6th Health Technology Assessment International Annual Meeting

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N.B. Members of the International Scientific Programme Committee also reviewed the abstracts.

Health Technology Assessment for a Globalised World

HARVEY V FINEBERG | *Institute of Medicine of the National Academies, United States of Amercia*

All societies have universal aspirations for health, face limited health resources, and need to rely on science to make informed decisions about health. Health technology assessment can improve decision-making at five levels: social and population-based health interventions, health programme design and organisation, investments by healthcare institutions, clinical choices and personal health-related behaviours. Many of these decisions are affected by forces of globalisation. This talk will consider six aspects of globalisation that will affect the future course of health technology assessment:

1. Transnational health threats, as exemplified by the recent emergence of H1N1 influenza and other emerging infections
2. Rising burden of chronic diseases in many societies related to demographic and epidemiologic transitions
3. Globalisation of the scientific and clinical research enterprise
4. Widespread marketing and distribution of drugs, devices, equipment, and other health technology
5. Global movement of patients seeking medical care outside their home country
6. Worldwide mobility of health professionals

While country-based systems of technology assessment will remain vital, increasing value will be gained from enhanced cooperation and transnational collaboration on health technology assessment.

PL1

Globalisation and HTA – How Much Impact does Globalisation Have on Healthcare?

This session will address the Conference theme from four perspectives that have an impact on the conditions under which HTA works. Globalisation puts national planning and regulation under pressure, and the industry develops and provides technologies to the market across countries and world regions. Today's consumer has a globalised perspective on healthcare, and globalisation changes the field of health policy dramatically.

National Planning and Regulation under Pressure

AKIKO MAEDA | *The World Bank, United States of America*

Industry Development and Provision of Technologies to a Global Market

CLARE MCGRATH | *Pfizer Inc., United Kingdom*

The Impact of Globalisation on Patients' Expectations

ANGELA COULTER | *United Kingdom*

What Does Globalisation Mean in the Field of Health Policy?

RONALD LABONTE | *University of Ottawa, Canada*

PL 2

Global Variations in the Use and Application of HTA Findings in Decision Making: Science and Policy-Making in Action

This session will outline different models for linking HTA to health policy and examine key success factors, including: Governance relationships between HTA producers and decision makers; intended use and intended users; understanding of the role of HTA in decision making; political willingness and capacity of decision makers to use HTA reports.

HTA Findings as Input to Decision Making: Malaysian Experience

RUGAYAH BAKRI | *Ministry of Health, Malaysia*

The Role of HTA in Comparative Effectiveness Research and How This Influences Health Care Reform in the US

JEAN SLUTSKY | *Agency for Healthcare Research and Quality, United States of America*

HTA in South Korea: Policy & Issues

YANG BONG-MIN | *Seoul National University, South Korea*

Brazilian Experience on HTA Process

FLAVIA TAVARES SILVA ELIAS | *Ministry of Health, Brazil*

PL 3

Globalisation and HTAi – Issues and Needs in Relation to HTA

This session will focus on how HTAi (and other organisations) can be relevant to the regions around the world especially in the Asia Pacific Region. It will attempt to foster an increased awareness of the issues and needs of countries at various stages of development of HTA, and address some of these, in efforts to overcome them.

Development and Challenge to HTA in China

CHEN JIE | Ministry *of Health, China*

Issues and Needs of HTA in Taiwan

TARN YEN-HUEI, TONY | *Centre for Drug Evaluation, Taiwan*

Health-care Decisions in Asian Developing Countries – The People, Practices, Processes and Possibilities

JOSEPH MATHEW | P*ostgraduate Institute of Medical Education and Research, India*

Towards a Global HTA Governance

LAURA SAMPIETRO-COLOM | *Fundacio Clinic for Biomedical Research, Spain*

Co-ordination of HTA Activities among Established HTA Agencies and Programmes

GUY MADDERN | *ASERNIP-S Australian Safety and Efficacy Register of New Interventional Procedures – Surgical, Australia*

Parallel Panel Session A

A1

Conflicts in HTA: Why They Occur, Why They are Important, and What Strategies are Available for Adjudication in Various Global Healthcare Settings

In keeping with the theme "Globalisation and Health Technology Assessment", this session will address an area of technology assessment that is becoming an increasingly important and unresolved issue: conflicts between technology assessments from different stakeholders in the HTA arena.

Several members of the proposed panel began an exploration of this complex problem in a parallel session in Montreal. Discussion from the audience and panel brought forth additional questions to be addressed. These are global concerns. The diverse nature of our membership makes the HTAi annual meeting the most appropriate venue to reason through key issues such as:

- how conflicts occur
- circumstances that make conflicts important (allocating limited resources, coverage/reimbursement decisions etc.)
- Varying value systems inherent in the culture of various

HTA stakeholders (Physicians, Private Entities, Government, Patients)

- the influence of economic status of the country where HTA is performed (highly developed/industrialised vs. underdeveloped)
- the influence of the healthcare delivery system (single payor/government national health vs. hybrid public/private insurance)
- strategies for resolution of conflicts
- identification of barriers to resolution of conflicts

At the completion of this Parallel Panel, participants will be able to:

- identify examples of HTA conflicts already present in our Global Healthcare System
- recognise contributing factors to why conflicts occur
- analyse issues of culture, economic status and healthcare delivery system on the potential for occurrence of HTA conflicts
- apply strategies for resolution of conflicts

It is important that we as HTA advocates understand and address adjudication of conflicts early in the HTA process.

HTA Conflicts: Examples from Asia & Developing Nations

SIVALAL SADASIVAN | *Monash University Malaysia, Malaysia*

HTA Conflicts: Examples from Europe & Government Health Care

ORIOL DE SOLA | *Catlan Agency for HTA, Spain*

HTA Conflicts in the Private Sector

CLIFF GOODMAN | The *Lewin Group, United States of America*

A2

Project SIGNEHT: A Model for Introduction of HTA in Developing Countries

Healthcare decisions in most developing countries are currently not based on HTA or even robust evidence of efficacy. One of the major reasons for this is the lack of knowledge and training in these scientific disciplines within most developing countries. Recognising this need, the HTAi Developing Countries Interest Sub-group (HTAi DC ISG) proposed twinning programmes between developed and developing countries among individuals/institutions/organisations with a common interest to initiate or sustain HTA in developing countries. This is envisaged through sharing of expertise and experience between the twinned partners. The first of these is a joint programme between Singapore and India to train a group of Indian professionals for capacity and capability building to initiate HTA in India. This project is called SIGNEHT, an acronym for Singapore-Indian Group Networking for Evaluation of Health Technologies. This panel session details the background, steps, goals and outputs of this programme, as a model that can be used by other twinned partners.

The objectives of this panel session are to describe:

- The status of healthcare in India and the need for HTA, as an example of the current situation in the developing world
- The expertise available with Singapore partners to share with developing countries and a unique funding source for a training programme
- The components of Project SIGNEHT
- Expected outcomes and outputs

This session will elucidate the steps taken by partners from developed and developing countries to initiate HTA in the latter through a joint twinning programme. This is in keeping with the HTAi vision of developing HTA all over the world, and also with the theme of the 6th HTAi Annual meeting in Singapore, "Globalisation and HTA"

Challenges to Initiate HTA in India

JOSEPH L MATHEW | *Postgraduate Institute of Medical Education and Research, Chandigarh, India*

Developed Countries' Contributions to Promulgating HTA Practices: The Singapore Experience

JEREMY LIM | *Singapore Health Services Pte Ltd, Singapore*

Project SIGNEHT

THALAKKOTUR LAZAR MATHEW | *VIT University, Vellore, India*

Lessons from Project SIGNEHT

ANG SHIN YUH | *Singapore Health Services Pte Ltd, Singapore*

A3

Coverage with Evidence Development: What's Next?

Medical evidence is costly to develop and is rarely sufficient to make confident conclusions about the benefits of new health technologies, many of which have small incremental effects over existing alternatives. This creates strong tensions between manufacturers, physicians and patients on one side and insurers on the other side. This frequently results in an impasse, as insurers have historically made black and white decisions while evidence is largely characterised by various shades of gray.

In 2005 the US Medicare programme developed and implemented a new paradigm, Coverage with Evidence Development (CED) that conditioned coverage on the collection and submission of patient level data. The hope was that those data would be analysed by various investigators and then

published in the peer reviewed medical literature, thus contributing to the body of evidence. CED can be accomplished with a range of study methods from registries to full-fledged randomised clinical trials.

Positron Emission Tomography (PET) for oncologic uses was one of the first Medicare coverage policies to incorporate CED. The National Oncologic PET Registry (NOPR) was implemented through a collaboration with interested specialty societies. In 2008, representatives of these societies submitted a formal request to the Centres of Medicare and Medicaid Services (CMS) to cover PET without the CED requirement. The requestors claim that NOPR data have demonstrated the clinical usefulness of PET in the management of oncologic conditions.

There is considerable public interest in the outcome of this request and its effect on future applications of CED by Medicare and by private insurers, especially since Medicare has proposed to expand PET coverage in light of evidence generated via CED. The speakers will discuss the future directions of CED in light of the outcome of Medicare's final decision.

Coverage with Evidence Development

LOUIS B. JACQUES | *Centers for Medicare & Medicaid Services, United States of America*

Formulating an Appropriate Research Programme under CED: Lessons from PET for Cognitive Impairment

DAVID MATCHAR | *Duke University and Duke-NUS Graduate Medical School, Singapore*

Prospects for Coverage with Evidence Development

SEAN TUNIS | *Center for Medical Technology Policy, United States of America*

A4

What do We Learn from International Experiences with Appraisal Processes in Relation to the Final Reimbursement Advice?

1. An appraisal process in progress, what do we learn from the first experiences?
2. Combining cost-effectiveness and severity of disease data for the appraisal process.
3. Experiences with the NICE technology appraisal process in England and Wales
4. An overview on common and different factors in the appraisal processes in the different countries

An Appraisal Process in Progress, What Do We Learn from the First Experiences?

WIM GOETTSCH | *Health Care Insurance Board (CVZ), The Netherlands*

Combining Cost-effectiveness and Severity of Disease Data for the Decision-making Process

NIKLAS HEDBERG | *Dental and Pharmaceutical Benefits Agency, Sweden*

Experiences with the NICE Technology Appraisal Process in England and Wales

MEINDERT BOYSEN | *National Institute for Clinical Excellence (NICE), United Kingdom*

Referent and Chairman of Discussion Panel

GERRIT-JAN VANDERWILT | *Radboud University Nijmegen Medical Centre, The Netherlands*

A5

The Socio-Economic Value of Medical Devices: Preliminary Evidence and Assessment Challenges

Medical devices have brought significant benefits to healthcare systems and patients, including differences in quality of life, disability levels and mortality rates. The introduction of medical devices has also positively contributed to improvements in the economy and general societal welfare. However, there is limited available evidence substantiating the value of medical devices and how it is or can be measured. Addressing this information gap is becoming more important, as medical devices are increasingly required to undergo evaluation of their safety, efficacy and cost-effectiveness, and countries have finite resources with which to adopt new technology.

This panel will address and discuss the socio-economic value of medical devices based upon recent empirical work focused in the area of cardiology. The presentations will provide a complementary examination of this broader aim. In particular, the panel has several objectives:

- Examine the impact of medical devices used in cardiovascular care (e.g., coronary stents) on health, economic, and broader social outcomes.
- Illuminate the methodological and practical challenges in demonstrating medical device value, and analyse any key differences compared to pharmaceuticals.
- Discuss cross-country similarities and differences in outcomes and in processes to assess value, where applicable.
- Highlight future challenges and opportunities for improving the evaluation of the socio-economic value.
- Identify potential policy options to facilitate the adoption of high-value medical devices and support evidence-based decision-making in this area.

This panel is important to address an important gap in the literature and associated discourse. To date, much of the attention regarding the value of health technologies has focused on pharmaceuticals. Therefore, participants will be exposed to

a relatively unexplored research area and can apply key points of the discussion in their respective functions (e.g., academic, industry leader, health professional, policy-maker). The panel will also serve as a forum to discuss future research and policy developments in this area.

Assessing the Socio-economic Value of Medical Devices: The Case of Cardiac Care

CORINNA SORENSON | *London School of Economics and Political Science, United Kingdom*

The Cost-Effectiveness of Coronary Stents in AMI Patients: Results from Germany

REINHARD BUSSE | *Berlin University of Technology, Germany*

Do Financing Systems Take Account of the Value of Medical Devices? Evidence from the Cardiovascular Setting in Italy

GIULIA CAPPELLARO | *Bocconi University, Italy*

Parallel Panel Session B

B1

HTA for Resource Allocation Decisions: Are Key Principles Relevant Globally?

One recent development in Europe, Canada and Australasia is that HTAs are more often being 'hard wired' into resource allocation decisions, such as those about the reimbursement of drugs and other health technologies. Given this shift in emphasis, a set of key principles has recently been developed to guide decisions about the structure of HTA programmes, the methods of HTA, the processes for conducting HTA and the use of HTA findings in decision-making (Drummond et al IJTAHC 24:3, 2008). The objective of this session is to explore whether these principles are relevant and useful in resource constrained countries, such as those in Asia and Latin America, where HTA is beginning to be used for resource allocation decisions.

Application of the Key Principles to HTA Activities in Latin America

ANDRES PICHON-RIVIERE | *University of Buenos Aires, Argentina*

Application of the Key Principles to HTA Activities in Korea

YANG BONG-MIN | *Seoul National University, Korea*

Application of the Key Principles to HTA Activities in Taiwan

TARN YEN-HUEI, TONY | *Centre for Drug Evaluation, Taiwan*

B2

Building Institutional and Technical Capacity for HTA in Developing Countries and Transitional Economies

Although the importance of HTA as a crucial pathway between scientific evidence and practice is being increasingly recognised, the capacity for undertaking HTA and applying evidence thus generated in decision-making in many developing countries remains generally weak. At the same time, there are a number of successful examples of establishing an effective institutional and human resource HTA capacity that usefully contributes to evidence-based decision-making and practice. The context, specific goals, and outcomes of such experiences may vary, but together they constitute a rich breadth of knowledge, out of which the HTA community should extract useful lessons for concerted efforts. The session aims at reviewing some of these experiences, draw lessons from successes and failures, and discuss respective roles of various stakeholders in translating those lessons into future concerted action.

Institutionalizing HTA – Iran Experience

SIMA MARZBAN | *Iranian Health Technology Assessment Institution, Iran*

Building Structured Foundations for HTA in Eastern Europe

KRZYSZTOF LANDA | *Central and Eastern European Society for Technology Assessment in Healthcare, EU*

Regional HTA Networks – Effective Way for Capacity Strengthening and Knowledge Sharing in Latin America and Caribbean

ANTONIO HERNANDEZ | *WHO Regional Office for the Americas/Pan American Health Organization, Washington D.C, United States of America*

Regional HTA Networks – Effective Way for Capacity Strengthening and Knowledge Sharing in Asia

SIVALAL SADASIVAN | *Monash University, Malaysia*

International Training Opportunities for HTA

KAREN RITCHIE | *INAHTA, United Kingdom*

B3

Comparing Different Approaches to Ethical Inquiry in the Context of HTA: An Empirical Study

The importance of exploring potential ethical implications that are associated with the development and use of healthcare technologies as part of an HTA is widely acknowledged.

However, little has been done in terms of developing and testing methods that would enable us to do this is in a transparent and systematic way, leaving important questions of validity and generalisibility largely unanswered. Recently, inventories have been made of various approaches by research collaborations such as INAHTA and EUNetHTA. The approaches appear to differ in a number of ways, such as whether technologies should be judged by their consequences or by their violation of ethical principles (consequentionalism vs. deontology), whether inductive or deductive approaches are most appropriate, the role of empirical inquiry, descriptive or prescriptive nature, stakeholder involvement, etc. Now is the time to further explore the opportunities and limitations of the various approaches. The faculty of this session will report the results of an inquiry into the ethical implications of specific healthcare technologies, each using a different methodological approach (e.g., principalism, narrative ethics, hermeneutic approach). Results will be compared in terms of process (e.g., stakeholder involvement) and outcome (e.g., nature of the conclusions, justification). Case studies will include topical subjects of substantial public health interest, such as bariatric surgery for obesity. The strengths and weaknesses of the various methodological approaches will be discussed.

Objectives:

To improve our understanding of the strengths and weaknesses of various approaches to ethical inquiry in the context of HTA; to develop guidance for conducting and reporting ethical inquiries.

Relevance to HTAi:

The importance of exploring ethical issues related to the development and use of healthcare technologies as a component of HTA is widely acknowledged; however, little guidance exists as to how such inquiries may best be conducted, and how their results should be reported.

An Empirical Study of Strengths and Weaknesses of Various Approaches to Ethical Inquiry in the Context of HTA

BJÖRN HOFMANN | *University of Oslo, Norway*

Comparing Different Approaches to Ethical Inquiry: The Importance of Context

ANNETTE BRAUNACK-MAYER | *University of Adelaide, Australia*

Towards a More Uniform Approach in Addressing Ethical Issues in the Context of HTA: Is it Feasible? Necessary? Desirable?

