane Reviews, the Methodological Expectations of Cochrane Intervention Reviews (MECIR) project was established. It specifies methodological expectations, or standards, for Cochrane Protocols, Reviews and review updates of the effects of interventions. These standards, and the methods for their development, are applicable beyond Cochrane Reviews to other evidence synthesis settings. They provide authors and users of *The Cochrane Library* with clear and transparent expectations of review conduct and reporting. They will enable Cochrane Review Groups to hold authors accountable during the editorial process and can be used to audit Cochrane Reviews. As part of this project, a MECIR Working Group on searching for studies was established, including information specialists within the Cochrane Collaboration (Trials Search Co-ordinators) and review authors and editors. The Group identified essential minimum standards with respect to the *conduct* of Cochrane reviews (reviews not meeting these standards should not be published) and highly desirable standards (practice which is expected but may be justifiably not done). These standards were widely consulted upon, released in October 2011 and updated in December 2011. These standards relate to new Cochrane Reviews (not protocols or updates) and will be reviewed in 2013. The next stage of the process is to identify and agree mandatory and highly desirable standards for the *reporting* of Cochrane Reviews. Also 'Good practice guidance' will list recommendations, beyond the conduct standards, on preferred practice for Cochrane Reviews and a 'Common errors' document will provide examples of errors that commonly occur in the preparation of Cochrane Reviews. This presentation will describe the process involved in reaching consensus in this complex area and outline the agreed standards with respect to searching for studies.

#### 150. IMPACT OF THE NATIONAL MANAGED UPTAKE OF MEDICAL METHODS -PROGRAM ON UPTAKE OF NEW TECHNOLOGIES IN SECONDARY HEALTH CARE IN FINLAND

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**Background:** Managed uptake of medical methods (MUMM) is a national program established to guide the use of new technologies in Finland. Together with the National Institute for Health and Welfare, hospital districts identify and evaluate technologies considered for use in specialized health care. Recommendations for the uptake of technologies are given by using traffic light signals.

**Objectives:** To analyze the impact of the MUMM-program on decision making and the uptake of assessed methods.

**Methods:** Application of recommendations given between 2008 and 2010 was evaluated. From the national registries for hospital discharge data and medical use of radiation, the annual numbers of methods that were identifiable by procedure codes were analyzed. The use of techniques without codes was assessed by a survey to hospital districts.

**Results:** Since 2008, 38 recommendations for 32 technologies were given including 5 red, 19 yellow and 14 green lights. Only four green lights were given without restrictions on the use of the technology. Yellow lights were given due to inadequate or contradictory effectiveness data or lack of long term results. Among recommendations given by the end of 2010, only 4 of 11 invasive techniques had a specific procedure code reported in the national

registry. The scarce data on the use of technologies reflected the traffic light. Two medical treatments and five bedside techniques could not be tracked from any registries. A survey concerning a technique having received a red light revealed that the majority of hospital districts had adjusted their practice according to the recommendation.

**Discussion:** Lack of specific procedure codes prevents tracking the use of new technologies from hospital discharge data. Furthermore, quantitative analysis is seldom sufficient for studying the impact of recommendations on the uptake and spread of technologies. Opinion surveys, at best, tell about the awareness of national recommendations as a source of guidance.

**Implications for the health system/professionals/patients/society:** National agreements on uptake of new technologies support clinical and administrative decision making in secondary health care. Methods for following the impact of recommendations need to be developed.

## 525. THE SIGNET PROGRAMME: A SIGNIFICANT MILESTONE IN COLLABORATIVE HTA CAPACITY AND CAPABILITY BUILDING

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**Background:** The need to apply principles of contextually relevant, evidence-based health-care has been felt in India for several years. However the capacity to undertake systematic reviews on efficacy of health technologies, did not translate to practice. The reasons included inability of end-users (as opposed to producers) to apply the results of systematic reviews; and the gap between research-evidence and real-world practice. SIGNET addresses this need by training users of evidence (policy-makers, clinicians, nursing personnel, and hospital administrators) to understand and apply the products of research evidence.

**Process:** The SIGNET training-of-trainers initiative is designed to build institutional capacity and capability in evidence-based health-care management in a cascading fashion. Key elements include (i) Learning-by-doing approach, (ii) Focus on local context, (iii) Efficient utilization of time and resources, and (iv) Partnership relationship between participating stakeholders.

**Outcomes:** Since its inception, 16 training workshops (480 personnel) and 12 short-term implementation projects have been undertaken to build and demonstrate individual capacity and institutional capability in evidence-based management of health technologies. Some of the significant outcomes in participating institutions are (i) reduction in procurement time of expensive health technologies by 50%, (ii) smooth patient flow in out-patient and emergency departments, (iii) reduction in hospital acquired infection, (iv) streamlining pharmacy services, (v) health education during outpatient waiting period, and (vi) cost-effective inter-departmental sharing of hi-tech technologies (ventilators and blood-gas analysers). A significant outcome is the changed mind-set that enhanced health-care management (applying EBM and HTA principles).

**Conclusion:** The SIGNET Programme is a successful model in the Indian health-care context and can be readily implemented in other resource-limited settings as well.

Note: A previous version of this abstract was rejected as a panel session proposal and is submitted here for oral presentation on the advice of the ISPC.

## 532. NATIONAL COLLABORATION TO SUPPORT ESTABLISHMENT OF A NATIONAL TRANSPLANT SERVICE

Brendon Kearney<sup>a</sup>, Simon Towler<sup>b</sup>, Suzanne Byers<sup>c</sup> and Paul Fennessy<sup>c</sup>

<sup>a</sup>Health Policy Advisory Committee on Technology. Australia. <sup>b</sup>Western Australia Health. Australia. <sup>c</sup>Victorian Department of Health. Australia.

**Background:** Australia's Nationally Funded Centres Program is a super-specialty program that supports provision of certain high cost, low volume procedures to ensure national equity of access and full coverage for all Australians (e.g. paediatric liver, heart and lung transplants). While there is limited demand for intestinal transplantation (ITx) in Australia (thought to be < 5 p.a.), suitable recipients are usually referred to the USA or UK for surgery. However, this is a costly venture, thought to range up to \$10M per case. Australia's only ITx case was successfully undertaken in 2010, resulting in interest to establish a local, national ITx program.

**Objectives:** A national ITx program could not function unless there was appropriate: i) clinical support within each Australian state to manage patients with intestinal failure (IF) both pre- and post-ITx transplant; and ii) support for a single national ITx provider. Establishing a national ITx program has training, workforce, process and funding implications.

**Methods:** HealthPACT, Australia's national horizon scanning agency, held a national workshop, attended by clinicians and policy makers, to address these issues and determine whether a way forward could be identified to: i) identify existing opportunities for managing those intestinal failure; and ii) support the establishment of a national ITx program.

**Results:** The workshop resulted in national agreement to: define & map IF service system configuration, model of care & referral pathways; review organ allocation protocols for ITx; estimate prices for ITx assessment, work-up and ITx; support establishment of a national travelling fellow position; seek Commonwealth government support to develop an Australian ITx service.

**Implications:** This national collaborative approach has the potential to support a coordinated implementation of high cost, low volume, high quality technologies and procedures that ensure national equity of access and full coverage for all Australians.

## 772. REGIONAL DEVELOPMENT OF HTA IN EUROPE: OPTIMISING CONSISTENCY AND EFFICIENCY

Michael Chambers<sup>a</sup>, Walter Ricciardi<sup>b</sup> and Michael Chambers<sup>a</sup>

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Local HTA development reflects organisation and priorities of specific health systems. A distributed 'regionalised' model, well established in Canada and Spain, is emerging in Italy. 'Value in HTA' (ViHTA) aims to share HTA methodology among Italian regions. Having mapped the current state of HTA the project has undertaken an educational programme tailored to regional needs. It is now supporting adaptation of European guidelines, methodological convergence between parties involved in drug evaluation, and quality improvements in Italy through enhanced peer review and information exchange. Drawing on the experience of ViHTA, this presentation will discuss the following: Objectives of regionally-based HTA organisations: how they may differ from National HTA and the advantages and disadvantages of centralised versus decentralised country models of HTA. How the organisation of regional systems of HTA can best maintain consistency and efficiency across regions, and in particular how local HTA organisations can co-ordinate assessments and share technical skills which may be inefficient to replicate at the local level. How stakeholders including Pharma companies and other technology

suppliers can best collaborate with a decentralised HTA model. How synergies be created across regionally organised countries and with pan-country organisations such as EUnetHTA.

### 30. SYSTEMATIC REVIEW OF ECONOMIC EVALUATION LITERATURE IN GHANA: IS HEALTH TECHNOLOGY ASSESSMENT THE FUTURE

Emmanuel Odame<sup>a</sup> and Daniel Adu Ankrah<sup>b</sup>

<sup>a</sup>Ghana Health Service, Ghana. <sup>b</sup>University Of Reading, UK.

In many countries, like Ghana, there is an increasing impetus to use economic evaluation to allow more explicit and transparent healthcare priority setting. However, an important question for policy makers in low income countries is whether it is possible to introduce economic evaluation data into healthcare priority-setting decisions. In addition to ethical, social and political issues, contextual issues need to be addressed. This paper systematically reviewed the literature on economic evaluation of health conditions in Ghana published between 1990 and 2010. Its aim was to analyze the quantity, quality and targeting of economic evaluation studies that can provide a framework for those conducting similar health technology assessment reviews in similar contexts. The review revealed that, the number of publications reporting economic evaluations was almost nonexistent. With the introduction of the National Health Insurance Scheme since 2004 policy makers are confronted with the challenge of allocating scarce resources rationally, i.e., they also have to make better use of available resources. Priority setting therefore has to be guided by a sound knowledge of the costs of providing health services the need for economic evaluation is thus important. The studies found were more costing studies, there were very few cost utility and cost effectiveness analysis studies. Furthermore, there are very few economic evaluation publications for the top 10 disease conditions in Ghana, indicating a poor distribution of research resources towards the determination of cost-effective interventions for diminishing the disease burden of certain major health problems. If economic evaluation is only useful for policy makers when performed correctly and reported accurately, these findings depict barriers to using economic evaluation to assist decision making processes in Ghana, hence the need for a health technology assessment unit.

### 188. WHAT'S THE PROBLEM? PATHOLOGISTS' ENGAGEMENT WITH EVIDENCE IN A DISINVESTMENT CONTEXT

Janet Hiller<sup>a</sup>, Katherine Hodgetts<sup>b</sup>, Amber Watt<sup>b</sup>, Adam Elshaug<sup>c</sup> and Astute Study Group<sup>b</sup>

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<sup>b</sup>University of Adelaide, Australia. <sup>c</sup>Harvard Medical School, USA.

**Background:** Pathology testing for B<sub>12</sub> and folate (frequently ordered as one conjoint B<sub>12</sub>/folate test) represents a sound disinvestment case study on multiple grounds: systematic review (SR) evidence demonstrates poor diagnostic accuracy; consensus-based clinical practice guidelines are inconsistent, and rapid growth in the use of the conjoint test is evident.

**Methods:** An evidence-informed stakeholder engagement around utilisation trends, clinical evidence and public subsidy of B<sub>12</sub>/folate tests was held in 2011. Participating pathologists deliberated around SR findings, and utilisation and audit data, to generate an informed contribution to future funding policy. Deliberations were transcribed and subject to qualitative analysis.

**Results:** Pathologists contested the usefulness of the SR evidence in informing disinvestment policy around B<sub>12</sub>/folate on two related grounds. They *contested the terms of the problem*. Pathologists argued that ordering of B<sub>12</sub> tests remains appropriate given that deficiencies are identified, have serious consequences, and their relative incidence has not decreased as utilisation has grown. They *reframed the terms of the problem* as a) attributable to folate testing alone (since mandatory fortification has made the identification of deficiency rare) and b) linked to inconsistent reference ranges defining B<sub>12</sub> deficiency (a barrier to a true analysis of effectiveness via SR). These reframings suggested that relevant disinvestment recommendations would involve a) splitting the combined test so that utilisation of folate testing would decrease and b) further research into B<sub>12</sub> reference ranges by pathologists themselves to improve diagnostic accuracy. While offering valuable insight and potentially material benefit, these recommendations refrained from addressing disinvestment options specifically pertaining to B<sub>12</sub> testing.

**Conclusions:** The negotiation of appropriate evidence is complex within deliberative policy processes. While vital in areas of technical complexity, stakeholder input may reflect concern around 'what stands to be lost'. Stakeholder involvement might usefully begin with explicit discussion of these issues to inform subsequent methods of data collection, evaluation and disinvestment debate.

### 265. FOLLOWING HEALTH TECHNOLOGIES (HT) AFTER INTRODUCTION INTO CLINICAL PRACTICE: THE CASE OF MINIMALLY INVASIVE CARDIAC VALVE SURGERY (MICS) IN A MIDDLE INCOME COUNTRY

Nathalia González-Jaramillo, Juan Santiago Jaramillo, Paula Goez, Gustavo González and Juan Camilo Rendón

*Clínica Cardiovascular Santa María.*

**Background:** Increasing technological innovation has brought significant challenges to most health systems worldwide. Early assessment of new technologies after they are covered by the health system is deemed crucial to promptly identify unforeseen problems that may arise when these are used in real world settings. Currently many organizations recognize that real benefits from the use of new HT depend on conditions that can only be evaluated after the approval and adoption into clinical practice. Nonetheless, it is clear that both individual operators and institutions learn through experience and change in effectiveness over time could invalidate health technology assessments if learning curve(LC) is not considered in analysis.

**Objectives:** To assess LC effect on postoperative morbidity and mortality and to compare clinical outcomes between conventional versus MICS after overcoming of LC.

**Methods:** After Institutional approval for implementation of MICS on a tertiary level center, 100 patients were treated between November 2010 and October 2011. We initially compared mortality, Length of stay (LOS), transfusions, cross clamp time (CCT), procedure time(PT), infections and costs between first and second halves. Comparison between techniques was done with both the entire group as well the last 50 patients. Statistical analysis for continuous variables was performed using the Mann-Whitney U test in SPSSv19. A value of p<0.05 was considered statistically significant.

**Results:** Overall mortality was 6%, after first fifty patients, mortality rate was improved from 8% to 4%. Improvement after LC was also observed for LOS, CCT and PT. MICS outperformed conventional technique in terms of CCT, transfusions, infections and LOS, whilst no difference was found on mortality or costs.

**Discussion:** This is an example of successful implementation of HT. Despite the additional risk posed initially by the learning curve, mortality rate in this middle income setting is comparable with that reported by the European Association for Cardio Thoracic Surgery.

## 270. INDUSTRY INVOLVEMENT IN EARLY AWARENESS AND ALERT ACTIVITIES

Sue Simpson and Claire Packer

*EuroScan International Network. UK.*

**Background:** A recent Joint Healthcare Industry Paper on the value of industry involvement in health technology assessment (HTA) (Joint Healthcare Industry Paper, The Value of industry involvement in HTA, December 2011) states that proper involvement of industry can support efficient decision-making, allocation of resources and informed uptake and diffusion of technology. Although the paper mentions involvement in the early stages of HTA there is no mention of input into early awareness and alert (EAA) activities. EuroScan International Network produced a position paper on the collaboration of EAA systems with industry in 2003, and plan to review this in 2012.

**Objective:** To determine the purpose and level of involvement with industry in EAA activities carried out by EuroScan members.

**Methods:** In November 2011, a short web-based questionnaire was sent to members of EuroScan. Closed questions asked about the level of collaboration, the type of industry collaborated with, and the purpose and methods of collaborating. A simple descriptive analysis was performed.

**Results:** Eighteen out of twenty (90%) EuroScan members responded. Of these over half (56%) collaborated with industry when carrying out EAA activities. The companies collaborated with most often are device and diagnostic companies. The most common reasons for collaboration are identification of emerging health technologies, and obtaining information to include in an early assessment. Half of agencies have a confidentiality agreement in place and meet regularly with some of the companies they collaborate with. The position paper on collaboration with industry developed by EuroScan was used by only 30% of members.

**Discussion:** The level of involvement with industry by EAA agencies was lower than expected given the potential importance of these partnerships. However those collaborating with industry involve them in multiple stages of the EAA process. In reviewing the position paper EuroScan will endeavour to strengthen collaboration for its members.

## 388. HOSPITAL-BASED HTA: DOES IT IMPACT ON MEDICAL TECHNOLOGIES' EXPENDITURE AND CONSUMPTION?

Paola Roberta Boscolo<sup>a</sup>, Oriana Ciani<sup>b</sup> and Aleksandra Torbica<sup>c</sup>

<sup>a</sup>CERGAS Bocconi University. Italy. <sup>b</sup>CERGAS Bocconi University and Exeter University (UK). Italy. <sup>c</sup>CERGAS Bocconi University; European Health Technology Institute for Socioeconomic Research. Italy.

**Background:** The early development of Italian hospital-based HTA is largely based on experimental approaches. HTA in hospitals can support administrative procedures increasing dialogue and transparency as well as promoting the bottom-up awareness generation around HTA principles. Whether HTA has an impact on actual hospital decisions regarding health technologies has not been investigated.

**Objectives:** 1) To survey the HTA activities at the hospital level in Italy in terms of structure, role, output and linking with decision-making. 2) To assess the relationship between the implementation of HTA principles in the healthcare trusts and the diffusion and expenditure of selected health technologies.

**Methods:** We run a survey on a sample of Italian Healthcare trusts. We asked for 2008-2009 data about consumption and unitary costs of selected medical devices (i.e. hip prostheses, coronary stents) and HTA activities. We tabulated the results and supplemented the dataset with additional information about hospitals' characteristics to assess

in a multivariate analysis whether an association exists between the implementation of HTA activities and medical devices diffusion at the local level.

**Results:** Given 65 respondents to the survey' part related to HTA's activities, 38 hospitals in 13 Italian Regions provided information related to hip prostheses expenditures. Among these, 20 (53%) have a commission for MDs. They meet monthly and encompass on average 10 members (SD = 5), whose at least 3 medical doctors, 2 pharmacists and 1 clinical engineer. Half of the commissions produce HTA forms, mainly focused on clinical effectiveness rather than economic, organizational, legal and ethical aspects. 19 (50%) hospitals declare a link exists between procurement and HTA activities, whilst in 6 (16%) cases they also contribute to MDs' consumption definition. A preliminary analysis on the association between HTA activities and hip prostheses diffusion highlighted a significant difference exists in the annual variation in uptake and consumption ( $p < .10$ ) of the technology.

**Discussion:** We suggests that HTA could potentially impact on health technologies' uptake and expenditure when realized together with other hospital units, thus providing local healthcare managers with a useful tool for budget control and planning.

## 576. INCORPORATING PERIPHERALLY INSERTED CENTRAL CATHETERS (PICC) IN HOSPITAL CLINICAL PRACTICE: AN EVIDENCE BASED PROCESS

Lucia Garate Echenique<sup>a</sup>, Inmaculada Moraza Dulanto<sup>a</sup>, María Ángeles López Salsamendi<sup>a</sup>, María Aránzazu Tomás López<sup>a</sup>, Victoria Armenteros Yeguas<sup>a</sup> and Erika Miranda Serrano<sup>b</sup>

<sup>a</sup>Osakidetza-SVS-Basque Health Service. Spain. <sup>b</sup>Unidad de Investigación. Álava. Spain.

**Background:** The incorporation of technology into hospital clinical practice is not always based on evidence criteria. Although the purchasing committee asks for a report containing scientific evidence, efficiency and applicability for every product requested, factors such as the achievement of management objectives, previous purchases or impressions of clinical benefit also influence shopping decisions the ways technology is incorporated.

**Objective:** To describe the evidence-based incorporation of PICC in Alava's University Hospital as an alternative to other venous access devices.

**Methods:** A review was conducted in UpToDate, Clinical Excellence, Cochrane, RNAO, NICE, Medline, EMBASE and CINAHL databases in February 2010. Articles were selected if PICC clinical or economic outcomes, insertion, maintenance or patient information were addressed. 130 documents were retrieved. Based on this evidence, protocols for PICC use, placement and care were developed. The commercial firm provided some catheters and training for nurses to place PICC using ultrasound. A database including success in catheter placement, reasons for withdrawal and complications was developed to study the PICC results in our hospital. Based in this whole analysis PICC and an ultrasound were requested to hospital's purchasing committee.

**Results:** PICC were included in the shopping catalog in October 2010 and the ultrasound in February 2011. Until January 2012, 218 PICC have been placed. Successful placement was obtained in 96.3% cases, with 92 days median duration per catheter. The rate for thrombosis and bacteremia were 0.30 and 0.06 per 1,000 catheter-days respectively. Since the incorporation of PICC, the implanted port consumption has been reduced by 32%.

**Discussion:** PICC are an example of how technology can be incorporated based on evidence criteria. However, in hospital routine this process may be insufficiently protected. The vast amount of technology hospitals manage and the effort needed to search and

create evidence constitute important difficulties to be faced in the technology incorporation processes.

**Implications:** PICC is now a central venous access device available in our hospital and preferable to other devices because of evidence-based clinical and economical results. The creation of technology evaluation committees in hospitals could support the process of incorporating technology following evidence-based criteria.

#### 189. ENSURING SYSTEMATIC EVIDENCE GENERATION FOR POLICY USE: DEVELOPMENT OF HTA PROCESS GUIDELINES IN THAILAND

Román Pérez Velasco, Usa Chaikledkaew, Sitaporn Youngkong, Sripen Tantivess and Yot Teerawattananon

*Health Intervention and Technology Assessment Program (HITAP), Thailand.*

**Background and objectives:** The Health Intervention and Technology Assessment Program (HITAP) is a semi-autonomous health technology assessment (HTA) agency under the Ministry of Public Health, Thailand. Although HITAP had methods guidelines, formal guidelines on HTA processes were lacking. This work aims to outline the organization's approach to development and dissemination of these guidelines.

**Methods:** International guidelines were reviewed to develop a conceptual framework, with the view to connect principles of good governance with the current processes through specific mechanisms. 3 stakeholder meetings were convened to validate both the principles and mechanisms encompassed in the framework.

**Results:** The framework proved useful in developing fit-for-purpose guidelines. This approach also showed to be effective in identifying additional mechanisms to meet the identified principles. The major HTA processes considered were grouped as follows: topic priority setting, assessment and preliminary appraisal of health technologies, dissemination of results and recommendations, and monitoring and evaluation. Meanwhile, the most relevant process principles were the following: transparency, accountability, inclusiveness, timeliness, quality, consistency, and contestability. Mechanisms on which stakeholders placed special emphasis were related to: broadening stakeholder representation, providing reference periods, rigorous management of conflict of interest, and increasing accessibility to and clarity of information, systematic and evidence-based selection of experts, establishing formal channels for appeal throughout the processes.

**Discussion:** International governance standards were considered but adapted to the particular context, including stakeholders' views and expectations. Because HITAP has no authority over decision-making and implementation issues, these issues were not covered. Finally, it is planned to widely disseminate the guidelines through both printed and electronic media, targeting a wide range of stakeholders (e.g., policymakers, healthcare insurers and professionals). To measure the impact of the guidelines, key performance indicators are under development.

#### 444. WHO NOTIFIES NEW PROCEDURES REQUIRING EVALUATION AND WHAT GUIDANCE IS THEN PUBLISHED ABOUT THEIR USE? TEN YEARS OF NICE EXPERIENCE IN THE UK

Hannah Patrick, Lakshmi Mandava, Lakshmi Murthy, Helen Gallo, K Jun Ong, Andrew Stainthorpe and Bruce Campbell

*National Institute for Health and Clinical Excellence, UK.*

**Background:** The rational introduction of new interventional procedures poses significant challenges. In the UK the National

Institute of Health and Clinical Excellence (NICE) has published guidance on new and/or controversial procedures since 2002. IP guidance reports evidence about the safety and efficacy of procedures. An open-access website notification portal enables anybody to notify procedures to NICE.

**Objectives:** To review who notified procedures over a ten year period; to examine why some procedures were not selected for evaluation; and to describe the types of recommendations published for their use.

**Methods:** Analysis of data from the electronic records for interventional procedures for 2002-11.

**Results:** A total of 1071 procedures were notified - 451 (42%) by clinicians, 62 (6%) by hospitals, 44 (4%) by a horizon scanning centre, 44 (4%) by private health insurers, 45 (4%) by patients and 33 (3%) by manufacturers. 13% were from a register of procedures (active before 2001), and the source was unclear in 24 % (being investigated further). 572 (54%) notifications were not selected for evaluation - for example because they were considered to be established; minor modifications of procedures; or were duplicates. Among the procedures with published guidance, the evidence was judged adequate to recommend normal use in 49%; more cautious use in 42%; use only in research in 7%; and "do not use" in 2%.

**Discussion:** Limitations of our study included missing information relating to notifiers of procedures inherited from the pre-2001 register and uncertainty about whether clinicians notified as individuals or for professional bodies.

**Implications for the health system/professionals/patients/society:** Guidance on new procedures aims to protect patients from harm while fostering the use of beneficial interventions, for patients, society and health services. Manufacturers and funders of care, as well as clinicians and their professional organisations, need to recognise and notify procedures which require evaluation.

#### 574. CRITERIA FOR ASSESSMENT OF NEW TECHNOLOGIES AT THE LOCAL LEVEL (MINI-HTA) AND THE NATIONAL LEVEL (HTA)

Helene Arentz-Hansen, Inger Natvig Norderhaug, Gro Jamtvedt and Brynjar Fure

*Norwegian Knowledge Centre for the Health Services, Norway.*

**Background and Objective:** Mini-HTA is a tool designed to support evidence-based processes when introducing new health technologies at the hospital level. A mini-HTA evaluates the effectiveness, safety, costs, ethical and organisational consequences of a new technology. We have, in cooperation with the Norwegian Directorate of Health and the Western Norway Regional Health Authority, developed criteria for when mini-HTA should be performed locally (in the hospitals), and when the assessment should be lifted to the national level. By this system mini-HTA is also a tool to identify new technologies that should lead to discussions around national priority settings.