SAMULI SAARNI | *National Public Health Institute, Finland*

B4

Working Together – HTA by Different Stakeholders

HTA should adopt a wide perspective, encompassing the impact of new technologies on patients, healthcare providers, and the health service as a system and society as a whole. Although the involvement of relevant stakeholders in the HTA process has been advocated, HTA is still largely conducted in silos, with limited or no collaboration between different stakeholders. Some HTA agencies will incorporate manufacturers' submissions to allow the input of unpublished data while others will not. Still other agencies advocate consumer and public involvement but even this is controversial. Given the different missions and positions undertaken by different stakeholders, it would be useful to evaluate the needs of different stakeholders and the outcomes of the HTA process by industries, healthcare planners and clinicians.

Objectives:

1. To explore the similarities and differences of HTA conducted by and for different stakeholders (pharmaceutical companies, healthcare practitioners, healthcare planners/payers and/or patients).
2. To explore opportunities for further collaboration between industry, consumers and healthcare planners in the HTA process.
3. To discuss use of qualitative and quantitative modelling to promote communication between different stakeholders.
4. To explore opportunities for harmonisation of HTA (including approaches and evidence requirements) across different stakeholders.

Use of Qualitative and Quantitative Modelling to Promote Communication between Different Stakeholders

DAVID MATCHAR | *Duke University and Duke-NUS Graduate Medical School, Singapore*

Interaction between Regulators and Payers

LLOYD SANSOM | *Pharmaceutical Benefits Advisory Committee (PBAC), Australia*

Harmonization of HTA

ANG SHIN YUH | *Singapore Health Services Pte Ltd, Singapore*

B5

Reallocating Resources in Health Care Systems: The Role of HTA Units in Identifying Existing Technologies of Low Added Value

The impact of new health technologies and pharmaceuticals in health systems is always a striking feature when discussing the sustainability of those systems. Frequently new technologies are not substitutive of existing ones; many are alternative, additive or just new for an indication. Notwithstanding this, there have been several studies which have pointed out that there are substitutive health technologies that are in use in health systems but are superseded, outmoded or obsolete technologies causing unnecessary costs and inappropriate care. The establishment of systematic identification and evaluation criteria, and even criteria for disinvestment from potentially obsolete technologies could provide an opportunity to invest in alternative proven and cost effective health interventions, taking always into account the impact that these initiatives could have in a specific social, political and clinical context.

HTA agencies are centrally positioned to be at the forefront of this burgeoning agenda. Despite the oft-perceived potential for controversy in this area, the panel will explore this as a positive process in terms of opportunities to reinvest in more secure, effective, efficient and socially accepted health technologies. This panel will outline several initiatives that are in place around the world to tackle the identification, assessment and policy approaches to address obsolete technologies.

Dr Bae will outline a scheme in Korea known as 'the positive list'. Under the positive list system, only drugs which have established their value in terms of clinical efficacy and cost-effectiveness can be listed. In addition to new drugs, currently listed drugs have also been scheduled to have their value re-evaluated during the period from 2007 to 2012. Based on the evaluation results, existing drugs with low added value will be de-listed. From the UK, Dr Sarah Garner will provide an update on NICE's activities in this area. Sarah will report the findings of a recent pilot project and explore the difficulties with identifying suitable candidates for disinvestment. Dr Iñaki Gutiérrez-Ibarluzea will report on a comprehensive inter-linked initiative – titled the GuNFT guideline – from the Basque Country (Spain). This includes components of broad consultation to support the identification and prioritisation process through to implementation of a scheme at the level of local hospitals. Finally, Dr Elshaug will outline the aims, objectives and research plan of a NHMRC-supported research project that has been awarded to the team from AHTA for a disinvestment programme in Australia.

This panel represents an opportunity to establish alliances and networks between those organisations working in this topic and a challenge to define common criteria and best practices built on the different proposals.

Re-evaluation of Existing Drugs in Korea

EUN YOUNG BAE | *Sangji University, South Korea*

An Update of NICE Activities – Including Outcomes from a Pilot Project

SARAH GARNER | *NICE, United Kingdom*

Criteria for a Rational Disinvestment of Health Technologies in Hospitals

IÑAKI GUTIÉRREZ-IBARLUZEA | *Osteba, Basque Office for HTA, Basque Country, Spain*

Commencement of a NHMRC-funded Disinvestment Project in Australia: Plan, Aims and Objectives

ADAM ELSHAUG | *Adelaide Health Technology Assessment (AHTA), University of Adelaide, and Hanson Institute, IMVS, Australia*

B6

Telehealth Evidence: What is its Impact on Practice and Policy?

This panel session will focus on the practice and policy implications of telehealth. Various perspectives will be presented by panellists from around the world who will discuss the experiences and challenges and uncertainties on evaluating telehealth applications within their respective healthcare systems.

Telehealth in Australia: Renal and Oncology

BRENDON KEARNEY | *Royal Adelaide Hospital, Australia*

Telehealth in the Basque Country and Spain

JOSÉ ASUA | *Health Department, Basque Government, Spain*

Telemental Health: Evidence, Policy and Practice

DAVID HAILEY | *Institute of Health Economics, Canada*

Parallel Panel Session C

C1

HTA and HTA-based Decision-making: Going Global

"…Fostering health policy and systems research and making ethical and effective use of innovations in medical technology and pharmaceuticals are relevant for all countries; health technology assessment should be used to support more informed decision-making." The Tallinn Charter: Health Systems for Health and Wealth; WHO European Region Ministerial Conference, July 2008

Irrespective of levels of national wealth, healthcare systems around the world are increasingly challenged by the diffusion of expensive new technologies, the burden of chronic disease,

inequities in access and health outcomes, unwarranted variation in quality and lack of professional best practice standards. To manage the tension between political commitments to effective care for all and the reality of finite resources, decision makers are increasingly turning to HTA as a means of informing healthcare resource allocation decisions. Models already tested in high-income economies or recently established in middle income ones are diffusing across different countries and being adapted, with different levels of success to individual country settings. However, decision-makers and patients around the world could potentially benefit from closer collaboration between countries, ranging from exchange of experiences to active provision of technical and strategic support to enhance or develop new HTA analytical capacity and, with it, the necessary, transparent and inclusive structures for allowing HTA to inform legitimate real world decisions adapted to local needs.

This session will bring together HTA developers and HTA users from a range of countries, including PBS/PBAC (Australia), NICE (UK), HIRA (South Korea) and HITAP (Thailand).

HIRA has pioneered the use of HTA to inform national listing decisions since the introduction of a positive listing system in 2007. At the same time, the Republic of Korea is in the process of setting up NECA dedicated to the generation of the necessary information to support decisions about coverage of medical technologies.

NICE has been at the forefront of methodological and policy developments in HTA and has, over the years, been involved in bilateral initiatives on developing HTA capacity and strengthening the institutional structures for evidence-informed decision-making, with counterparts in a number of countries, including Turkey, South Africa and Colombia. NICE is working together with HIRA and HITAP to address common challenges and share experiences.

Australia's PBS, the first national programme to adopt HTA in coverage decision making, has served as a point of reference for countries around the world and its leadership in both methods and policy has influenced developments internationally.

HITAP in Thailand is another example of an entity using HTA to inform national policy – at the same time, Thai policy makers are investing in building capacity in HTA and seeking to establish international collaborations in the field.

We will present the challenges and opportunities of international collaborations using our collective experiences using real world case studies and focusing on the methodological, procedural, political and ethical aspects of globalising HTA. In addition to bilateral initiatives, we will discuss recent trends among Asian countries to develop networks to foster collaboration in evidence-based decision-making. The session will conclude with the identification of mechanisms – including through HTAi – for enhancing and broadening such international collaborations into the future.

HTA in Australia: National and International Experiences

LLOYD SANSOM | *Pharmaceutical Benefits Advisory Committee (PBAC), Australia*

HTA in UK: 10 Years of NICE Experience

DAVID BARNETT | *University of Leicester, United Kingdom*

Establishing Evidence Synthesis and Evidence-based Decision Making System in South Korea

LEE SANG MOO | *National Evidence-based Healthcare Collaborating Agency (NECA), South Korea*

Working Together to Build Up HTA Capacity at International Level: the Past Experience and Future Challenges

YOT TEERAWATTANANON | *Ministry of Public Health, Thailand*

C2

Methodological Developments in HTA – Contributions from European Network for Health Technology Assessment (EUnetHTA)

The purpose of this session is to present the results and methodological developments which have been obtained in the EUnetHTA project. Besides the session will focus on how these developments will be carried forward in a continued EUnetHTA Collaboration. The presentations will focus on a broad area of issues including:

- Production of HTA – the HTA core model
- Adaptation of HTA reports from one setting to another
- Improvement of the interface between HTA and policy
- Improvement of international collaboration on evidence development for promising technologies

The panellists will describe how the results of their work can impact future developments within their area.

Objectives:

- To present the results from the European Network for Health Technology Assessment (EUnetHTA)
- To present the methodological development obtained in EUnetHTA
- To discuss the broader implications of the methodological developments

Importance:

Continued methodological developments and information sharing within HTA is necessary to become better at producing HTA and ensuring utilisation of HTA. In the light of the comprehensive work in EUnetHTA it is important to: 1) share the results with HTA producers and users outside of EUnetHTA, and 2) have an opportunity to present the methodological advances to ensure a continued thriving discussion of methods within the HTA community.

The HTA Core Model – A Novel Method to Support International Production and Utilisation of HTAs

MARJUKKA MAKELA | *National Institute for Health and Welfare (THL), Finland*

Methodological Developments in HTA – Contributions from European Network for Health Technology Assessment (EUnetHTA)

ANDREW COOK | *National Institute for Health Research, United Kingdom*

Improvement of the Interface between HTA and policy

CAMILLA PALMHØJ NIELSEN | *National Board of Health, Denmark*

Facilitating Evidence Development for Promising Health Technologies

LEE SUE-HAE, ROBIN | *French National Authority for Health (HAS), France*

C3

Relying on Surrogate Outcomes in HTA: Concepts, Terms and Issues

Surrogate outcomes are commonly relied upon as a critical contribution to health technology assessment. In the 6 months leading up to the HTAi conference in June 2009, it is expected that three reviews of the place of surrogate outcomes in HTA will be promulgated in three different countries (United Kingdom, Germany and Australia). A session to discuss these reports and reflect on recent Canadian experience would assist in setting the directions of the newly formed Surrogate Outcomes Working Group of HTAi's Policy Forum. An early challenge for HTA practitioners is to sift through the widely varying terminology to discern the essential concepts underneath. The Working Group was established by Policy Forum in 2008 as a basis for developing an important HTA technical issue from a policy perspective.

An objective of the panel session therefore is to have comparatively short presentations and comparatively long opportunities for audience participation.

Transforming Surrogate Outcomes: An Australian Review

ANDREW MITCHELL | *Australian Government Department of Health and Ageing, Australia*

The Use of Surrogate Outcomes in Model-based Cost-effectiveness Analyses

ROD TAYLOR | *Peninsula College of Medicine and Dentistry, United Kingdom*

Considering the Cost-effectiveness of Drugs based on Surrogate Outcomes: Recent Canadian Experience

DON HUSEREAU | *Canadian Agency for Drugs and Technologies in Health (CADTH), Canada*

C4

Improving Drug Prescribing and Use: International Models for Evidence Uptake

The session will highlight programmes, products and services to promote evidence-based drug prescribing and describe the collaborative effort required to successfully implement such programmes. Drawing on examples from Canada, Australia and the USA, the session will focus on lessons learned and stimulate discussion on how to apply what has been learned in other settings and jurisdictions.

The session is important because interventions to promote the optimal use of drugs are a natural extension of traditional HTA programmes, providing a direct link between evidence and practice.

Improving Drug Prescribing and Use: The Australian Model

LYNN WEEKES | *National Prescribing Service (NPS), Australia*

Improving Drug Prescribing and Use: The Canadian Model

BARB SHEA | *Canadian Agency for Drugs and Technologies in Health (CADTH), Canada*

Improving Drug Prescribing and Use in the United Kingdom

MIRELLA MARLOW | *National Institute for Health and Clinical Excellence, United Kingdom*

C5

Minimum Requirements for a Documentation Unit in a HTA Agency. Skills, Resources and Communication Plans

Even when the methodological approaches and the workflows of the different HTA agencies are common, there is a high variability in their composition, staff knowledge and skills and structure. There has recently been some researches (EUnetHTA, AUnETS) on the need for documentation or information units and/or resource subscriptions in the HTA agencies and it seems to be that there is a need to determine the minimum requirements of those units in existing and future HTA agencies. Finally the impact of the HTA products is dependent on a good policy of diffusions, and good examples of best practices in this area will be provided.

Knowledge and Skills to be Fulfilled in a Information Unit

MALENE FABRICIUS JENSEN | *DACEHTA, Denmark*

Staff Ratios and Communication Needs: Improving the Diffusion and Impact of HTA Products, Perspective of the HTA Information Units

ORIOL DE SOLÀ-MORALES | *Catalonian Agency for HTA, Catalonia, Spain*

Optimising Resources. Information Resources to be Subscribed in a HTA Agency

IÑAKI GUTIÉRREZ-IBARLUZEA | *Osteba, Basque Office for HTA, Basque Country, Spain*

C6

Electronic Medical Records (EMR) – Worth the Cost or Just Over-Hyped?

The development of Electronic Medical Records (EMR) in the United States of America and Europe has been driven by the need to enhance the quality of healthcare. Decision-support systems, in particular e-prescribing systems, are becoming important tools in efforts to reduce medication errors and enhancing patient safety. Nonetheless, the development of EMR systems is laden with challenges even in resource rich countries.

Given scarce resources, fragmentation of providers and poor IT infrastructure in many health systems, development of EMR systems is commonly perceived to be impractical or at least hugely expensive and not 'cost-effective'. However, with falling IT costs, improving computer literacy and success stories coming out of early pioneering health providers, it is timely to explore further the feasibility of establishing EMR systems in both developed and developing countries.

During this panel session, evidence on the benefits and cost-effectiveness of EMR systems will be discussed. A practical definition for Quality of Care can be expressed as a ratio of the number of times that a medical event occurs over the number of times that it is expected to occur in a defined patient population. The expected number (the denominator) is defined by an index condition without associated disqualifying conditions. The numerator is composed of one of more medical events that satisfy the definition of the medical intervention or adverse event. Certain features of an EMR are related to recognising the denominator condition and the numerator event. Some EMRs are built to discourage adverse events and promote the performance of the desired medical intervention. The hypothesis is that the implementation of an Electronic Medical Record System designed to identify index patients, promote adherence to quality and avoid adverse events is followed by measurable quality enhancement.

Speakers will also share on Singapore's experience in developing a centralised EMR system.

The "One Patient One Record" mission is to build a national Electronic Health Records system for every Singaporean. The main objective is to achieve better quality of care and improve clinical outcomes for patients. Patients who need treatment at any hospitals, specialty centres and polyclinics no longer have to rely on paper folders, containing hardcopy medical data like laboratory test results, hospitalisation summaries and radiology images for review. Instead, doctors are able to readily access and view their record digitally on the EMR system enabling patients to move seamlessly across the care continuum for treatment at any institution. The EMR system in Singapore has overtime proven its worthiness, impacting the patient, the clinicians and the institutions, particularly in the area of Quality, Service and Efficiency.

Key Success Factors in the Development of Electronic Medical Records

OWEN HALEY | *Eclipsys Corporation, Singapore*

Electronic Medical Records and Quality of Care – What does the Evidence Tell Us so Far?

TOBIAS SAMO | *Eclipsys Corporation, Singapore*

One Patient, One Record – Singapore's Experience in Electronic Medical Records

CHONG YOKE SIN | *Singapore Health Services, Singapore*

Parallel Panel Session D

D1

Health Technology Assessment of Influenza Pandemic Control Strategies: The Role of Vaccines and Neuraminidase Inhibitors

There are great uncertainties about the timing, virulence, and general scope of a future human influenza pandemic. WHO experts observe that in the Best case scenarios, modelled on the mild pandemic of 1968, project global excess deaths in the range 2 million to 7.4 million.

The aim of this parallel panel session is to give, from the perspective of the HTA approach, a broader view of the Influenza Pandemic control strategies. The session will cover the following items:

- Epidemiology of Influenza Pandemic;
- Social and economic impact on the societies from the Influenza Pandemic;
- Economic Evaluation of Influenza Pandemic Mitigation Strategies;
- Organisational aspects of Influenza Pandemic.

The session will give an updated view of the Influenza Pandemics control strategies and an overview on how to help policymakers weigh the options for pandemic planning.

Epidemiology of Influenza and Systematic Review of the Efficacy of Influenza Vaccine

LAMBERTO MANZOLI | *University of Chieti, Italy*

Economic Evaluation of Influenza Pandemic Mitigation Strategies in the US using a Stochastic Microsimulation Influenza Model

SANDER BEATE | *University of Toronto, Canada*

Neuraminidase Inhibitor Stockpiling for Pandemic Influenza

VERNON J LEE | *Tan Tock Seng Hospital, Singapore*

D2

Adapting HTA for Use in Other Jurisdictions

The session will explore challenges and successes in transferring or adapting existing Health Technology Assessment evidence developed in one jurisdiction for use in policy making in another jurisdiction. Since HTA can be labour intensive and time-consuming, the ability to transfer and contextualise evidence rather than duplicate all the work could reduce duplication of effort and ease pressure on limited health budgets, particularly in jurisdictions where HTA is just getting established.

Adapting HTA for Use in Taiwan

TARN YEN-HUEI, TONY | *Center for Drug Evaluataion (CDE), Taiwan*

Adapting HTA for Use in Poland

IGA LIPSKA | *Agency for Health Technology Assessment in Poland AHTAPol, Poland*

One Agency, Thirteen Health Systems: Making HTA Relevant in a Decentralised Health System

DON HUSEREAU | *Canadian Agency for Drugs and Technologies in Health (CADTH), Canada*

D3

Should Health Technology Assessments Value Labour Market Participation as a Clinical Outcome? The Case for Early Intervention and Management of Musculoskeletal Disorders (MSDs) in the EU

In this workshop we will examine and discuss the economic, social and clinical consequences of enhancing and prolonging the labour market participation of sufferers of Musculoskeletal Disorders (MSDs) of working age. The session's objectives will be to:

1. Hear evidence from multi-country studies which have examined the benefits of work on the job retention, rehabilitation, physical well-being and psychological well-being of MSD patients in the EU (including those with Chronic Low Back Pain and Rheumatoid Arthritis) through early intervention and management practices.
2. Examine the macro- and micro-economic consequences of early and intermittent withdrawal from the labour market among MSD sufferers.
3. To assess the extent to which Health Technology Assessment (HTA) regimes in EU countries are permitted to take these costs into account when examining the clinical and other benefits of treatments and therapies for MSD sufferers.
4. To discuss the methodological, political and socio-economic consequences of adapting HTA regimes to take account the impact of active early intervention and management of MSDs on labour market outcomes alongside clinical outcomes.

There is a growing body of evidence that work related inactivity among many MSD sufferers of working age has a number of high-impact economic, social and clinical consequences. Most MSD sufferers want to work, but many are denied this opportunity because a large proportion of employers and Primary Care clinicians fail to recognise that being in good quality work can aid condition management, rehabilitation and psychological resilience. It can also reduce the economic burden on the State, on employers and on individuals and their families. Yet, in many countries the Health Technology Assessment regimes do not allow the quantification of labour market outcomes when assessing the costs and benefits of treatments and therapies, which may significantly improve job retention or vocational rehabilitation. While this current approach may reduce healthcare costs in the short-term, it also may increase social insurance costs if, as a consequence, MSD sufferers remain workless for long periods.

Many countries are concerned about minimising unemployment and attendant costs, maximising labour market participation and, ultimately, stimulating economic productivity. This workshop will offer an opportunity to debate the ways that HTA can make a positive contribution to this goal.

Productivity and The Wider Societal Perspective in HTA: Beyond MSDs

LEELA BARHAM | *The Work Foundation*

The Clinical Benefits of Early Return to Work among Patients in the EU with Well-Managed Chronic Back Pain

AMERICO CICCHETTI | *Università Cattolica Sacro Cuore, Italy*

Work Productivity and HTA: Are these Two Concepts Friends or Foes?

THOMAS MITTENDOR | *Gottfried Wilhelm Leibniz Universität Hannover, Germany*

D4

Impact of Including Patient Aspects in HTA

Many in the HTA world are concerned about the practicality of patient involvement in HTA and some are sceptical about its value. This panel session will seek to explicitly demonstrate the value of involving patients in HTA and understanding their needs/preferences in a robust scientific manner.

This panel session will present HTAs that have included patient perspectives. Speakers will give concise presentations to describe how patient perspectives were included in the HTA process and explain the impact that this work had on the final HTA report and its recommendations. Ample time will be left for discussion and interaction among the audience and panel.

An example from Italy will explain how all stakeholders (including patients) are asked to contribute to an HTA report. The presentation will then focus on an HTA of Wireless Capsule for Endoscopy, in which a survey of patients was particularly influential to decision makers.

A systematic review undertaken in the UK on the effects of smoking cessation in pregnancy will be used to illustrate key requirements for meaningful patient and public involvement in assessing health technologies, and the added value this brings.

The final presentation will discuss two HTA reports from Denmark on caesarian section and chronic renal failure. These demonstrate the impact of including assessments of patient related aspects in HTA on both the content and implementation of an HTA report.

The objectives of the session are to:

- show how patient aspects can be included in HTAs, by presentation of real examples
- demonstrate the value of inclusion of patient aspects in HTA
- encourage more people to include patient aspects in HTA.

Patient Views on Wireless Capsule for Endoscopy – Illuminating Safety

MARCO RATTI | *National Agency for Regional Health Services, Italy*

Smoking Cessation Programmes in Pregnancy – What are Women's Concerns?

SANDY OLIVER | *Institute of Education, University of London, United Kingdom*

Patient Aspects in Danish HTAs – from Caesarian Section to Chronic Renal Failure

HELGA SIGMUND | *DACEHTA, National Board of Health, Denmark*

D5

Expanding Economic Evaluation in HTA – Can We Get More for Less?

The core elements of HTA are evidence search and synthesis, and subsequent analyses of ethical, organisational and economic consequences of the technology in question. While knowledge of effectiveness and ethical issues in many cases may be easily translated from one country to another, the organisational and economic issues may not. The cost-effectiveness of a technology will depend on unit prices, utilisations of healthcare, and other aspects, which may vary widely, even in relatively similar countries. Economic evaluations therefore need to be country specific.

Unfortunately, it is usually a more resource intensive task to develop a full economic analysis than a more narrow synthesis of evidence of effectiveness. Consequently, the number of economic studies is much more limited than the number of systematic reviews and meta-analyses even though governments in most countries require economic evaluations.

HTA-centres are often faced simultaneously in different countries with demand for evaluation of a particular technology. While different centres may develop models independently, better collaboration may prevent unnecessary duplication. The aim of this plenary session is to explore practical methods to improve collaboration across HTA units and better utilise economic models in many countries. Various models of collaboration will be considered:

- Publishing the economic models including the data files on the web alongside pdf-files of HTA reports.
- Informal network of researchers with a web-page and mailing-lists. The list could consist of names, expertise and a list of completed and ongoing economic evaluations and publications related to these.
- A secure web-page (model-bank) for the health economists at the HTA-centres. On the web-page, both detailed information about the models, and the models themselves can be available.
- Another option is to take a lesson from the pharmaceutical industry in developing a single "core" model for an area in medicine or for single interventions. In these models, industry changes unit costs and utilisation data while other parameters are kept constant across countries. A similar approach might work also for HTA-centres, for example based on the EUnetHTA project.

The aim of the session is to explore how these ideas for cooperation might be developed further for possible adoption in practice.

Ways to Collaborate within the EUnetHTA

SUVI MÄKLIN | *FINOHTA, Finland*

The Canadian Experience with HTA and the Ministry of Health

MURRAY KRAHN | *University of Toronto and THETA, Canada*

Collaboration between HTA Agencies and Academic Institutions

UWE SIEBERT | *UMIT – University for Health Sciences, Austria*

Cooperation - The Way Forward

TORBJØRN WISLØFF | *Norwegian Knowledge Centre for Health Services, Norway*

D6
Emergency and Unscheduled Care: Coping with Demand, Providing Appropriate Care

Provision of appropriate, clinically and cost effective emergency and unscheduled care is a challenge worldwide. Although there is no evidence that the rate of serious trauma and cardiac arrest (immediately life threatening events) is increasing, systems are under strain as demand grows due to:

- Ageing population
- Increasing burden of chronic disease
- Lack of capacity elsewhere in the healthcare system
- Consumer culture

Emergency and unscheduled healthcare systems may comprise primary and secondary care, pre-hospital emergency ambulance care, telephone advice and information, and helicopter responses. It is increasingly recognised that different elements of the system need to be integrated in order to provide safe and appropriate care to patients who seek immediate care. There are many differences internationally in the systems that have been set up, with variations in: healthcare model, skill mix, response standards expected, options on scene and healthcare funding.

The objectives of this proposed panel session are to:

1. share information across diverse health settings and systems about what works in emergency and unscheduled care provision
2. discuss how clinical performance can be measured in emergency and unscheduled healthcare
3. plan further HTA research related to emergency and unscheduled care

International Cooperation in Provision of Emergency Care: Opportunities and Barriers

MICHEL BAER | *Head of SAMU des Hauts-de-Seine, Garches, France*

Measuring Performance in Emergency Care: Counting Beans?

JON NICHOLL | *Sheffield University, United Kingdom*

Information Systems in Emergency Care - Enabling an Appropriate Response and Performance Management

JERRY OVERTON | *Richmond Ambulance Authority, United States of America*

Parallel Panel Session E

E1

Health Technology Assessment in Middle-Income Countries

Health technology assessment (HTA) plays an important role in healthcare systems by supporting decision making in healthcare policy and practice. Although HTA is most advanced in industrialised countries, there is a vibrant and growing community around the world that is interested in developing and using HTA.

In recent years, the concept of evidence-based medicine (EBM) is gaining popularity in low and middle-income countries as a way to rationalise healthcare interventions. However, other aspects such as feasibility, cost and cost-effectiveness, acceptability among stakeholders, scope of sustained application etc. are critical to rationalise decision making processes in these countries to ensure a more efficient allocation of health care resources. For this purpose, HTA is of utmost importance.

The objective of this panel session is to discuss the HTA needs, challenges and possible solutions for middle-income (and where possible developing) countries.

For this purpose, a study on the situation of HTA in selected middle-income countries (Argentina, Brazil, China, Colombia, Israel, Mexico, Philippines, Korea, Taiwan, Thailand and Turkey) was carried out and the results will be presented by Dr Wija Oortwijn.

We will also present the challenges encountered by those countries where HTA systems are set-up and active and will discuss the founding principles that should underpin the establishment and working of HTA agencies with policy-making responsibility (Dr Rod Taylor).

To (further) stimulate the development and use of HTA in middle-income and developing countries, we will discuss the role of the HTAi Interest Group (ISG) on Developing Countries (Dr Joseph Mathew). This ISG was formally created in 2008 to stimulate discussion of HTA needs, challenges and solutions pertaining to developing and middle-income countries.

Furthermore, we provide practical information on how to establish HTA in countries with limited HTA capacity by outlining practical guidance on capacity building in HTA (based on WP 8 of EUnetHTA, which was supported by a grant from the European Commission (2006-2008)) (Dr Hindrik Vondeling).

The Role of Health Technology Assessment in 10 Middle-Income Countries

WIJA OORTWIJN | *ECORYS NL, The Netherlands*

Principles of Health Technology Assessment Practice

ROD TAYLOR | *Peninsula College of Medicine and Dentistry, United Kingdom*

What Role Can the HTAi Interest Group on Developing Countries Play in (Further) Developing HTA in Middle-Income Countries?

JOSEPH L MATHEW | *Postgraduate Institute of Medical Education and Research, India*

How can new HTA Agencies in middle-income countries organise their working process and develop strategies to disseminate their products?

HINDRIK VONDELING | *University of Southern Denmark, Denmark*

E2

Challenges and Opportunities for Assessment of and Access to Medical Devices and Diagnostics in Asia-Pacific

Patients are increasingly expecting universal access to essential health technologies (drugs, medical devices and diagnostics). However what technology to include as an essential health technology is a major health policy issue. This panel session will focus on the assessment of and access to medical devices and diagnostics in Asia-Pacific. The speed at which medical devices and diagnostics change requires rapid assessment of this technology, including assessment of the financial impact on the healthcare system, to assure integration into the healthcare system without restricting medical choices for individual care. Issues of how to assess medical devices in a timely manner will be discussed. Experiences and lessons learned will be focused from an Asia-Pacific perspective with a special emphasis on methodologies for assessing medical devices.

Challenges and Opportunities of HTA in the Medical Devices in Asia Pacific

ASHOKE BHATTACHARJYA | *ISPOR Asia-Pacific Medical Device & Diagnostics Council, India*

Universal Access to Essential Health Technology and HTA: China Case

CHEN JIE | *ISPOR Asia-Pacific Medical Device & Diagnostics Council, China*

Provider Payment Mechanism for Health Technology: Philippines Case

MADELEINE DE ROSAS-VALERA | *ISPOR Asia-Pacific Medical Device & Diagnostics Council, Philippines*

E3

HTA Methods Guidelines for Analyses to Support Decision Making: What are the Barriers to International Harmonisation?

There has been an international proliferation in HTA methods guidelines for analyses to support decision making regarding the coverage/reimbursement of new medical technologies. A number of reviews of these guidelines have identified fundamental differences in their required methods. Given that different healthcare systems internationally are often deliberating about the value of the same technologies informed by analyses commissioned or undertaken by the same technology manufacturers, there may be gains in efficiency (as well as in the quality of decisions) from greater harmonisation in guidelines. However, an essential precursor to increased harmonisation is to understand why particular methods have been advocated in some guidelines but not in others. Explanations for differences might include differences in the objectives, constraints and responsibilities of the decision maker, variation in the decision making processes and alternative judgments about scientific methods. The aim of this session is to describe differences between international methods guidelines in selected healthcare systems in terms of a series of major methods issues, and to provide an explanation for why particular approaches have been selected. These methods are likely to include selection of comparators, measurement and valuation of health outcome, sub-group analysis and source of clinical evidence. The panel will consider the implications of these comparisons for future harmonisation of methods guidelines. The three countries to be considered in detail are Australia, Canada and the UK where methods guidelines have recently been updated. The panel brings together extensive experience relevant to the topic, and consists of academics and employees of public agencies who have been involved in the development of methods guidelines internationally and in the use of HTA to inform healthcare decisions.

Comparing International Methods Guidelines: NICE's Approach in the UK

MARK SCULPHER | *Centre for Health Economics, University of York, United Kingdom*

Comparing International Methods Guidelines: CADTH's Approach in Canada

DON HUSEREAU | *Canadian Agency for Drugs and Technologies in Health (CADTH), Canada*

Comparing International Methods Guidelines: PBAC's Approach in Australia

ANDREW MITCHELL | *Australian Government Department of Health and Ageing, Australia*

E4

Supporting Healthcare Innovation Management by Comprehensive Early Assessment

Global changes in disease spectra, in available healthcare technologies, and in patients' role and behaviour put healthcare systems in urgent need for innovation on the product, process and structural level. Innovation processes themselves undergo important alterations with stakeholder groups adopting new and powerful roles in initiating, guiding, supporting, or hindering innovation on its way from invention to routine application.

In the early phases of research and development, the stakeholder groups are confronted with decisions about the new technology (e.g. start, sponsor, authorise, or participate in a clinical trial) for which they often lack the suitable evidence base. Information needs vary between stakeholder groups and stages of development of the new technology. Although different instruments exist to identify and support technologies with high potential for improvement (horizon scanning, constructive HTA, innovation hubs etc.), an evidence gap remains for many decision situations.

The EU-funded project Inno-HTA has identified these gaps and makes suggestions which indicators on the emerging technology's characteristics strengthen the evidence-base for decision-making from the various stakeholder groups' perspectives.

The parallel panel session will connect this and other initiatives as a step forward to a comprehensive approach of early HTA and healthcare innovation management which integrates the requirements of the different stakeholder groups.

Requirements for Healthcare Innovations from the Public Health Perspective

FINN BORLUM KRISTENSEN | *National Board of Health, Denmark*

Approaches to Identify, Assess and Manage Healthcare Innovations

INAKI GUTIERREZ IBARLUZEA | *Basque Office for Health Technology Assessment, Spain*

Innovation Management in the Pharmaceutical Sector

CLARE MCGRATH | *Pfizer Inc, United Kingdom*

Early to Late Stage HTA in Cooperation with the Industry in the Medical Device Sector

LOTTE STEUTEN | *Maastricht University Medical Centre and Care Innovations Research and Consultancy, United States of America*

E5

Scaling Up Health Service Delivery - What Resources are Needed: WHO Integrated Healthcare Technology Package (iHTP)

Providing healthcare effectively requires a delicate balance of an extraordinary array of technological resource inputs. Clear policy guidance and effective tools for handling complex technology choices are necessary if efficient healthcare delivery practices are to be adopted in countries. Addressing this urgent global need, WHO has developed a resource planning and costing methodology and set of software tools known as the Integrated Healthcare Technology Package (iHTP) successfully being implemented in a growing number of Member States. iHTP provides guidance on the optimal mix of resource inputs (human resources, medical devices, pharmaceuticals and facilities) required for any particular health intervention or their selected set that is specific to the local needs and conditions. iHTP integrates healthcare needs, disease profiles, patient demographics, clinical practice, human resource and technology requirements, availability and constraints, associated capital and recurrent costs, and links these to a defined set of health services, and via software simulation, computes the resource requirements necessary to provide these services mapping current technology gaps and future resource needs for scaling up healthcare interventions coverage and quality at all levels of the health system.