**Findings:** The proposed criteria are as follows: 1. Mini-HTA should be performed at the local level when there is uncertainty or disagreement regarding the effectiveness or safety of a new technology, or if the introduction of the technology in the health care system raises ethical questions. 2. The assessment of the new technology should be lifted to the national level (HTA at the Knowledge Centre) in cases where mini-HTA reveals: still uncertainty or disagreement regarding the effectiveness or safety compared to current practice; significant costs compared to standard treatment; ethical considerations of public interest; consequences for the goal of equal services nationally. 3. The assessment should always be carried out at the national level when the new technology: involves screening programmes; involves highly specialised medical care; involves drugs; affect vulnerable populations and patients with rare diseases.

**Comment:** It is important to ensure that new health technologies are properly evaluated before they are introduced into the health care system. This evaluation can be conducted with a mini-HTA at the local level or an HTA at the national level. It is decided that mini-HTA should be introduced into the Norwegian health services in 2012.

## 892. MEASURING THE GAP BETWEEN DEMAND AND ACCESS TO MEDICINES IN THE BRAZILIAN PUBLIC HEALTHCARE SYSTEM

Mariana Social

*Johns Hopkins Bloomberg School of Public Health. Brazil.*

**Background:** The coverage package of the Brazilian Public Health Care System includes free provision of medicines. Insufficiencies in the provision of drugs may harm patients by preventing the initiation of treatment or by interrupting ongoing regimens.

**Objectives:** To review the existing evidence on the gap between demand and access to medicines within the Brazilian public health care system.

**Methods:** Review of the literature through the Medline medical database (US National Library of Medicine). Keywords: Brazil, SUS, demand, access, utilization, medicines, drugs.

**Results:** Near half of the adult population in Brazil utilizes medicines. The utilization of medicines increases with age reaching more than 70% of individuals aged 60 years or older. Medicines are prescribed in more than 60% of medical consultations. Although almost 60% of all health care consultations are provided by the public health system up to 75% of all medicines consumed are paid out-of-pocket. The mean private expenditure with medicines per month exceeds 50% of the minimum wage among the elderly. Around 10% of patients who receive a medical prescription are entirely unable to obtain the medicines they need. The most frequently reported reasons are lack of financial resources and lack of availability of medicines in public pharmacies. The median availability of essential drugs in public pharmacies is 30%.

**Discussion:** The available evidence demonstrates the inefficiency of the provision of medicines by the Brazilian public health care system. Lack of public availability of drugs shifts the financial burden of medical treatment to users, compromising significant amounts of income. Individuals who cannot afford to buy medicines are disproportionately harmed, contributing to increased inequality. Improvements in budget forecasting and health planning are needed in order to increase availability of drugs in the Brazilian public health care system and should be grounded on empirical and epidemiologic evidence.

Monday 25<sup>th</sup> June 2012. 18.00-20.00

## 71. STRATEGIC DEVELOPMENT OF PATIENT AND PUBLIC INVOLVEMENT IN A MAJOR COMPARATIVE EFFECTIVENESS RESEARCH PROGRAMME IN THE UK

Alison Ford, Elaine Williams and Ruairidh Milne

*NIHR Evaluation Trials & Studies Coordinating Centre. UK.*

**Background:** For the past eighteen years the NIHR's Health Technology Assessment Programme has funded major comparative effectiveness research studies. Patient and public involvement (PPI)

was developed in the early stages of the programme but the growth of the organisation since 2008 required a more extensive and consistent strategic approach to PPI.

**Objective:** To create a quality standards framework for patient and public involvement that would ensure the appropriate level of PPI across the whole research cycle, both within the organisation's research management practices and in the design and conduct of HTA-funded research by external research teams.

**Methods:** Quality standards for PPI were developed by review of existing internal and best external practice and through consultation with the INVOLVE network of public contributors in the UK. Extensive consultation and relationship-building enabled staff of the organisation to collectively commit to developing PPI.

**Results:** A strategic framework for PPI was agreed by the organisation, clearly defining three areas of action: for the organisation, for external researchers and for patients and members of the public. An operational plan for the period 2011-2013 followed, with commitment to resources and senior leadership support in the organisation and externally.

**Conclusions:** The HTA has many years of patient and public involvement but the organisational commitment to the PPI framework acknowledges that this can always be refined and improved. The framework specifies how to better support patients and the public to engage, and identifies future challenges, taking into account the needs and interests of patients and members of the public.

## 276. THE VALUE OF PERSONALIZING MEDICINE: MEDICAL ONCOLOGISTS' AND PATIENTS' PERSPECTIVES ON GENOMIC TESTING OF BREAST TUMOURS IN CHEMOTHERAPY TREATMENT DECISIONS

Yvonne Bombard<sup>a</sup>, Linda Rozmovitz<sup>b</sup>, Maureen Trudeau<sup>c</sup>,  
Natasha Leigh<sup>d</sup>, Ken Deal<sup>e</sup> and Deborah Marshall<sup>f</sup>

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*Science Centre & University of Toronto. Canada. <sup>d</sup>Princess Margaret Hospital & University of Toronto. Canada. <sup>e</sup>McMaster University<sup>e</sup>.*

*Canada. <sup>f</sup>McMaster University & University of Calgary. Canada.*

**Background:** The benefit of adjuvant chemotherapy for early-stage breast cancer patients depends on baseline recurrence risk. Gene expression profiling (GEP) of tumours informs baseline risk prediction, potentially reducing unnecessary treatment and healthcare costs. Limited evidence exists on its clinical utility; we explored patients' and oncologists' perspectives on GEP in chemotherapy decisions.

**Methods:** We used a qualitative design, comprised of individual interviews with medical oncologists (n = 10) plus focus groups and individual interviews with breast cancer patients (n = 20) from Ontario, Canada. Patients treated for breast cancer, who underwent genomic testing of their tumours ('OncotypeDx'), were recruited through oncology clinics from two academic hospitals in the Greater Toronto Area. Medical oncologists were recruited through participating oncology clinics, professional advertisements and referrals from the research team. Qualitative data were analyzed using interpretative qualitative methods, including content analysis, qualitative description and constant comparison techniques.

**Results:** Patients and oncologists valued GEP as an additional decision-support tool, complementing existing clinical indicators, though it is perceived utility varied between patients and oncologists. Patients valued the test highly, suggesting it was one of the primary determinants of their treatment decision. All patients followed the course of action their results suggested. Patients with intermediate scores often used the results to reinforce their pre-existing treatment preferences. Oncologists were mixed about the test's utility. Some considered it another tool supporting their approach to risk

assessments, while others used it more definitively to resolve their uncertainty. Oncologists explained the test's contribution to decision-making but remained uncertain about patients' understanding and expectations of the test. Some raised concerns about the variability of its use and interpretation within their medical community.

**Discussion:** Patients and oncologists valued the test, often using it as a primary determinant in their treatment decision, despite oncologists' concerns about its technical limitations and patients' limited understanding. Results identify a need for informational decision aids and practice guidelines to support patient understanding and standardized application of the test.

## 605. THE VIEWS OF PATIENTS AND CARERS INVOLVED IN THE DEVELOPMENT OF NICE TECHNOLOGY APPRAISALS

Lizzie Amis and Heidi Livingstone

*NICE - National Institute for Health and Clinical Excellence. UK.*

**Objectives:** NICE appraises health technologies for the NHS, and has a formal policy stating patients, carers and citizens are involved throughout each appraisal. Written submissions from national patient/carer organisations complement clinical- and cost-effectiveness evidence. Patient/carer organisations also nominate 'patient/carer experts' to participate in appraisal committee meetings. Producing patient-centred health technology assessments (HTAs) helps ensure health systems are also patient-centred. A recent INAHTA survey (INAHTA. Involvement of consumers in the HTA activities of INAHTA members, 2011) showed that many agencies involve consumers in their HTA work, but "evaluation of consumer input to HTA programs remains uncommon." This paper: describes a two-phase, comparative study exploring the experiences of patient/carer experts attending appraisal committee meetings; identifies topics where committee chairs felt that patient/carer contributions influenced decision making.

**Methods:** We: reviewed responses from a questionnaire sent to all patient/carer experts (N = 61) who attended committee meetings during an 18 month period between April 2006 and October 2007 (Phase-1); sent an updated questionnaire to all patient/carer experts (N = 67) who attended committee meetings during a second 18 month period between July 2010 and December 2011 (Phase-2); obtained feedback from committee chairs about the impact of patient/carer contributions to the appraisal process.

**Results:** There was a high response rate for both phases. Quantitative results and qualitative quotes demonstrate both positive and negative perceptions of patient involvement. Comparisons between the phases show areas which have improved, and areas needing further improvement. Comments from chairs broadly support questionnaire results and identify examples of impact and influence.

**Conclusions:** Patient/carer contributions can have an impact on committee decision making. Improvements have been made since 2007, but processes can always be improved to facilitate even more effective patient involvement. However, there remain some tensions between NICE's remit and processes and patient/carer expectations of these.

## 917. TRANSITIONAL CARE FOR PEDIATRIC PATIENTS WITH NEUROMUSCULAR DISEASES – HEALTH TECHNOLOGY ASSESSMENT

Jiixin Tran and Jiixin Tran

*University of Medicine and Dentistry of New Jersey. USA.*

**Introduction:** Advancements in science and technology help an increasing number of pediatric patients with significant

disabilities survive to adulthood. However, transition of youth with special needs to adult services remains a largely uncoordinated process. Individuals burdened by childhood-onset neuromuscular diseases (NMDs) are left especially vulnerable, because they require vigilant monitoring and proactive interventions to maximize quality of life.

**Objectives:** Identify systematic and unique barriers to a successful transition of care for adolescents with NMDs. Recommend comprehensive strategies to improve the experience for patients, family members, and health providers alike.

**Method:** A systematic literature review of publications between January 2000 and December 2011 in the following scientific databases: Cochrane, PubMed, MEDLINE, NARIC, and CINAHL.

**Results:** This review confirms that patients with NMDs and family members find the transfer between pediatric and adult care taxing. Actual transitions are complicated by poor communication, disjointed medical records, and lack of access to specialty resources. Several studies suggest that families may benefit from a dedicated coordinator. Literature also highlights the importance to empower patients in their own care and to attend to their psychosocial needs with a multidisciplinary team. While a few pediatric diseases have early success testing a model of transitional care, providers for NMDs struggle with limited manpower to address multi-organ involvement from various sequelae. Significant time commitment and low reimbursement rates further contribute to the challenge.

**Implications:** Transitional care is critical to maximize quality of life for pediatric patients with NMDs. These individuals have various needs and their services may be disrupted unless a structured, collaborative approach is taken during the transition.

## 301. HOW TO PROMOTE THE PRESCRIPTION OF EVIDENCE-BASED NON-PHARMACOLOGICAL TREATMENTS IN FRANCE?

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**Background:** Non-pharmacological treatments (e.g. diet, psychological treatment, lifestyle changes) require strong commitment from patients. These treatments are advocated through clinical guidelines for a number of conditions like cardiovascular diseases or insomnia. However there is a substantial gap between guidelines and physicians' prescribing patterns regarding such treatments.

**Objectives:** To identify the barriers to prescribing non-pharmacological treatments and to define strategies to circumvent these barriers in France.

**Methods:** A literature review was conducted on quantitative and qualitative studies aiming at assessing extra-medical factors that influence physicians' prescribing decisions. Results were discussed and put in the perspective of the French health care system by a multidisciplinary working group of 54 experts (physicians and other health care workers, patients' representatives, social scientists).

**Results:** Barriers to prescribing non-pharmacological treatments can be classified in 4 categories: (1) psychosocial dimensions of drug prescribing in physician-patient encounter; (2) perceived time pressure during medical consultations resulting from physicians' fee payment system; (3) lack of evidence about non pharmacological treatments' effectiveness due to specific methodological issues

(compared with pharmacological treatments, they are more difficult to describe, to standardize, to administer consistently and then to assess); (4) economic inequalities (they induce substantial financial and non-financial costs to patients).

**Discussion:** Potential strategies to alleviate these barriers have been identified. They range from practical tools (local directories of professionals specialized in non-pharmacological treatments) to more structural evolutions of the health care system (development of alternative physicians' payment system), through the promotion of adapted methodological standards to evaluate non-pharmacological treatments.

**Implications for the health system/professionals/patients/society:** Collective representations about medical care are still largely focused on curative pharmaceutical prescriptions. They should be broadened to encompass both pharmaceutical and non-pharmaceutical treatments in a preventive-curative prospect.

### 639. THE DEVELOPMENT OF A HTA GUIDELINE FOR HOSPITALS IN CROSS-BORDER REGIONS – RESULTS FROM WORK PACKAGE 5 OF EUREGIO II

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**Background:** The use of HTA to support the decision making process is not only growing at the national level but also increasingly used at the regional or local level, because decision makers increasingly base their decisions on scientific evidence. However, problems can arise when using national HTA products in the local setting as for example the perspective may differ. It is also possible that no national evidence is available. Therefore hospitals are increasingly carrying out their own HTA studies, the so-called local or mini-HTAs. Several countries (e.g. Denmark, Sweden and Canada) have developed a guideline for HTA in hospitals, but there is no guideline for hospitals in cross-border regions.

**Objectives:** To develop a HTA guideline in hospitals in cross-border regions.

**Methods:** First, the existing literature on HTA in cross-border settings, HTA in hospitals and the use of HTA by local decision makers was explored. Second, six semi-structured interviews with local decision makers in cross-border regions were carried out on the use of HTA in their hospitals. After consultation with experts it was decided to use the Danish mini-HTA guideline as a starting point for the guideline to be developed. A number of adaptations were considered necessary using the collected information.

**Results:** A number of new topics are added to the guideline, namely cross-border issues, legal questions and reimbursement issues. The developed guideline consists of three sections: a general section, a section for not cooperating hospitals and a section for hospitals cooperating with hospitals on the other side of the border, whereby only section two or three has to be used.

**Discussion:** To our knowledge this is the first HTA guideline for hospitals in cross-border settings. The guideline will be of help for hospitals in cross-border settings who would like to perform HTA studies and take their specific situation into account.

### 678. THE APPLICATION OF HEALTH TECHNOLOGY ASSESSMENT IN THE FIELD OF BIOLOGICS: AN EVALUATION OF ETANERCEPT FOR TREATING RHEUMATOID ARTHRITIS

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**Background:** Biologic drugs are used in patients with Rheumatoid Arthritis (RA) with inadequate response to non-biologic disease-modifying anti-rheumatic drugs (DMARDs). Etanercept is an anti-Tumor Necrosis Factor (TNF)  $\alpha$  and it is one of the first biologics which has been approved.

**Objectives:** Because of the availability of several biologics, this HTA was aimed at studying the current impact of etanercept use in Italy.

**Methods:** In order to assess the burden of the disease and the competitors an extensive literature search was done: papers dealing with RA prevalence, incidence, mortality, disability and treatments effectiveness and safety were selected. A cost-effectiveness analysis was performed from the National Health Service viewpoint to evaluate benefits of choosing etanercept in comparison to DMARDs and other anti-TNF  $\alpha$  on the base of the Italian Study Group on Early Arthritis data. A comprehensive analysis of tools and services to be promoted was done to evaluate organizational aspects of managing RA.

**Results:** Literature review showed that RA prevalence in Italy ranges from 0.33% to 0.46% with an incidence of 0.98% being these estimates close to the international ones. RA is an important cause of Years Lived with Disability and determines an increase risk for death and losing work. Experimental studies have shown etanercept as well as other biologics to be effective; anyhow etanercept showed lower discontinuation rates due to adverse events. The cost-effectiveness analysis demonstrated that etanercept costs more than DMARDs but allows gaining more benefits being the best option, with regard to other anti-TNF  $\alpha$  commonly used, in many scenarios considered. Anyway, in order to get better outcomes from available treatments, a multidisciplinary team should be involved for early disease detection and patients empowerment in the view of chronic care model.

**Implications:** This HTA demonstrated that etanercept is worth to be utilized in comparison to other anti-TNF  $\alpha$ .

### 816. METHODS, MATHEMATICAL MODELS, DATA QUALITY ASSESSMENT AND RESULT INTERPRETATION: SOLUTIONS DEVELOPED IN THE IFEDH FRAMEWORK

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**Background:** As health care systems in all countries have to deal with limited resources and upcoming new technologies, high quality decision support and HTA based on dynamic and static modeling is getting more and more essential. In Austria the research project Innovative Framework for Evidence based Decision support in Health care (IFEDH) founded by The Austrian Research Promotion Agency is developing a framework addressing HTA questions.

**Objectives:** Main focus of the project lies on the development of processes leading an interdisciplinary group of experts in the field of

HTA, statistics, modeling, visualization and database analysts through the whole HTA production cycle. The modeling process and design of adequate modeling methods are one core part.

**Methods:** In the context of IFEDH a model based framework has to be implemented using detailed knowledge of the partners from different domains. The first step in the project is the analysis of model and structure know how as well as gathering the state of the art of modeling in HTA in Austria. Based on this information a specification of requirements regarding model structure and documentation of simulation outputs are set up. The core working tasks of the network is the development of reusable modeling structures and methods. Furthermore modular model parts are developed. The analysis of data sources and interface descriptions finalize this task.

**Results:** The development of modern modeling methods and setting up an interdisciplinary process, dealing with the rising questions in HTA especially for infectious diseases and vaccination strategy evaluation is realized.

**Discussion:** The description of the research project presented in the paper shows how different scientific domains can be joined to a joint overall approach in model based HTA. As decision support has to become faster, parameter sources and modular reusable model parts have to be developed in advance.

## 99. IMPROVING THE VALUE OF PATIENT SUBMISSIONS ON DRUG REVIEW PROCESSES

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**Background:** In 2010 Canadian agencies responsible for reviewing drugs for reimbursement by public drug plans introduced the option for patient submissions.

**Objectives:** The Consumer Advocare Network conducted two workshops to prepare patient representatives for making submissions. A simulated drug review process was used to investigate several issues: perceived added value of patient submissions, potential influence of drug and disease type on recommendations, and impact of group discussion methods on deliberation process and outcomes.

**Methods:** About 50% of 90 participants in Session 1 and 65% of 75 in Session 2 were patient representatives. Patients and nonpatients worked in separate 8-person groups. Each group reviewed three of four drugs, varied in terms of prevalence and severity of disease, incremental benefit of the drug, and cost utility. Participants evaluated initially without and then with patient submissions. Each group used three of four "group discussion" methods (open discussion, nominal group technique, deliberative dialogue, and multiple attribute rating technique) to arrive at a consensus on funding recommendations; however, only two of the three drugs could be approved.

**Results and Discussion:** Both quantitative and qualitative responses were analyzed. All participants felt the patient submissions added significantly to understanding the value of the drugs to patients. The most important factors influencing recommendations were disease severity, other treatment options, and risks/benefits. The MART was best liked and had the most influence on achieving group consensus. Overall, patient groups behaved very similarly to the non-patient groups.

**Implications:** Patient submissions are perceived to provide information of added value; however the value and impact on decisions may vary. It is important for HTA bodies to consider the optimal process by which the patient submissions are presented, discussed and integrated into decision-making.

## 620. ASSESSMENT OF AN EMERGING TECHNOLOGY: WELFARE TECHNOLOGY AND ITS ETHICAL CHALLENGES

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**Background:** Due to demographical changes in high income countries the need of health care services will increase but the number of people to provide them will decrease. Welfare technology is launched as an important means to meet this challenge. As other health technologies it needs assessment of its ethical implications.

**Methods:** A Socratic method for addressing ethical issues in HTA is used, and a literature search identified 1976 references, of which 281 studies were included.

**Results:** The literature review reveals that welfare technology is a generic term for a heterogeneous group of technologies. There are few studies documenting their efficacy, effectiveness, efficiency, and safety. Many welfare technologies break with the traditional health care organization. It introduces technology in new arenas, such as in private homes, and it offers new functions, e.g. social stimuli and entertainment. At the same time welfare technology is directed at groups that have not been extensive technology users. This raises a series of ethical questions with regard to the development and use of welfare technologies: 1) Alienation when advanced technology is used at home, 2) conflicting goals, as welfare technologies have many stakeholders with several ends, 3) respecting confidentiality and privacy when third-party actors are involved, 4) guaranteeing equal access and just distribution, and 5) handling conflicts between instrumental rationality and care in terms of respecting dignity and vulnerability.

**Conclusions:** Addressing ethical issues is important for developing and implementing welfare technologies in a morally acceptable manner. Addressing ethical issues can give important input to emergent technologies, even before data on outcome and safety are available.

## 687. ETHICAL APPROACHES IN INAHTA AGENCIES REPORTS

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**Objectives:** To determine the type of ethical approaches used in the reports of the INAHTA agencies.

**Methods:** We collected at random 101 reports from the database of the CRD-INAHTA in the period 2004-2009. This period included three years later and two prior to the adoption by INAHTA of the document on how to deal with ethical analysis in HTA reports. Qualitative variables were described using frequency tables and percents. In the bivariate analysis, we used the test of Chi-square or Fisher exact test. For the allocation of ethical approaches to contexts of application and its correlation with philosophical, theological or anthropological schools, four reviewers participated in the identification and one bioethicist conducted in-depth analysis.

**Results:** The proportion of reports that included ethical analysis was higher in the period 2006-2009 than in 2004-2005 (43% vs 30%), these differences were not significant ( $p > 0.05$ ). 41 reports showed ethical approaches (40,59%), 58 did not have any ethical analysis (57,43%) and 2 only the summary was recovered. Of the 41 documents with ethical analysis: 20 (48,78%) had a short chapter reflecting on the ethical implications of the technology, its implementation or the status of the patient, 8 (19,51%) documents described the implications of the technology and patients' data use and their participation in two

clinical trials, the principlism approach appeared in 6 (14.63%), 5 (12.19%) papers included an in-depth pragmatic approach and 2 (4, 88%) studies used an axiological ethical analysis.

**Discussion:** The proportion of HTA documents that incorporate ethical analysis within their content is low. Ethical approaches used are consistent with those described by members of international networks of HTA. Principlism, pragmatic and axiological approaches were mostly used.

#### 774. WHICH KIND OF ETHICAL ISSUES IN HTA PROCESSES? RESULTS AND CONSIDERATIONS FROM THE APPLICATION OF ETHICS EXPERTISE IN HTA PROCESSES IN ITALY

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**Background:** The ethics domain is intrinsic to HTA processes even if the practical experiences are still limited.

**Objectives:** The contribution deals with the kinds of the ethical issues recognized within HTA processes where bioethicists of the Institute of Bioethics of the Università Cattolica (Rome, Italy) were involved.

**Methods:** The overall HTA processes performed from 2007 to 2011 are seven. The technologies assessed were the following: three pharmaceuticals (Lapatinib, Lucentis, Dabigatran etexilate), two antipneumococcal vaccines (Synflorix, Prevenar 13), one diagnostic procedures (PECT and SPECT scanning for early diagnosis of minimally cognitive impairment), one surgical tool (Ultrasound harmonic scalpel in surgery). EUnetHta Core models were utilized for research questions, and the "triangular model" as ethics approach.

**Results:** The ethical issues assessed regarded: 1. Effectiveness/safety of the technologies, particularly the need for patients' strata to optimize the benefit from the utilization of new pharmaceuticals (often very expensive for a National Health Service); 2. respect for patient's dignity, integrity, autonomy, values, as well healthcare professionals, and the benefit/harms for other stakeholders; 4. distributive justice issues, with reference to National/Regional Healthcare Service coverage for the technology, its Regional supply; the fairness of the availability of the technology.

**Discussion:** Today, the available HTA tools for ethics analysis (e.g.: EUnetHTA Core Model), can consent a good recognition of specific issues related to healthcare technologies assessment, even considering the different ethical approaches (e.g.: casuistry, utilitarianism, etc.). Still, an important open space for further methodological implements/reflections about ethical domain integration and practical running in HTA processes remains.

**Implications for the health system/professionals/patients/society:** Because health technologies embody a variety of social and political aspects for individual and people, technologies cannot be assessed only through the (also necessary) narrow lens of cost-effectiveness analysis. Health decision-making processes need to be informed by the values that prevail in a given society.

#### 110. COST-UTILITY OF HPV FOR PREVENTION OF CERVICAL CANCER IN THE STATE OF RORAIMA (BRAZIL): A MARKOV MODEL APPROACH

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**Background:** Invasive cervical cancer (ICC) remains an important public health problem, particularly in developing countries. The

Brazilian amazonic region is an high incidence area of ICC, comparable to low-income countries (crude incidence rate: 46/100.000), what suggests weaknesses in the current secondary prevention programs. Vaccines against oncogenic HPV serotypes have demonstrated efficacy, safety and ability to induce prolonged immunologic memory, but their real effects on the magnitude of the ICC will take years to be available. Mathematical models can be usefull tools for the evaluation of preventive strategies, assisting medical decisions that are needed now.

**Objective:** Assess cost-utility of the prophylactic HPV vaccination on the prevention of ICC in Brazilian amazonic region (State of Roraima).

**Method:** A Markov model was developed as an analytic tool to simulate the natural history of HPV and its progress to ICC, considering the current preventive programs. Transition probabilities assumptions were based mainly on empirical data of local and national studies. The model evaluated the addition of the vaccine to 3 cervical cancer screening scenarios (0, 3 or 10 exams throughout life).

**Results:** The scenario of three Pap tests resulted in satisfactory calibration (base case). The addition of HPV vaccination would reduce by 35% the incidence of ICC, in a setting of 70% vaccination coverage. The incremental ratio of cost-effectiveness (IRCE) was R\$ 1,200 for each year of quality-adjusted life (QALY) saved. The sensitivity analysis confirms the robustness of this result, and duration of immunity was the parameter with greater variation in IRCE.

**Implications:** Vaccination has a favorable profile in terms of cost-utility, and its inclusion in the immunization schedule would result in substantial reduction in incidence and mortality of ICC in amazonic region of Brazil.