Participants will be exposed to this innovative HTA methodology and tool, followed by experiences of its country implementation, demonstrating the variety of its practical applications and impact on policy development, stratygic planning, service delivery, and use of technology. The session will be of interest to a broad audience of healthcare professionals including policy and decision makers, planners, managers and administrators, academics and clinicians, technical assistance and donor agencies.

Mapping Resource Requirements for National Health Priority Programmes in Mexico

ROSA CEBALLOS | *National Centre for Health Technology Excellence, Mexico*

Resource Planning and Costing the Health System Strengthening Strategy in the Democratic Republic of Congo

DIEDONNE KWETE | *Ministry of Health, DRC, Republic of Congo*

Resource Needs and Costing of ARV Roll Out in South Africa

YAPONDO MUKENDI | *Department of Health, Limpopo Province, South Africa*

Improving Perinatal Care in Ukraine through Optimized Resource Planning

LUIDMILA ROZHKO | *Health Administration, Volyn Oblast, Ukraine*

E6

HPV Vaccination Policy in Different Settings: Any Role of HTA Evidence?

Cervical cancer is the second most common cancer in women worldwide. In particular, it is a major cause of deaths in low- and middle-income countries. The development of this cancer is associated with the infection of Human Papilloma virus (HPV) of some strains. The disease is preventable by introducing screening tests such as Pap smear and Visual Inspection with Acetic acid (VIA). However, owing to the poor coverage and quality of such interventions, cervical cancer remains an important public health problem in many settings. In 2006, the first vaccine against HPV was approved by the US Food and Drug Administration. Currently two vaccine products are available on the global market at very high prices. Such a prophylactic intervention is claimed as a medical breakthrough to reduce HPV infection and cervical cancer.

One of the key features of globalisation is rapid diffusion of new technologies and related information. Over the past two years, HPV vaccines got approval in developed and developing countries. In less-resource settings, the high cost of these products makes them available and accessible in only the private sector. Meanwhile, governments of many industrialised nations adopt the policy to provide HPV vaccination through their publicly-funded benefit or insurance schemes. The literature suggests that the public provision and subsidisation of the vaccines for schoolgirls and adolescents are contentious. Debates for and against the immunisation programmes involve a wide range of arguments, not only on the health benefits, budget impact and cost-effectiveness, but also on religious and moral concerns including equity, child rights, potential promiscuity and other unsafe sex practices. Given that these assertions and involvement of vaccine advocators and the oppositions are context-specific, the role of health technology assessment (HTA) information in decision making inevitably varies across health systems.

HPV vaccination policies in Denmark, Japan, Taiwan and Thailand are selected as case studies since cervical cancer, the target disease of the vaccines, is a life-threatening illness that afflicts large numbers of the female population. While this intervention has been proved effective and safe in short-time span clinical trials, the high cost, complex management and several psychosocial aspects of the immunisation programmes for young girls make the policy adoption arguable. The controversy is also on limited information on the cost-effectiveness of the vaccination, transferability of such evidence to different settings, and research methodology to assess the costs and outcomes of this newly-launched technology.

The general objectives are to discuss the development of HPV vaccination policy in selected developed and developing countries, with the emphasis on the role of HTA evidence in decision making.

New Technology Assessment in Taiwan – An Example on HPV Vaccination Evaluation

JASMINE PWU | *Center for Drug Evaluation, Taiwan*

The Role of HTA in the Development of HPV Vaccination Policy in Thailand

SRIPEN TANTIVESS | *Health Intervention and Technology Assessment Programme, Ministry of Public Health, Thailand*

Cost-effectiveness of HPV Vaccination in Japan

TAKASHI FUKUDA | *School of Public Health, University of Tokyo, Japan*

The Current and Future of HPV Vaccine in Turkey

RABIA KAHVECI | *Evidence based Medicine Association, Turkey*

O1 – HORIZON SCANNING AND EARLY ASSESSMENT

O1.1

What is Innovation in Public Health?

M FUNG[1], S SIMPSON[1], C PACKER[1]
[1]*University of Birmingham, UK*

Background: The National Horizon Scanning Centre (NHSC) is involved in the early identification of significant emerging health technologies. The NHSC's remit includes the identification of public health interventions (PHIs), but does not actively identify such interventions.

Objectives: We set out to define innovation in public health, investigate current methods of systematically identifying new and innovative PHIs in England and elsewhere, and to evaluate the NHSC's current methods for the identification of health technologies and current filtration and prioritisation criteria to determine relevance to new/innovative PHIs.

Methods: A literature review was conducted which informed the iterative development of a 2-stage quasi Delphi-technique questionnaire. Questionnaires were sent to a panel of 106 public health professionals, and international/early identification experts between May and July 2008.

Results: Response rates were 33% and 24% for the first and second round questionnaires, respectively. A definition of innovation in public health was achieved after the second-round questionnaire:

'Innovative PHIs are generally new and different to established models of intervention. They should be equitable, applicable to all in a population, cost-effective, and may address health determinants in the non-health sector of society. A good evidence base is ideal, but sometimes it may be necessary to implement PHIs with uncertain efficacy'.

Participants suggested various sources for the identification of innovative PHIs, including: peer reviewed journals, public health focused conferences, specialist websites and public health blogs. Current NHSC methods were found to have been developed for the identification of drugs, devices and diagnostics, rather than the identification of innovative PHIs.

Discussion: Although a definition was established, not all participants agreed fully. One reason was hypothesised to be the issue of context. Perhaps an idiosyncratic definition, specific to an organisation, or similar organisations, is the best we can, and indeed should anticipate achieving.

O1.2

A Toolkit for the Identification and Assessment of New and Emerging Health Technologies

I GUTIERRREZ-IBARLUZEA[1], J HILLER[2], S SIMPSON[3], MEMBERS EUROSCAN[4]
[1]*Osteba, Basque Office for HTA, Spain,* [2]*ANZHSN, Australia,* [3]*NHSC, UK,* [4]*EuroScan, International Information Network on New and Emerging Health Technologies, UK*

EuroScan is a collaborative network of member agencies for the exchange of information on important new and emerging health technologies. Each member agency is unique in the way it approaches its work but all have a common goal of informing their customers about new and emerging health technologies that may have a significant impact on their health system.

Aim: To outline, in the form of a toolkit, the various methods that members of EuroScan employ to find, select and evaluate important new and emerging health technologies and to provide valuable information to those interested in establishing, or improving an existing, early awareness and alert system (EAAS).

Material and Methods: All members of EuroScan (19) contributed to the content to ensure different healthcare systems, contexts and methods were represented. A first draft was proposed by one of the members followed by four rounds at which three to four members were given the opportunity to add to or comment on previous versions. The final document was reviewed by all members (even those who were not members when starting the project in 2008).

Results: EAASs are also known as early warning systems or horizon scanning systems. They aim to identify, filter and prioritise new and emerging health technologies, to assess or predict their impact on health, costs, society and the healthcare system, and to inform decision makers. The toolkit resulting from the consultative process incorporated guidance on all or the majority of the following stages: identifying the market, determining the time horizon, identification, filtration, prioritisation and assessment of health technologies, dissemination of the information and updating the information. The collaborative approach resulted in an end product covering all aspects of EASSs processes as well as presenting key questions and offering possible solutions.

Conclusion: The toolkit has been constructed on the basis of one size does not fit all, as it was constructed utilising the heterogeneity of its members, the EuroScan network itself. This approach to producing a toolkit could be valuable for other collaborations. It is proposed that this will be a live tool that can continuously be enriched with new proposals and solutions.

O1.3

Differences in New and Emerging Health Technology Identification Process: Analysis of the EuroScan Database

N IBARGOYEN-ROTETA[1], I GUTIERREZ-IBARLUZEA[1], G BENGURIA-ARRATE[1], L GALNARES-CORDERO[1], J ASUA[1]
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Introduction: There is a growing interest to provide information on new and emerging technologies. The agencies that collaborate in EuroScan (http://www.euroscan.bham.ac.uk/) share the information found about these technologies in a database, in which more than 1,000 registries have already been recorded. The aim of this study was to analyse the EuroScan Database and to describe and compare the characteristics among the included technologies and participating agencies.

Methodology: Data of interest were exported from the EuroScan Database to Excel and to SPSS. A descriptive analysis depending on the agency, type of technology, stage of diffusion and technology purpose was conducted. Frequency distribution analysis of diffusion stage for different types of technologies and assigned purposes was made with EpiCalc 2000 Calculator. A P <0.05 was considered as statistically significant.

Results: Four agencies introduced the great majority of the technologies (81%). Drugs represented the 46, 26% of the total, followed by devices (21, 21%). Thirty-four, 58% of the technologies were identified in investigational or phase III stage, 21, 65% in a nearly established stage and 25, 96% when they were established. The purpose of 24, 5% of total technologies was not specified. Frequency distribution of diffusion stage at identification was similar for devices and diagnostics (P = 0,543), but compared to devices, drugs were identified earlier (P = <0,001). Some agencies focused their work on drugs and others mainly on devices. Differences among agencies were also observed in the stage of diffusion at which technologies were identified.

Conclusion: This is the first analysis of one of the most important databases on new and emerging health technologies. Our study shows that more active strategies should be designed to provide an earlier identification, mainly in the case of devices.

O1.4

Criteria to Evaluate the Value of Horizon Scanning Sources

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Background: The English National Horizon Scanning Centre (NHSC) routinely scans 35 sources including company pipelines, peer reviewed journals and Internet resources to identify emerging technologies. Criteria to evaluate the value of each source scanned could result in a more efficient approach in the selection of sources to scan.

Objective: To develop and apply a set of criteria to evaluate the value of scanning sources for the identification of emerging health technologies.

Methods: Evaluation criteria were developed following a review of the literature and discussions with experienced horizon scanners. Proposed criteria were piloted on a random selection of six sources. Lead horizon analysts applied the final eight criteria to each of the 35 scanning sources. Results were analysed using the Analytic Hierarchy Process (AHP), and a numerical weight (or priority) was derived for each criteria (8 = most important, 1 = least important). The maximum total score possible was 240 and the pre-defined "cut-off" total score was identified as ≤100.

Results: Eight factors were identified as being most relevant for assessing the value of scanning sources (see below),

Coverage i.e. proportion of relevant content: 8*
Quality e.g. accuracy, objectivity, reliability: 7
Efficiency e.g. time required to scan: 6
Accessibility e.g. RSS, daily alert: 5
Frequency e.g. monthly, weekly, daily: 4
Cost e.g. subscription: 3
Memory or archive: 2
Contact point provided: 1
*number denotes AHP Priority.

Application of the criteria to current sources identified 7 sources that fell beneath the pre-defined cut-off and were recommended for removal from routine horizon scanning.

Conclusion: The criteria were considered useful in the assessment of current sources, and have the potential to be used to assess new ones. These criteria may be useful for other horizon scanning centres to pilot and validate.

O1.5

Creating Evidence Pathways for New and Emerging Medical Technology: Cases of When Not to Follow the Pharmaceutical Example

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Introduction: Health Technology Assessment (HTA) for medical technology has, to a large extent, been modelled on HTA for pharmaceuticals. This trend fails to acknowledge the basic differences between medical technology and pharmaceutical products and the significance of these differences to the evidence pathway. A large percent of HTAs conducted by the Medical Services Advisory Committee (MSAC) conclude with a negative recommendation for funding due to "insufficient evidence".

Method: Case studies of a selection of new and emerging medical technology in Australia. These cases were used to examine how unique the evidence pathways have been for recent assessments of medical technologies as well as the significance for future assessments.

Results: Medical technology such as capsule endoscopy, laparoscopic robotic surgery and gastric balloon, evaluated by MSAC in recent years, all had evidence "gaps" and there was a need to develop a unique evidence pathway for each of these medical technologies.

Conclusion: It may be that evidence pathways for medical technologies not only differ from the traditional pharmaceutical pathway of randomised, head-to-head, double-blinded clinical trials but also may need to be uniquely designed for the individual medical technology. The role of horizon scanning could also be expanded to not only identify possibly important medical technology as early as possible but to also identify unique evidence pathways.

O1.6

What Sources Should be Taken into Account for the Identification of New and Emerging Health Technologies?

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Introduction: The large number of sources of information that can be accessed at the time of gathering information on new and emerging health technologies creates differences in the use that HTA agencies make of such information sources.

Objective: To analyse and compare the information sources used by the different HTA agencies for the detection of new and emerging health technologies.

Methodology: An open survey with a list of different information sources and the possibility of inclusion of new ones was sent to HTA agencies. Previously, a draft was sent to the HTAi-IRG members. The information collected from the completed questionnaires, was used to assess and classify the different sources used by the agencies, depending on the kind of information requested (devices, procedures, diagnostics, pharmaceuticals, programmes, settings)

Results: Thirteen HTA agencies responded to the survey. The analysis of responses generated a ranking of various types of information sources divided into six categories based on the type of the target technology. In all cases, a number of primary sources of information was identified (NHS, EuroScan, BMJ, FDA, ECRI, ANZHSN, etc.). Regarding other sources of information a higher variability was observed.

Conclusion: Despite different agencies working under the same search criteria for quality information on new and emerging health technologies, a wide variability has been observed which often could be context dependent. The results suggest the need for a comprehensive analysis of the information sources, especially those with the higher variability, and the establishment of the criteria for using these sources and, if necessary, organising a partnership to access them.

O2 – IMPLEMENTATION AND IMPACT OF HTA

O2.1

The Philippine Health Insurance Corporation's Experience in the Dissemination and Implementation of Clinical Practice Guidelines

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Background: This study was done to determine the level of knowledge, attitudes and practices of Philippine Health Insurance Corporation-accredited physicians on the use of clinical practice guidelines (CPG).

Method: This was a multi-method research composed of surveys, focus group discussion, interactive sessions with case vignette and review of patient records in 14 hospitals in the National Capital Region (NCR) and three hospitals in the provinces (one from Ilocos Norte and two from Oriental Mindoro). The awareness survey and attitude survey was measured using a self-administered questionnaire. Knowledge was measured using case vignette discussion in an interactive session. Clinical records of patients admitted for acute gastroenteritis (AGE) in children, pneumonia in adults and normal deliveries were also reviewed.

Results: A total of 169 physicians participated in the survey, comprising of internists (18.9%), obstetricians/gynaecologists (16.6%), and pediatricians (16.0%). The average awareness score was 89.0%. In terms of overall attitude score, the mean score was 54.2% out of the possible 100%. There is a mild negative correlation between awareness to CPG and overall attitude to CPG (Pearson r = -0.23, *P* value = 0.004). In terms of their knowledge in the management of AGE in children, the score was only 45.5% (SD 33.6) while for maternal care the score was only 62.5% (SD 35.1). The average compliance score by health providers was 33% (SD 11%) for AGE, 37% (SD 9%) for normal deliveries, and 49% (SD 25%) for pneumonia.

Conclusion: The level of awareness to CPG is high, however, their attitude toward CPG implementation is low and showed to be negatively correlated. The physicians' actual practice score is lower than their current knowledge of CPG recommendations.

O2.2

Supporting the Adoption and Implementation of New Technologies into NHS Scotland

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Objective: To make available to managers, appropriate and timely information in the health service in Scotland at the point of decision making on the adoption of new diagnostic and therapeutic non-drug interventions. This will facilitate the provision of clinically and cost effective healthcare for the Scottish population.

Methods: A system has been established to provide information on new and existing healthcare interventions directly to a committee of healthcare decision makers - the Scottish Health Technology Group (SHTG) - and to respond to their needs for further information. This has been achieved by the collaboration between NHS Quality Improvement Scotland and the agency responsible for procurement for the NHS in Scotland. A quarterly report summarising findings from newly published health technology assessments, guidelines, and other evaluations of new interventions published by NICE, SIGN, NHS Quality Improvement Scotland, UK universities and international HTA agencies is produced for SHTG. This report gives details of the clinical and cost effectiveness evidence supplemented with existing information on the current use of these technologies and devices. The report also provides contextual information relating to the clinical service in Scotland and an indication on the likely impact on the organisation of services, costs and resource use where possible.

Results: Since April 2008, SHTG has been presented with regular reports. The committee has subsequently requested a further appraisal of the evidence, a full report of the potential quantifiable resource impact, and the development of tools to assist with implementation on a range of topics. These have included drug-eluting stents, cardiac imaging, bariatric surgery and vacuum assisted wound therapy.

Conclusion: This approach will facilitate improved identification and knowledge of new technologies in the NHS in Scotland allowing better planning of services and resources to support implementation.

O2.3

Funding Medical Innovation – the Health Service Development Programme of the Ministry of Health, Singapore

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Objective: The Singapore Ministry of Health instituted its Health Service Development Programme (HSDP) in 2001 to support the introduction of new medical technologies into the public healthcare system. HSDP provides funding to public healthcare institutions to pilot cutting edge treatments, established but costly technologies and improved models of clinical service delivery. After the 3 to 5 year pilot periods, HSDP projects are evaluated to determine their suitability for absorption into mainstream services, taking into account their cost-effectiveness and national public health value.

Methods: Around August each year, 1-page abstracts are submitted by interested public healthcare institutions (including MOH Departments). After shortlisting by MOH and public healthcare cluster HQs, project directors then submit full HSDP applications, including HTA justifications and budget breakdowns. Second round selection involves external reviews by independent subject matter experts and an MOH ranking panel. The Director of Medical Services gives final approval. Successful projects start in the next Financial Year and outcome indicators are reported to MOH on a 6-monthly basis.

Results: Over 50 projects have been supported since HSDP's inception. Annually, around US$10 million goes into the programme to fund new and existing projects. We track outcome indicators to identify successful projects that can be scaled up to national clinical service programmes after their pilot periods. As of December 2008, around half of the HSDP projects have ended and, of these, nine successful projects have obtained additional Government funding to scale up to national clinical services. These include:

- The National Addictions Management Service
- Integrated Management of Osteoporosis
- Outpatient Prostate Cancer Brachytherapy

Other smaller-scale projects have continued to be provided (self-funded) by their respective healthcare institutions.

Conclusion: MOH's HSDP has proven to be an effective means of introducing new health services into Singapore.

O2.4

The Scope and Influence of Rapid HTAs from Members of INAHTA

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Objective: To obtain information on rapid HTAs prepared by members of the International Network of Agencies for Health Technology Assessment (INAHTA) and their influence on healthcare decision making.

Method: A questionnaire was prepared, drawing on earlier INAHTA documents for recording HTA impact. The questionnaire was posted on the INAHTA website and a request for responses sent to member agencies, seeking information on rapid HTA reports prepared during 2006.

Results: Responses were provided on 15 rapid HTAs, which covered both new and widely distributed technologies, including drugs and other substances, devices and procedures.

Most requests for rapid HTAs came from health ministries or departments. The most common purpose (n = 8) was to inform coverage decisions, but all other categories given in the questionnaire attracted some responses (capital funding, formulary decisions, referral for treatment, programme operation, guideline formulation, influence on routine practice, and indications for further research). All of the rapid HTAs were considered by the agencies to have had some influence. The most common indications of influence were consideration by the decision maker, use of the HTA as reference material (both n = 10), and acceptance of recommendations or conclusions (n = 8). External opinions were available for 9 HTAs and were consistent with the agencies' opinions. Examples of action following the HTAs included developing performance measures for hip replacement, establishing hospital utilisation rules for autologous blood transfusion, and supporting further research on triptans for acute migraine.

Conclusion: Responses to the survey provided useful information on the influence of rapid HTAs and how they are being used. Such HTA reports are used for a broad range of technologies, to inform several types of decision and are effective in informing the decision making process. Supplementation of their findings by further assessments will be appropriate in some cases.

O2.5

Profile of HTA Users and Applicability of HTA Reports to Inform Decisions in Latin America

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Background: The Institute for Clinical Effectiveness and Health Policy (IECS), an INAHTA member since 2005, is a major HTA agency in Latin America (LA) which has published over 300 HTA reports (HTAr). More than 7,200 registered users (RU) in IECS's network (mainly decision-makers from Argentina - 65% and other LA countries -25%) have unrestricted web-based access to abstracts. One way to assess the impact of our HTA activities is to analyse their website use.

Objective: To evaluate RU profiles, HTAr consulted and perceived impact on policy decisions.

Methods: Between July and November 2008, a confidential self-administered survey was implemented to RU accessing HTAr. Data retrieved included subject characteristics, type of HTAr consulted and its perceived impact.

Results: A total of 1,575 surveys were completed by 677 RU. While 179 HTAr were accessed, 10 were responsible for nearly a quarter of consultations (e.g., Bevacizumab for colorectal cancer, HPV vaccines and rheumatoid arthritis treatments). Cancer-related HTAr were the most consulted (23%) followed by osteomuscular (15%) and cardiovascular (9%) topics. HTAr on drugs (48%) accounted for nearly half of the searches, followed by procedures (38%) and diagnostic tests (18%). Consultation reasons were institutional in 58%, professional (patient-oriented) in 27% and personal (patients and relatives) in 15%. Regarding applicability, 70% considered reports useful or very useful for decision-making. Purposes of HTAr consultations included informing coverage policy decisions (46%), elaborating practice guidelines (20%), arranging referrals (19%), framing indications for a technology (19%), reshaping health services (12%) or defining research priorities (8%) and capital investments (8%).

Conclusion: IECS HTAr are increasingly applied in Argentina and LA and are perceived as highly influential in defining coverage policies and responding to individual requests. This research contributes to the knowledge of the growing usefulness of HTA services to inform decisions in developing countries.

O2.6

Triangulation of Methods to Assess the Impact of Evidence Reports

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Introduction: Instruments of evidence based medicine are increasingly used to guide healthcare for people with chronic diseases in Germany. In 2006, the Institute for Quality and Efficiency in Healthcare prepared an Evidence Report on short-acting insulin analogues for patients with diabetes Type 2. The report's impact on healthcare was assessed.

Methods: Quantitative and qualitative methods were triangulated: analysis of outpatient prescription data (source: AOK Research Institute (WIdO)), from 1996 to 2007, semi-structured interviews with diabetes specialists, document analysis.

Results: Compared to all insulins, prescriptions of short-acting insulin analogues increased steadily from 1996 to 2005 (0.57% to 19.31%) and decreased in 2006 (18.89%). Analysis of quarterly figures showed a slight reduction of prescriptions following the publication of the report. The policy decision, to cover short-acting insulin analogues by statutory health insurance only in the case of it being cheaper than regular human insulin, was informed by the report. This was followed by a decrease of prescriptions to 15.58% during the last quarter of 2006. In 2007 there was a continuing overall decrease (18.32%), however, the number increased over the quarters of the year. In interviews, physicians disagreed with the recommendations of the report, but fears of exceeding their budgets resulted in reconsidering the prescription.

Conclusion: The decrease of prescriptions ensuing the report and the report-based decision, indicate an influence. The results of the interviews suggest that not the report itself, but the resulting policy decision was the determining factor of the

development. To demonstrate this, triangulation was necessary (Gerhardus et al. 2008).

O3 – PRIMARY CARE

O3.1

The Effectiveness of Citronella Products Against Mosquito Bites: A Systematic Review

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Background: Citronella products have been claimed to have mosquito repelling property, but supporting evidence is lacking. This study aims to determine the effectiveness of citronella products as mosquito repellent.

Methods: Multiple computerised databases such as PUBMED, EMBASE, Cochrane CENTRAL, CINAHL and AMED were searched. To be included in this systematic review, studies needed to compare the effectiveness of citronella products and control in repelling mosquito. All articles were reviewed independently by two investigators. Outcomes measures were protection time and percent repellency. When sufficient data were available, the weighted mean difference and 95% confidence interval were calculated comparing the outcomes in the citronella and control groups. The meta-analysis was performed using the DerSimonian and Laird method under a random-effects model.

Results: Eight studies met inclusion criteria. Citronella products were different in several aspects including dosage form, concentration of citronella oil, and specification of preparation methods. In six studies using cage method, the protection time in the citronella group for Aedes spp was consistently shorter than that in the DEET (N,N-diethyl-m-toluamide) group. Based on a meta-analysis, the protection time in the citronella group was less than those in the DEET group [253 minutes (95% confidence interval: 336 to 169)]. For Anopheles spp and Culex spp, the protection time in the citronella and control groups was not different in the studies using citronella products prepared by extraction method. In 2 studies employing room method, both citronella 25% to 40% and DEET 50% had complete repellency for 6 hours for Aedes spp and Culex spp, while complete repellency was reported only for 9 hours in the citronella group and 12 hours in the DEET group for Anopheles spp.

Conclusion: These results demonstrate that citronella products are less effective than DEET products. However, the repellent efficacy and duration of protection vary considerably among products and mosquito species.

O3.2

Primary Care Professional's Perceptions on Frequent Attendance: Definitions, Motives, Profiles and Relationships with Frequent Attendee Patients.

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Objective: To know the primary care (PC) professional's perceptions of the criteria for defining the frequent attendance, as well as to know their perceptions about the reasons for the visits, the patient profiles and their relationship with frequent attendees.

Design: Qualitative study using semi-structured interviews during the period from December 2007 to April 2008.

Setting: Primary Care Centres of six health areas of the Community of Madrid.

Participants and/or contexts: The inclusion criteria were: to have cared for the same patients for at least 1 year and show interest in the subject of frequent attendance. Recruitment was carried out through the Technical Professionals of the six areas that participated in the study design.

Methods: Eighteen interviews were conducted, three per area (two physicians and one nurse). Structural sampling was carried out with regards to the variables that could influence the discourse: health area, occupation, sex and number of years worked. The conversations were tape-recorded and transcribed. The transcriptions were analysed by two investigators and reached an agreement of interpretation.

Results: The proportion of frequent attendees cared for by each professional is variable and defined more by quality than by the number of visits. They make appointments associated with chronic diseases but also for psychosocial or labour problems. There are profiles of over-users of all ages and both sexes and the doctor-patient relationship depends on each individual case.

Conclusion: According to PC professionals, many of the frequent-attendee patients seek consultations for psychosocial problems, and it would be a great help to streamline coordination with psychosocial resources to achieve more efficient and effective PC consultations.

O3.3

Identifying Potentially Cost Effective Chronic Care Programmes for People with Heart Failure, Diabetes or COPD

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Objective: To review published evidence regarding the cost effectiveness of multi-component chronic care programmes and to illustrate how potentially cost effective programmes can be identified.

Methods: Systematic search of Medline and Cochrane databases for evaluations of multi-component disease management or chronic care programmes for adults with heart failure, diabetes or COPD, describing process, intermediate and end results of care. Data were independently extracted by two reviewers and descriptively summarised.

Results: One hundred and thirty-two original articles and 35 reviews were included. There is evidence for significant improvements in process and intermediate outcomes for heart failure and diabetes, but less so for COPD. Overall, programmes generate end results equivalent to usual care, but programmes containing >3 components show significantly lower relative risks for hospitalisation than less comprehensive programmes and usual care. There is limited scope for programmes to break-even or save money.

Conclusion: Identifying cost effective multi-component chronic care programmes remains a challenge due to scarce methodologically sound studies that demonstrate significant improvements on process, intermediate and end results of care. Estimations of potential cost effectiveness of specific programmes, illustrated in this presentation, may in the absence of 'perfect data' support timely decision-making regarding these programmes. Nevertheless, well-designed health economic studies are needed to decrease the current decision uncertainty.

O3.4

Cost Impact of Self-Measurement of Blood Glucose (SMBG) on Complications of Type 2 Diabetes in Spain

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Background: Despite the increasing prevalence of Type 2 diabetes, its financial burden on the Spanish healthcare system remains unclear. This study was conducted to determine the cost share of self-measurement of blood glucose (SMBG) by comparing the direct costs of reduced diabetic complications in SMBG users vs. non-users in the Spanish statutory health insurance system.

Method: Matched-pair analysis of the average annual total direct cost of diabetes monitoring, treatment-related services, complications and follow-up in the RetrOlective Study Self-Monitoring of Blood Glucose and Outcome in Patients with Type 2 Diabetes (ROSSO) study cohort, updated to 2008 from the year of occurrence or diagnosis of diabetes.

Results: In patients treated with oral anti-diabetic drugs only, total annual costs were €1,934 in SMBG users and €1,982 in nonusers. In those treated with oral antidiabetic drugs plus insulin, total annual costs were €3,451 and €4,167, respectively. By increasing the number of patients using SMBG, the Spanish statutory health insurance system might save several million Euros annually.

Conclusion: The analysis showed that the promotion of self-measurement of blood glucose in patients with Type 2 diabetes is associated with considerable cost savings for the Spanish healthcare system.

O3.5

Cost-Effectiveness of Interventions Based on Physical Exercise in the Treatment of Various Diseases: A Systematic Literature Review

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Background: Interventions based on physical exercise have been shown to be beneficial in the treatment of a number of diseases. Their cost-effectiveness, however, remains poorly documented.

Objective: To review, based on a systematic approach, studies reporting the cost-effectiveness of exercise-based interventions in the treatment of various diseases.

Methods: Systematic search of the literature using the Medline, CRD and Cochrane Library electronic databases. Initial screening using identified articles based on abstracts were read independently by two of the authors, full-text articles again evaluated by two authors, who made the final decision on whether an article should be included.

Results: The search identified 934 articles of which 95 were obtained for closer review. Of the reviewed full-text articles, 59 reported on cost-effectiveness or use of healthcare services, and were included in the review. Most of the studies were randomised controlled trials. Of the included studies, 26 dealt with musculoskeletal disorders, 16 with cardiology, 4 with rheumatic diseases, 4 with pulmonary diseases, 2 with urinary incontinence and 2 with vascular disorders. In addition, there was 1 study each in the fields of oncology, chronic fatigue, endocrinology, psychiatry, and neurology. The studied exercise interventions in musculoskeletal disorders were deemed to be cost-effective in 50% of the cases, in cardiology in 56% of the cases, and in rheumatic diseases in 75% of the cases. Furthermore, there was some evidence that exercise interventions might be cost-effective in the treatment of intermittent claudication, breast cancer patients, diabetes and schizophrenia.

Discussion: The number of studies assessing cost-effectiveness of exercise interventions in various diseases is still rather limited, and the results show large variation. The results suggest that some exercise interventions, however, can be

cost-effective. Most convincing support was found for rehabilitation of cardiac patients and back-pain patients, however, even in these cases, the evidence was partly contradictory.

O3.6

Folic Acid with and without Aspirin in the Chemoprevention of Colorectal Cancer: A Systematic Review

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Objective: Folic acid has been proposed as a possible agent in the chemoprevention of colorectal cancer, and has been the subject of a number of recent trials. The aim of this review therefore was to assess the effectiveness of this agent in reducing the recurrence of adenomatous polyps (precursors of colorectal cancer) and colorectal cancer among populations with a history of adenomas.

Method: A systematic review of randomised controlled trials comparing folic acid alone, and with other agents, with placebo. The following databases were searched for published and unpublished literature: Cochrane Library, MEDLINE, PreMEDLINE, CINAHL, EMBASE, Web of Science, Biological Abstracts and Research Registers. Studies were appraised and extracted. Meta-analysis was performed.

Results: The search retrieved 3,791 unique citations, of which 3 studies (6 papers) were relevant. Two good quality trials found that, compared with placebo, folic acid had no effect either on recurrence of any adenomas (RR 1.14, 95% CI: 0.96 to 1.34, $P = 0.13$) or on advanced adenomas (RR 1.33, 0.95 to 1.88, $P = 0.10$). A third, smaller trial of lower quality found apparently significant higher rates of adenoma recurrence in the placebo group, but event data were not reported, preventing meta-analysis. The two good quality trials also found that folic acid plus aspirin had no significant effect on recurrence of adenomas (RR 1.01, 95% CI: 0.88 to 1.15, $P = 0.92$) or advanced adenomas (RR 1.03, 95% CI: 0.76 to 1.40, $p = 0.85$). Only one trial assessed colorectal cancer as an outcome, and found no effect (RR 1.28, 95% CI: 0.86 to 1.90, $P = 0.22$).

Conclusion: Folic acid either as a single agent, or in conjunction with aspirin, an agent of apparent effectiveness in the chemoprevention of colorectal cancer, is not effective in the chemoprevention of colorectal cancer in populations with a history of adenomas.

O4 – HTA IN IMAGING AND SCREENING

O4.1

Beyond Test Accuracy: Data Collection Helps Address Some Uncertainties in Positron Emission Tomography (PET)

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Australia

Background: PET has been subject of many health technology assessments (HTAs) since its introduction. Early assessments focused on test accuracy, noting uncertainties around the impact of PET on health outcomes (Medical Services Advisory Committee [MSAC], 2001). In recent years there has been a second wave of activity regarding PET, including the publication of patient management data (Scott et al, 2008; Hillner et al, 2008). It would be hoped that in re-reviewing PET, some of the earlier uncertainties noted by the HTA community can be addressed.

Methods: Systematic review of PET head and neck literature from 2001 to August 2008. The review updates a previous MSAC review (2001) and a recent HTA from the UK (Facey et al, 2007). The review also incorporates Australian primary data purposely collected during an interim funding period to capture the impact of PET on patient management.

Results: In addition to conventional staging, PET/CT improves the accuracy of staging of newly diagnosed or recurrent cancer, and leads to a change in management in the majority of patients in whom additional disease is detected. PET changed management in 32% of all patients (70% when additional lesions were detected, 11% when there were no additional lesions) (Scott et al, 2008).

Conclusion: A lack of evidence presents challenges to decision makers about whether to introduce a new technology. PET is an example of where the review of published literature alone has been unable to answer uncertainties around patient benefits (Adams et al, 2006). HTA agencies are increasingly engaged in initiatives to address these limitations (Lyratzopoulos et al, 2008). In Australia, the collection of primary data has enabled conclusions to be made regarding the therapeutic impact of PET. However, it still remains uncertain to what extent patients benefit from management changes. Further initiatives, again beyond accuracy, are needed to assist decision makers introducing new technologies.