#### 111. HOW TO ASSESS PERSONALISED MEDICINES FOR REIMBURSEMENT DECISIONS? DEVELOPING A FRAMEWORK FOR AUSTRALIA

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**Background:** Since the mapping of the human genome in 2003, the development of biomarker targeted therapy and clinical adoption of 'personalised medicine' has accelerated. There is, however, increasing international recognition that current reimbursement models may not adequately assess the safety, effectiveness and cost-effectiveness of these medicines due to the nature of their evidence-base.

**Objectives:** Our aim was to develop a methodological approach for assessing a biomarker/test/drug ('co-dependent technologies') package to inform a national reimbursement decision.

**Methods:** Personalised medicine case studies were identified from recent reimbursement applications to government. Commonalities in the information provided in these applications were extracted, and a gap analysis undertaken to identify information considered important for the decision-making process. Relevant international regulatory and reimbursement guidance documents were reviewed and the collated information was synthesised into a cohesive structure that was grounded in Bradford-Hill causality theory. The assessment framework was circulated to policy-makers - with responsibility for reimbursement decisions - and technical experts, and their input was

incorporated. The finalised document was released for public consultation.

**Results:** Determining whether a biomarker is a treatment effect modifier or a prognostic factor was considered crucial to assessing whether the biomarker test/s, the drug, both or neither should be reimbursed. Seventy-nine evidentiary items were proposed that would assist the assessment of personalised medicines submitted for reimbursement. Explanatory material was developed to assist sponsors of co-dependent technologies when addressing these evidentiary items in their reimbursement applications.

**Discussion:** To aid in pragmatic decision-making, the assessment framework explicitly allows the linkage of different types of evidence to examine whether targeting the biomarker varies the likely clinical benefit of the drug, and if so, to what extent.

**Implications for the health system:** The first national framework to assess personalised medicines for reimbursement decisions has been developed and introduced in Australia, and may be a suitable model for other health systems.

### 178. COST-MINIMIZATION ANALYSIS OF IMMUNONUTRITION FOR SURGICAL PATIENTS WITH GASTROINTESTINAL CANCER

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**Background:** Immunonutrition (IN) has been demonstrated to decrease complications and the length of hospital stay in surgical patients with gastrointestinal (GI) cancer in randomized clinical trials (RCT) and meta-analyses (Drovers et al, 2011; Cerantola et al. 2011).

**Objectives:** The objective of this research is to compute the costs of relevant complications in GI surgical patients using hospital cost data and to assess the economic impact for the hospital to use IN for these patients.

**Methods:** The relative risk (RR) of complications of IN vs control patient groups was based on a recent meta-analysis (Cerantola et al. 2011). The cost of IN was based on the price of the IMPACT<sup>®</sup> nutritional therapy in the Swiss setting. The cost of complications was computed using a Swiss university hospital database (2006-2010). The hospital costs of 420 patients undergoing major upper and lower GI cancer surgery were retrieved, including 64 patients with at least one relevant complication. To take into account the severity of patients' profiles with no link to the presence of complications, we developed a method using the cost-weight of the corresponding Diagnosis Related Group (DRG) to derive an exogenous-severity score (ESS). A regression of the cost of the stay on the ESS and a binomial variable representing complications allowed to get the cost impact of the complications. Finally, the incremental cost of complications was computed for the IN and control groups, and a sensitivity analysis of the baseline complication rate (control group) was carried out.

**Results:** The RR of complications for IN patients is 0.48 for the pre-, 0.50 for the peri- and 0.65 for the post-operative periods. The incremental cost of having at least one of the relevant complications amounts to CHF 14,949 (95%CI 10,712-19,186) per patient. The net economic impact per patient stay of IN represents a saving of CHF 2,598 for the pre-, CHF 1,588 for the peri- and CHF 1,137 for the post-operative administration.

**Implications for the health system/professionals/patients/society:** IN for patients undergoing surgery for GI cancer is an efficient

intervention as it decreases post-surgical infectious complications and hospital costs.

### 430. APPROACHES FOR ESTIMATING BURDEN OF PNEUMOCOCCAL AND ROTAVIRUS DISEASES: CONCEPTUAL FRAMEWORK AND SYSTEMATIC REVIEW

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**Background:** Estimate burden of disease in a country facilitates the potential control of the problem and can prioritize the planning and implementation of programs. This will optimize the use of resources tend to be scarce and limited, particularly in some countries of Latin America and the Caribbean

**Methods:** From a review of major studies on the burden of rotavirus and pneumococcal disease, 6 experts developed an algorithm that allows a flow of decision to choose which approach would be better focusing mainly on the data typically available in middle and low income countries of LATAM&C. There were two rounds of peer review. Also, we did a systematic literature review between January 1995 to September 2010 based on the main literature international and regional databases, generic and academic Internet search and meta-search engines, to validate the frequency of these approaches were reported and the data sourced used more often.

**Results:** The algorithm developed include five approaches: based on end results; based on the end and intermediate results (using health services); based on incidence and end results; partial approach; and based on incidence. The systematic review retrieves 2998 articles. After pair assessment, we include 164 in title/abstract phase and finally 67 in full text phase for extraction. The most frequently approach used was the mixed one, based on incidence and end results (preliminary).

**Conclusions:** In the countries of the region is of great importance to have a framework for making decisions based on local context.

### 761. COST UTILITY ANALYSIS OF ENDOSCOPIC BILIARY STENT IN UNRESECTABLE HILAR CHOLANGIOCARCINOMA IN THAILAND

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**Background:** Endoscopic biliary drainage using metal and plastic stent in unresectable hilarbcholangiocarcinoma (HCA) is widely used but little is known about their cost-effectiveness value.

**Objectives:** To determine the cost-utility of endoscopic metal and plastic stent drainage in unresectable complex, Bismuth type II-IV, HCA patients from health system perspective.

**Methods:** A Markov model was constructed to mimic natural history of unresectable complex HCA patients by projecting the life time outcomes including costs and quality-adjusted life years (QALYs). Most transition probabilities (TPs) were derived from the only existing trial comparing the effectiveness of endoscopic metal and plastic stent in 108 unresectable complex HCA patients in a University-affiliated hospital through parametric survival regression models, while only few parameters were obtained from international

literature. Health state utilities were elicited based on EQ5D collected in patients included in the trial. Direct medical costs were derived from the electronic hospital database. Discounted rate of 3 percent was used. Incremental cost per QALY gained was presented. A series of sensitivity analysis and cost-effectiveness acceptability curves (CEAC) were constructed.

**Results:** Under the base-case analysis, metal stent is more effective but more expensive than plastic stent. An incremental cost per QALY gained is 192,650 baht (US\$ 6,072). The CEAC reveals that at the willingness to pay of one and three times GDP per capita or 158,000 baht (US\$ 4,980) and 474,000 baht (US\$ 14,939) in year 2010, the probability of metal stent being cost-effective is 26.4% and 99.8%, respectively.

**Discussion:** Endoscopic metal stent drainage is a cost-effective intervention compared to plastic stent in unresectable complex HCA.

**Implications:** Our findings were consistent with the policy decision made in 2010 to include metal stent in the benefit package of Universal Coverage Scheme in Thailand. The cost-effectiveness results fulfilled the missing piece of information, which strongly supported the policy decision made.

### 307. EXPLORING THE RELATIONSHIP BETWEEN HEALTH TECHNOLOGY ASSESSMENT AND KNOWLEDGE MANAGEMENT-TWO SIDES OF THE SAME COIN

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**Background:** The costs of innovative, new health care technologies along with the replacement of obsolete, old technology are rising. This has led to increased importance on the use of evidence and knowledge in decision-making to assess, appraise and reassess health technologies. Comprehensive strategies to manage, exchange and facilitate technology-related knowledge are needed.

**Objective:** This presentation will explore the relationship between knowledge management (KM) and health technology assessment (HTA) and describe the development and implementation of a knowledge management and knowledge translation (KM/KT) plan developed by the Alberta Health Services' Health Technology Assessment and Innovation Department.

**Methods:** In spring 2011, a KM/KT plan was developed that outlines four strategies in the application and use of HTAs: Identify, connect and engage people in evidence-informed decision making through the dissemination of recommendations and results of technology assessments and appraisals, reassessments, results of access with evidence development and innovation projects; Provide skills and tools to use evidence through the application of the knowledge cycle; Support sharing of HTA and innovation knowledge by engaging stakeholders through knowledge transfer activities (communities of practice, website, and other knowledge exchange activities); Facilitate, review, implement and evaluate best and innovative practices in HTAI in the continual learning loop.

**Results:** HTA and KM are inter-related. HTA can be considered an ally in advancing KM in health care. Implementation of the KM/KT plan is underway and has come with its own challenges of obtaining human and financial resources and evaluation.

**Discussion and Implications for Health System:** KM and HTA are not to be considered an either or option but rather two sides of the same coin. Both are required in evidence-informed decision making as it relates to the management and acquisition of health care technologies; and both will be required in the future technological needs of the health care system.

### 330. THE NEW HTAI VORTAL: FROM DEMONSTRATOR TO WORKING PROTOTYPE

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<sup>c</sup>NOKC - Norwegian Knowledge Centre for the Health Services. Norway.

**Background:** The HTAi vortal was established in 2005 by the HTAi Interest Sub-Group on Information Resources (IRG). This Web directory lists selected online resources aimed at supporting the HTA doers' day-to-day work. In 2010, a survey was conducted to evaluate the use and satisfaction of the clients and to prepare an evolution of the vortal.

**Objectives:** To present the design process and resulting Website of the new HTAi vortal.

**Methods:** Structure and content of the current vortal were analysed and re-organised taking into account the results and proposals of the clients' survey. A Website (demonstrator) was build and fitted with a minimal set of records for evaluation purpose.

**Results:** The demonstrator is a dedicated Website branded with the HTAi logo and color scheme. It is structured in four main sections: 1) Directory of HTA agencies organised by geographical areas, which links to general Websites, but also to specific sections (projects, publications...); 2) Repertory of useful web resources on HTA (web pages, articles...) organised by categories; 3) The Information Retrieval reference tool (current IRG project); 4) Repertory of resources for career development. The demonstrator also includes a bibliography module to view and export selected references (standard formats), and offers links to PubMed and Google scholar, if possible. A subgroup of IRG members audited the demonstrator and endorsed the new design, structure, additional functionalities and scheduled content. The demonstrator was thus transformed into a prototype, filled with all existing and some new information. More information resources will be added step-by-step.

**Conclusions:** The IT infrastructure being in place, setting up the collaborative update process, evaluating the tool and additional functionalities (2.0 interactivity) will be done in 2012.

**Implications for professionals:** HTA doers will benefit of a better structured online resource that provides up-to-date and validated information relevant to their day-to-day work.

### 419. DISSEMINATION OF HTA PRODUCTS. NEW LINES OF ACTION

Marisa López-García, Beatriz Casal-Acción, Leonor Varela-Lema and Raimundo Alcázar-Alcázar

*Galicia HTA Agency. Spain.*

**Background:** With the broadening of the audiences of health technology assessment (HTA) products it has become evident that every user has different needs and thus adaptation of the contents and formats is required, warranting their dissemination. Within Spain, an ongoing project is underway to analyze current practices and follow up previous strategies proposed for improving dissemination.

**Objectives:** 1) Review national and international policies for the dissemination of HTA products. 2) Verify that strategies have been implemented in national agencies and propose new lines of action.

**Methods:** 55 organizations were selected for assessment purposes. The websites of international agencies were reviewed and a questionnaire focused on dissemination strategies sent to Spanish agencies. A working meeting was held with a panel of experts and recommendations developed following dynamic group techniques.

**Results:** There are important differences between the variety of products published by agencies, being more diversified the Spanish production. Overall, almost 50% of agencies use a news bulletin or RSS for dissemination. Web 2.0 has little presence, being the most used Twitter. Most of international agencies have at least executive summaries translated to English. Complete versions in English are available in around 20%. Few organisations publish formats that are purpose-adapted to patients.

**Discussion:** 25% of agencies produce materials tailored to the audience, which is acknowledged to be very relevant. The diversity of channels used shows that important efforts have been dedicated to achieve a successful dissemination. However, at the national level, dissemination strategies proposed in a preceding report were not implemented, suggesting the need for more specific actions.

**Implications for the professionals:** The expert group agreed on several recommendations, highlighting the following: 1) Promote the creation of a repository of scientific production, periodic newsletters, and motivate agency staff to use them. 2) Promote and systematically incorporate organizations' production in the information resources that are developed collaboratively through networks. 3) It is recommended that the results of HTA reports and technical consultations be published in peer review papers to reach the scientific audience. It is also advisable to apply for a specific section in national journals specialized in health management.

#### 425. ASSESSING THE INTERNATIONAL USE OF HEALTH TECHNOLOGY ASSESSMENTS: EXPLORING THE MERITS OF DIFFERENT METHODS WHEN APPLIED TO THE NIHR HTA PROGRAMME

David Wright, Ruairidh Milne, Alison Price, Nicola Tose and Nick Hicks

*NIHR Evaluation. Trials and Studies Coordinating Centre (NETSCC). University of Southampton. UK.*

**Background:** The impact of health technology assessment in generating knowledge and influencing policy and practice is an important concern for funders. However, most studies assessing the impact of research investment fail to explore the international influence of research findings.

**Objective:** To identify and explore different approaches for assessing the international use of Health Technology Assessments.

**Methods:** (1) A systematic literature review was conducted to identify different approaches to impact assessment. Three potential approaches to identifying international use were then assessed. (2) Bibliometric analysis (number of publications, impact factor and international citations) of the 10 most cited NIHR HTA reports was used to explore academic use. (3) Webtrend analysis of UK and International visits to the NIHR HTA website was used to explore internet use. (4) Analysis of citations in international HTA reports identified through the CRD database was used to explore uptake by HTA agencies.

**Results:** (1) Numerous models of research impact assessment have been used, the most common being the 'Payback' approach. (2) Bibliometric analysis identified published output and international citations with 41% of the 549 journals citing NIHR HTA reports being based in the United States. Definitions of international publication remain contested, however. (3) 9 out of 10 most downloaded reports from the NIHR HTA website had >50% of visits outside the UK. (4) 4 out of 10 selected reports were cited in 28 HTA reports, 18 of these outside the UK.

**Discussion:** International use is multiply determined and therefore requires multiple approaches to assessment.

**Implications for the health system/professionals/patients/society:** Bibliometric, Webtrend and HTA report citation data reveal

aspects of international use, although each has limitations that need to be addressed before application.

#### 560. TOOLS TO SUPPORT THE ADOPTION AND DIFFUSION OF MEDICAL TECHNOLOGIES

Katie Worrall, Alaster Rutherford, Gary Shield and Val Moore

*National Institute for Health and Clinical Excellence. UK.*

**Introduction:** Since December 2010, NICE issues medical technology guidance aimed at promoting rapid uptake of new products. Where NICE recommends adoption of a technology, the NICE implementation team develops and delivers a strategy to support those responsible for putting the guidance into practice. Research indicates this will promote compliance with the recommendations. This new range of guidance has led to the development of novel tools for new professional audiences.

**Methods:** Through liaison with guidance developers, experts and clinicians we seek to identify barriers and levers to implementation, adoption and benefits realisation. Tools tailored to the needs of decision makers and clinicians are published on the NICE website at guidance launch for free download. These include: Implementation podcasts – explain technical issues and benefits to clinicians and patients, using a clinical champion. Costing template – enables calculation of local costs and savings of implementing the guidance based on national assumptions which can be amended to reflect local circumstances. Educational slide set – recommendations, technical information and costing, with local discussion questions. Factsheet – highlights technical features and benefits of the technology. Links to other organisations supporting uptake of the technology. Implementation also looks to: Incorporate guidance into existing related NICE clinical guidelines; Plan dissemination of the guidance to key stakeholders.

**How do we measure success?** Feedback from NICE field team of implementation consultants. Analysis of downloads. Compared to other NICE guidance implementation tools, downloads are three percentage points superior, measured as a proportion of guidance downloads. Implementation tool user surveys. Confidential uptake data from manufacturers. Development of metrics to assess adoption and variation.

**The Future:** The proposed national NICE Implementation Collaborative will be a key driver for change, with high-level expectations for system-wide prompt implementation and adoption of NICE guidance.

#### 677. HOW INNOVATIVE IS THE BASQUE HEALTH INFORMATION SYSTEM?

M. Isabel Izarzugaza, Ruth Martínez, Covadonga Audicana, Manuel Errezola and Nieves Rodríguez-Sierra

*Basque Health Department. Spain.*

**Introduction:** Information is a key factor in order to take decisions based on evidence. The Basque Health Department understood and developed this concept from 1986. Since then, several population-based registries were set up. Because mortality rates are decreasing in several diseases and population is aging, the evaluation of the health system faces a reorganization of the care in order to guarantee the quality of the care and patient satisfaction in the most cost-effective manner.

**Method:** Several registries were set up in the Basque Country some of them in relation to the Spanish ones, and legal basis were established as well as confidential rules. Active and/or passive collection of data from the patients attending the Basque Health

Service/Osakidetza or the population was defined for the following registries: mortality, hospital discharge records, drug treatment-emergencies-mortality, legal abortion and cancer. Specific software and their modifications were developed to implement every registry and its objectives.

**Results:** Routine analysis have followed up and every year more than 11000 cancer cases, 244402 hospital discharges, 19600 death certificates, 2755 new treatments to drug addicts and so on are collected. Collaboration with other national or international groups was established in order to provide more specific information for the planning of new health care services (for the Basque population or patients) such as cancer screening programmes, planning of services for pregnant women or drug addicts, and so on. The experience of the Basque health information system, providing basis on main indicators such as mortality and its evolution, determinants of health or chronic diseases, and some innovations such as hospital practice variability, mortality inequalities and cancer survival, shows that the challenge to provide the best organization in the health care based on good and detailed information was foreseen on time.

Tuesday 26<sup>th</sup> June 2012. 14.00-15.30

### 37. INTERFERONS ALFA PEGYLATED (2A AND 2B) AND RIBAVIRINA FOR TREATMENT CHRONIC HEPATITIS C, GENOTYPE 1: A COST-EFFECTIVENESS ANALYSIS

Gabriela Bittencourt Gonzalez Mosegui<sup>a</sup>, Cid Manso de Mello Vianna<sup>b</sup>, Marcus Paulo da Silva Rodrigues<sup>b</sup>, Renata de Mello Perez<sup>b</sup>, Frances Costa e Silva<sup>b</sup> and Antonio Augusto Freitas Peregrino<sup>b</sup>

<sup>a</sup>Universidade Federal Fluminense. Brazil. <sup>b</sup>Universidade do Estado do Rio de Janeiro. Brazil.

**Objectives:** A cost-effectiveness analysis and also a budget impact analyses were conducted for treatments indicated to adults infected with type 1 genotype of hepatitis C virus. The use of alfapeguinterferon 2a plus ribavirina was compared with alfapeguinterferon 2b plus ribavirina having non-treatment as baseline.

**Methods:** A Markov model projected hepatitis C development in a group of 1000 patients within 30 year, and for the several states of the disease development.

**Results and discussion:** The ribavirina therapies combined with 2a/2b alfapeguinterferon have presented effectiveness statistically identical when evaluated in a 30 year period of the disease development. As for the treatment impact in life-years of life and quality adjusted life-years (QALY), the years of life gained by life quality in relation to the disease development without treatment, it was 1.67 and 1.63 respectively to the therapy combined with 2a/2b alfapeguinterferon applying 5% discount rate. The treatment strategy with 2a alfapeguinterferon plus ribavirina has been more cost-effective and dominated the alternative treatment. Although, there aren't significant differences of effectiveness between the 2 types of alfapeguinterferon, the price difference between them makes the alternative with 2a alfapeguinterferon plus ribavirina be more efficient. The budget impact for the 2008/2017 period, the use of 2a alfapeguinterferon plus ribavirina results in expense reduction of approximately 19%, if all the patients were treated with all the therapeutic schemes mentioned above.

**Conclusions:** Alfapeguinterferon 2a plus ribavirina has been more cost-effective.

### 190. COST EFFECTIVENESS OF ABDOMINAL AORTIC ANEURYSM SCREENING IN A MODERN WORLD: SHOULD WE RESCREEN?

Rikke Sogaard<sup>a</sup>, Jesper Laustsen<sup>b</sup> and Jes Lindholt<sup>c</sup>

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<sup>b</sup>Department of Cardiothoracic and Vascular Surgery. Aarhus University Hospital. Denmark. <sup>c</sup>Vascular Research Unit. Viborg Hospital. Aarhus University Hospital. Denmark.

**Background:** Mortality related to abdominal aortic aneurysm (AAA) can be reduced by about 50% when men above the age of 65 are screened. Several health economic models have assessed the cost effectiveness of such population screening programs but they do not necessarily represent the more recent understanding of the disease process and treatment modalities.

**Objectives:** To assess the cost effectiveness of four screening scenarios from the perspective of a modern health care system. These four strategies include no screening, one-off screening, rescreening after five years and lifetime rescreening every five years.

**Methods:** A Markov model informed with data from the literature, Danish trial research registers and Danish national registers for vascular surgery and mortality was developed. After model validation, microsimulation of cohorts of 100,000 individuals was used to provide detailed epidemiological results for each strategy, and Monte Carlo simulation was used to examine the model parameters' joint uncertainty. Expected lifetime costs (2010-£) and outcomes (quality adjusted life years, QALYs) are reported.

**Results:** Screening appears to be highly cost effective compared to not screening. When rescreened once, 32% will benefit from early detection, whereas continued lifetime rescreening leads to detection of an additional 24% who develop aneurysms over time. The probability that some form of systematic screening will be cost effective at a threshold of £20,000 was estimated to be 0.92. The contributions of the 3 screening strategies to that probability were 26%, 33% and 33%, respectively, and the corresponding incremental cost effectiveness ratios were £555, £10,013 and £29,680 per QALY.

**Discussion and policy implications:** There is significant decision uncertainty associated with the choice between screening strategies. Nevertheless, this study confirms the cost effectiveness of screening versus no screening and furthermore leads support to considerations of rescreening at least once.

### 289. COMPARATIVE COST-EFFECTIVENESS ANALYSES OF MAGNETIC RESONANCE IMAGING AND CORONARY ANGIOGRAPHY COMBINED WITH FRACTIONAL FLOW RESERVE TEST

Karine Moschetti<sup>a,b</sup>, David Favre<sup>a</sup>, Christophe Pinget<sup>b</sup>, Jean-Blaise Wasserfallen<sup>a,b</sup> and Juerg Schwitler<sup>c</sup>

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**Background:** Patients with coronary artery disease (CAD) should undergo revascularization if myocardial ischemia is present. While coronary angiography (CXA) allows the morphological assessment of CAD, the fractional flow reserve (FFR) has proved to be a complementary invasive test to assess the functional significance of CAD, i.e. to detect ischemia. Perfusion Cardiac Magnetic Resonance

(perfusion-CMR) has turned out to be a robust non-invasive technique to assess myocardial ischemia.

**Objectives:** To compare the cost-effectiveness of two algorithms used to diagnose hemodynamically significant CAD in relation to the pretest likelihood of CAD: 1) a perfusion-CMR to assess ischemia before referring positive patients to CXA (Perfusion-CMR+CXA), 2) a CXA in all patients combined with a FFR test in patients with angiographically positive stenoses (CXA+FFR).

**Methods:** The costs, evaluated from the third-party payer perspective in the Swiss and United States contexts, included public prices of the different tests, costs of complication and costs induced by diagnosis errors (false negative). The effectiveness criterion was the ability to accurately identify a patient with hemodynamically significant CAD. Clinical data were based on the published literature. Using a mathematical model, we compared cost-effectiveness of both diagnosis algorithms for hypothetical patient cohorts with different pretest likelihood of CAD.

**Results:** The cost-effectiveness decreased hyperbolically with increasing pretest likelihood of CAD for both strategies. Perfusion-CMR+CXA and CXA+FFR were equally cost-effective at a pretest likelihood of CAD of 64% in Switzerland (63%, in the United States) with costs of CHF 5,607 (US\$ 4,967) per patient correctly diagnosed. Below these thresholds, perfusion-CMR+CXA showed a lower cost-effectiveness than CXA+FFR.

**Implications for the health system/professionals/patients/society:** These results facilitate decision making for the clinical use of new generations of imaging procedures to detect ischemia. They show that the choice of cost-effective diagnosis algorithms to diagnose CAD depends on the prevalence of the disease.

### 299. COST-EFFECTIVENESS OF NUTRITIONAL INTERVENTION ON HEALING OF PRESSURE ULCERS

Akinori Hisashige<sup>a</sup> and Takehiko Ohura<sup>b</sup>

<sup>a</sup>Institute of Healthcare Technology Assessment, Japan. <sup>b</sup>Pressure Ulcers and Wound Healing Research Center, Japan.

**Background:** Pressure ulcers not only affect quality of life among the elderly, but also bring a large economic burden. There is limited evidence available for the effectiveness of nutritional interventions for treatment of pressure ulcers. In Japan, recently, a randomized controlled trial of nutritional intervention on pressure ulcers demonstrated improvement in healing of pressure ulcers, compared with conventional management.

**Objective:** To evaluate value for money of nutritional intervention on healing of pressure ulcers, cost-effective analysis was carried out.

**Methods:** The analysis was carried out from a societal perspective. As effectiveness measures, pressure ulcer days (PUDs) and quality-adjusted life years (QALYs) were estimated. Prevalence of pressure ulcers was estimated by the Kaplan-Meier method. Utility score for pressure ulcers is derived from a cross-sectional survey among health professionals related to pressure ulcers. Costs (e.g., nutritional interventions and management of pressure ulcers) were estimated from trial and follow-up data.

**Results:** For observation and follow-up, nutritional intervention reduced PUDs by 9.6 and 16.2, and gained  $0.226 \times 10^{-2}$  QALYs and  $0.382 \times 10^{-2}$  QALYs, per person, respectively. In addition, costs were reduced by \$542 and \$881 per person, respectively. This means nutritional intervention is cost saving and greater effectiveness. The sensitivity analyses showed the robustness of these results.

**Conclusion and Policy Implication:** Economic evaluation of nutritional intervention on healing pressure ulcers showed that this intervention is cost saving and can be considered as a cost-effective intervention to be accepted for wide use in Japan.

### 310. EVALUATION OF TRANSITION SCENARIOS FOR BREAST CANCER SCREENING IN FRANCE TO INCREASE PARTICIPATION OF WOMEN AGED 50 TO 74 YEARS

Stephanie Barre, Isabelle Hirtzlin and Catherine Rumeau-Pichon

Haute Autorité de Santé, France.

**Background:** In 2004, France implemented a nationally organised mammography breast cancer screening programme for women aged 50-74 years. In 2009, the programme reached only an estimated 52.5% of its target population, far below the recommended European objective (80%). That women retain the option of having opportunistic screening mammography following medical prescription could explain this low participation. Transition scenarios were simulated to explore possible strategies for increasing participation in breast cancer screening in France.

**Objectives:** First, to determine the best approach to improve the effectiveness and cost-effectiveness of breast cancer screening in France, i.e. organised; opportunistic; or combined (both screening approaches) (current situation). Second, to evaluate the ability of 5 possible strategies to reach this objective: discontinuation of opportunistic mammography coverage (S1); quality control for opportunistic screening (S2); operational changes in organized screening (S3); fees changes (S4), incentives for health care practitioners (S5).

**Methods:** Simulation was based on a static analytic model (organisational and budgetary impact).

**Results:** Compared with the current situation, full switch to organised screening appears to increase the total number of cancers detected and reduce total costs from a societal perspective. Strategies S2, S3 and S4 lead to worsened situations. Only S1 and S5 would lead to the transfer of the entire target population to organised screening. Compared with the current situation, these 2 strategies would result in 71 to 283 additional cancers detected and in savings of € 0.9M to € 3.1M.

**Discussion:** Results are highly sensitive to screening withdrawal rate and to transfer rates. The transition strategies are hypothetical and could be combined. Implications for the health system/professionals/patients/society. Our work could be useful for French health decision-makers in adjusting breast cancer screening policy. Alongside the discontinuation of opportunistic mammography coverage, various incentives toward health care practitioners could be designed, to increase participation and at the same time detecting more cancers at a lower cost.

### 366. METHODS FOR ADJUSTING SURVIVAL ESTIMATES TO ADJUST FOR TREATMENT CROSSOVER: A SIMULATION STUDY

Nicholas Latimer<sup>a</sup>, Paul Lambert<sup>b</sup>, Michael Crowther<sup>b</sup>, Keith Abrams<sup>b</sup>, Allan Wailoo<sup>a</sup> and James Morden<sup>c</sup>

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**Background:** Treatment crossover is an important issue that is becoming more commonplace in clinical trials of cancer treatments. Crossover occurs when patients in the control group switch onto the experimental treatment at some point during follow-up (usually after disease progression). In such circumstances an intention to treat analysis will result in biased estimates of the overall survival advantage –and therefore the cost-effectiveness– associated with the experimental treatment. Often 'naive' censoring or exclusion approaches are used to adjust for crossover, but these are prone to bias.

**Objectives:** We aimed to identify and assess statistical approaches for adjusting survival estimates in the presence of treatment crossover in order to determine which methods are most appropriate in a range of scenarios.

**Methods:** We identified relevant methods by systematically searching the literature. We also reviewed methods used in National Institute for Health and Clinical Excellence (NICE) technology appraisals of cancer treatments. We conducted a simulation study to assess the performance of the identified methods in a range of novel scenarios.

**Results:** 'Naive' methods always resulted in high levels of bias. More complex randomisation-based methods (eg Rank Preserving Structural Failure Time Models (RPSFTM)) were unbiased only when the treatment effect was not time-dependent. Observational-based methods (eg inverse probability of censoring weights (IPCW)) coped better with time-dependent treatment effects but are heavily data reliant, are sensitive to model misspecification and often produced high levels of bias in our simulations.

**Discussion:** Randomisation-based methods can accurately adjust for treatment crossover when the treatment effect received by crossover patients is the same as that received by patients randomised to the experimental group. Trial data should be analysed to identify whether this is likely to be the case. If it is not observational-based methods should be considered, but results should be interpreted with caution. 'Naive' methods should not be used.

### 503. A UNIFIED METHODOLOGICAL FRAMEWORK FOR THE ECONOMIC EVALUATION OF THERAPEUTIC MEDICAL DEVICES

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To inform policy decisions economic evaluation (EE) studies require the systematic identification and (quantitative) synthesis of the relevant evidence base on the clinical effectiveness, quality of life (QoL) and costs associated with the use of competing health technologies. Existing methods for EE are linked to principles of evidence-based medicine and, as such, are geared primarily towards the evaluation of pharmaceuticals. Some authors have claimed that medical devices (MDs) cannot be evaluated using the same principles. We take the opposite viewpoint and argue that used within the right evaluative framework existing EE methods are indeed appropriate to assess the cost effectiveness of therapeutic MDs. What makes the (economic) evaluation of MDs challenging is the fact that the *quantity, quality, and characteristics* of the evidence base around them, is often fragmented, heterogeneous and associated with high levels of uncertainty. In these circumstances it is important to acknowledge the value of eliciting and quantitatively summarising physicians and other experts' beliefs regarding the effectiveness and resource use demands associated with MDs already in use. Using real life examples this paper shows how a Bayesian stepwise iterative approach has helped address some of the challenges associated with the EE of MDs, while guiding policy decisions regarding technology adoption, research funding and design. Relevant steps include: (a) identification of existing evidence base and elicitation of experts' beliefs on clinical effectiveness, QoL and costs - i.e. "*a priori evidence base*"; (b) quantitative synthesis of this *a priori evidence base* to inform the parameters of an EE model; (c) initial estimation of the model; (d) assessment of the economic value of conducting further research (Vol); (e) collection of new patient level data (PLD) in a pilot study; (f) new evaluation of the EE model updating the *prior estimates* using primary PLD; (g) further VOI analysis.

### 583. COMPARISON OF USING CONFIDENCE BOUNDS AND PREDICTION INTERVALS FROM RANDOM-EFFECTS META-ANALYSES IN AN ECONOMIC MODEL

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Health Information and Quality Authority. Ireland.

**Background:** Economic models often vary treatment effect in a probabilistic sensitivity analysis. When incorporating treatment effect estimates derived from a random effects meta-analysis it is tempting to use the confidence bounds to determine the potential range of treatment effect. However, prediction intervals reflect the potential effect of a technology rather than the more narrowly defined average treatment effect.

**Objectives:** Using a case study of robot-assisted radical prostatectomy, this study investigates the impact on a cost-utility analysis of using clinical effectiveness derived from random-effects meta-analyses presented as confidence bounds and prediction intervals, respectively.

**Methods:** To determine the cost-utility of robot-assisted surgery, an economic model was developed. The clinical effectiveness of robot-assisted surgery compared to open and conventional laparoscopic surgery was estimated using meta-analysis of peer-reviewed publications. Assuming treatment effect would vary across studies due to both sampling variability and differences between surgical teams, random effects meta-analysis was used to pooled effect estimates.

**Results:** Using the confidence bounds approach the ICER was €26,731/QALY (95%CI: €13,752 to €68,861/QALY). The prediction interval approach produced an equivalent ICER of €26,643/QALY (95%CI: -€135,244 to €239,166/QALY). Using prediction intervals, there is probability of 0.042 that robot-assisted surgery will result in a net reduction in QALYs.

**Discussion:** Using prediction intervals rather than confidence bounds does not impact on the point estimate of treatment effect. In meta-analyses with significant heterogeneity the prediction interval will produce wider ranges of treatment effect than defined by the confidence bounds. In this example, the use of prediction intervals gives rise to a probability of poorer outcomes using a programme of robot-assisted surgery.

**Implications for professionals:** When estimating the cost-effectiveness of a health intervention, the potential treatment effect rather than the average treatment effect should be considered.

### 182. WHEN DOES NICE RECOMMEND THE USE OF HEALTH TECHNOLOGIES WITHIN A PROGRAMME OF EVIDENCE DEVELOPMENT?

Louise Longworth<sup>a</sup>, JiHee Youn<sup>a</sup>, Laura Bojke<sup>b</sup>, Stephen Palmer<sup>b</sup>, Susan Griffin<sup>b</sup>, Eldon Spackman<sup>b</sup> and Karl Claxton<sup>b</sup>

<sup>a</sup>Brunel University. UK. <sup>b</sup>University of York. UK.

**Background:** The National Institute for Health and Clinical Excellence (NICE) in the UK can issue guidance to approve the routine use of a health intervention, reject routine use or recommend use within a research programme. These latter recommendations have restricted use to 'only in research' (OIR) or have recommended further research alongside routine use ('Approval with research' or AWR). However the considerations that lead to the use of these types of recommendations are currently not clear.

**Objective:** This study aims to identify NICE Technology Appraisals (TA) where OIR or AWR recommendations were made and to examine the characteristics of the technologies and the key considerations that led to those decisions.

**Methods:** Draft and final guidance including OIR/AWR recommendations were identified. The documents were reviewed to establish the characteristics of the TA, the cost-effectiveness of the technologies, the key considerations that led to the recommendations and the types of research recommended.

**Results:** 29 final and 31 draft guidance documents included OIR/AWR recommendations. Of these, 86% were phrased as OIR, 83% were for technologies considered cost-ineffective and the majority of final guidance (69%) specified the need for further evidence on relative effectiveness. The use of OIR/AWR is decreasing over time and they have rarely been used in appraisals conducted through the Single Technology Appraisal process. OIR/AWR was more likely to be issued for medical devices and procedures than for pharmaceuticals.

**Discussion:** NICE has used its ability to recommend technologies within research programmes, although predominantly within the Multiple Technology Appraisal process. The key considerations appear to be where a technology is considered cost-ineffective, there is uncertainty related to relative effectiveness and uncertainty over long-term outcomes although these do not account for all recommendations.

**Implications:** A formal framework for the use of OIR/AWR recommendations could further improve NICE decision-making.

## 291. THE DEVELOPMENT OF CONDITIONAL COVERAGE FOR MEDICAL PROCEDURES IN SWITZERLAND

Urs Bruegger<sup>a</sup>, Bruno Horisberger<sup>a</sup> and Alois Gratwohl<sup>b</sup>

<sup>a</sup>Winterthur Institute of Health Economics, Zurich University of Applied Sciences, Switzerland. <sup>b</sup>Medical Faculty, University of Basel, Switzerland.

**Background:** In the Procedures Ordinance of January 1<sup>st</sup> 1996, the Swiss Basic Health Insurance scheme accepted for the first time a medical procedure for reimbursement, which was novel and promising, but for which existing evidence was incomplete. It concerned palliative neurosurgical interventions for patients with otherwise intractable epilepsy, in order to control the attacks and improve QoL. Temporary coverage was granted with the stated goal of further data collection. For that an evaluation register had to be kept. The approach proved to be useful. Since then the conditional coverage option has been further developed and sophisticated. A 2001-2007 study reported 33 procedures reimbursed under constraints, 75% of which therapeutic, a quarter diagnostic or prophylactic and there is continuing interest in this option.

**Objectives:** The aim is to pursue the development of the modality from 1996 to 2012 and to demonstrate the transition to flexible solutions, with or without registries and with or without a joint quality management system.

**Methods:** Analysis of all technologies reimbursed under constraints by the Swiss Basic Health Insurance year after year. Demonstration of the systems dynamics, interaction between applicant and regulator, flexible definition of temporary constraint according to underlying technology with a brief history of real-world examples of CED solutions.

**Results:** Systems synthesis in tabular form of the evidence obtained from the Swiss CED approach. Quantitative distribution of typical solutions: “yes, in evaluation”, “yes with indication limitation”, “yes with centres limitation”, separate and in combination. Experience with national and international registries for therapeutic interventions.

**Conclusion:** The appropriate selection of innovative medical procedures for temporary conditional coverage by the Basic Health Insurance scheme may enable patients to obtain access to promising technologies early in their life-cycle at a justifiable risk. The collection of clinical (and economic) data minimizes uncertainty and promotes the quality of outcomes at the same time.

## 317. POST-INTRODUCTION OBSERVATION OF HEALTHCARE TECHNOLOGIES AFTER COVERAGE: THE GALICIAN EXPERIENCE WITH TRANSCATHETER AORTIC-VALVE IMPLANTATION

Leonor Varela Lema, Teresa Queiro Verdes, Marisa López García and Jeanette Puñal Riobóo

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**Background:** Evidence shows that performance of health technologies in real world settings can be different to the outcomes observed in controlled environments. To this end, post-introduction observation schemes are recognized to be very promising for collecting additional data to resolve residual uncertainties and allow for decision making on definitive reimbursement. However, experience in this field is limited and important doubts have been raised regarding the added value and success of this type of evaluative research.

**Objectives:** This work aims to present a comprehensive overview of how post-introduction observation was successfully implemented within the Galician Regional Health Authority (Spain) and how it served to inform decision making.

**Methods:** Using the example of transcatheter aortic-valve implantation (TAVI), the work describes the different steps of the implementation (prioritization, creation of multidisciplinary working group, protocol development, data collection web tool) and decision making re-evaluation process. With the aim of helping other organizations that are thinking about adopting these schemes, the work also summarizes the different problems that have been encountered and the strategies proposed to resolve them in the future.

**Results:** The post-introduction assessment of TAVIs has served to underline the need for stricter patient selection criteria and formalize the creation of Hospital Commissions for decision making regarding the indication of TAVI. The main problems encountered during information collection were: different follow up times, omitted result variables and delay in the submission of information.

**Discussion:** This work demonstrates that post-introduction assessments are feasible under conditional coverage schemes. It shows that these type of assessments can serve to regulate practice patterns, providing valuable information to decision makers and to the health community, information that would be otherwise very difficult to obtain.

**Implications for the health system:** The implementation of post-introduction observation schemes is challenging since it requires specific policy frameworks, commitment from different stakeholders and the dedication of specific resources.

## 533. MANAGED INTRODUCTION OF NEW HEALTH TECHNOLOGIES: RETURN ON INVESTMENT

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**Background:** In 1997 the Australian state of Victoria established its New Technology Program (NTP), which continues to support the introduction and targeted diffusion of new health technologies into the public hospital system. Since 1997, more than \$100 million has been allocated to support this objective. At HTAi2010, we highlighted that the NTP represents a “safe fail” approach to the managed introduction of new health technology, since not all health technology investment will result in an ideal outcome, despite the best of intentions. We have commenced an analysis on the return on

investment (ROI) of the NTP/Victorian Government new technology investment since 2005-06.

**Objectives:** To determine the extent, if any, of the ROI from new technology investment since 2005-06.

**Methods:** The ROI calculation was based on individual health technologies and utilised: Implementation costs, both upfront and ongoing. Benefits of the change associated with the health technology. Assumptions for ongoing maintenance costs. Total costs (investment) compared with total benefits. The benefits from each introduced new health technology were then extrapolated across the Victorian health system to derive total system benefits.

**Results:** Preliminary analysis was based on the group of new health technologies with an interventional focus. The ROI was found to be significant in terms of both patient outcomes and cost savings across the system. With the released value calculated in terms of both cost savings and numbers of patients, the ROI for interventional technologies substituting for surgical procedures was also used to estimate additional patient throughput capacity in busy surgical hospitals.

**Implications:** Demonstrating and quantifying a return on investment is imperative in informing strategic planning and health technology investment in tight fiscal environments, competing innovations and within the context of an ageing population demanding greater health care needs.

## 595. UNIFYING RESEARCH AND COVERAGE DECISIONS: HOW THE ASSESSMENT REQUIRED CAN BE INFORMED

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The value of access to a technology, the value of additional evidence about the performance of a technology, and the type of research needed can be informed by value of information analysis. However, whether widespread approval should be withheld until research findings are available (an only in research (OIR) policy), or granted while the research is being conducted (an approval with research (AWR) policy), requires a comparison of the value of early access to a technology and the value of additional evidence which will accrue to future patients. This depends on: i) the possibility that widespread access to a technology might reduce the prospects of particular types of research; ii) whether there are sources of uncertainty which cannot be resolved by research but only over time; and iii) any costs, or opportunity costs that once committed by approval cannot be recovered. A general framework and associated algorithm is developed to identify the assessments required to inform policy choice. Using probabilistic models of enhanced external counterpulsation (EECP) for the treatment of angina and clopidogrel (CLOP) for the management of non ST segment elevation acute coronary syndromes, we show how the principles and assessments can be applied using a seven point checklist to inform policy choices of OIR, AWR, Approve or Reject. In particular, EECP highlights the impact of irrecoverable opportunity costs. Even when a technology is expected to be cost-effective, OIR may be more appropriate than AWR if there are opportunity costs which cannot be recovered should the results of the research indicate that its initial approval should be withdrawn. CLOP illustrates the impact of different sources of uncertainty (including price change) on the value of research and the time taken to report. The studies demonstrate that cost-effectiveness is a necessary but *not* sufficient condition for approval.

## 94. UTILIZATION INDEXES FOR MEDICAL EQUIPMENT. A PILOT MODEL

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**Background:** Medical equipment in hospitals has increased in number through the years. No literature is available providing indexes that could help Clinical Engineering (CE) or administration understand the actual use of medical devices. A way to assess the actual utilization of major devices is needed.

**Objectives:** Propose a model to define productivity indexes for medical equipment and to verify whether they are fulfilled or not.

**Methods:** Many variables can be linked to the clinical workflow (human resources availability, case mix). Two approaches were considered: on one hand theoretical productivity was calculated as product of available exams in daily schedule and number of devices installed; this data were compared to the number of exams reported to billing office. If a difference was found, organizational, technical and practical issues were analyzed to explain such difference.

**Results:** Ultrasounds, gastroscopes and infusion pumps were considered. Ultrasound machines were analyzed in a specific ward. Data showed that only 70% of possible exams (billed divided by available) were actually carried out. In this specific case, each ultrasound machine in the ward carries out 2.2 exams/day. Gastroscopes: 5,000 exams/year were billed (out of 5,000 slots available). 14 gastroscopes are available in the ward, meaning that each carries 1.4 exams/day; this value is considered correct only when the sterilization process is taken into account. Infusion pumps were analyzed considering the number of sets utilized by each ward. Given that each infusion set is certified to work for 48 hours max, mean value of utilization index (real utilization vs theoretical) was 34% (min: 12%, max 61%), meaning that most of the installed pumps aren't used during most of the year.

**Discussion:** Results show that a great deal of optimization in the use of medical equipment is possible simply by monitoring billed exams, slots available in daily schedule and number of equipment available in each ward.

**Implications:** Such analysis allows optimization of device distribution in the hospital by sharing policies, optimizing logistics, etc., allowing more efficient access to assets for patients and better cost-efficiency in use of medical device.

## 231. OPPORTUNITIES TO ENHANCE PRESCRIBING EFFICIENCY FOR PATIENTS WITH DIABETES IN ABU DHABI WITHOUT COMPROMISING CARE

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**Background:** Previous studies have shown considerable opportunities to enhance prescribing efficiency in Abu Dhabi. This includes the PPIs and statins. Diabetes is a growing public health problem in Abu Dhabi. Consequently, may also be opportunities to improve prescribing efficiency without compromising care.

**Objectives:** (a) Analyse current treatment approaches among patients with Type 2 diabetes (T2DM) and compare these with international standards; (b) Assess the extent of different management approaches among the different facilities providing care to direct future initiatives to improve the quality and efficiency of care.

**Methodology:** Audit of 561 random patients across 3 facilities treating T2DM patients over 1 year. Data included extent of patient monitoring (BP, lipids, HbA1c, weight, renal function, etc.), oral glycaemic drugs prescribed, whether these were prescribed at maximal doses (NICE guidance) before insulins, whether insulin treatment delayed and insulin type.

**Results:** Different prescribing patterns across the 3 facilities. Alongside this (a) appreciable utilisation of MR versus standard oral drugs; (b) over 52% of patients on gliptins (NICE recommends insulin treatment should not be delayed); (c) up to 38% of patients on newer long acting insulins depending on the facility; (d) generally limited use of older insulins including Insultard. Variable HbA1c measurement - with HbA1c > 10% between 10 to 17% of patients depending on the facility, with between 42% to 51% > 7.5%. Greater number of patients on 3 or more oral drugs in specialist centres. Costs could be reduced by approximately 30% through following international guidelines and reducing utilisation of expensive MR preparations. Care also improved by regular monitoring of HbA1c levels.

**Conclusions:** Potential to appreciably improve quality and efficiency of care of T2DM patients in Abu Dhabi mirroring the findings for PPIs and statins. Introduction of Pharmacy Benefit Management Systems should improve appropriate step wise care and reduce the use of expensive modified release preparations and long acting insulins.

### 263. HEALTH TECHNOLOGY REASSESSMENT (HTR): AN ENVIRONMENTAL SCAN

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**Background:** Health Technology Reassessment (HTR) is a structured, evidence-based assessment of the clinical, social, ethical and economic effects of a technology currently used in the health care system, to inform optimal use of that technology in comparison to its alternatives. Little is known about current international HTR practices.

**Objective:** To summarize international HTR initiatives and to identify factors critical to program success.

**Methods:** A mixed methods approach, using a survey and in-depth interviews, was taken to address this objective. The survey covered 8 concepts: prioritization/identification of potentially obsolete technologies; program development; implementation; mitigation; program championing; stakeholder engagement; monitoring; and reinvestment. Members of INAHTA and HTAi formed the sampling frame. Participation was solicited via email and the survey was administered online from October 24<sup>th</sup> – November 7<sup>th</sup> 2011. To gather more in-depth knowledge, semi-structured interviews were conducted among organizations with active HTR programs. Interview questions were developed using the same 8 concepts. The hour-long interviews were recorded, transcribed and analyzed. Survey results were analyzed through SurveyMonkey using descriptive statistics.

**Results:** Ninety-five individuals responded to the survey: 21 said they were beginning to discuss HTR, 9 were imminently going to develop a program and 49 were not discussing it. Sixteen participants had programs and were conducting reassessments; 9 of whom agreed to participate in a follow-up interview. The importance of early and extensive stakeholder engagement was reiterated throughout the survey. Interview participants echoed this with many citing stakeholder and champion engagement as the most important factors for success. Participants used different processes to conduct reassessments. Most survey participants were unsure whether funds liberated through HTR were reinvested which suggests a need for monitoring.

**Discussion:** HTR is in its infancy. Although HTRs are being conducted, there is no standardized approach. Future work should focus on developing and piloting a comprehensive methodology for completing HTR.

### 336. EVIDENCE-BASED DISINVESTMENT AS A TOOL FOR SUSTAINED HEALTHCARE QUALITY

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Many healthcare systems are faced with severe budget strains due to medical advances and a growing elderly population. Disinvestment of healthcare practices has been suggested as a means to make cost-neutral reallocations of resources. Studies indicate that a significant part of all healthcare services is unnecessary or even harmful. By reducing the use of practices that offer little or no benefit to patients, resources can be redirected towards more cost-effective alternatives and quality improvements. Initiatives for disinvestment have been commenced in several countries. These may include disuse of practices as well as transfer from public to private funding. Sweden has a well established national framework for priority setting in healthcare but this has so far been used predominantly in decisions on new investments and not for disinvestment purposes. Many healthcare providers in Sweden point out disinvestment as a means of cost containment in their budget plans for 2012, but very few have a plan for accomplishing this. The aim of this present study is to map current initiatives for disinvestment in selected healthcare systems and to analyse these against a reference framework developed from a pilot literature review. Literature studies on disinvestment will be combined with interviews with experts in the fields of disinvestment, priority setting and rationing. We have identified the following elements that are important in a disinvestment framework: Scanning for health care services that are not evidence based. Methods and criteria for selecting services for further evaluation. Methods and criteria for selecting services to be removed from public funding. Overarching principles to guide the disinvestment processes. Public and professional involvement in the process. Transparency of the processes and appeal procedures. Implementation of the framework. Implementation of disinvestment decisions. Strategies to achieve changes in practice. Assessment of the impact of disinvestments. The study will gather experiences of barriers and enablers in developing and implementing such programmes and how to make ethically robust and legitimate disinvestment decisions.

### 448. FINDING THE NEEDLE IN THE HAYSTACK: IDENTIFYING LOW-VALUE MEDICAL INTERVENTIONS FROM THE MEDICAL LITERATURE

Sarah Garner, Thomas Hudson, Moni Choudhury and Tarang Sharma  
*NICE. UK.*

**Background:** The identification of low-value healthcare interventions with the intention of withdrawing them ('disinvestment'), interests all health systems. However, little research has explored methods for identifying low-value interventions. One potential source is the medical literature.

**Objective:** To explore the feasibility of identifying disinvestment candidates from the medical literature.

**Methods:** Pragmatic search strategies were developed, informed by contact with other HTA agencies. These were applied to Medline, Medline in-Process; Embase and the Cochrane Methods Register. Titles and abstracts were filtered for relevance. Relevant papers were coded as potential disinvestment candidates, methodological articles or policy papers.

**Results:** The initial search identified 3045 articles yielding 246 potential disinvestment candidates. Of these 62 were supported by a systematic review; further exploration of the topics resulted in 20 agreed disinvestment candidates. A further 183 potential topics

required further resource-intensive exploration with a systematic review potentially having to be undertaken. In addition, there were 50 methodological papers and 12 policy articles.

**Conclusions:** Searching for disinvestment-related articles is a challenge due to the lack of a widely-adopted, shared vocabulary and the absence of specific index terms. It provides a low-yield of potential topics. In addition many such interventions have been inadequately researched, and many trials with negative results remain unpublished (publication bias). Given how resource intensive this approach is, efforts may be better focussed on alternative identification strategies, for example engagement with clinicians.