O4.2

Mini-HTA: Focused Assessment with Sonography for Trauma (FAST)

SC TONG

Introduction: Focused Assessment with Sonography in Trauma (FAST) is a point-of-care ultrasound examination performed in the emergency setting to determine the absence or presence of free intraperitoneal or pericardial fluid in

patients with a history of significant trauma. We reviewed existing literature that compares the safety, efficacy and cost-effectiveness of FAST with conventional Computed Tomography (CT).

Methodology:

Population – Patients presenting to the Emergency Department with a history of thoracic and/ or abdominal trauma

Intervention – FAST
Comparison – CT scanning
Outcomes – Specificity, sensitivity, speed and accuracy
Databases: PubMed (from 2003 to 2008), Cochrane, NHS Centre for Reviews and Dissemination Database (CRD) and the National Guidelines Clearinghouse
Search terms: 'Emergency' 'Ultrasound' 'Trauma' "CT" and 'FAST' were used.
Non-English papers and those without abstracts were excluded. Search results were also checked for relevance to the above PICO.

Results: Sixteen publications (1 HTA, 12 Primary Studies, 1 economic evaluation and 1 clinical guideline) were reviewed. Most studies use CT as the reference. Studies report that ultrasound sensitivity ranges from 26% to 100%, specificity from 71% to 97%, and accuracy from 93.1% to 97%. These disparities can be accounted for by operator experience as well as the type of injury screened. The economic evaluation compared the use of ultrasound between surgical residents and technicians as well as the use of CT scans against the use of ultrasound, concluding that the use of FAST to screen before CT would have significant cost savings. The guidelines recommend FAST as an initial screening examination to detect hemoperitoneum in blunt abdominal trauma (BAT).

Conclusion: While CT remains the gold standard for the evaluation of patients with suspected intra-abdominal injuries, ultrasound's bedside application, lack of radiation, speed and accuracy of assessment and lower costs confer significant advantages upon it as an initial screening tool, especially in patients who are clinically unstable to undergo CT scanning.

O4.3

Appropriateness of Diagnostic Imaging Technologies for Acute Abdominal Pain

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Objectives: Diagnostic imaging is an essential technology in clinical practice often inappropriately used. Variation in diagnosis imaging use, greater availability of imaging procedures and increase of healthcare costs led to the development and implementation of appropriateness criteria or guidelines. The objective of our study is to define appropriate criteria for frequently used diagnostic imaging procedures in abdominal pathologies in Primary and Secondary Care.

Methodology: We performed a comprehensive review to assess the appropriate use of abdominal diagnostic imaging: radiography (X-ray), computed tomography (CT), ultrasound (US) and magnetic resonance imaging (MRI). Literature search strategy was developed in order to find guidelines, systematic reviews, HTA reports and primary information studies in electronic databases (Medline, Cochrane Database, HTA database). Websites of international technology assessment agencies and international radiology organisations were explored. Critical appraisal of selected articles was done and relevant data were presented in evidence tables. A Delphi process has been conducted to evaluate the appropriate criteria for abdominal imaging procedures. Expert panel included professionals from different clinical specialties involved: radiology, general surgery, emergency and primary care.

Results: Retrieved articles were mainly guidelines and documents of prestigious radiologist organisations including Referral Guidelines (6th edition) from The Royal College of Radiologists (RCR) and American College of Radiology (ACR). An appropriateness use protocol draft of abdominal imaging studies was developed. The expert panel determined whether the imaging examination was appropriate for the diagnosis of different abdominal pathologies. For each imaging study there is a recommendation based on supporting evidence and availability of imaging procedures in different healthcare settings.

Conclusion: Appropriateness protocol with criteria based on scientific evidence and clinical expertise provides an effective strategy to optimise the use of imaging services, to decrease the clinical practice variability and it provides the best diagnostic option for a specific abdominal patient's condition.

O4.4

Is MRI Effective for Staging Newly Diagnosed Rectal Carcinoma? That depends on whether it changes management.

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Aim: To determine the safety and effectiveness of using MRI to stage newly diagnosed rectal carcinoma.

Methods: A health technology assessment was performed which included a separate non-systematic literature search on patient preferences surrounding the staging and treatment of rectal carcinoma. No direct evidence was available on the health benefits resulting from adding MRI to CT for staging rectal carcinoma, therefore, a linked evidence approach was used for the systematic review.

Results: MRI was highly accurate at predicting the circumferential resection margin (CRM), which is of high prognostic importance in rectal carcinoma. This information is

useful for determining the risk of local recurrence and therefore, whether neoadjuvant therapy is recommended. However, the side-effects of neoadjuvant therapy frequently lower quality of life, and the literature was inconsistent regarding whether neoadjuvant therapy extends survival. There were no studies on how using MRI would change patient management. Patient preferences varied on how much quality of life they would be willing to trade to lower their potential risk of local recurrence.

Discussion: If patients would be unwilling to risk a lower quality of life in order to have a small absolute risk reduction of local carcinoma recurrence, then further staging with MRI will not impact patient management, as these patients would refuse neoadjuvant therapy. Conversely, if patients are risk averse, and are willing to trade a large amount of quality of life for less chance of local recurrence, then they may receive neoadjuvant therapy regardless of CRM status. In these cases staging with MRI will not influence the management of patients.

Conclusion: The results of this HTA provided a reminder that knowing the accuracy of a test and the treatment benefit is not enough to establish effectiveness. Assessing patient preference and management implications are also vital to understanding a test's impact.

O4.5

Systematic Review of the Effectiveness of the Single, Two and Three Field Retinal Photography for Screening Diabetic Retinopathy

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Objective: The gold standard for screening diabetic retinopathy (DR) is the seven-field stereoscopic fundus photography, however, owing to resource constraints, fewer fields such as single, two or three fields are used for screening DR. A systematic review was performed to investigate the effectiveness of the single, two and three field retinal photography for screening DR.

Methods: Medline, Embase and CINAHL databases were searched from 1985 to November 2008. Searches were restricted to the English language. To be included, studies had to use the seven-field stereoscopic fundus photography as the reference standard. Studies were reviewed independently by two reviewers. Methodological quality of included studies was assessed using an adapted version of the critical appraisal tool for diagnostic studies developed by the Public Health Resource Unit. Data were extracted for all studies that met the inclusion criteria.

Results: The search yielded 410 publications. Of these, 12 met the inclusion criteria. However, on appraisal, three studies were excluded as sensitivity and specificity data were not provided or could not be calculated. The final nine articles included eight primary (prospective cross-sectional) studies and one review. Among the eight primary studies, only three studies compared more than one field type to the reference standard, two studies compared the single and three fields and one compared two and three fields. The sensitivity (for detecting any retinopathy) of the single, two and three fields ranged as follows: 66% to 78%, 86% to 100%, and 66% to 98%, respectively. Specificity ranged from 45% to 96%, 78% to 100% and 72% to 93%.

Conclusion: Both two and three field retinal photography were able to achieve the minimum sensitivity level of 80% recommended by the British Diabetic Association Working Group. The review findings are limited by the number of relevant studies, especially those comparing more than one screening type.

O5 – HTA AND POLICY DEVELOPMENT

O5.1

Strengthening Country Capacity to do Resource Planning and Costing Using Localised Global HTA Frameworks: Results and Lessons Learned in the Democratic Republic of Congo

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Resource planning is a major challenge in every health system, and especially so in low-, and middle-income countries. When interventions are assembled to constitute a healthcare package, the resource computations are not simply a linear combination of the results for individual interventions. Resource sharing and non-linearity in scale up require a reworking of the calculus for each specific combination of interventions. Furthermore, resource calculations must take into account local health priorities and conditions.

The Integrated Healthcare Technology Package (iHTP) is an HTA methodology which quantifies, qualifies, and costs the optimal mix of resource inputs (human resources, drugs, equipment and infrastructure) required for a set of health interventions. It was developed for use in different types of settings, including resource-poor ones. Calculations are based on data fed into graphical representations of clinical pathways, much like the Map of Medicine used in the NHS, UK.

The iHTP was used for planning and costing the package of services defined in DR Congo's national health strategy. Using normative values for key variables, the exercise resulted in a 'bare bones minimum' cost (it cannot be cheaper than this) necessary to revitalize a model Congolese health district as described in the national health strategy. The results obtained have contributed to strengthening the position of the Ministry

of Health to negotiate with donors and the Ministry of Finance.

Resource planning and costing are being embedded into a core competency within the MoH, as well as integrated into the planning, programming, and monitoring processes. The next step is for resource planning and costing at national level to feed back into health policy dialogue and decision-making, in order to support and sustain primary healthcare packages that capture the synergies and benefits of integrative care. This paper demonstrates the methodology and results of the resource planning and costing exercise in the DR Congo.

O5.2

Maximising Health Outcomes from Surgical Interventions

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In Australia today, the introduction of new interventional procedures into the health system is managed by a variety of processes, involving advisory committees at the state and national level, as well as hospital or health service based committees. Evidence-based assessment of a new procedure's safety and clinical and cost-effectiveness has been instituted over the last decade. Therefore, ineffective interventions that diffused into clinical practice prior to the establishment of these assessment processes may still be in use today. However, changing clinical practice in relation to such procedures is challenging due to a number of factors, including a lack of formal processes for their identification and evaluation.

ASERNIP-S recently completed a pilot project aimed at strengthening the evidence base of clinical practice and improving clinical outcomes in relation to funding of surgical interventions. This project was focused on developing a process for identifying and reviewing surgical interventions that may be of questionable clinical benefit. Throughout the course of the project a range of key stakeholders were consulted. Initially, a systematic search of the international peer-reviewed literature was conducted to identify processes that have been used to evaluate existing interventional procedures that may be of questionable clinical benefit, and change clinical practice in relation to these procedures. The next stage of the project involved identifying and prioritising for further evaluation five surgical interventions that may be of questionable clinical benefit. The safety and effectiveness of these procedures was then evaluated using a rapid review of the published literature. The findings of each rapid review were then presented to, and discussed with key stakeholders. The details of this process will be presented, including the main outcomes of consultations with key stakeholders.

O5.3

A Comparison of Public Perceptions and the Australian Plan on Pandemic Influenza using Grid/Group Analysis

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Purpose: The fast evolution of pandemic influenza has ignited global worries in recent years, leading the World Health Organisation to recommend that countries prepare for a pandemic. In response the Australian government has developed the Australian Health Management Plan for Pandemic Influenza (AHMPPI), and this plan includes strategies to contain and/or manage a pandemic. To implement these strategies successfully, community compliance is necessary.

Method: In this study, the Grid/Group analysis of Mary Douglas is applied, using qualitative data from a citizens' jury and interviews with experts, to investigate the extent to which the antiviral drug and vaccine allocation of the AHMPPI corresponds with community views about the prioritisation of antiviral drugs and vaccines. Mary Douglas' Grid/Group analysis suggests that people's choices are made in accordance with social norms and values and the way people ascribe legitimacy to institutions and rules of procedure, mentioned by Mary Douglas as 'Cultural Bias'. By determining the cultural bias of the AHMPPI and the South Australian population a comparison could be made on the reasoning behind the allocation and determine if the population would comply to the AHMPPI.

Conclusion: The results of the analysis suggested that the allocation recommended in the AHMPPI corresponds fairly well with community views. Both allocations were based on the preferences for a hierarchical structure in planning and allocation. Some differences were found on community involvement in the decision process of the AHMPPI allocation. The public would like to be more involved, while only expert committees have been consulted in the decision process. Also on information provision to the public, the government is more reluctant then the public, mainly because sensitive information could upset the public. This study recommends that Governments should involve the public more into decision making and inform them about Health Technology Assessment policy to establish better public compliance.

O5.4

Perceptions of NHS Decision-Makers of NICE Interventional Procedures Guidance – A Qualitative Study

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Objectives: To identify how NHS decision-makers perceive NICE interventional procedures guidance (IPG) and to determine whether there would be additional information that would be useful to present to decision-makers.

Methods: Qualitative study using one-to-one semi-structured interviews. Using the framework approach, the data generated from 14 participants were analysed and emergent themes coded. Data were analysed separately for providers and commissioner organisations.

Results: Perceptions about how IPGs are managed in provider organisations varied considerably. Some decision-makers considered that guidance is handled very well. Others think that management is sub-optimal and haphazard and that it is unclear about whether clinicians follow procedure for cautionary guidance. In commissioner organisations, IPGs are not seen as a priority by most and are not considered as an area that will soon enter routine clinical practice. Moreover, they felt that IPGs lacked relevance as there is no consideration of whether procedures are cost-effective or affordable. In terms of timeliness, decision-makers at both types of organisations perceive that IPGs often arrive after a procedure is being carried out, but not too late to influence what will happen next. In general, respondents perceive that the content and quality of guidance is satisfactory. Additional types of information useful to include would be: prevalence, incidence, cost, patient views, effectiveness, cost-effectiveness.

Conclusion: Results indicate that management of IPGs in the NHS can be improved. These results are important to understand the usefulness of IPGs and how it meets decision-makers' needs in the NHS.

O5.5

The Current Capacity and Future Development of Economic Evaluation for Policy Decision Making: A Survey among Researchers and Decision Makers in Thailand

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Objective: This study aims to explore the knowledge, experience, and attitudes towards economic evaluation (EE) between decision makers and researchers in Thailand.

Methods: Researchers were purposively selected from all Thai academics, public and private research organisations related to EE. Decision makers at provincial level were purposively selected from the members of the Management Committees of Provincial Health Offices and those at hospital level were randomly selected from the members of the public and private hospital formulary drug committees throughout Thailand. The questionnaire covered demographic characteristics, their knowledge and experience, training needs, importance, usefulness and barriers in relation to EE. A self-administered postal questionnaire survey was conducted in April 2007. Univariate and bivariate analyses were applied.

Results: Of the total 2,575 questionnaires distributed, 768 (29.8% response rate) were completed and sent back. More decision makers (70.6%) had never had EE training compared to researchers (50.0%). Researchers had significantly more EE knowledge compared to decision makers. Both roles indicated that cost-effectiveness was one of the top five most important issues to consider for health technology adoption and EE evidence was the most useful information when making decisions on national drug formulary. The main barriers for researchers were the lack of EE methodological skills (19.3%), critical mass of researchers (17.5%) and data (17.5%). The main barriers for decision makers were the unavailability of CEA threshold (22.9%) and EE studies (22.7%) and the potential sponsorship bias in EE studies (20.2%).

Conclusion: In Thailand, even though EE is one of the essential information for health policy decision making, both researchers and decision makers still lack EE knowledge and skill. Findings from this study contribute to the short- and long-term plans for research capacity building and strengthening in EE of healthcare.

O5.6

Technology-driven New Diseases in The Context of Traditional Assessment of Effectiveness: Are They Recorded Appropriately and are The Potential Risks and Benefits considered under Ethical Aspects?

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Objectives: Our aim was to check innovations regarding their potential to cause technology-driven diseases and their recording and consideration in the context of ethical benefit/harm evaluations in HTA reports respectively systematic reviews.

Methods: We performed a systematic search in biomedical databases such as MEDLINE and EMBASE by using the

search terms "technology-driven", "therapy-induced", "treatment-induced" and screened the resulting documents according to predefined inclusion and exclusion criteria. Technology-driven diseases were included, adverse drugs effects were not. The potential to harm of the technologies identified was subsequently estimated by additional literature searches. Finally, relevant systematic reviews were assessed with regard to whether technology-induced diseases had been considered in the assessment.

Results: The initial search resulted in 1,400 hits. Our screening yielded a high variety of new technologies with an associated risk for new diseases. Besides risk-associated treatments (e.g. nephropathy in HAART), diseases have been identified, which are newly created by the technology, e.g. in-stent-stenosis due to stenting or graft-versus-host disease (GvHD) due to allogeneic stem cell transplantations. The benefit/risk balance of the identified health technologies in general proved to be very different. For example in assessments on stents, the in-stent-stenosis and their restenoses are captured by the parameters 'target lesion', 'vessel revascularisation' or 'in-stent-stenting' to the benefit achieved by coronary artery dilatation. Ethical implications have mostly been neglected in the existing reviews. Acute and chronic GvHD are one of the most serious complications of allogeneic stem cell transplantations, which might be lethal in the advanced stage. Benefits and harms are partly presented in existing reviews, but ethical issues are rarely discussed.

Conclusion: Taking into account that up to now even known technology-induced diseases are not incorporated in a considerable number of systematic reviews, we recommend a benefit/harm assessment by using the methods on integrating ethical issues in effectiveness assessments.

O6A – ECONOMIC EVALUATION AND STUDY METHODOLOGY

O6A.1

The Cost Effectiveness of an RCT Comparing Alendronate with Vitamin K1

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Introduction: Alendronate is the recommended treatment in England and Wales for women with osteoporosis. The efficacy of alendronate compared with no treatment has been estimated from RCTs involving almost 5,000 women per arm, and is 0.58 (0.50 to 0.67), 0.72 (0.58 to 0.88) and 0.82 (0.74 to 0.90) for vertebral, hip and other fractures, respectively. From a trial of 250 women per arm, vitamin K1 has an estimated efficacy compared with no treatment of 0.46 (0.22 to 0.99), undifferentiated by fracture type. Probabilistic sensitivity analyses conducted using a mathematical model indicates that vitamin K1 would be the recommended treatment given current evidence. However there is considerable uncertainty in this decision. We aim to estimate if an RCT directly comparing alendronate with vitamin K1 would represent a cost effective use of resources in England and Wales.