## 606. SEARCHING FOR “DO NOT DO” RECOMMENDATIONS FROM NICE GUIDANCE – A PILOT STUDY

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*National Institute for Health and Clinical Excellence (NICE). UK.*

**Background:** Since 1999 there has been continued pressure on NICE to produce more recommendations on interventions that should not be used (do not do). A review of guidance indicated that NICE was producing these recommendations, but not publicising them. A project was initiated to explore and identify the best method in retrieving ‘do not do’ recommendations and then make them easily accessible via a web-based, searchable database.

**Methods:** Three search methods allocated to three independent reviewers, using an agreed list of search terms, were applied to two NICE clinical guidelines: Method 1: Reading through a copy of the full guideline, picking out all incidences of optimal practice. Method 2: Applying the terms (for example, ‘discontinued’, ‘should not’, ‘do not’) in an electronic/PDF copy of the guideline using single and/or combined searches, in the ‘find and replace’ tool. Method 3: Applying the terms in the prototype (Access) database of the guideline using single and/or combined searches.

**Results:** Feedback from the three reviewers highlighted that due to the lack of standardised terminology method 1 was the best in capturing all relevant ‘do not do’ recommendations within context: “In asymptomatic children and young people with heterozygous [familial hypercholesterolaemia] FH, evaluation of coronary heart disease is unlikely to detect clinically significant disease and referral should not be routinely offered” (a recommendation identified by this method only). A database of all identified recommendations is now available on the NICE website. Feedback from the NHS is positive.

**Conclusion:** NICE guidance contains ‘do not do’ recommendations, and they can be highlighted as standalone. Many more areas of uncertainty are identified but where there is a lack of evidence, experts are reluctant to recommend that something should not be done.

## 246. QUANTIFYING THE CLINICAL BENEFITS OF NEW IMAGING TECHNOLOGIES: A NICE TECHNOLOGY ASSESSMENT OF EOS 2D/3D X-RAY IMAGING SYSTEM

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**Background:** EOS is a new biplane X-ray system designed to provide weight-bearing, simultaneous posteroanterior and lateral, full body 2D and 3D imaging, with low dose radiation.

**Objectives:** To quantify the clinical benefits of EOS 2D/3D X-ray imaging system in orthopaedic patients.

**Methods:** We performed a systematic review (searches up to November 2010) of the clinical effectiveness of EOS, compared with standard film, computed radiography (CR) and digital radiography

(DR), for evaluation of orthopaedic conditions. Furthermore, we assessed cancer risk due to radiation exposure. Data were sought from the major reports produced by large radiation protection and safety agencies. To complement these, we performed a systematic review of adverse effects of diagnostic radiation for orthopaedic patients.

**Results:** Three small non-randomised studies of limited quality compared EOS with standard CR or film. While image quality remained comparable or better with EOS, the entrance surface dose (ESD) of radiation was considerably lower with EOS than CR or film. No data regarding patient health outcomes were reported. Cancer risk estimates were derived from four major reports in which the primary source of cancer risk data was derived from the Life Span Study (Atomic Bomb survivors). Four primary studies assessing cancer risk of diagnostic radiation for orthopaedic patients, all based on the same US scoliosis cohort, showed an increased risk of breast cancer mortality in female scoliosis patients.

**Discussion/conclusion:** Clinical evidence to support the use of this new imaging technology was sparse. Only poor quality evidence was available to inform the quality of the image compared to standard X-ray technology and there was no evidence of patient benefits from the innovative features of this new technology. In the absence of evidence for other patient benefits, radiation reduction was considered to be the primary benefit, but most of the data were derived from sources other than the target population.

## 337. HEALTH TECHNOLOGY ASSESSMENT OF INTEGRATED HOME CARE FOR ELDER, FRAIL, SOMATIC PATIENTS

Torben Larsen

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**Background:** The fragmented delivery of healthcare and social services as advanced by WHO 2002.

**Objectives:** This project of international collaboration assesses integrated home care (IHC) for frail elder somatic patients as compared to usual hospital care.

**Methods:** The HTA follows the special application for Tele-medicine (MAST). An introductory literature review identified stroke, heart failure (HF) and COPD as prototypes of IHC. Pre-existing evidence has been complemented by additional trials and surveys.

**Results:** 1. Definition/organization of IHC: (1) Is carried out by a multidisciplinary team visiting the home; (2) Considers effectiveness, quality, access and user satisfaction in an economic way and uses Tele-facilities as far as they serve these goals; (3) Has finance across organizational settings. 2. Clinical effectiveness of IHC for moderately disabled patients by 6-12 months follow-up: *Stroke:* In 14 randomized trials (N = 2139) intervention patients were by meta-analysis significantly less likely (p = 0.001) to be dead or dependent compared with conventional care. *HF:* 2 RCT (N = 386) demonstrate each a significant reduction of all-cause readmissions (p = 0.003 and p = 0.001). *COPD:* 5 studies (2 RCT, 2 cohorts and 1 CT) (N = 1249) demonstrate each a significant reduction in readmissions/total admission days (p < 0.05). 3. Health economic evaluation: For each selected condition the first year benefit surmounts the costs of intervention using the Dutch Standardization by Oostenbrink as a common price catalogue across resources/trials/countries. 4. Patient satisfaction: Focus group interviews confirm literature findings of very good satisfaction by IHC both among patients/carers and health professionals.

**Discussion:** Calculated net savings of 1450€ per patient in IHC are not supposed to materialize in ‘cool’- cash but enables local negotiation of adapted solutions with a minimum of national legislation/finance (Meso-strategy of dissemination).

**Implications:** IHC is an approach to clinical continuity for a majority of frail elder somatic patients.

### 432. HOW TO INCREASE UPTAKE IN ONCOLOGIC SCREENING: EFFECTIVENESS AND COST-EFFECTIVENESS OF ORGANISED PROGRAMS COMPARED TO SPONTANEOUS SCREENING

Eliana Ferroni, Laura Camilloni, Beatrix Jimenez, Giacomo Furnari, Gabriella Guasticchi, Piero Borgia and Paolo Giorgi Rossi

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**Background:** Screening for cervical, breast and colorectal cancer (CRC) represent public health interventions universally recommended for their proved effectiveness in reducing mortality.

**Objective:** To assess the effectiveness of two ways of implementing organised programs, by letter invitation and GP-based, on screening uptake for breast, cervical and CRC compared to spontaneous access. To compare the effectiveness in increasing participation of the two organised program models, the one based on invitation letters and the one on GP's reminder.

**Methods:** Literature search was made on electronic databases including studies on interventions, strategies or programs aimed at increasing screening participation. A first comparison was made between spontaneous screening (no intervention) vs. systematic invitation of the target population by letter or vs. GP-based programs. A second analysis compared the two organised programs. A systematic review of cost and cost-effectiveness studies for screening programs organization was conducted.

**Results:** The invitation letter compared with no intervention showed a significant increase in participation for breast (RR = 1.60), cervical (RR = 1.52 95%) and CRC screening programs (RR = 1.15). GP-based interventions showed a significant effect if compared with no intervention only in breast (RR = 1.74) and CRC (RR = 1.04) screening programs. The comparison between systematic invitation by letter vs. GP-based interventions found no significant difference in breast (RR = 0.99) and cervical screening programs. Studies comparing the cost of invitation letter found consistently low costs per person gained to screening.

**Discussion:** Organised screening strategies based on systematic invitation may increase participation compared with spontaneous screening. Some studies reached similar coverage of those obtained with systematic invitation of the population, by strategies which considered GP's reminder for people not adequately covered by test. Interventions based on GP's reminder increased participation rates, especially for breast cancer screening compared with usual care.

**Implications for the health system/professionals/patients/society:** Organised programmes are more effective than spontaneous screening in obtaining higher testing uptake. Both invitation letter-based and GP-based programmes are effective, but the first ones seemed to be more consistently cost-effective.

### 755. CASE STUDY: LIMITS AND POTENTIAL IMPACT OF MULTIDIMENSIONAL ASSESSMENT OF PAROXETINE AT REGIONAL LEVEL

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The need to assess health technologies according to a multidisciplinary framework is a growing necessity at different levels of National Health System (NHS). As far concern the drug market, safety and efficacy are the main dimensions taken into account. HTA principles and competition among producers and molecules require to consider other aspects as effectiveness and cost-effectiveness at

different levels of NHS. In Italy, Lombardy Region requested last years to producers to assess their pharmaceuticals according to a given HTA model. In particular, attention was devoted to antidepressant drugs. Paroxetine was one of the molecules under assessment for each of the therapeutic indication for which it granted EMA's authorization (major depression, obsessive-compulsive disorder, panic disorder, social anxiety disorder, generalized anxiety disorder, post-traumatic stress disorder). The group of experts of "A.Gemelli" University Hospital participated at the assessment. The evaluated dimensions were: general relevance, safety, efficacy and effectiveness, economic and financial impact, equity and ethic impact, and organizational impact. The main source of information were scientific literature and real data, where available. The proposed model articulated each domain in a rich set of questions. For each of them evidence should be collected, reported and evaluated according to a given quality scale. The paroxetine case study could be useful to consider the applicability of a HTA model in real life setting. Duplication of evidence requested in the model, low relevance of some questions for the specific drug, uncompleted coverage of drug specific issues were the main limitations of an otherwise well-designed HTA model. Theory and practice of HTA should be assessed at different levels of NHS as in the case study here presented.

### 760. DO HEALTH DECISION-MAKERS CONSIDER NON-HEALTH EFFECTS GENERATED BY HEALTH INTERVENTIONS? RESULTS FROM QUALITATIVE INTERVIEWS IN EIGHT COUNTRIES

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**Background:** Health interventions seek to generate health benefits but can also have wider effects, including improvements in labour productivity of patients and their carers, savings to other public programmes, and an increase in national income. The health economics literature recognises that health interventions can have non-health effects and provides different approaches to incorporate them in economic evaluations. However, the inclusion of these effects remains controversial and infrequent.

**Objectives:** The purpose of this study was to assess the extent to which non-health effects of health interventions are considered by decision makers internationally.

**Methods:** We conducted semi-structured interviews with a sample of personnel from national Ministries of Health and bodies responsible for reimbursement decisions of health interventions (identified as HTA bodies), and academic experts in eight countries. Two questionnaires were developed: one exploring the attitude of HTA agencies regarding non-health effects and the other assessing whether those effects are considered in government budget setting decisions.

**Results and discussion:** We found that with the exception of one country no decision maker considers non-health effects generated by health interventions on a regular basis. This is the case in HTA-type decision making processes and when resources are allocated to government departments. Based on our results, we identified and discussed a number of barriers to the inclusion of non-health effects in decision making. They include: methodological issues related to the incorporation of non-health effects in cost-effectiveness evaluations and lack of reliable data demonstrating those effects; structural/organisational issues arising from a culture of silo-budgets where health departments should only concentrate on health; and practical issues due to the added complexity and effort required if those effects are included in decision making.

## 64. THE COMET (CORE OUTCOME MEASURES IN EFFECTIVENESS TRIALS) INITIATIVE

Paula Williamson<sup>a</sup>, Doug Altman<sup>b</sup>, Jane Blazeby<sup>c</sup>, Mike Clarke<sup>d</sup> and Elizabeth Gargon<sup>a</sup>

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There is growing recognition that insufficient attention is paid to the outcomes measured and reported in clinical trials. Selection of outcomes is crucial to trials designed to compare the effects of different interventions. For the findings to influence policy and practice, the chosen outcomes need to be relevant to patients and the public, healthcare professionals and others making decisions about health care. Trials in a specific condition often report different outcomes, or address the same outcome in different ways. Inconsistency in reported outcomes causes well known problems for those who attempt to synthesise evidence, and many meta-analyses have to exclude key studies because relevant outcomes are not reported. Furthermore, the measured outcomes may not always be important to patients or health service users. Much could be gained if an agreed core outcome set (COS) of a minimum number of appropriate and important outcomes was measured and reported in all clinical trials in a specific condition. Key stakeholders, including patients, should be involved in establishing COS, to ensure consideration of appropriate outcomes. COS may encompass all stages or severities of a condition or may focus on a particular disease category. Likewise, a COS may be for use in trials of all treatment types or only trials of a particular intervention. The scope of a COS should be defined to identify the relevant health condition, population and types of interventions. The COMET Initiative (<http://www.comet-initiative.org/>) aims to foster and facilitate methodological research in the area of standardising outcomes, to develop much needed standards for methods of COS development and to develop and maintain a publically available internet-based resource to collate the knowledge base for COS development. Work on COS has been identified in over 80 clinical areas. The database will be demonstrated, progress to date presented, and the impact of COS discussed.

## 209. PROSPERO: AN INTERNATIONAL PROSPECTIVE REGISTER OF SYSTEMATIC REVIEW PROTOCOLS

Lesley Stewart<sup>a</sup>, Alison Booth<sup>a</sup>, Mike Clark<sup>b</sup>, Gordon Dooley<sup>c</sup>, Davina Ghersi<sup>d</sup>, David Moher<sup>e</sup> and Mark Petticrew<sup>f</sup>

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Launched in February 2011, PROSPERO is an international online prospective register of health related systematic reviews, initiated by the UK Centre for Reviews and Dissemination (CRD) and developed in collaboration with an international advisory group. Although protocol development is integral to systematic reviews carried out or funded by many organizations, PROSPERO provides the first opportunity to record information on the systematic review protocol in a free, publicly accessible register. This presentation will describe the establishment of PROSPERO, highlighting its importance within Health Technology Assessment. PROSPERO captures key elements of a systematic review protocol in advance of the main

reviewing activity to encourage transparency, provide a safeguard against reporting bias and reduce unplanned duplication of systematic reviews. It offers free registration, with a dedicated web-based interface that is electronically searchable and open to all (<http://www.crd.york.ac.uk/PROSPERO/>). Registration provides advantages to many stakeholders including researchers, commissioners and funders, guideline developers, methodologists, journal editors and peer reviewers, and is in the interest of patients and the public. Importantly, PROSPERO allows researchers to comply with the 2009 PRISMA statement which advocates registration of systematic review protocols. Following an international Delphi consultation in 2011, registration requires provision of 22 data items with the option to provide details of a further 18. Prospective registration supports the efficient use of funding and timely updating of systematic reviews, provides a way of helping to identify and reduce the risk of reporting bias, and should in time contribute to improving the quality of reviews and the decisions that rely upon them. Registration offers advantages to many stakeholders in return for modest additional effort from the researchers registering their review. We therefore believe that prospective registration should become standard best practice for those who commission, fund and conduct systematic reviews.

## 392. THE EVALUATION OF RCTS VS. OBSERVATIONAL STUDIES IN HTAS ON SELECTED MEDICAL DEVICE THERAPIES: WHAT IS THE REAL STATUS OF THIS RELATIONSHIP AND WHAT IMPLICATIONS MAY IT HAVE?

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**Objective:** HTA best practice principles recommend the inclusion of a broad range of evidence types. This study aims to assess the extent to which HTAs performed on selected medical device therapies include and evaluate non-randomised or observational studies and the impact of their inclusion on HTA outcomes.

**Methods:** A systematic search of medical and HTA agency databases was conducted to identify full published HTA reports that evaluated the following therapies: Deep Brain Stimulation (DBS), Intrathecal Baclofen (ITB), Sacral Nerve Stimulation (SNS) and Cardiac Pacemakers (IPGs).

**Results:** 27 full-text HTAs published between 1999 and 2011 from 9 different countries were included for review. All included HTAs (27/27) searched for RCTs only while 74% (20/27) searched for and included non-randomised or observational evidence. Interestingly, all of the HTAs performed on IPGs (5/5) explicitly excluded non-RCT evidence as part of their search criteria. Of the 20 HTAs that included non-randomised studies, 8/20 did not assess the quality of these studies, 11/20 applied some form of evidence grade as a proxy measure of quality and only 1/20 performed a thorough assessment of study biases and overall quality. HTAs with unfavourable outcomes or recommendations were more likely to have fewer of all study types (both RCT and non-RCT data) compared to those in which favourable conclusions were made.

**Conclusions:** RCTs and rigorously conducted observational studies can be used synergistically to obtain more and better information about the relative merits of new interventions. This study encouragingly demonstrates that observational evidence has been searched for and included in HTAs performed on selected medical device therapies. Yet the subsequent evaluation of observational studies, in particular the critical review of their quality is often not performed. The implication of this practice requires further examination.

## 426. A NEW MODEL FOR HTA-BASED ASSESSMENT OF TELEMEDICINE – MAST

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**Background:** In 2009 a HTA-based Model for Assessment of Telemedicine, MAST, was developed for the European Commission on the basis of workshops with stakeholders, a systematic literature review and the EUnetHTA Core Model for interventions.

**Objectives:** The objective is to describe MAST and the first experiences from its empirical test in the European project RENEWING HEALTH including assessment of 18 telemedicine applications in 9 regions. The project runs in 2010-13 and includes 5000 patients.

**Methods:** MAST can be used when the assessment aims to describe effectiveness and contribution to quality of care of telemedicine applications and produces basis for decision making. MAST defines the relevant assessment as a multidisciplinary process that summarises and evaluates information about the medical, social, economic, organizational and ethical issues related to the use of telemedicine in a systematic, unbiased, robust manner. MAST includes three elements: Preceding considerations of issues that should be considered before assessment is initiated. Multidisciplinary assessment of the outcomes of telemedicine within seven domains. Assessment of the transferability of the results.

**Results:** The use of MAST in Renewing Health demonstrates that MAST provides a useful and comprehensive framework for data collection and assessment, and ensures comparability of results for telemedicine studies in diverse cultural contexts. However, to produce valid results a number of tools must also be used: Scientific study protocols; Pre-defined minimum dataset; A generic patient acceptability questionnaire; Monitoring of data collection; Common clinical database; Guidelines on data analysis and **Conclusions:** The empirical test of MAST is ongoing and revision will be made based on the results. However, MAST and the tools developed can be helpful to new studies of telemedicine. Recently e.g. another large European project, inCASA, has adopted MAST.

## 742. THE INFLUENCE OF THE CONSORT STATEMENT ON THE QUALITY OF REPORTING OF RCTS: AN UPDATED SYSTEMATIC REVIEW

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**Background:** The Consolidated Standards of Reporting Trials (CONSORT) Statement was developed in response to concerns about the quality of reporting of randomized controlled trials (RCTs). It is an evidence-based minimum set of recommendations for reporting RCTs, intended to facilitate complete and transparent reporting and aid in critical appraisal and interpretation. A 2006 systematic review examining the effectiveness of CONSORT for improving the reporting of RCTs in endorsing journals (i.e. those which, at minimum, recommend that authors use CONSORT), found CONSORT endorsement to be associated with better quality of reporting, despite poor methodology of some included studies. Five years on from the publication of that review, an update is needed.

**Objective:** To update the systematic review of CONSORT effectiveness by Plint et al.

**Methods:** Conventional systematic review methods employed in the original review were followed. The search for new comparative studies evaluating the quality of reporting of RCTs spanned August 2005 – March 2010. Two reviewers independently screened studies for eligibility; data extraction and study validity assessments were conducted by a single reviewer and verified by a second reviewer.

**Results:** In the five year period since publication of the original review, 41 new eligible studies were identified in addition to the eight included in the original review. When comparing endorsing and non-endorsing journals, items such as sequence generation, allocation concealment and participant flow were reported better in those endorsing CONSORT. Further details of the comparison between endorsers and non-endorsers as well as between trials published before and after CONSORT publication (both 1996 and 2001) will be presented.

**Impact:** This review will provide further evidence on whether CONSORT is effective at improving the reporting of RCTs. This information will be helpful to authors, peer-reviewers and journal editors in helping to decide whether to endorse CONSORT.

## 422. BRINGING PATIENTS' OUTCOME AT THE FOREFRONT IN HTA OF DIAGNOSTIC TESTS, USING THE GRADE APPROACH

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**Background:** Clinical effectiveness of a diagnostic test is determined by its capacity to impact on patients' health outcome. However the lack of evidence on clinical outcomes often leaves HTAs on diagnostic test incomplete.

**Objective:** To test an innovative approach, proposed by the GRADE group, for the evaluation of impact on patients' outcomes within a guideline production programme on use of Positron Emission Tomography (PET).

**Methods:** Two multidisciplinary panel of 40 experts convened to produce recommendations on use of PET in breast, esophageal, lung, colo-rectal and head & neck cancer. Participants were asked to express judgement following a decision-making algorithm entailing a multi-dimension definition of appropriateness of a diagnostic test, based on the test's capacity to modify the initial diagnosis and to induce a change in management resulting in clinical benefit. Results and level of evidence on diagnostic accuracy, based on systematic review of literature, were presented to the panels. Lack of direct evidence on patient-important outcomes was bypassed using GRADE's approach for eliciting experts' judgement on clinical consequences of testing true/false positive and negative. Results of two rounds of votes were analysed using the RAND/UCLA Appropriateness Method.

**Results:** Level of appropriateness was discussed for 43 clinical indications: for 32 the panel reached an agreement, while for 11 there was persistent disagreement. The decision-making algorithm based on interaction between benefits, risks and diagnostic accuracy resulted applied in 74% of the clinical questions: Agreement between level of appropriateness voted by the panel and expected level of appropriateness was good (weighted kappa = 0.97).

**Discussion and implications:** the GRADE approach was determinant in shifting experts' focus from diagnostic accuracy to patients' important outcomes while evaluating appropriateness of PET. Despite its high complexity, experts accepted and applied the analytic framework, which represents a viable option to explicitly and transparently evaluate clinical effectiveness of diagnostic tests.

#### 478. A NEW GENERIC APPROACH FOR SCOPING HTAS

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**Background:** Using PICO has appeared to be not optimal in formulating the scope of a full HTA. Description of patients (P) has been identified as not sufficient, and defining single outcomes (O) not so pertinent because of the huge variety of relevant outcomes in a full HTA. The need for accurate scoping is particularly important for collaborative full HTAs, where several authors from several countries assess various aspects of the topic. This is the case in the Core HTA projects using the EUnetHTA Core Model. Deviating from a common scope would lead into inconsistencies in the final report and probably also unnecessary work.

**Objective:** To develop an adjusted method in the EUnetHTA Core Model Online for scoping Core HTAs.

**Methods:** The problems identified in the first two EUnetHTA pilot Core HTAs were used to develop a new improved scoping method. It was implemented in subsequent pilot Core HTAs and their feedback was iteratively used to improve the methods.

**Results:** Five essential elements were identified for scoping a full HTA: 1) the technology (e.g. MSCT coronary angiography); 2) intended use of the technology (e.g. prevention, screening, diagnosis, treatment, monitoring); 3) target condition (disease or health condition); 4) target population (a subset of all with target condition or people with certain level risk of having the target condition, e.g. women over 40 years old with the condition; or people with high risk of having the disease); and 5) comparator. A generic scope for a full HTA would be thus: Technology in the Intended Use of Target Condition in Target Population compared to Comparator.

**Discussion:** Accurate, yet flexible, scoping method is necessary to guide the work of collaborative HTA projects. The proposed structure will be further piloted and improved.

#### 851. ACCOUNTING FOR ALL RANDOMISED CASES: HANDLING NON-COMPLIANCE AND MISSING DATA IN SURGICAL TRIALS

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**Background:** Randomised controlled trials are widely acknowledged as the gold standard in medical research though their validity can be undermined by non-compliance with allocation and missing data. Due to the nature of the intervention, surgical trials face particular threat to compliance and data collection. For example, ineligibility for the intervention may only become apparent once the operation has commenced. It is unclear how such cases are reported and dealt with.

**Objectives:** The objective was to assess non-compliance and missing data in surgical trials.

**Methods:** Titles and abstracts of reports of all trials involving surgical procedures published in 2010 from six general medical and 12 surgical journals were retrieved from MEDLINE. Data on the trial design, primary outcome, non-compliance to allocation and how missing data was addressed in the statistical analysis were extracted.

**Results:** Of 463 titles and abstracts identified, 93 studies (17 from the general medical journals) were included in this review. Fourteen (82%) and three (18%) studies from the general medical and surgical journals respectively reported primary outcome missing data. Non-compliance was reported in all studies from the general medical journals and in 58 (76%) studies from the surgical journals. Five (36%) studies in the general medical journals compared with 34 (63%) in the surgical journals used complete-case analysis to handle missing data.

The use of modern methods of handling missing data was found in 5 (35%) and 1 (2%) studies in the general medical and surgical journals respectively.

**Discussion:** Missing data and non-compliance commonly occur in surgical trials. The reporting of compliance to allocation and the handling of missing data were typically suboptimal. There is a need for clarity in reporting by defining the intervention and fully accounting for all randomised cases. Transparency in reporting would facilitate evidence synthesis.

#### 873. COST-EFFECTIVENESS OF TRAP TO CAPTURE THE DENGUE ADULT VECTOR IN THE CONTEXT OF THE PUBLIC HEALTH SYSTEM, IN BRAZIL

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The Brazilian's Government data show a rising trend in the number of cases of dengue in all regions of Brazil in 2011, 254,734 cases reported until March. Resources have been invested in strategies of elimination the *Aedes aegypti*. However, the efficacy of those approaches is still controversial. So, innovative methods of control adult mosquitoes are being developed and applied. Objective: To estimate the cost-effectiveness of trap to capture the dengue adult vector as compared to the usual program of dengue control, from the perspective of the Public Health System, in Salvador/Bahia, Brazil. The effectiveness was obtained from the longitudinal epidemiological study conducted in the Peninsula Itapagipana in Salvador. The primary outcome was the incidence of dengue in children aged zero to fourteen, followed by 12 months. The procedures performed were listed according to criteria of the Ministry of Health of Brazil and the costs were obtained from the SIGTAP/SUS and Price Bank of the Ministry of Health of Brazil considering only direct medical costs. The cost of the trap was determined according to the manufacturer. An analytical model was developed to compare the cost-effectiveness of the interventions. The dengue incidence was 11.43% in the houses with trap and 15.55% on without trap, showing a 26.5% reduction in disease incidence. The cost/year of the trap was approximately R\$259.20, the cost/days of treatment for Dengue Classic was R\$287.76 according with SIGTAP and for Dengue type A was R\$174.50. This analysis showed that the intervention without trap was considered dominant over the one with trap, what represented a saving of resources for the National Health System. The sensitivity analysis to assess the consistency of this result is ongoing. To help health managers in making coherent and rational decisions about the incorporation of this new technology, it is important to consider the disease severity.

#### 481. COST-EFFECTIVENESS OF DIAGNOSTIC STRATEGIES FOR FAMILIAL HYPERCHOLESTEROLEMIA (FH)

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**Background:** FH is an autosomal inherited genetic disorder leading to an increased risk of heart disease, affecting over 100,000 people in the UK. Elucigene FH20 and LIPChip are targeted tests for the most commonly occurring FH causing mutations in the UK. Comprehensive Genetic Analysis (CGA) identifies all known FH causing mutations.

**Objectives:** To assess the cost-effectiveness of testing strategies for index cases with clinical diagnosis of FH and cascade testing of relatives.

**Methods:** A health economic model was developed and populated using data from a systematic diagnostic accuracy literature review. Twelve testing strategies were modelled. Diagnostic accuracy data were linked using a markov model to lifelong cost (diagnostic, statin therapy and cardiovascular events) and QALY outcomes. Tests were ranked in ascending order of costs. Principles of simple and extended dominance excluded tests which were clearly not cost-effective. Deterministic and probabilistic sensitivity analyses illustrated uncertainty in the model.

**Results:** Targeted tests as a pre-screen to more comprehensive tests were dominated by the single more comprehensive test. Elucigene FH20, LIPOchip and CGA were all cost-effective when compared to current practice (LDL-C), with ICERs below £2,000 per QALY gained. CGA generated the greatest QALY gain at modest additional total cost and was the most cost-effective strategy. Results were robust to sensitivity analyses and probability analysis suggested a greater than 90% probability of cost-effectiveness for CGA.

**Implications for the health system:** CGA is the most expensive diagnostic strategy and there may be practical and resource issues in its widespread implementation. However, CGA generates the greatest QALY gain at high initial diagnostic cost, but modest total cost (accounting for savings from reduced cardiovascular events). CGA detects all known FH causing mutations, thereby reducing any inequality associated with tests targeted specifically to a UK Caucasian population.

#### 664. SELF-REPORT METHODS TO ASSESS COSTS: HOW VALID ARE THEY?

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**Objective:** Overall guidelines and standards advise to perform economic evaluations from a societal perspective, including all relevant costs. In economic evaluations cost data can be obtained via self report methods; such as questionnaires and diaries completed by the patient, or via data recorded by health care providers, insurance companies, etc. Despite the widespread use of self-reports, little evidence has been synthesized on the validity of self-report methods to measure costs in economic evaluations. The objective of this review is to provide a comprehensive overview of published articles that have evaluated the validity of self-reported cost data compared to registered cost data.

**Methods:** A literature search was conducted in online databases using the keywords 'self-reports', 'cost measurement', 'registered data', and 'economic evaluation'. Additional articles were retrieved using snow-balling. Original articles published in English and comparing self reported cost data to registered cost data were included.

**Results:** Eight original full English articles were included. In general the volumes did not differ significantly when comparing self-reported cost data to registered cost data. Self-reported data was more reliable as uncertainty was minimized. Self-reported costs were even found more valid because they were more complete regarding type, frequency, and magnitude of the expenditures that were directly or indirectly related to an illness or intervention. Self-reported data are sensitive as they represented the expected differences and appeared feasible in the circumstances applied.

**Conclusion:** High levels of agreement have been found between self-reported cost data and registered cost data. Registered data however are often unavailable, expensive or unable to capture a person's complete utilization of resources. Self-reported data were

found to be more reliable and valid. Although the choice of an assessment tool depends crucially upon the context of its use, we generally recommend cost data to be obtained through self-reporting channels such as questionnaires and diaries.

#### 783. REPRESENTING UNCERTAINTY AND ITS CONSEQUENCES IN COST-EFFECTIVENESS ANALYSES

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Reimbursement and coverage decisions are increasingly being made close to the point of licence when the evidence base is least mature, which inevitably increases the uncertainty surrounding the assessment of cost-effectiveness. How best to represent this uncertainty (parameter and structural) and its consequences has not been sufficiently explored in the literature. Within this work we have developed a novel approach to explore uncertainties in the context of the following assessments: (i) how uncertain is a decision based on mean cost effectiveness; (ii) what are the likely consequences if an incorrect decision is made; (iii) what are the causes of uncertainty, and (iv) is it worthwhile conducting new research to resolve these. Conventional approaches applied to probabilistic decision analytic modelling were used (e.g. separate sensitivity and scenario analysis), alongside a series of more novel ones. These consisted of, for example, the use of elasticities, or the further development of relevant methods of analyses when multiple scenarios exist. The approach developed was illustrated using an existing appraisal of clopidogrel for the management of patients with non-ST-segment elevation acute coronary syndromes. Results show there was substantial uncertainty over the decision to adopt clopidogrel: the net health of the population is expected to increase by 5194 QALYs if uncertainty could be immediately resolved. Our approach shows that important uncertainty remains about the cost-effectiveness of clopidogrel itself, not just the duration of its treatment; also, that relative effectiveness is the most significant source of uncertainty. When an alternative scenario was considered together with the base case, the consequences of overall uncertainty were valued at 4667 QALYs. Resolving parameter uncertainty but not between scenario-uncertainty was of less value (2356 QALYs). The integrated framework presented here aids exploring the level and consequences of uncertainty, and may thus facilitate greater transparency if used to inform reimbursement and coverage decisions.

#### 835. MODEL-BASED PROJECTION OF CLINICAL EFFECTIVENESS AND COST EFFECTIVENESS OF CATHETER-BASED RENAL DENERVATION IN HYPERTENSIVE PATIENTS WITH DIFFERENT CARDIOVASCULAR RISK PROFILES

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**Background:** Catheter-based renal denervation (RDN) is a new treatment for patients with resistant hypertension, and has been shown to lead to significant reductions in systolic blood pressure (SBP). Our goal was to analyze differences in long-term clinical effectiveness and cost effectiveness of RDN versus standard of care among five cohorts with different cardiovascular (CV) risk profiles.

**Methods:** A Markov model was used to predict the risk of stroke, myocardial infarction (MI), coronary heart disease (CHD), heart failure (HF), end-stage renal disease (ESRD), CV and all-cause death. Per the

results of the Symplicity HTN-2 randomized clinical trial (n = 106 patients, baseline SBP: 178 mmHg), we assumed RDN treatment to be associated with a 32 mmHg reduction in SBP. From the JNC7 guidelines we defined five cohorts with increasing total CV risk using combinations of the following risk factors: total cholesterol, HDL, corresponding LDL, smoking status, and diabetes. From a starting age of 58 years, we computed ten-year clinical event rates and relative risks (RR), as well as lifetime incremental cost effectiveness ratios (ICER) for RDN.

**Results:** For all clinical events, RRs for RDN generally increased with worsening CV risk profiles. Stroke: 0.70-0.77; MI: 0.68-0.87; CHD 0.77-0.89; HF: 0.84-0.95; ESRD: 0.71-0.75; CV death: 0.69-0.85; all-cause death: 0.83-0.88. ICERs increased from \$5,741/QALY to \$12,307/QALY with worsening risk profile.

**Discussion:** While RR reductions associated with the SBP reduction from RDN were greatest for the low-risk cohorts except for all-cause mortality, absolute risk reductions for the respective events followed a more variable evolution with increasing CV risk. While all cohorts had acceptable ICERs, the economically most attractive cohort was the one with lowest CV risk.

**Implications for the health system/professionals/patient/society:** The results suggest that renal denervation is a clinically effective and cost effective treatment option for resistant hypertensive patients over a wide array of cardiovascular risk profiles.

### 891. THE RISK OF ASSUMING FOREIGN COST-EFFECTIVENESS RATIOS: THE CASE OF PALIVIZUMAB IN COLOMBIA AND NORTHERN CANADA

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**Background:** Palivizumab (PVZ) is a monoclonal antibody against the fusion protein of human respiratory syncytial virus (RSV). PVZ was approved in 1998 as prophylaxis for RSV infections, particularly in pre-term infants. Numerous cost-effectiveness studies have been published, most of them assuming an efficacy similar to the one described in the original randomized double-blind placebo controlled clinical trial (55% reduction in hospitalization).

**Objectives:** We want to illustrate with an extreme example how "cost-effectiveness does not travel", despite the basic assumption that effectiveness of the intervention is similar in different countries.

**Methods:** For two independent cost-effectiveness studies, we have collected data of the local epidemiology of RSV infections in premature children in Colombia and in Northern Canada, as well local costs of resources used in RSV prophylaxis and treatment. Costs reflect third party payer perspective, and are expressed in euros (1€ = Can\$1.31 = Col\$2,354).

**Results:** Canadian Inuit children have the highest incidences of RSV, 166 per 1000 infant-years. Epidemiologic data on RSV are scarce in Colombia, with one study suggesting 3 to 5% infection rates in prematures, with no clear seasonal variation (which would imply all year round use of PVZ). The dose of PVZ is estimated according to the child's weight. The price per mg of PVZ is similar in both countries: €11.48 in Canada and €10.97 in Colombia. In a sample of 514 Inuit children with lower tract respiratory infection, the average cost of treatment was €21,575 (€22,970 in the RSV+ subgroup); 45% of this cost was due to transportation expenses. On the other hand, in Colombia the estimated hospitalization cost of a lower tract infection is €777 (7.8 days in hospital, 1.37 of them in ICU).

**Conclusions:** using foreign cost-effectiveness data may lead decision makers to make inappropriate choices, local information, and adaptation of models is essential.

### 67. SIX YEARS OF GLARGINE FINANCE BY THE MINAS GERAIS STATE GOVERN, BRAZIL: SHOULD THE GOVERNMENT DISINVEST?

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**Background:** Influenced by the growth of judicial demand and by the promise of better efficacy in terms of reducing the hypoglycemia episodes, in 2005 the glargine analogue was incorporated in the Minas Gerais State Public Health System (SUS) for type 1 diabetes mellitus. Currently around 2.7 thousand people are receiving the drug by the SUS free of charge. The expenses for State Government are approximately six million dollars year (2010). The crescent budget impact and recent studies about glargine and incidence of malignancies motivated managers to demand the Federal University of Minas Gerais for appraisal about efficacy and safety of the drug.

**Objectives:** To assess efficacy and safety of glargine analogue compared with NPH insulin in order to evaluate the pertinence of maintenance of the drug on the list of SUS from Minas Gerais State in Brazil.

**Methods:** Systematic Literature Review.

**Results:** Starting from 803 studies found in selected databases just eight trials matched the inclusion criteria in this review. Most of them had poor methodological quality or high risk of bias, with a mean score of 2.25 based on the Jadad scale. No study could be classified as double blind and were not identified results that prove more efficacy of glargine analogue simultaneously in relation to glycemic control and hypoglycemic episodes.

**Discussion:** The present study showed no benefit of therapy with glargine over other insulins studied, when analyzed together the glycemic control and the frequency and severity of hypoglycemia. It is therefore recommended to the State Authority of SUS the disinvestment or the renegotiation towards to reduce manufactory's prices.

**Implications for the health system:** This study would implies in a considerable reduction of budget as it reveal that there is no additional benefit for the extra cost of monthly treatment with glargine compared to NPH insulin and recommended to the State Authority of SUS the disinvestment or the renegotiation towards reducing prices.

### 165. THE APPLICATION OF FRAMEWORKS AND TOOLS USED FOR DISINVESTMENT AND REALLOCATION DECISION-MAKING OF HEALTH CARE TECHNOLOGIES: A SYSTEMATIC REVIEW

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**Introduction:** Technological change accounts for approximately 25% of health expenditure growth. To date, limited research has been published on frameworks and tools used for disinvestment and reallocation decision-making for ineffective health technologies. Our research objective was to review the application of these frameworks and tools for disinvestment and reallocation decisions on health technologies across health system contexts.

**Methods:** A systematic review of studies that describe the use of frameworks and tools for disinvestment and reallocation decision-making in health care was conducted. An electronic literature search was executed for studies on disinvestment, obsolete and ineffective technologies and priority health care setting that were published

from January 1990 until December 2011. Databases searched were Medline, Medline In-Process & Other Non-Indexed Citations, BIOSIS Previews, and EMBASE.

**Results:** Nine case studies on the application of frameworks and tools for disinvestment and reallocation decisions were included. Most studies (n = 6) described the application of programme budgeting and marginal analysis (PBMA) at the regional or institutional level, and two reports used health technology assessment (HTA) methods for coverage decisions in a national fee-for-service structure. Numerous health care technologies and services were covered across the studies. The criteria considered for decision-making were disease burden, clinical effectiveness and patient safety, cost-effectiveness and opportunity cost, health services impact, sources of data, and stakeholder engagement. The strengths and limitations of these frameworks and tools are highlighted.

**Conclusions:** The frameworks and tools examined have common attributes, as well as unique ones. Disinvestment and reallocation decisions require evidence to ensure their transparency and objectivity. PBMA was used to assess resource allocation of health services and technologies in a broad population, while HTA reviews focused on specific technologies. Future studies can explore opportunities to increase the quantity of available evidence and evaluate the appropriateness of existing frameworks and tools for disinvestment and reallocation decisions.

## 229. THE INFLUENCE OF DIFFERENT INITIATIVES TO ENHANCE PRESCRIBING EFFICIENCY FOR CV DRUGS, PPIs AND ATYPICAL ANTIPSYCHOTICS IN SCOTLAND: IMPLICATIONS FOR THE FUTURE

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**Background:** Plethora of supply and demand side measures led to considerable prescribing efficiency for both PPIs and statins in Scotland (2001 to 2007). No analysis of measures to enhance atypical antipsychotic prescribing efficiency following generic risperidone (late 2008) as recognise management of schizophrenia more complex and therapeutic substitution difficult.

**Objectives:** (a) Analyse whether prescribing efficiency for PPIs and statins extended beyond 2007; (b) analyse influence of reforms to enhance atypical prescribing efficiency; (c) contrast with other classes and suggest additional reforms if needed.

**Methods:** Retrospective observational DU study of influence of reforms on PPI and statin utilisation and expenditure 2001 to 2010 (2010 DDDs), and atypical antipsychotics 2005 to 2010 (2011 DDDs) using NHS Scotland Warehouse data. Clozapine not included as reserved for resistant patients. Demand side measures collated under the 4 Es.

**Results:** (a) Increasing utilisation of generic PPIs and statins at low prices continued prescribing efficiency – PPI expenditure reduced by 56% 2010 vs. 2001 despite 3 fold increase in utilisation; projected savings of GB£159mn in 2010 (5.2mn population), statin expenditure increased only 7% despite 6.2 fold volume increase; projected savings of GB£290mn in 2010; (b) Risperidone utilisation decreased – 21% of total atypicals in 2005 to 16% in 2010, with utilisation of newer atypicals (quetiapine, aripiprazole and paliperidone) increasing (17.5% to 32%), (c) Expenditure/DDD for oral generic risperidone fell in 2010 to 84% below pre-patent loss prices, although still increasing atypical expenditure; (d) Demand side measures for atypicals included formularies (education) and prescribing targets for oral vs. patented dispersible risperidone (engineering).

**Conclusions:** Measures continued PPI and statin prescribing efficiency. Demand side measures appreciably lower influence for atypicals. Consequently, will need specific targeted interventions to enhance prescribing of generic risperidone first line/first switching to enhance prescribing efficiency vs. similarly effective but appreciably more expensive patented atypicals.

## 397. KEEPING AN 'EYE' ON THE PROBLEM: DEVELOPING A DISINVESTMENT METHODOLOGY TO REVIEW AUSTRALIAN MEDICAL SERVICES – 'OPHTHALMOLOGY' AS A TEST CASE

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**Background:** In 2009-10, the Australian Government put in place a new evidence-based framework for managing the Medicare Benefits Schedule (MBS). Rolling reviews of existing publicly funded services were to be conducted with the aim of encouraging evidence-based, cost-effective clinical practice and to identify and evaluate current MBS services that present potential safety and quality issues.

**Objectives:** To develop a methodology for reviewing established services funded by Medicare and to apply this methodology to the first whole-of-specialty 'demonstration review' of 61 ophthalmology services.

**Methods:** A review protocol was drafted with the assistance of a Clinical Working Group and underwent public consultation. Given the often poor evidence-base for "established" technologies, a mixed-methods approach was suggested. The aim was to use multiple methods to flag potential problems (if any) with the service being reviewed. Five methodologies were employed:

analysis of claims data on usage of services; analysis of the concordance between clinical practice guideline recommendations and MBS item descriptors (outlining eligible patient indications for the service); mini-HTAs tailored to be "fit-for-purpose" – ie conducting a descriptive or analytic assessment of the medical service, using an hierarchical approach to literature review and selection; qualitative analysis of patient/consumer literature on values and preferences concerning specific ophthalmology services; and negotiation with stakeholders on minor wording amendments to item descriptors.

**Results:** Only 20 of the 61 currently funded MBS items escaped change. Recommendations for the remaining 41 items were to have the item descriptors' clarified, split, merged, or to have the service entirely removed from public funding, in order to be consistent with evidence-based practice and the review's findings.

**Implications for the health system:** A framework for reviewing the public funding of established technologies has been developed. This methodology is now standard for 'whole-of-specialty' reviews of established medical services in Australia and may be a suitable model for other health systems.

## 529. SURGICAL DISINVESTMENT: ENDOBRONCHIAL ULTRASOUND FOR LUNG CANCER STAGING

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**Background:** In 2007-08, the Department of Health funded the introduction of endobronchial ultrasound (EBUS) for biopsy and staging of lung cancer at Austin Health, one of Melbourne's major tertiary teaching hospitals. Following review of 24 month outcomes data, EBUS was introduced into two other tertiary teaching hospitals,

Monash Medical Centre and Royal Melbourne Hospital. At HTAi2010, we highlighted that the best outcomes associated with introducing a new health technology, and demonstrating value for money and health care savings, was to link this with disinvestment of an existing clinical practice. We now report on the impact of EBUS on mediastinoscopy at these three hospitals.

**Objectives:** To determine the impact of targeted diffusion of EBUS on disinvestment in mediastinoscopy, an invasive and costly procedure requiring a general anaesthetic and multi-day admission, and if that disinvestment could be sustained.

**Results:** EBUS has replaced > 90% of all mediastinoscopy procedures after 12 months, which was sustained after three years. EBUS has also resulted in: improved biopsy yields (91% sensitivity, 100% specificity); reduced patient waiting times to procedure; reduced patient length of stay from > 2 days to same day; relocation of EBUS from OR to the endoscopy suite (i.e. outpatient setting); better targeted (i.e. reduced number of) lung resections; health system savings of > \$5,000 per patient.

**Discussion:** Despite a significant learning curve and additional costs associated with maintaining and repairing fragile endoscopes, EBUS has resulted in almost 100% disinvestment of mediastinoscopy after three years. This level of sustained disinvestment at one hospital informed targeted state investment in EBUS elsewhere, with similar sustained disinvestment demonstrated.

**Implications for the health system:** The success of EBUS has led to broad patient acceptance, a cheaper procedure, greater patient throughput and a good return on investment for the Victorian public health system.

## 662. IDENTIFYING OPPORTUNITIES FOR HEALTH CARE DISINVESTMENT: EXPERIENCES AND METHODS REVIEW

Beatriz Valentín-López, Nerea Fernández de Larrea Baz, Daniel Callejo Velasco, María José López-Pedraza Gómez, Sergio Maeso Martínez and Juan Antonio Blasco Amaro

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**Objectives:** To identify health care practices and technologies of uncertain effectiveness, safety and efficiency for disinvestment.

**Methods:** A scientific literature review of methods and experiences of health care disinvestment in electronic databases (CRD, Cochrane Database, Medline, ISI Web of Knowledge) and websites of international and national organisations was performed. HTA reports, systematic reviews and documents that develop criteria for identifying and selecting potentially non-effective and cost-effective practices for disinvestment process were considered. Disinvestment experiences of ineffective health care practices, interventions and technologies were included.

**Results:** Different institutions have implemented disinvestment experiences. NICE has identified over 800 clinical interventions for potential disinvestment published as “do not do” recommendations. Scottish Health Technology Group has disinvestment as part of its remit and identified that development of SIGN guideline processes could provide support for disinvestment. Australian academics have published papers to provide support to the challenges in governmental policy processes for disinvestment. It had also been proposed criteria to facilitate systematic and transparent identification of potentially cost-ineffective interventions. In Australia and Canada most of targeted disinvestment practices have been related to safety concerns of health interventions and practices. In Spain, HTA agencies published a guideline to identify, prioritise and assess potentially obsolete technologies and another guideline for Not Funding Health Technologies (GuNFT) to facilitate the process setting to assess the potential health care interventions, practices and technologies for disinvestment.

**Discussion:** Different approaches have been developed depending on the health care context as complete disinvestment with withdrawal of health resources and efficient reallocation to areas of better value, and partial disinvestment with changes in clinical practices, restriction of indications and limiting the duration/frequency of treatment.

**Implications:** Systematic and transparent criteria will improve the disinvestment process and will help to identify opportunities.

## 167. THE IMPACT OF HEALTH TECHNOLOGY ASSESSMENT REPORTS ON DECISION MAKING IN AUSTRIA

Ingrid Zechmeister-Koss and Ines Schumacher

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**Objectives:** Health Technology Assessment (HTA) was established in Austria in the 1990s and since then it has gained considerable importance. In this study we aim to analyse whether the HTA reports that have been produced at the Institute for Technology Assessment (ITA) and at the Ludwig Boltzmann Institute for HTA (LBI-HTA) have had an impact on decision making within the Austrian health care system and what the economic consequences from that have been.

**Methods:** We selected all reports that were intended for supporting a) reimbursement/investment or b) disinvestment decisions. 11 full HTA reports and 58 rapid assessments fulfilled the inclusion criteria. We used interview data and administrative data on volumes, tariffs and expenditure of products/services to analyse whether and how reports were in reality used in decision making and what the consequences for health care expenditure and resource distribution have been.

**Results:** Five full HTA reports and 56 rapid technology assessments were used for reimbursement decisions. Four full HTA reports and two rapid assessments were used for disinvestment decisions and resulted in reduced volumes and expenditure. Two full HTA reports showed no impact on decision making. Impact was most evident for hospital technologies.

**Conclusions:** HTA has played some role in reducing volumes of over-supplied hospital technologies, resulting in reduced expenditure for a number of hospital providers. Additionally, it has been increasingly included in prospective planning and reimbursement decisions of late, indicating re-distribution of resources towards evidence-based technologies. However, further factors may have influenced the decisions, and the impact could be considerably increased by systematically incorporating HTA into the decision-making process in Austria.

## 460. A PUBLIC PROCESS TO GUIDE THE APPLICATION OF HTA IN HEALTH INSURANCE POLICY DECISIONS IN THE UNITED STATES

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In the United States, there are many barriers to the use of rigorous HTA by health insurers as they make coverage decisions. Problems that have been perceived to reduce the application of HTA reviews to payer policies include 1) the length and complexity of HTA reviews; 2) lack of coordination in the timing of HTA reviews with decision timelines; 3) the absence of a framework for the inclusion of information on cost and cost-effectiveness; and 4) the lack of public trust in payer interpretation of evidence to restrict coverage. This oral presentation will describe the early experience and lessons learned from an initiative launched to address these barriers. This initiative is known as the New England Comparative Effectiveness Public Advisory Council (CEPAC). Initially

funded by a grant from the federal Agency for Healthcare Research and Quality (AHRQ), CEPAC is a regional, independent body of 19 members, composed of clinicians and public representatives from each New England state. CEPAC holds public meetings at which it considers the results of adapted HTA reviews, receives provider and other stakeholder input, and then votes on the adequacy of evidence to demonstrate the comparative clinical effectiveness and value of different approaches to diagnosis or treatment. The presentation will cover the structure of CEPAC and its Advisory Board, the design of the adapted HTA reports provided to CEPAC, and the process for the votes on comparative clinical effectiveness and value that are the most tangible product of CEPAC meetings. I will also discuss the lessons learned from the use by payers of CEPAC final votes and reports. Included here will be a discussion of the influence of a positive CEPAC vote on the recent announcement of first-in-the-nation Medicare coverage in New England for an innovative treatment option for patients with depression.

#### 491. DECISION MAKING IN MANAGEMENT OF LARGE MEDICAL EQUIPMENT

Ilya Ivlev and Peter Kneppo

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The 2010 WHO report suggests as a solution to a part of the described problems, creation of systems for management of medical equipment. Thus, creation of a system for rational selection of medical equipment becomes one of key prerequisites for building a clear system for resources control in health care. The purpose of the study is to develop a theoretical and methodological foundation for a universal system of rational choice of medical equipment using MRIs as an example. The Analytic Hierarchy Processes by T.L. Salty approach was determined to be the best Multi-Criteria Analysis method for solving problems in medical equipment choice. The Delphi method was used for compiling expert opinions. A method was developed to determine the qualifications for the expert team (quality and quantity). This method utilized the degree of participation in problem solving, level of professionalism, statistical methods, and completeness of the expert's replies for determining the quality of the expert's opinion. To determine a sufficient quantity of experts, the Kendall's coefficient of concordance method was used. The system of rational choice of medical equipment was created. This system can be applied for any type of medical equipment or devices in any type of medical facility. Kladno Regional Hospital (Czech Republic) is currently implementing our system while buying MR-imagers. Use of our system will help to minimize financial expenses in global system in public health, help to fix mistakes in management system of healthcare, help to optimise control system of technical resources and improving the actual quality of medical care.