Methodology: Expected values of sample information (EVSI) techniques were used. Hypothetical RCTs of 1,000, 2,000, 5,000 and 10,000 women per arm were simulated. The EVSI represents the increase in net benefit to be achieved and was the current recommended decision to be altered following the RCT. Subtracting the costs of conducting the RCT provides the expected net benefit of sampling (ENBS) for each trial size. The trial size with the bigger EBNS was assumed to be the optimal from those analysed, if this EBNS was negative then the RCT would not be cost effective.

Results: For a wide range of values of assumed risks of fracture, cost per QALY thresholds, cost per woman of undertaking the RCT and the number of women who will benefit from the data collected, an RCT of 2,000 women per arm would consistently provide high estimated EBNS values.

Conclusion: An RCT recruiting 2,000 per women per arm would represent a cost effective use of resources in England and Wales.

O6A.2

Early to Late Stage HTA in Cooperation with the Industry in the Medical Device Sector

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Medical device companies are under growing regulatory and market pressure to provide health-economic evaluations of their innovations. As a result, cost-effectiveness analyses are increasingly undertaken as a one-off exercise at the last development stage before applying for market approval and/or obtaining reimbursement. Since the probability of reimbursement is a key factor to determining to proceed with or abandon a product during its process of development, health economic analysis undertaken from the early stages of the development cycle, can help to anticipate the eventual outcome of the reimbursement decision and herewith support innovation management and decision-making. The Multidisciplinairy Assessment of Technology Centre for Healthcare (MATCH) provides academic support to medical device industries for incorporating the methods of iterative Bayesian economic evaluation into their research and development processes. Yet, to deal with the relative scarcity of data and time that characterises the early development stages of new technologies, these methods need to be adapted. Therefore, we have recommended a three-stage economic evaluation, starting from an early phase where simple methods allow for a quick prioritisation of competing products. In a mid-stage, the data is synthesised into a decision model, the parameters for which

more information is most valuable are identified, and the uncertainty surrounding the decision is explored. In the late-stage analysis, all relevant information is synthesised to inform a reimbursement decision. During the presentation, the application of this approach will be illustrated using an innovative examplar device, and the implications of this approach for innovation management from a societal as well as a commercial decision-making context will be discussed.

O6A.3

Predicting Recruitment to Clinical Trials

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Background: Clinical trials which recruit participating centres on an ad-hoc basis often under recruit. This is bourne out by a systematic review of publicly funded trials (1994 to 2002) which found that only 31% attained their original participant recruitment target.

Aim: To systematically review the literature on recruitment curve modelling in terms of both centre recruitment and participant recruitment to multi-centre randomised controlled trials (RCT), and consider how a tool might be constructed to enable more accurate recruitment prediction for future trials.

Methods: Two biomedical databases (MEDLINE and EMBASE) were searched in July 2008. The search was restricted to 1980 to 2008. Terms covered recruitment, patient selection and a range of statistical modelling methods.

Results: Three hundred and twenty-six papers were initially identified, of which eight met the full inclusion criteria. None of the articles addressed centre recruitment to multi-centre RCTs, instead focussing on participant recruitment. Seven articles developed a model to predict recruitment prior to trial start. Four of these included a model that could be used for monitoring recruitment throughout the trial. One article developed a retrospective model using actual data on recruitment over time from a number of trials.

Discussion: In trials without a pre-existing network of participating centres, the recruitment of centres is a major driver to the ultimate ability to recruit patients. We did not discover any consideration of this in the literature.

Conclusion: Prediction of participant recruitment to trials must take into account the recruitment of centres when the trial takes place outside a pre-existing network. A tool is needed to assist researchers to more accurately predict recruitment at the planning stage, reduce costs and enhance trial validity. We present a discussion of what this tool might look like, and how it may be calibrated and validated.

O6A.4

Quantifying Survival for Health Technology Assessment from Trials with Incomplete Follow-Up: An Empirical Example

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Background: Survival data can be difficult to interpret due to positive skewness and censoring. Hazard ratios (HR) are calculated by statisticians to quantify survival differences, however HRs are not a useful measure for Health Technology Assessment (HTA) in the absence of knowledge about the underlying baseline risk. Mean and median survival tend to be calculated to quantify survival differences, however, incomplete follow-up data adds further challenge.

Objectives: To investigate the robustness of measures used to quantify survival in the presence of varying degrees of incomplete follow-up.

Methods: Data was analysed from a completed trial with two planned interim analyses. Three comparative measures of survival were calculated from each analysis: HR (95% CI), difference in median survival and mean survival (95% CI). With incomplete follow-up, mean survival was calculated from observed data and by extrapolation to 'complete' dataset. Survival measures were compared for robustness. Kaplan Meier (KM) plots were produced and overlayed to determine the uncertainty associated with later data-points.

Results: Hazard ratios provided consistent, robust estimates of survival, with 95% CI reflecting the degree of uncertainty associated with earlier interim analyses. Median survival was not reached for the first interim analysis, however there was concordance between median survival differences from the second and final analyses. Mean survival was the least consistent, reflecting statistical literature that mean survival is biased and influenced by longer follow-up of a few individuals. Overlayed KM plots demonstrated concordance for all three analyses at earlier time-points, however data at the end of KM plots fluctuated and interpretation of these data-points should be avoided.

Conclusion: There is little literature regarding the appropriate choice of statistic to quantify survival differences for HTA. This empirical example demonstrates care needed when relying upon one measure of survival and cautions against visual interpretation of KM plots.

O6A.5

Using Bayes' Theorem to Support Individual Treatment Decisions

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Background: Bayes' theorem can be used to calculate how probability estimates should be revised when new evidence becomes available. It is widely accepted in the context of diagnosis, where the prior probability equals the prevalence of the disease condition. The result of a diagnostic test constitutes the 'new evidence' about a specific patient. On the basis of the Likelihood Ratio (LR) of the test, the posterior probability is calculated. Surprisingly, Bayes' theorem has hardly been used to support individual treatment decisions. Our objective was to explore the usefulness of Bayes' theorem to support individual treatment decisions in patients with newly diagnosed rheumatoid arthritis (RA) who are treated with methotrexate (MTX).

Method: To estimate the prior probability of success, results of recently reported trials were used. As 'new evidence' from individual patients, the score on the Disability Index of the Health Assessment Questionnaire (HAQ) was used. To calculate the LR of an improved HAQ score, data from 267 patients were used from our registry. Treatment response was defined in accordance with internationally accepted criteria.

Results: On the basis of the literature, the prior probability estimate of treatment success at 3 months is approximately 10%. The LR of an improved HAQ score was 2.5 (95% CI: 1.5 to 4.0). Combining prior probability of treatment success with this LR results in a posterior probability of 0.21.

Interpretation: Bayes' theorem can be used to support individual treatment decisions, in a way that is fully comparable to its application in diagnosis. In patients with RA, an improvement in HAQ score at 3 months doubles the probability that the patient actually responds to treatment, but the absolute probability at this stage is still quite low.

O6A.6

Health Technology Assessment and Pragmatic Controlled Trials

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HTAs are based on systematic reviews and often rely on the hierarchy of research design for evidence-based medicine. RCTs are ascribed the greatest weight because of internal validity. Even with the generally broad definitions of HTAs, several studies show a more narrow perspective in reality. Greatest emphasis is on clinical aspects. Social, organisational and patient-related issues are seldom assessed all which mainly are assessed using less controlled study-designs. This discrepancy highlights the reliance on the hierarchy of research design in HTAs and the non-applicability on other issues than efficacy. As a consequence of this, decision-makers are presented with a selection of consequences of a health technology. This is verified in several studies showing low correspondence between the need of the decision-makers and the contents of HTAs. One way to overcome some of these discrepancies between producers and users is to broaden the spectre of research methods in HTAs. Pragmatic controlled trials (PCT) are suggested as research methods to supplement RCTs. PCT implies greater external validity by inclusion of effectiveness-studies in daily use, normal practice and in real-life settings with less strict criteria for inclusion and thereby a more varied spectrum of patients. PCT gives possibilities of inclusion of a broader spectrum of issues such as patient experiences, organisational and social issues and creates more correspondence between the preferences of decision-makers and the HTAs, which is further enhanced by assessment of the technology in own local context in PCTs. PCTs can supplement but not replace RCTs. When a certain amount of RCTs with similar results exists, it is useful to initiate PCTs in order to expand the range of results both in terms of assessed issues and in terms of external validity. But PCTs demand carefully conducted and methodologically sound experiments and different methodological skills and experiences with quasi-experiments and external validity.

O6B – HEALTH SERVICES RESEARCH – UTILISATION OF SERVICES AND OUTCOMES RESEARCH

O6B.1

Hospital Standardised Mortality Ratios as a 'Big Dot' Measure for Hospital Quality of Care

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Introduction: Developed by Sir Brian Jarman of the Dr Foster Unit at Imperial College in the United Kingdom, Hospital Standardised Mortality Ratio (HSMR) is now widely used in several countries around the world as part of quality management and improvement programmes. HSMR is also one of the 'Whole System Measures' recommended by the Institute for Healthcare Improvement in its 2007 White Paper. Our study aimed to evaluate the feasibility of computing this measure using administrative databases for tracking quality of care in public hospitals in Singapore.

Methods: The analysis was based on hospital administrative databases, and included all Singaporeans and permanent residents aged 18 years or older admitted to public hospitals with principal diagnosis associated with 85% of deaths and length of stay of 365 days or less from 2001 to 2007. Those transferred out to other hospitals, admitted to specialty institutions, and day surgery cases were excluded from the analysis.

HSMR is defined as a ratio between observed and expected deaths within a hospital. The risk-adjusted expected deaths were computed using multiple logistic regression with adjustment for factors such as age, gender, transfers-in status, admission type (emergency vs. elective), length of stay, principal diagnosis, Charlson's comorbidity index, DRG type (surgical vs. medical), and palliative care.

Residual mortality effects would thus be due to factors most likely to be contributing to inter-hospital variation in outcomes, enabling HSMR to be used for 'like-for-like' comparison of hospital performance.

Results: A total of 40,449 deaths (6.3%) occurred in the public hospitals during the study period. The overall HSMR for the hospitals varied from 90.1 to 108.6 with consistent differences across hospitals.

Conclusion: The study demonstrated that HSMR analysis using administrative database is reliable and able to detect significant differences in HSMR between hospitals, indicating likely variations in quality of care. Further analysis will be conducted for disease/condition-specific HSMRs to assist hospitals in identifying specific gaps for improvement.

O6B.2

A Comparison of Healthcare Resource Utilisation and Expenditure Among Attention-Deficit Hyperactivity Disorder Subjects Treated with Stimulants versus Nonstimulants

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Objectives: To examine differences in healthcare resource utilisation and expenditure among subjects taking stimulant or nonstimulant medication for attention-deficit hyperactivity disorder (ADHD).

Methods: Claims from newly treated ADHD subjects, aged ≥6 years, given a stimulant or nonstimulant as index (initial) therapy, and continuously enrolled in a US commercial health plan 6 months prior and 12 months after their first prescription (1 January-30 September 2006) were studied. Healthcare resource utilisation was measured for 1 year from the date of the first prescription fill and comprises a) outpatient or office visits, b) emergency room (ER) visits, c) occupational/speech/physical therapy visits and d) inpatient hospital admissions.

Results: Healthcare utilisation in the follow-up period was significantly higher among subjects on nonstimulants (n = 12,992) compared with those on stimulants (n = 47,018), with a higher mean number of outpatient visits (1.89 vs. 1.62, P <0.001), a higher mean number of ER visits (0.71 vs. 0.66, P <0.05) and a higher mean number of inpatient admissions (0.07 vs. 0.05, P <0.01). Within both treatment groups, subjects with an additional mental health diagnosis were significantly more likely (all P <0.001) to have an outpatient visit (47.3% vs. 31.0% stimulant, 49.8% vs. 33.4% nonstimulant), an office visit (98.9% vs. 95.7%, 98.3% vs. 94.0%), an ER visit (29.4% vs. 16.0%, 30.1% vs. 17.1%), an inpatient stay (6.8% vs. 1.6%, 7.7% vs. 1.9%) or an occupational health, speech therapy or physical therapy visit (1.5% vs. 0.6%, 1.3% vs. 0.7%).

Conclusion: Healthcare resource utilisation was higher among subjects treated with nonstimulants compared with those treated with stimulants. The largest differences in healthcare utilisation were observed between subjects with an additional mental health diagnosis and those without.

O6B.3

Use of Geographic Information Systems in Understanding the Pattern of Emergency Departments Utilisation in Singapore

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Aims: To evaluate the pattern of restructured hospitals'

emergency departments (EDs) utilisations and availability of outpatient services using geographic information system (GIS).

Methodology: A cross-sectional national survey was conducted at the ED of 5 restructured hospitals over a 2-week period (26 August 2008 to 9 September 2008). Patients aged 21 and above, with initial triage status of P2 or P3 were systematically selected. Patients triaged as P2 are ill and non-ambulant and the severity of their symptoms requires early attention, failing which early deterioration of their medical status is likely. Patients triaged as P3 are ambulant and have mild to moderate symptoms requiring acute treatment. The geographical information, including locations of EDs, outpatient services during and after office hours, and origin of patient attending the EDs were obtained and geocoded using the valid postal codes. These locations were mapped with boundaries of urban planning areas using GIS software Mapinfo.

Results: Of the 4,115 eligible patients, 3,578 (87%) responded to our survey and the geocoding located approximately 76% of the respondents. The geographical distribution of attendances and the catchment of each ED were identified. The results showed that there was a clustering in the target service area for three out of five hospitals. For the other two hospitals, there was a wider scatter of patients from all over the island. The availability of outpatient services after office hours was also studied, with gaps being identified for certain catchment areas, particularly in the western parts of the island. This could have accounted for some of the non-emergency utilisation of ED services.

Conclusion: The findings of this study provided a better understanding of geographical distribution of patients and catchment of the emergency department at five restructured hospitals. This would enable and facilitate the identification of service gaps geographically for planning purposes.

O6B.4

Providing Immediate Concurrent Feedback for Antimicrobial Prescription – Can it Decrease Antimicrobial Resistance?

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Introduction: Antimicrobial resistance is increasing globally as a result of inappropriate or excessive antibiotic prescribing, especially broad-spectrum by physicians. Antimicrobial stewardship programmes have been advocated to enable clinically robust, professional-driven interventions to decrease inappropriate usage. We review the evidence for immediate concurrent audit of antimicrobial use by a multi-disciplinary team with same-day feedback to prescribing clinicians.

Methodology:

Populations – All patients on pre-identified antimicrobials

Intervention – Immediate concurrent audit and feedback intervention programme

Comparator – Prescribing without an antibiotic steward programme

Outcome – To reduce inappropriate and excessive usage of broad-spectrum antimicrobials

Literature review was performed in NHS Centre for Reviews and Dissemination databases (DARE, NHS EED, HTA), Cochrane Database of Systematic Reviews, PubMed (MEDLINE) and National Guidelines Clearinghouse using the following search terms: Antibiotic OR antimicrobial stewardship programme OR concurrent feedback Antibiotic OR antimicrobial stewardship effectiveness Antibiotic OR antimicrobial stewardship cost-effectiveness Antimicrobial* AND resistance AND prospective audit.

Results: Literature search revealed one guideline, one survey, two prospective observational studies and ten topic review articles. Three systemic reviews on all interventions aimed at decreasing inappropriate antibiotic prescription reported inconsistent evidence in decreasing incidence of multi-drug resistant infections and deaths. Post-prescription review better managed antimicrobial recommendations in a hospital with six times more interventions for inappropriate prescribing compared to "Prior Approval" schemes (where hospital formulary is restricted to certain approval physicians). 71.9% of post-prescription review recommendations were followed. American professional societies' guidelines recommend concurrent audit of antimicrobial use with direct feedback to the prescriber. The recommendations are supported by findings of a 22% reduction in unnecessary use of antimicrobials and a 19% reduction in antimicrobial expenditures post-intervention.

Conclusion: Post-prescription review with immediate concurrent feedback can effectively reduce inappropriate use of antibiotics with resultant cost savings.

O6B.5

Practical Trial: Cost-Effectiveness Analysis of Intensive Care Post-Discharge Review Clinics

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Purpose: Approximately 10,000 people are admitted to intensive care units in Scotland per year. Even after discharge from hospital these people continue to experience severe physical and psychological problems. These problems have implications not just for patients but represent a continuing draw on scarce health service resources. Despite the lack of an evidence base, over 40 hospitals across the UK have developed Intensive Care post-discharge review clinics in an attempt to improve outcomes after ICU discharge. We present a pragmatic RCT based economic evaluation of intensive care post-discharge review clinics compared with standard practice.