#### 496. WHICH HTA PRODUCT DO I NEED? DEVELOPING A DECISION GUIDE FOR POLICY MAKERS

Ann Scott<sup>a</sup>, Christa Harstall<sup>a</sup> and Joan Berezanski<sup>b</sup>

<sup>a</sup>*Institute of Health Economics. Canada.* <sup>b</sup>*Alberta Health and Wellness. Canada.*

**Objectives:** To establish an inventory of HTA products. To establish an inventory of criteria for determining which HTA product types are needed for particular policy questions. To develop a framework for using the various HTA products in the Alberta Health Technology Decision Process (AHTDP).

**Methods:** A systematic literature search was conducted to identify relevant literature published in English to March 2011. An Internet search, which included the websites of major publically funded HTA

agencies in North America, the United Kingdom, and Australia, was conducted to identify grey literature.

**Results:** *Inventory of HTA products:* Three relevant secondary studies were identified. The products listed were compared with those produced by the provincially funded HTA Program administered by the Institute of Health Economics to produce a comprehensive list of HTA products. *Inventory of criteria for matching HTA products to policy questions:* Two relevant articles were identified. Full HTAs were appropriate when a policy decision must be made quickly, there is a large evidence base but questions remain unanswered, the technology will be implemented on a large scale, the topic is broad, or the question involves more than two technologies for a single condition or one technology for multiple conditions. Rapid HTAs were better suited to questions with a narrow scope. The results were used to develop a decision matrix worksheet for facilitating dialogue between policy makers and HTA producers to determine the right type of HTA product to commission for particular policy questions.

**Conclusions:** The framework and decision matrix were refined in consultation with key stakeholders. The resulting questionnaire can be used to match the evidence needs of policy maker with the research-oriented listing of available HTA products. The questionnaire is currently being piloted within the Health Ministry's AHTDP to ensure that it is useful and compatible with existing processes.

#### 519. HEALTH TECHNOLOGY ASSESSMENT AND EVIDENCE-BASED POLICY MAKING: QUEENSLAND HEALTH EXPERIENCE

Hong Ju and Kaye Hewson

*Queensland Health. Australia.*

**Background:** Faced with rapidly escalating healthcare costs worldwide, health policy makers increasingly rely on evidence-based policy-making for better resource allocation. In this context, Queensland Health has developed a new model to introduce innovative health technologies into public healthcare system through a Health Technology Assessment (HTA) program.

**Methods:** The Queensland Policy and Advisory Committee for New Technology was established in 2009 to oversee the state-wide HTA program. The committee is made up of clinicians from various disciplines, health administrators, and representatives from research division and similar national assessment agencies. In addition, a number of sub-committees at health service district level were set up to monitor the uptake of technologies which are new to that district. The committees are supported by a multidisciplinary secretariat comprising personals with key HTA skills including epidemiology, health economics, policy, planning and clinical knowledge. *Process:* The process starts with HTA applications, which are then shortlisted according to pre-specified criteria. The secretariat undertakes evaluation of shortlisted applications through due diligence process adopting a rapid evidence assessment approach, considering the burden of disease/clinical need, the clinical benefits, the economic evaluation, the feasibility of adoption, and the societal and ethical consideration of adopting the technology. Based on the assessment, recommendations are made employing a deliberative decision-making process guided by the GRADE and National Health and Medical Research Council tools to ensure its consistency and transparency. With positive recommendation, a technology is generally piloted in a local setting for a period of time, until "proof of concept" is achieved before its system-wide diffusion.

**Results:** Although the program is only in its infancy, it has assisted health administrators from different districts in prioritising their health technology agendas. It has gained trust and wide support from policy makers and is increasingly used to support funding allocations,

indicating the increasing awareness of and confidence in the evaluation process.

### 309. QUANTIFYING INNOVATION OF END-OF-LIFE TREATMENTS APPRAISED BY NICE

Adam Hutchings<sup>a</sup>, Michael Harris<sup>b</sup>, Louisa Pericleous<sup>b</sup>, Anthony Batty<sup>c</sup>, Andrew Briggs<sup>d</sup>, Anne Prenzler<sup>e</sup>, Michael Lees<sup>b</sup> and Max Lebmeier<sup>b</sup>

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**Background:** Innovation is central to the NICE remit, but has proved difficult to measure. In the NICE methods guidelines appraisal committees are instructed that innovative treatments may justify a higher QALY threshold if the benefits from innovation are not adequately captured in the QALY measure.

**Objective:** To assess how innovation is incorporated within NICE decisions on end-of-life treatments.

**Methods:** NICE methods guidelines, end-of-life criteria, and related NICE policy documents were reviewed to identify elements of innovation that may be rewarded implicitly within the end-of-life guidance. A composite metric was identified that reflected NICE's implied measure of innovation. Data for all treatments that were deemed to meet end-of-life criteria between January 2009 and November 2011 were analysed and compared with appraisal outcomes in order to identify any historical relationship between the level of implied innovation and the result of the NICE process.

**Results:** The ratio of the therapeutic benefit (additional survival) to disease life expectancy provided a measure of innovation that was quantified for 16 treatments previously evaluated under end-of-life guidance. The 8 end-of-life products that had been given a positive decision by NICE were seen to have higher levels of innovation (i.e. a greater proportional increase in survival) than those that had been rejected. However, within the group of products that were given a positive decision by NICE, there was no discernible correlation between the magnitude of innovation and the ICER at which the treatment had been approved.

**Discussion:** Appraisal Committees appear to have implicitly recognised innovation, however for products that were approved by NICE the ICER threshold has not been seen to be related to the magnitude of treatment innovation.

**Implications:** Were end-of-life ICER thresholds to reflect innovation levels, it is possible that some treatments would be approved at higher ICERs than have previously been seen in end-of-life appraisals.

### 543. TOWARDS BEST PRACTICES FOR FUTURE HEALTH TECHNOLOGY ASSESSMENTS FOR HPV VACCINATION IN EUROPE

Uwe Siebert

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**Background:** Health technology assessments (HTAs) for human papillomavirus (HPV) vaccination were conducted by health authorities or HTA agencies in most Western European countries and played an important role in the decision-making for implementing HPV vaccination in girls.

**Objectives:** Our research aims to point out lessons learnt from previous HTAs for HPV vaccination and to suggest general best practices for future HTAs of HPV vaccination.

**Methods:** A comprehensive research was conducted into the current HTA landscape in Western Europe. A multidisciplinary and pan European group of experts has been established to discuss the development of best practices to optimise future HTAs for HPV vaccination.

**Results:** The research shows that different approaches and methods were used in previous HTAs for HPV vaccination and the conclusions influenced differently the decision-making. Expert consensus was reached that such HTAs should follow a comprehensive approach, including all key HTA domains (disease burden, medical needs, vaccine efficacy/safety, cost-effectiveness, ethical/legal/social implications, advice for implementation, monitoring). All evidence available when HTA is conducted should be integrated, considering part of existing uncertainty including trend and severity of all HPV-diseases burden, vaccine duration of protection, relative effectiveness, public health impact, and vaccination coverage. The use of dynamic transmission models (including herd immunity), considering all HPV-related outcomes and decision-analytic aspects (incremental comparisons, time horizon, discounting, sensitivity analyses) is critical to handle validity and uncertainties at first assessment time. New scientific evidence coming to light will serve to address uncertainties.

**Discussion:** HTA for HPV vaccination should be a lively process. Future policy decisions on HPV vaccination should reflect the changes in scientific knowledge and new public health issues arising since latest HTA.

**Implications for the health system/professionals/patients/society:** Public health researchers and policy makers, stakeholders involved in HTA, epidemiologists, health-economists, modelers will learn about past and future HTA conducted on HPV vaccination.

### 676. SHOULD THE NORWEGIAN PUBLIC PRENATAL CARE PROGRAM INCLUDE ULTRASOUND SCAN IN THE FIRST TRIMESTER?

Siv Cathrine Høymork, Hege Wang, Vigdis Lauvrak and Ånen Ringard

*The Norwegian Knowledge Centre. Norway.*

The Norwegian public prenatal care currently offers one ultrasound scan in the second trimester to check for length of the pregnancy, number of fetuses, the placement of the placenta and general fetal development. Politicians have proposed an expansion of the program to also include ultrasound in the first trimester. The Norwegian Council for priority setting in Health Care is set up by the Ministry as a permanent advisory board for assessing new health technologies. The members are leaders representing health authorities and health services and patient organizations. The Council questioned whether an expansion of the prenatal care program would impact the health condition for the fetus/mother and the costs of the program. To support the decision, an HTA was requested from the Norwegian Knowledge Centre (NOKC). The HTA was prepared by a multidisciplinary working group; researchers and health economists, specialists in medical ethics, pediatrics, gynecology, fetal medicine and general practice. There was consensus among the working group members on the main conclusions: (1) Ultrasound in the first trimester would reveal no health benefits for the fetus/mother. (2) The pregnant women would probably be more satisfied, and (3) the birth rate for children with Down's syndrome would decline. (4) The running costs of the program would probably not increase. The HTA was presented for the Council in December 2011. The Council decided – despite the lack of health benefits shown in the HTA – to advice for an expansion of the prenatal care program. The arguments were that women would be more satisfied and reassured. As there is substantial unorganized use of ultrasound scanning today, a public program can

ensure better quality and social and geographical equality. There comes that other countries already have established similar programs. The final decision will be made in the Parliament.

### 699. ASSESSING THE SIGNIFICANCE OF IRRECOVERABLE OPPORTUNITY COSTS: IMPLICATION FOR REIMBURSEMENT, PRICING AND RESEARCH DECISIONS

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An assessment of the cost-effectiveness of healthcare interventions is based on the total expected costs and health effects. Although commonly summarised as an ICER, cost-effectiveness can also be expressed as the expected net health effects (NHEs) per patient or for a population. Costs, health benefits and therefore the NHEs accrue at different times over sometimes very long time horizons. Although discounting takes account of the timing of costs and benefits, it is also important to consider how NHEs cumulate over time. This is particularly important if reimbursement decisions are uncertain and might change due to research reporting, new interventions becoming available, or changes in prices. We illustrate how this profile of NHEs can provide valuable information to help assess the 'risk' associated with reimbursing an intervention even in the absence of capital costs (e.g., equipment, facilities and training). For example a cost-effective intervention with initial treatment costs and later benefits will have initial negative NHEs (losses) compensated by later positive ones (gains). It is possible to calculate the breakeven point: the time, since initiation of treatment (for a patient) or since reimbursement for a population, when the initial losses are just compensated by later gains. The time until breakeven as well as the scale of potential losses, gives an indication of the 'risk' associated with reimbursement. An early indication of potential significance of irrecoverable opportunity costs can be based on: their scale relative to expected net health effects; the point at which any initial losses are expected to be compensated by later gains; whether treatment decisions are reversible and what opportunities to improve health might be forgone by a delay to initiating treatment. The circumstances in which reimbursement of a cost-effective technology ought to be withheld or price renegotiated are examined, including the irrecoverable costs associated with displaced technologies.

### 89. SYSTEMATIC REVIEW OF SIALENDOSCOPY IN SALIVARY GLAND DISEASE

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**Objective:** The sialendoscopy that diagnoses salivary disease patients, removes salivary stones and expands salivary ducts was assessed to see if it was safe and effective.

**Methods:** The sialendoscopy was assessed using 8 domestic databases including KoreaMed and Ovid-MEDLINE, Ovid-EMBASE and Cochrane Library. Through a search strategy, a total of 350 works were identified. Of them, study types such as animal experimental or

studies not published in Korean or English were excluded. A total of 25 works were included in the final assessment. Two reviewers screened all references independently, for assessing included article's quality and extracted data.

**Results:** Safety: The safety was assessed through a total of 21 studies. The main complication rate (duct perforation, lingual nerve palsy) were 0-12.5% and the sub complication rate (swelling recurrence, infection, pain) were 0-22.2%. Since the main complications were relieved after conservative treatment or not. Effectiveness: The effectiveness was assessed through a total of 25 works. Salivary duct stricture finding rates of sialendoscopy were similar to sialography (15.0%). Additional sialolithiasis finding rates were 3.1-4.5% in 5 works. The success rates of stone removal were 38.5-100%. The four studies where the success rates of stone removal were lower than 60%. Actually, in these cases the subjects were children, salivary stones were very large to exceed 7mm in diameter or stones were buried in surrounding tissues and thus it was anatomically difficult to remove stones. Salivary duct expansion success rates were 53.3-100%. Actually, the one study of 53.3% (8/15) was anatomically difficult due to severe masseter muscle bending and assessed the sialendoscopy showed effectiveness similar to sialography (75.3-82%).

**Conclusions:** The sialendoscopy could additionally find mucoid plugs(not calcified), showed effectiveness similar to existing procedures in salivary stone removal and salivary duct expansion success rates while having fewer adverse affects and preserving salivary glands.

### 256. REVIEW OF INFORMATION RETRIEVAL – FIRST EXPERIENCES IN GERMANY WITH MANUFACTURER DOSSIERS ON NEW DRUGS

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**Background:** Since July 2011 the Institute for Quality and Efficiency in Health Care (IQWiG) has been assessing the added benefit of newly-approved drugs in Germany on the basis of manufacturer dossiers. These early benefit assessments include a review of the completeness of the evidence base.

**Objectives:** The aim of our presentation is to describe how IQWiG has implemented the review of information retrieval for manufacturer dossiers. This also includes the conduct of our own literature searches if shortcomings in the searches performed by the manufacturers were identified.

**Methods:** We will present the requirements for information retrieval specified in the dossier template and show how we checked their implementation, using examples from specific dossiers. We will analyse IQWiG's evaluation of content and formal requirements of the search in bibliographic databases and trial registries for dossiers published up to June 2012. We will also present our approach to our own literature searches, conducted to check the completeness of the study pool in selected dossiers, and describe whether this yielded additional relevant studies.

**Results:** A preliminary analysis showed that common shortcomings detected in the searches performed by the manufacturers included lack of sensitivity, inconsistencies in search documentation and search strategy errors. Due to the shortcomings identified, for most dossiers an additional search by IQWiG was required to check the completeness of the study pool retrieved by the manufacturer. It was also evident that the diversity of search strategies, e.g. searches for indirect comparisons, posed a particular challenge in the review of information retrieval.

**Discussion:** We identified a noticeably high number of shortcomings in information retrieval in manufacturer dossiers. Our

approach to the review of information retrieval in manufacturer dossiers seems to be useful.

**Implications:** Besides the review of search strategies, peer review of information retrieval should cover all aspects of a search.

#### 470. THE EFFECTIVENESS OF THE BRAF GENE, MUTATION [ALLELE-SPECIFIC PCR] WITH THE DIAGNOSTIC ACCURACY AND THE EFFECTS ON HEALTHCARE OUTCOMES

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**Object:** It was intended to assess the BRAF gene, mutation [Allele-specific PCR] using the allele-specific PCR to see if it is safe and effective in identifying BRAF(B-type Raf Kinase) gene mutations being reported as a causal gene of thyroid papillary cancer.

**Method:** The BRAF gene, mutation [Allele-specific PCR] was assessed using 8 domestic databases including KoreaMed and overseas databases of Ovid-MEDLINE, Ovid-EMBASE and Cochrane Library. Each of stages ranging from literature searches to the application of selection criteria and data extraction was independently implemented by the subcommittee and two assessors.

**Results:** The diagnostic accuracy was assessed using a total of three works by comparing the method with the Direct Sequencing, PCR-RFLP and Pyrosequencing in the individual works based on histological diagnoses as standards. Meta analysis of this technology was conducted and the results showed an integrated sensitivity of 0.82 (95%CI 0.78-0.86), an integrated specificity of 0.99(95%CI 0.98-1.00), a SROC AUC of 0.9348 (SE = 0.1582). In two works, Meta analysis of sequencing was conducted with the two works and the results showed an integrated sensitivity of 0.73 (95%CI 0.66-0.80), an integrated specificity of 1.00 (95%CI 0.93-1.00). In one work, the sensitivity of PCR-RFLP was 0.673, specificity was 1.000 and test accuracy was 0.723 and Pyrosequencing showed sensitivity at 0.865, specificity at 1.000 and test accuracy at 0.918 in one work. The effects of this test on healthcare outcomes were assessed using a total of one work. It was reported that surgery was performed in five patients with benign tumors due to false positive results in Allele-specific PCR and that specimens from the five patients were analyzed using Direct Sequencing and all the five specimens showed negative results.

**Conclusion:** Based on these study results, the BRAF gene, mutation [Allele-specific PCR] as a test that was safe and effect as a supplementary test to help diagnosing thyroid papillary cancer in cases where the patient was negative in fine needle aspiration cytology but was clinically suspected of malignant cancer and in patients who showed uncertain findings in fine needle aspiration cytology.

#### 477. DIRECT-TO-CONSUMER BREAST CANCER IMAGING DEVICES: A SYSTEMATIC REVIEW OF THEIR DIAGNOSTIC AND SCREENING EFFECTIVENESS

Thomas Vreugdenburg<sup>a</sup>, Janet Hiller<sup>b</sup>, Cameron Willis<sup>a</sup> and Linda Mundy<sup>c</sup>

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**Background:** Internationally, numerous direct-to-consumer (DtC) devices are currently being advertised as safe and effective solutions for breast cancer screening and diagnosis. Promoters of these devices offer questionable evidence to support their use, risking patient safety through unknown false negative and false positive results.

**Objectives:** The aim of this review was to evaluate all available evidence on the effectiveness of three classes of DtC breast cancer imaging devices: thermography (DITI), electrical impedance (EIS), and elasticity imaging.

**Methods:** A systematic search of seven biomedical databases was conducted in March 2011. Data were extracted using a standardized form, and all extracted forms were validated by secondary authors prior to analysis. Meta-analyses were conducted using summary hierarchical receiver operating characteristic (HSROC) curves to estimate pooled values for diagnostic accuracy.

**Results:** From 6808 search results, 267 full text articles were assessed, of which 60 satisfied the inclusion criteria. No screening studies were identified, hence all included studies involved symptomatic populations. Positive and negative likelihood ratios for DITI (1.76, 0.33) and EIS (2.06, 0.33) were poor, while ultrasound elastography (6.86, 0.17) had moderate evidence of diagnostic performance. We found very limited (n = 2), poor quality evidence for electronic palpation imaging—a subclass of elasticity imaging.

**Discussion:** Ultrasound elastography shows promise as a potential diagnostic tool for detecting breast cancer in symptomatic women, whereas DITI and EIS are limited by their ability to correctly identify benign tumors and disease-free women.

**Implications:** The ability of devices to be advertised for screening and diagnosis without a review of their effectiveness highlights a significant deficiency in the level of pre-market scrutiny placed on medical devices deemed to be 'low risk' by regulators, despite their potential for harm through incorrect and misleading results. As this review illustrates, without stringent regulations consumer health is being placed at risk by DtC diagnostic devices with poor accuracy.

#### 84. TOWARDS NATIONAL SURGICAL SURVEILLANCE IN THE UK – A PILOT STUDY

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**Background:** The Bristol heart enquiry highlighted the lack of standards for evaluating surgical performance and quality. In contrast, standardised metrics like maternal and infant mortality have long been used in public health surveillance. In 2009, the WHO proposed six standardised surgical metrics (SSMs) for surgical surveillance.

**Objectives:** This is the first study to collect and analyse WHO SSMs from a cohort of NHS Trusts. This would determine the feasibility of gathering SSMs and their utility in measuring surgical performance and quality.

**Methods:** Freedom of Information Act requests for WHO SSMs were made to 36 NHS Trusts in England during autumn 2010. Additional data was obtained from the NPSA, Dr Foster and the Guardian Newspaper. Analysis was performed using mixed-effect logistic regression.

**Results:** 30/36 trusts responded (83%). Over five years, 5.4 million operations were performed with a 24.2% increase from 2005 to 2009. There was a statistically significant trend of some hospitals increasing in mortality ratios and some decreasing. The rising volume of operations within hospitals over the five year period was associated with lower mortality ratios. Odds ratio for 30-day mortality = 0.94 (95% CI 0.87,1.00). There is no evidence that HSMR is associated with surgical mortality (p = 0.7).

**Conclusions:** SSMs can provide policy makers and commissioners with valuable summary data on surgical performance allowing for statistical process control of a complex intervention. Together with other measures they can help build a picture of surgical surveillance in the UK.

### 438. COMPARISON OF EFFECT SIZES ASSOCIATED WITH SURROGATE AND FINAL PRIMARY OUTCOMES IN CLINICAL TRIALS: A META-EPIDEMIOLOGICAL STUDY

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PCMD. UK.

**Background:** Surrogate outcomes are defined as outcomes that do not directly measure how patients feel, function or survive. Whilst studies have shown the association between treatment effects estimates and trial characteristics, none has compared the effect sizes in trials using surrogate versus final outcomes.

**Objectives:** To compare the effect sizes of randomised controlled trials (RCTs) reporting a surrogate primary outcome ('surrogate trials') with RCTs reporting a final outcome ('final trials').

**Methods:** We searched for all RCTs published in major medical journals in 2005-2006 and categorised them according to type of primary outcome. Surrogate and final trials were matched on clinical area of intervention, patient population, journal and year of publication. Effect sizes (OR) were calculated for binary outcomes and effect sizes were pooled through a stratified random-effects meta-analysis. Meta-regression was used to estimate the ratio of odds ratios (ROR) adjusted for trial information (e.g. follow-up, population, intervention, funding/sponsorship). We compared RCTs' risk of bias (i.e. ITT, randomisation sequence generation/allocation concealment, blinding) in surrogate and final trials ( $\chi^2$ -test).

**Results:** In total, 51 surrogate and 83 final trials allowed calculation of an OR. Study characteristics were well-balanced between the two groups, except for sample size ( $p < 0.001$ ). Surrogate trials reported larger treatment effects than final trials (adjusted ROR: 1.47, 95%CI: 1.05-2.04), without showing evidence of poorer methodological quality.

**Discussion:** The results show that the effect sizes of surrogate trials were on average 47% higher than in final trials. These findings were not explained by differences in the methodological quality or other differences in trials' characteristics, such as disease area. Our findings raise the question of whether reliance on surrogate outcomes may be leading to exaggeration of the true benefits of treatments in licensing decisions and HTA.

### 463. COMPARATIVE EFFECTIVENESS RESEARCH AND EVIDENCE GAP IN JAPAN

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**Background:** Valid comparative effectiveness research (CER) and/or randomized controlled trial (RCT) are one of the key foundations for evidence-based healthcare. However, they have been greatly lacking in Japan. It is important to analyze present situation and identify critical issues for reducing this evidence gap.

**Objectives:** To identify the number of RCTs and CERs in Japan, and evaluate their characteristics and quality, a cross-sectional survey for RCTs and CERs conducted in Japan was carried out.

**Methods:** RCTs was selected as a study design for CERs. RCTs conducted in Japan were identified by using Japanese database (Japan Medical Abstract) and international databases (MEDLINE, EMBASE, CINAHL, and PsycINFO) in 2010. Among 2975 studies located by searching databases, 1570 were excluded as duplication among databases. 1405 abstracts were reviewed and 785 RCTs were identified

by independent reviewers. Characteristics and quality of these RCTs were reviewed and evaluated.

**Results:** Among all RCTs ( $n = 785$ ), the proportion of head-to-head comparison (i.e., CER) was 44.3% and that for placebo control was 40.8%. Main types of interventions were drug (45.1%) and physical therapy (12.1%). Main categories of diseases were circulatory system (18.5%) and digestive system (12.5%). The main study design for RCT was parallel (79.8%). The proportion of sample size less than 50 was 53.1%, followed by 50-100 (20.5%). Among CERs, the proportion of sample size less than 100 was 70.7%. There was no statistical difference in several characteristics between CERs and overall RCTs. The quality of CERs was poor.

**Conclusions:** In Japan, the number of RCTs is recently increasing. However, it is relatively low and not enough to make evidence-based decision making. Characteristics of RCTs (e.g., interventions or target diseases) are not corresponding to healthcare needs. Moreover, CERs are greatly lacking and their quality is poor. Health policy for promoting CER and funding it are urgently needed.

### 555. WHAT IS IMPORTANT FOR PATIENTS, CAREGIVERS AND PROFESSIONALS WHEN RECEIVING AND PROVIDING PALLIATIVE CARE SERVICES? A SYSTEMATIC REVIEW OF QUALITATIVE STUDIES

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**Background:** Palliative care is delivered to vulnerable population and aims to provide comfort in the process of dying. These characteristics makes this care especially sensitive, and for this reason, the common numerical indicators used to evaluate other health care services are not always appropriate.

**Objectives:** To identify the dimensions to be measured when developing and evaluating palliative care services.

**Methods:** Systematic review of qualitative studies using the Ritchie & Spencer framework for synthesis.

**Results:** Sixty-six studies were included out of 1541 abstract reviewed: 29 from the professional perspective, 26 from the patient perspective and 34 from the caregivers or family perspective. The services included were: hospitals, hospice, day care, specialist palliative care, primary and community services, McMillan and specialist nurses, and oncology services. Four dimensions were categorized as a result of the study: physical, psychological-emotional-spiritual, family and social relations, and work. The dimensions are specified in a list of questions which should be taken into consideration when elaborating or evaluating palliative care assistance. The list of questions helps in reflecting on the type of care which is provided and if it is organized to achieve what is important for the patient and family, without forgetting the difficulties of the job of the professionals who manage this type of cases.

**Conclusions:** The use of data from qualitative studies in the design and evaluation of health care services is useful to provide a realistic approach to the values of the users, including the way in which care should be developed and provided, and to give more value to the effort and type of care which is provided by some health care professionals. The list of questions developed can be used to specify

indicators which include the perspective of professionals, patients and caregivers in palliative care.

### 766. A COMPARATIVE ANALYSIS OF HTA OUTCOMES IN FIVE COUNTRIES ACROSS THREE THERAPY AREAS: CANCER, ORPHAN AND CENTRAL NERVOUS SYSTEM DISEASES

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**Objectives:** To identify diverging HTA recommendations in three therapy areas across five countries, understand the rationale for decision-making and suggest ways to minimize these inter-country differences.

**Methods:** A comparative analysis of HTA recommendations in three therapy areas (cancer, orphan and central nervous system (CNS)) issued in Canada, Australia, England, Scotland, and Sweden between 2007-2009 based on secondary sources. Associations between HTA recommendations issued within a therapy area were measured using a two-way correspondence analysis (STATA12).

**Results:** The null hypothesis of independence was rejected ( $\chi^2 = 187$ ;  $p < 0.0001$ ), demonstrating that associations exist. The correspondence analysis biplot illustrates these associations, where differences are seen across countries in the likelihood of positively appraising drugs in different therapy areas. In Scotland, cancer and orphan drugs are more likely to be rejected (48% and 65% respectively), whereas CNS treatments are more likely to be restricted (41%); in England, cancer and orphan drugs are more likely to be restricted (each at 63%), while CNS treatments are more likely to be recommended with or without restrictions (42% and 42% respectively); in Canada, cancer and orphan drugs are mainly restricted (52% and 50%) or rejected (44% and 50% respectively), whereas CNS drugs are mainly rejected (70%). In contrast, all three therapy areas are more likely to be recommended in Sweden (80%, 69% and 72% of cancer, orphan and CNS), and restricted in Australia (63%, 63%, and 42% respectively).

**Conclusions:** This study demonstrates that although agency-specific guidelines are homogeneous for all treatments, expectations from HTA bodies in terms of relative (cost-) effectiveness may differ depending on the drugs' and diseases' characteristics resulting in inter-country differences in HTA recommendations. To minimize these, agency-specific submission guidelines should be differentiated based on the drug's and disease's characteristics, by more explicitly stating which expectations HTA bodies have in terms of relative (cost-) effectiveness depending on these characteristics.

### 356. FROM SUBMISSION TO PUBLICATION: REDUCED TIME LAG BETWEEN FINAL SEARCHES AND PUBLICATION OF HTA REVIEWS

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**Background:** Systematic reviews (SRs) are a gold standard for evidence-based decision making, and are the key building blocks for clinical practice guidelines (CPGs). They help improve quality of care and raise the efficiency of health systems. SRs should be up to date to maintain their importance in informing healthcare policy and practice. However, little guidance is available about when and how to update SRs. Updating policies and practices of some organizations that commission or produce SRs are unclear.

**Objectives:** We investigated the time gap between the final search and publication of NIHR-HTA systematic reviews, between the date of submission of the final report and date of publication. We also compared the publication of the selected NIHR-HTA reports and their related peer reviewed publications.

**Methods:** HTA reports published between 2005 and 2007 were identified. For each NIHR-HTA review date of last search, date of submission of final report and date of publication was extracted by two reviewers. We also identified the date of publication of other peer reviewed publications for each HTA report.

**Results:** Fourteen HTA reports and 30 reviews were included. Each of the 14 NIHR-HTA reports included a median of 1 review and a median of 47 trials. The time lag between the last search and date of publication of the reviews ranged from 9-53 months, between submission of final report and date of publication ranged from 12-39 months; between last search and date of submission of final report of the reviews ranged from 4-26 months. However, the time lag was observed to be narrowing over time and a detailed description of these will be presented.

**Conclusions:** HTA reviews showed a reduced time lag between 2005 and 2007 and an improvement in the process. The study has made recommendations for conduct of systematic reviews by the HTA programme.

### 381. THE USE OF 'COLLOQUIAL EVIDENCE' IN HTA: THE EXPERIENCE OF NICE

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**Background:** Colloquial evidence (CE) is the non-scientific evidence that helps provide context to experimental evidence and is used to inform guidance in areas where there are gaps in the published literature. Despite the inherent biases, the use of CE is becoming increasingly important in HTA where scientific literature is sparse, for example at NICE when valuing the benefits and costs of devices and diagnostics, and for social care.

**Objectives:** To identify best practice in the use of CE and to ascertain how CE is used across the guidance-producing programmes at NICE.

**Methods:** A focused literature review was undertaken. Relevant data was extracted from NICE technical and process manuals by two reviewers, using standardised forms and quality assured and analysed by a third reviewer.

**Results:** The review illustrated that evidence considered in healthcare decision-making is both scientific (that can be context-free such as trial data or context-specific such as epidemiological studies) and colloquial. CE could range from information from experts or users based on their own values and experiences, to published policy documents and reports outside the peer-reviewed literature. CE is utilised across all guidance producing programmes at NICE and at all stages of development. Primarily, as expert/professional and patient/carer/lay views, grey literature (including evidence from internet and policy reports) and testimony from stakeholder consultation. It is considered with scientific evidence during the deliberative process at committee meetings and to inform implementation tools. There is no standardised approach.

**Discussion:** As decisions often need to be made on areas where there is a lack of scientific evidence, using CE appropriately is essential. There is lack of appropriate methods for integrating the different types of evidence and appraisal tools and therefore development is needed. A priority is a validated CE data quality checklist' to assist decision makers.

## 511. IR REFERENCE TOOL - A TOOL TO SUMMARISE AND MAP THE EVIDENCE BASE ON INFORMATION RETRIEVAL FOR HTA

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**Background:** Increasing numbers of research papers about information retrieval (IR) for HTA and other evidence syntheses are being published. Keeping up-to-date on the latest developments in the field is thus time-consuming. All information specialists have to assess the same papers before putting evidence into practice.

**Objectives:** To present the development process of the IR Reference Tool.

**Methods:** A new working group of the HTAi ISG on Information Resources has been created to develop an IR Reference Tool describing and mapping on the state of current research evidence. Meetings occur face to face or through Web/phone conferencing. Domain structure of the HTA Core Model, an on-going project to standardize the structure of HTA developed by EUnetHTA, has been selected to structure the Tool. A specific format has been created for structured summaries of research papers.

**Results:** The prototype of the Tool is available as a section of the new HTAi vortal. All members of the working group can create and edit content on the website. A click on a domain name of this section takes the user to a chapter summarizing the current research evidence within this respective domain. Each chapter contains links to a bibliography providing current research evidence within the field of information retrieval for HTA, and to structured summaries of the relevant selected studies. References in the bibliography module provide links to online research articles when existing. In addition, the Tool provides chapters summarizing research-based information on general methods (e.g. how best to peer-review search strategies, and to document and report search processes).

**Conclusions:** IR Reference Tool will contribute to more evidence-based day-to-day working for HTA information specialists, further standardization of search methods and will serve as a common platform for all HTA information specialists. Content will continue to be added for a final version in 2013.

## 513. UPDATING THE GUIDE TO METHODS OF TECHNOLOGY APPRAISALS AT NICE; STEP CHANGE OR FURTHER CONSOLIDATION?

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**Background:** NICE has a 4 year cycle of review of its Guide to Methods of Technology Appraisals. In 2011 a review was initiated which included late breaking HTA methods research from the UK Medical Research Council (MRC) and a review of methodology needed for development of an HTA informed value based pricing process.

**Objective:** To develop and deliver a systematic and inclusive process for identification and discussion of areas of HTA methodological change or controversy.

**Methods:** A shortlist of topics was developed systematically with support from methodological experts from the NICE Decision Support Unit (DSU), taking into account the MRC work as well as the series of DSU Technical Support Documents. Workshops were held with methodological experts and attended by internal and external stakeholders. A working party with membership drawn from the

stakeholder communities - patient and professional organisations, academia and life sciences industry - reviewed the output of the workshops, as well as a number of other key methodological themes in eight full day meetings.

**Results:** Fifteen areas were identified for exploration. Six were prioritised for discussion at multi-stakeholder workshops: 'perspective', 'measuring and valuing health', 'QALY weighting', 'multi criteria decision analysis', 'patient evidence' and 'equity'. The remaining nine topics were only presented to the working party: 'extrapolation and cross-over', 'evidence synthesis', 'sequences and downstream costs', 'comparators', 'discounting', 'costs', 'only in research', 'surrogate outcomes', and 'companion diagnostics'.

**Discussion:** Publication of the draft of the updated guide for consultation is planned for the beginning of June; just before this HTAi conference. Key points drawn from the discussion at the workshops and the working party meetings will be presented, particularly those that have resulted in a change to the Guide to Methods of Technology Appraisals.

## 569. WHAT IS RELEVANT CLINICAL EVIDENCE IN HTA? A CRITICAL REVIEW OF INTERNATIONAL HTA GUIDELINES IN AUSTRALIA, CANADA, FRANCE, THE NETHERLANDS, SWEDEN, AND THE UNITED KINGDOM

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**Background:** International HTA networks have recently deployed several initiatives aimed to harmonise the relative effectiveness assessment of pharmaceuticals. The extent to which national (and sub-national) HTA requirements differ between jurisdictions, particularly in terms of evidential and methodological requirements, needs to be explored to determine the feasibility of a 'core' set of standards.

**Objective:** Critically compare HTA guidelines published by established HTA agencies—CADTH (Canada), CVZ (Netherlands), HAS (France), NICE (England and Wales), PBAC (Australia) and SBU (Sweden)—to better understand the differences in clinical evidence requirements and evidence synthesis methods used worldwide.

**Methods:** A literature review and country-specific website searches were performed to retrieve guidelines from selected HTA agencies. Information on scoping and comparator(s), evidence identification methods, types and sources of clinical evidence, and quantitative and qualitative evidence synthesis was extracted.

**Results:** All agencies recommend a systematic review of the literature in line with the pre-specified scope of the HTA to identify clinical evidence. Although a similar hierarchy of evidence is used by all, with a strong preference for randomised controlled trials, the prioritisation for 'second-best' data sources differed. There is noticeable variation on the guidance provided by HTA agencies on conducting meta-analyses and especially on the use of indirect/mixed evidence. In addition, the use of unpublished data was not acknowledged by SBU. A possible explanation is that Sweden's HTA process is independent; whether HTA is based on an independent review of the literature or a manufacturer submission also influences the level of prescription witnessed in the guidelines.

**Conclusion:** Our review suggests that key differences in evidence consideration and synthesis in the context of relative effectiveness assessment, even by the most established HTA agencies in the world, remain. Such differences may hamper collaborative efforts to harmonise comparative effectiveness research and should be considered when adapting HTA guidelines to other countries.

Wednesday 27<sup>th</sup> June 2012

### 290. POP-DB, THE EUNETHTA PLANNED AND ONGOING PROJECTS DATABASE: CONTENT AND USE

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**Background:** The EUnetHTA Planned and Ongoing Projects (POP) database was developed to facilitate the exchange of information on (planned and ongoing) HTA projects before publication and the identification of potential collaborations among EUnetHTA partners.

**Objectives:** To present the content of the POP-db and its potential and actual use by contributors.

**Methods:** We are contacting all EUnetHTA partners every three months (POP requests) reminding them to update their projects listed in the POP-db. Access to the db is regulated by the give-and-take principle. The db matches MeSH-terms assigned to each project, resulting in a list of identical or similar projects for each contributing agency.

**Results:** In terms of content, the EUnetHTA POP-db currently stores around 1.000 planned, ongoing and recently published projects of 42 EUnetHTA partners from 24 countries. In our experience, about 10% of these projects are identical (same indication, same technology) and more than one third are similar (e.g. same indication but alternative interventions). Concerning use, first “spin-offs” were both collaborations between agencies at an early stage of an HTA like exchange of search strategies, extraction tables, etc. and actual co-operations like jointly conducting an HTA. Since January 2010, our institute initiated co-operation on 8 rapid assessments regarding pharmaceuticals and medical devices with 9 EUnetHTA JA partner agencies.

**Discussion:** The POP-db is adopted with great interest by EUnetHTA partners. Both the use of the POP-db and the impact on collaboration will need a regular monitoring.

**Implications for health system:** The db potentially reduces the duplication of HTAs and therefore increases efficiency. In the future, this may impact the standardisation of the methodology, increase the output of bi-lingual assessments and eventually increase HTA-productivity.

### 313. EVALUATION OF PSYCHOSOCIAL FACTORS INFLUENCING HEALTHCARE PROFESSIONAL ACCEPTANCE OF TELEMONITORING FOR CHRONIC PATIENTS

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**Background:** The acceptance of telehealth services by nurses and physicians is regarded as an important requirement for successful diffusion of this technology.

**Objectives:** Based on an extended Technology Acceptance Model (TAM) framework, this study examines the psychosocial factors related to telemonitoring acceptance among primary healthcare professionals.

**Methods:** A validated questionnaire, based on an extension of the TAM, was distributed to a total of 605 nurses, general practitioners and paediatricians. Cronbach alpha were calculated to measure the

reliability of the model. Construct validity was evaluated using inter-item correlation analysis. Logistic regression analysis was performed to test the theoretical model. Adjusted odds ratios (OR) and their 95% confidence intervals (CI) were computed.

**Results:** A response-rate of 44.3% was achieved. The original TAM model was good at predicting intention to use the telemonitoring system ( $\chi^2$  was significant, Nagelkerke  $R^2 = 0.63$ ). However, the extended model, which included other theoretical variables, was still significant and more powerful (Nagelkerke  $R^2 = 0.72$ ). Perceived Usefulness, Compatibility and Facilitators were the significant predictors of intention. A detailed analysis showed that intention to use telemonitoring was best predicted by healthcare professionals' beliefs that they would obtain adequate training and technical support and that telemonitoring would require important changes in their practice.

**Discussion:** Our findings show that the extended TAM is a good predictive model of healthcare professionals' intention to use a telemonitoring system for chronic care patients in primary care. The perception of facilitators in the organisational context is the most important variable to consider for increasing healthcare professionals' intention to use the new technology.

**Implications for the health system/professionals/patients/society:** This study confirms the value of this framework for examining telemonitoring acceptance among primary care professionals and provides a validated instrument for the investigation of key factors for successful telemedicine implementation.

### 370. EVALUATION OF TELEPHONE TRIAGE AND ADVICE SERVICES USING A DECISION ANALYTIC MODEL

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**Background:** Telephone triage and advice services (TTAS) have been increasingly used to assess patients' symptoms, provide information and refer patients to appropriate levels of care (attempting to pursue efficiency and quality of care gains while ensuring safety). However, previous studies have pointed out for the need for adequately evaluating TTAS.

**Objectives:** To develop a decision analytic model to evaluate both retrospectively and prospectively the benefits of TTAS in both the viewpoints of patients and of the healthcare system; to apply the model for the evaluation of Portuguese National Healthcare Service TTAS, 'Saúde 24'.

**Methods:** A decision tree model combined with a multicriteria model was developed to structure all possible pathways of service use for unscheduled acute care and to bring together all the evaluation impacts. Data from previous studies and reviews and from 'Saúde 24' was used to calibrate the model.

**Conclusions:** The model was found useful to synthesize, transfer and combine results of previous studies, to identify key determinants of TTAS benefits and to support decisions concerning future contracts. Results point out for the need of further research.

### 442. THE ROLE OF THE ECONOMIC EVALUATION IN THE RENEWING HEALTH PROJECT

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**Background:** The European Project RENEWING HEALTH aims to implement large-scale real-life test beds for the validation and

evaluation of innovative telemedicine services for chronic patients by means of a patient-centred approach and a common rigorous assessment methodology.

**Objectives:** One of the project's key objectives is the multidisciplinary assessment of its telemonitoring services. The methodology adopted (MAST methodology, a spin-off of the METHOTELEMED Project) entails seven domains of evaluation, one of which is dedicated to economic aspects.

**Methods:** The economic analysis that will be conducted is mainly based on Drummond (2005), and consists in cost-utility evaluations (based on patients' SF-36 v2 scores) and cost-effectiveness evaluations, based on clinical outcomes (e. g. readmissions). Furthermore, business case analyses will be carried out for each pilot site, thus showing how the service impacts the Local Health Authorities' budget.

**Results:** Results from the Renewing Health project will allow policy makers to understand the economic and financial viability and sustainability of the services, and to make informed decisions on the further deployment of the telemonitoring applications.

**Discussion:** Even though the advantages resulting from remote monitoring have been already studied, the absence of a cohesive body of rigorous economic evaluation studies is a key obstacle to the widespread adoption, proliferation, and funding of telemedicine programs (Dávalos, 2009). The results of this study will give important insights on how the service generates value and therefore help in structuring effective business models for the large-scale implementation of the Renewing Health services.

**Implications for the health system/professionals/patients/society:** The economic results are expected to shed a light on the services' capability of generating value by: ensuring better quality of life for the patient, organizing health professionals' work more efficiently and lowering the National Health System's costs.

#### 475. IMPROVING DIRECTLY OBSERVED THERAPY FOR TUBERCULOSIS WITH A HOME TELEHEALTH SERVICE

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**Background:** Direct observation of ingestion of medication to treat tuberculosis is recommended by the World Health Organisation, to improve cure rates and prevent multiple drug resistant tuberculosis, but implementation is limited by cost, available healthcare worker time, and practical difficulties of coordinating the observation with patients.

**Objectives:** To compare a home videophone service with a traditional drive-around outreach service for patients receiving tuberculosis treatment, using a mixed methods approach.

**Methods:** The telehealth service was operated by a health call centre in Adelaide, South Australia, and used 3G enabled desktop videophones installed in patients' homes to conduct daily video observation of medication ingestion for the duration of the tuberculosis treatment. Service evaluation was conducted by: 1. A retrospective cohort study of the proportion of missed observation episodes, using data extracted from patient casenotes. 2. An comparative economic analysis and model of the two means of service delivery. 3. A qualitative investigation of patient acceptability and service sustainability.

**Results:** The videophone service was found to: 1. Significantly reduce missed observations. 2. Have an Incremental Cost Effectiveness Ratio of \$AUD1.73 per additional day of successful observation, and under all conditions use less healthcare worker time. 3. Be acceptable to patients because observations could be conducted at mutually convenient times, including evenings and weekends. Increased

communication and integration with referring health services was also noted.

**Discussion:** The videophone service was more patient-centred, allowing patients to fit the direct observation around their work or study schedules, whilst maintaining privacy. It has become part of the routine operations of the health call centre.

**Implications:** This model of direct observation could be replicated in other developed countries, and applied to the treatment of other conditions. A service model using mobile phones has potential for developing countries.

#### 43. EFFECTIVENESS OF VIRTUAL REALITY BASED IMMERSIVE TRAINING FOR EDUCATION OF HEALTH PROFESSIONALS: SYSTEMATIC REVIEW

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**Background:** Virtual Reality (VR) refers to a computer generated artificial environment in which one's actions partially determine what happens in the environment. In medical education and training, VR simulators use computer-generated objects on computer interface and allow the trainee or student to manipulate objects to receive feedback on the performance.

**Objectives:** The research question was: "compared to usual or traditional approaches, for physicians, nurses, and other health professionals directly involved in patient care in a number of care settings, what is the overall effectiveness of virtual reality based training programmes"?

**Methods:** A systematic search of PubMed, CINAHL Eric, CENTRAL, Cochrane Database of Systematic Reviews, Embase, HTA Database and Google Scholar resulted in an initial retrieval of 1379 relevant titles and abstracts of peer reviewed publications. After application of pre-defined inclusion/exclusion criteria, a total of 24 publications were selected for critical appraisal (CA) using methods outlined in the Cochrane Reviewer's Handbook and NHMRC.

**Results:** CA resulted in identification of 12 different types of applications and nine overlapping 'themes' related to Virtual Reality simulations and clinical skill training, such as, assessment of psychomotor performance, improvement of surgical skills, and importance of haptic feedback.

**Discussion:** The review demonstrated that VR simulators can be considered a useful tool for improvement of clinical skills performance especially for novices with limited experience. In combination with existing opportunities to work with real patients, VR based training can increase the range of experience to learn about and deal with medical problems as learners and practitioners. The current evidence on the effectiveness of using VR training applications for improvement of clinical skills of health professionals is limited but sufficiently encouraging to justify additional clinical trials in this area.

#### 216. ASSESSMENT OF THE APPLICABILITY OF THE CERTIFICATION PROCESS OF THE BRAZILIAN SOCIETY FOR HEALTH INFORMATICS TO THE ELECTRONIC HEALTH RECORD SYSTEMS AT A UNIVERSITY HOSPITAL

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**Background:** The Brazilian Society for Health Informatics (SBIS) electronic health record (EHR) certification process follows the ISO TC-215 - Health informatics standardization and has been developed in partnership with the Brazilian Federal Council of Medicine (CFM).

Certification requirements are outlined in the Certification Manual SBIS version 3.3, which contains mandatory, recommended and optional requirements for building and evaluating the architecture of an EHR. A guideline for the implementation of test scripts is provided by the Operational Manual of Tests and Analysis version 1.2 ([www.sbis.org.br](http://www.sbis.org.br)).

**Objectives:** To verify the applicability of the SBIS/CFM EHR certification process for a university hospital with many homemade systems.

**Methods:** SBIS manuals have been used as a guideline for the EHR assessment. The study was conducted over the Electronic Prescription module (medicine and diet) of the EHR system of the Medical Center at School of Medicine of Ribeirão Preto at University of São Paulo. Level 1 security, structure, content and feature requirements were verified. A total of 84 scripts were applied concerning to 106 requirements.

**Results:** It was found that EHR functions were in compliance with 44.04% of SBIS requirements. Partially-compliance was found for 4.77% and non-compliance for 7.15% of SBIS requirements. A total of 44.04% of SBIS requirements were not applicable for Hospital EHR system.

**Discussion:** Results have shown that the application of the SBIS certification process can detect deficiencies in EHR systems. Although the certification process has been developed for general application, its approach appears to be more adequate for commercially available off-the-shelf products, what probably explains the number of not applicable requirements. It would be interesting to have a specific version for university hospitals homemade systems.

**Implications for the health system:** Software certification is a way to guarantee data security and consistency for EHR and must be understood as an important HTA issue.

### 535. NEED FOR HTA TRAINING IN DEVELOPING COUNTRIES IS MORE THAN DEVELOPED COUNTRIES

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**Background:** Although training programme in HTA is gradually initiated in developed western countries, it is virtually non-existent in developing countries, where it is probably needed most because of paucity of resources. This study focuses on training needs assessment of a developing country like South Africa.

**Methods:** A need assessment was done among the senior managers in public institutions in South Africa to identify their training needs in the current setting of impending introduction of comprehensive NHI. A qualitative study design involved interviewing a convenient sample of practitioners and experts (n = 32).

**Results:** The participants believe that decision-making on HT without any formal training seriously affect the efficient and effective use of technology in health-care setting in a developing country like South Africa. They do believe the urgent need of formal training programme in HTA for health managers in developing countries where resource is scarce. Based on a focused group discussion, following areas of competencies were identified which should form the basis of such a training programme: Identification of pertinent outcome measures in a variety of health interventions and technologies, and formulation of plan for data collection; Undertaking systematic reviews and interpretation of results; Identification and application of appropriate appraisal tools; Ability to participate in the elaboration of a protocol of an economic evaluation; Develop an understanding of principles of decision-

modelling and ability to construct simple models in terms of use of technology; Develop an understanding of health policy, health management, ethical and social issues related to H; Implementation of clinical guidelines.

**Conclusions:** The study identified need for urgent training and areas of competencies to be covered by such a training programme. CMERC-HTA-Unit (only recognized HTA-unit in Africa) in close collaboration with its collaborative partners are in the process of developing such a training programme which would not only serve South Africa but also rest of Africa.

### 842. KICK-OFF OF HOSPITAL-BASED HTA IN TURKEY: THE ROLE OF INTERNATIONAL COLLABORATION

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**Background:** Recent changes in hospital budgets control; have increase the already existing interest in evidence based medicine as well as to recognize the need for an evidence based use of resources in hospital settings. A group of experts at the Ankara Numune Training and Research Hospital (ANEAH), a leading teaching hospital in Turkey, decided to set up a HTA unit and started the work. However, no previous experience in the country was available to help. Mixes of activities were foreseen to promote the HTA activity among clinicians.

**Method:** A first HTA analysis was performed to improve the appropriateness of human albumin (HA) use in hospital. After this work, in order to better raise HTA awareness and capacity building, it was decided to look for international collaboration. Two experienced hospital based HTA units (A. Gemelli University Hospital in Rome and Hospital Clinic Barcelona) were contacted. A course was developed fit for purpose. Clinicians and managers of hospitals were invited to attend the course.

**Results:** The first HTA study end up with a guideline resulting in improving the use of HA and savings of 120,000 Euros/year. 48 professionals attended the Hospital Based HTA course. The level of satisfaction was very high, showing that international collaboration is useful when kicking off a HTA program in a hospital.

**Conclusion:** A successful kick-off of a hospital based HTA program requires a mix of activities aimed to solve real problems and improve HTA awareness. The bench with international peers is a key to success.

### 902. FACILITATION OF PATIENT-CENTRED HTA BY AN INDEPENDENT MULTISTAKEHOLDER HTA WORKING GROUP IN AUSTRALIA, A COMMUNITY VIEW PILOT PROJECT

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It is not enough to seek patient engagement in HTA processes by simply providing a templated form on a website. HTA\_Aus is an independent Working Group that has come together to ensure a more equitable, effective and valued process. This is a working group of people involved in HTA in Australia, with experience as patient representatives, in industry, HTA committees and policy making. We are working to facilitate and support the feedback mechanisms so that the feedback provided is timely and can inform the decision-

making processes. An important part of this work is to develop appropriate knowledge and expectations amongst patients and their organisations. An important part of our project is working with patient groups to determine who informs these groups about when submissions can be made and how to approach the submissions; and what the specific background knowledge is of those informants. This presentation will describe the underlying conceptual framework involving education, awareness, and support for patient engagement in HTA and how it is being applied by the Working Group. Consumer representatives on key HTA committees are important members of this Group as they have learned the HTA language and processes and

can effectively open communication channels with patient organisations and groups to set the way for the provision of better informed responses. Meaningful healthcare user input addresses patient needs in relationship to a technology where the four key elements are the technology, the patient, organisation of care and cost effectiveness. The consumer representatives are teamed up with broadly based industry representatives and people with regulatory experience who are able to develop a more complete perspective on the importance of the HTA regulatory and funding processes and allow for discussions on the tensions in meeting regulatory requirements.