Methods: Participants were randomised to attend post-discharge clinics at 3 and 9 months or standard care. Cost data were collected on NHS based health services resources used (e.g. inpatient stay, outpatient contacts, primary care contacts). Costs and Quality adjusted life years (QALYs), based on responses to the EQ-5D, were estimated for the 12 month trial follow-up for both arms of the trial. Analyses were conducted on intention to treat basis and we used multiple imputation techniques to deal with missing data.

Results: Intensive care post-discharge review clinics were on average more costly (e.g. cost difference = £2100) and slightly more effective (e.g. QALY gain = 0.011) than standard practice. Therefore, an additional QALY can be gained at an extra cost of £196,000. Preliminary sensitivity analyses show these results to be robust.

Conclusion: Intensive care post-discharge review clinics are unlikely to be considered cost-effective. The proliferation of ICU post-discharge clinics in the UK should be reconsidered.

O6B.6

Good Governance in Health Outcome Research: A Case of Vietnam with Foreign Aid Assistance

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Objective: The aim of this research is to review the foreign aid funded national health projects in researches of economic evaluation in Vietnam and how principles of global governance are utilised in these researches.

Methods: We conducted a literature review and data analysis from the OECD-DAC data bank to examine the foreign aid funded health projects in Vietnam from 1995 to 2005 in the field of economic evaluation. The framework of examination is through the principles of good governance - transparency, predictability, efficiency and accountability, to make a judgment code on how the outcome of the health service researches correlate to the principles of good governance. The official report from the OECD was also tapped into the eventual findings.

Findings: We found the foreign aid funded health projects in economic research and evaluation have been decreasing for the past decade and the proportion of health outcome researches has been gradually low (10%). The principles of good governance have provided a framework to illustrate how the evidence of health services research can be effectively enhanced. We propose a hypothetical framework of good governance in the arena of health outcome research in developing countries in our study and discuss how this framework can integrate with other development work for health.

Conclusion: Health outcome researches funded by foreign aid can be more effectively conducted in line with the principles of good governance in developing countries in the era of globalisation.

O7 – HTA METHODOLOGY

O7.1

Methods for Synthesising Different Types of Evidence in Health Technology Assessment (HTA)

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Objective: Synthesis of clinical and cost-effectiveness evidence is now an established approach in HTA to inform policy and future research. This review provides an overview of evidence synthesis methods and guides the synthesis of qualitative and quantitative data in HTAs. The review also identifies novel/alternative methods for synthesising evidence and develops a reference tool for researchers on the selection of appropriate synthesis methods.

Methods: A systematic literature search, scanning other research and HTA websites as well as insights gained from using different methods in undertaking HTAs at NHSQIS were employed. The features of each of the evidence synthesis methods identified are summarised using a list of predefined criteria (purpose, context, strengths, limitations, comparisons, challenges etc).

Results: A descriptive summary of systematic approaches to evidence synthesis using qualitative, quantitative and mixed methods in HTAs is presented. A total of 17 evidence synthesis methods were identified. Some of these methods used a mix of both qualitative and quantitative data. Nine approaches were quantitative of which eight used a series of often related statistical techniques (either frequentist or Bayesian) to address different analytical issues. A further decision modelling method was identified which might be used in combination with other methods. Around eight qualitative approaches were also identified. Four of the identified methods were promising novel/alternative methods (harvest plot, mixed treatment comparison meta-analysis, multi-parameter evidence synthesis and confidence profile method) for synthesising evidence. Information is presented to relevant audiences (HTA developers) in a simple and accessible way (Tabular/graphical form) to enable appropriate selection of methods.

Conclusion: This taxonomy of methods will help researchers involved in undertaking HTAs to have an adequate understanding of the methods and inform judgement on the range of approaches that can be used.

O7.2

Questionable Reproducibility of Systematic Reviews: A Case-Study on Treatment for Stress Urinary Incontinence

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Background: Data from primary studies are often reported ambiguously. Drawing conclusions involves making assumptions about the data. Different reviewers may make different assumptions (e.g. about the number of people contributing data for an outcome). It may be possible to verify data extraction results by comparing with earlier reviews, if the same studies are included, but similar or different assumptions may have also been made in earlier reviews. If these assumptions are not well reported then this will make it difficult to reproduce a review. The aim of this study was to identify and analyse inconsistencies caused by differences in the interpretation of reported study data.

Methods: We conducted a systematic review of treatment for stress urinary incontinence using duloxetine and compared our data extraction results with those of an existing review on the same subject.

Results: We found many inconsistencies in data extracted from eight RCTs included in the two reviews. Some of these were random errors or inconsistent rounding of numbers. However, more extensive discrepancies arose from different assumptions being made, particularly in instances where primary studies had reported percentages without reference to an actual number of participants, or where studies claimed to have used an "intention to treat" method but this was not clearly described. This is particularly problematic where there is differential withdrawal between trial arms.

Conclusion: While individual inconsistencies can be resolved through discussion between relevant review authors, discrepancies caused by the need to make assumptions can not only hamper review reproducibility, but may bias treatment effect estimates. The quality of reporting in primary studies needs to improve further. Reviewers extracting data from primary studies should explicitly report any assumptions that they make during this process.

O7.3

Judge the Quality of Studies Instead of Using a Hierarchical Structure for Grading Evidence – Comments on the Controversy of Randomised Controlled versus Observational Studies

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This study discusses discrepancies between observational and randomised controlled studies (RCTs). Two often quoted examples where observational studies more systematically have shown results not in line with large RCTs are the relationships between coronary heart disease and hormone replacement therapy and use of vitamins, respectively. On the other hand, a recent example where meta-analyses of RCTs have severely missed adverse events of drugs is the case of aprotinin for reducing blood loss during bypass surgery.

In the case of hormone replacement therapy and vitamins, the main reason for observational studies showing results later contradicted by large RCTs was due to lack of confounding control for socioeconomic factors. Furthermore, a systematic review in prestigious scientific journals showed that less than 30% of observational intervention studies did control for socioeconomic factors.

A Cochrane review of aprotinin restricted the analysis of adverse events to small RCTs. None of the RCTs had sufficient statistical power to detect differences in mortality. Seven out of 51 RCTs had mortality outcome as one of the objectives. Only very few described the follow-up method or the follow-up time. The observational studies showing adverse effects of aprotinin were on the contrary large and well-conducted including control for many confounding factors like socioeconomic factors.

Conclusion: Control for socioeconomic position is nearly non-existent in observational intervention studies. The quality of observational intervention studies would increase substantially if socio-economic factors were included in the analysis. It is doubtful to include small RCT studies in meta-analysis if they do not have the purpose to study the specified outcome and if the methods or time for follow-up are not adequately described. The aprotinin saga shows an overconfidence in small RCTs of inferior quality compared to well done observational studies.

O7.4

The Approach for a Minimal HTA (Health Technology Assessment)

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Aims: Epidemiological analysis in the catchment area, assessment of the state of technology in research field, cost and income breakdown of the health services and evaluation of clinical advantages with new techniques require knowledge, people and time. These resources are only available at "Macro" or "Meso" levels in Public Health organisations and in large-size hospitals at "Micro" level.

Methods: HTA is used mainly for the introduction of consolidate technologies or for the updating of obsolete equipment, and many hospitals could not afford a committed Unit to developing the whole HTA process. For these reasons a new approach, "Mini" HTA, is proposed to carry out an evaluation for diffusion and renewing of technologies using limited resources without losing effectiveness.

Results: For the introduction in hospital of technologies already consolidated on the market, the evaluation of few

parameters could be enough for "Mini" HTA. This methodology only examines: clinical needs of patients, technical capacities of equipment, worker flexibility in the organisation, and economic balance of health services.

For the updating of obsolete equipment already used in hospital, "Mini" HTA analyses only few parameters: total cost of ownership of equipment, clinical effectiveness for in-patients, new technical capacities of equipment, improvement and support to the organisation.

Conclusion: For both, introduction of consolidate technologies and updating of obsolete equipment, the evaluation could be carried out by a temporary team of internal resources exploiting their knowledge and expertise. "Mini" HTA has been implemented in our hospital for 2 years with modules and procedures and consists in creating a multi-disciplinary committee with the following Unit managers: Healthcare Direction (organisation and people), Pharmacy (medicines and medical devices), Clinical Engineer (technology and maintenance) and Management Accounting (incomes and costs). "Mini" HTA, used diffusion and renewing of technologies, implement an essential but sufficient assessment using limited resources without losing effectiveness.

O7.5

KNOW ESSENTIALS© – A Tool for Informed Decision-Making in the Absence of Formal HTA.

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Background: Healthcare stakeholders (physicians/policy-makers/patients) often have to make decisions in the absence of formal HTA systems, especially in developing countries. KNOW ESSENTIALS© is a novel tool facilitating informed decision-making by all stakeholders, using available information from literature. This presentation outlines the tool, its merits and a sample application (Figure1).

KNOW ESSENTIALS© Tool: The three preliminary steps (acronym KNOW) to consider any health technology are establishing (i) Knowledge of need (KN), (ii) Outcome of interest (O), (iii) Who/Which is the stake-holder involved (W). The tool should be applied when all three are clearly defined.

Each health technology is evaluated using ten criteria, categorising each criterion into one of four coloured channels, red (unfavourable), green (favourable), yellow (insufficient data) and white (not-applicable). The basis for colour coding is elaborately defined for each criterion and each stakeholder to obviate subjectivity, although it cannot be presented in this abstract for lack of space. The criteria form the acronym *ESSENTIALS*: (i) Evidence of effectiveness/efficacy, (ii) Safety, (iii) Social quotient (encompasses consumer acceptability and ethical/legal/moral propriety), (iv) Economic issues viz cost and cost-effectiveness. These four are mandatory criteria and stakeholders should proceed only if all are categorised green. The other criteria are (v) Novelty (newness), (vi) Time to outcome of interest, (vii) Integration with existing services/facilities, (viii) Alternate options, (ix) Likely impact of not choosing the intervention, and (x) Sustainability.

Merits: The tool can be applied by all stakeholders (policy-makers/physicians/patients/healthcare payers) to make objective decisions for their setting, based on explicit criteria, thus saving time and cost. It is an excellent teaching aid for informed decision-making, especially in resource-poor settings.

Current status: Pilot testing considering various health technologies and stakeholders suggests that outcomes are objective, reproducible, and preferred by most stakeholders to current decision-making mechanisms. A randomised trial comparing it against formal HTA is planned.

Conclusion: KNOW ESSENTIALS© is a simple and practical tool for informed decision-making in settings lacking formal HTA systems.

O7.6

A Bibliometric Analysis of 100 Most Cited Systematic Review and Meta-Analysis Articles

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Background: Systematic reviews can be a very useful decision-making tool because they objectively summarise large amounts of information, identify gaps in medical research, and identify beneficial or harmful interventions. The number of citations an article receives after its publication reflects its impact on the scientific community, but also the impact of the authors' creativity, a specific institution, or even a country in the field studied. There were a few recent attempts to identify and analyse "the most cited articles" in various specialties. However, the analysis of top-cited systematic review and meta-analysis (SRM) articles has not yet been reported.

Objectives: To identify and examine the characteristics of the most frequently cited SRM articles.

Methods: The 100 most frequently cited SRM were identified using the Science Citation Index database of the Institute for Scientific Information.

Results: The most cited articles received 3,762 citations, and the least-cited article received 447 citations. The oldest article was published in 1977 and the most recent article in 2005. All the 100 top-cited articles were published in English Language. The 100 originated from 15 countries, with the United States contributing 50 articles, followed by the United Kingdom with 20 and Canada with 13. Only 16 articles originated from non-English speaking countries. The top-cited articles were published in 42 journals. General and internal medicine is the main topic covered by these highly cited articles. Top cited articles were more likely to be published in journals with a high impact factor and immediacy index.

Conclusion: Our analysis gives an encyclopaedic review of citation frequency of top-cited SRM articles. Since the late 1970s, United States, United Kingdom, and Canada have taken leadership in the production of citation classics papers. No developing regions had contributions in the top-cited 100 articles examined.

O8 – REIMBURSEMENT AND COVERAGE

O8.1

International Comparison of Publicly Funded New Technologies: Is It Necessary?

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Background: To improve the well-being of their populations, countries strive to add new beneficial health technologies to the publicly covered list of health technologies. Since 1998 Israel has a unique and systematic method for the prioritisation of new technologies for adoption in the National Health basket taking into consideration clinical, economic, social, ethical and legal aspects.

Aim: To create a supportive international comparison of the adoption of new health technologies in other countries to complement policy making strategies.

Method: The 2008 updates to the publicly funded Israeli National List of Health Services (NLHS) served as a basis for comparison. Details of the technologies were compiled and emailed to colleagues from Austria, Belgium, Brazil, Canada (Ontario, Quebec), Denmark, France, New Zealand, Spain, Sweden, Switzerland and Taiwan who had agreed to collaborate on this international study. Results underwent comparative SAS analysis.

Results: Initial findings showed that European and Scandinavian countries involved in the study had adopted most of the technologies (58 to 79 out of 86 technologies). Brazil, New Zealand and Ontario adopted only a few of these new technologies (17, 23 and 32, respectively), while Quebec and Taiwan adopted more than half of the technologies. A total of 38 technologies (44%) were adopted by 9 countries or more.

Conclusion: International comparisons of adoption of new health technologies constitute a supportive tool in the decision-making process in order to include or exclude new technologies and defend decisions in the light of public criticism. These results highlight the need for a central international database with easily accessible information on evaluations and national policies on new health technologies. Such a platform would facilitate swifter understanding and assessment of new technologies for decision-makers. An international comparison of policy-making processes and mechanisms is needed in the future.

O8.2

Analysis of Factors Associated with Reimbursement Decision Making in Health Technology Assessment (HTA)

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Objectives: Health technology assessment is used to inform reimbursement decisions for pharmaceuticals globally. The national HTA agencies of the developed world have broadly similar methods and use common factors when evaluating technologies but sometimes come to different decisions. The aim of this study was to investigate the context level and product-related level factors affecting reimbursement decisions between countries.

Methods: A systematic search was conducted to obtain the documentation for reimbursement decisions on cancer and cardiovascular medicines. Where insufficient information was published, or reports were not available in English, decisions were excluded. The analysis was conducted using multinomial logistic regressions and the independent variable included three types of decision: recommended, recommended for restricted use and not recommended.

Results: Detailed information was obtained on 194 decisions from Australia, Belgium, Canada, England, France, Scotland and Sweden. The pooled analysis showed that 27% of medicines were recommended, 41% were recommended for restricted use and 32% were not recommended. The results demonstrated that several factors were important in producing the different types of decision. These included the number of RCTs, publication date, sensitivity analysis, budget impact, type of

medicine and public interest. A sub-analysis for decisions in England showed that the cost per QALY value was statistically significant.

Conclusion: The results may in part be explained by the different approaches between countries to conducting economic analysis, differences in cost-effectiveness thresholds and variation in the weight given to economic evidence. Further variation may be explained by factors relating to the country's context such as the norms, culture and policy objectives which influence the methods and importance of different product level factors included in the HTA. The next stage of the research is to investigate these factors directly.

O8.3

An Investigation of How the Scottish Medicines Consortium (SMC) has Shaped Medicines Use Across NHSSCOTLAND

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Objectives: SMC advises NHSScotland whether new licensed medicines, major indications and formulations are 'accepted for use', 'accepted for restricted use', or 'not recommended'. Between January 2002 and December 2005, SMC issued advice for 207 medicines. An investigation was undertaken to examine how this advice has shaped medicines use.

Methods: Of 207 medicines, 74 were selected for investigation based on available data: 20 'not recommended' and 54 'accepted for use' or 'restricted use'. Medicines utilisation data were obtained for primary care medicines (n = 61) and hospital medicines (n = 13) through PRISMS (PRescribing Information SysteM for Scotland) and hospital pharmacies/manufacturers, respectively. Profiles summarising medicines use were developed for each medicine. A qualitative review was undertaken to identify factors to explain patterns of medicines use.

Results: Several factors were identified that may explain patterns of use of SMC 'not recommended' primary care medicines:

- Delay between UK launch and initial SMC advice
- Availability of alternative treatment(s)
- No licensed alternatives
- Influence of pharmaceutical industry marketing strategy
- Variation in advice from national bodies to NHS Boards and clinicians
- Lack of engagement of relevant clinical experts

For SMC 'accepted for use' or 'restricted use' primary care/hospital medicines, factors included:

- Limitations of data obtained from NHS Boards and manufacturers
- Challenges in interpreting data for 'restricted use' medicines
- Availability of alternative treatment(s)

Conclusion: This investigation provides direction for an evidence-based plan to develop further the assessment, implementation and monitoring of new medicines in NHSScotland.

O8.4

HEALTH TECHNOLOGY ASSESSMENT IN MIDDLE-INCOME COUNTRIES

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Objective: The study provides an overview of how HTA is organised in a selection of middle income countries: Argentina, Brazil, China, Colombia, Israel, Mexico, Philippines, Korea, Taiwan, Thailand and Turkey. European middle-income countries were excluded because of tentative plans for a study specifically of those countries.

Methods: We selected middle-income countries where HTA systems are established and active. For these countries, we systematically collected and reviewed relevant information to describe the healthcare and reimbursement systems and how HTA relates to coverage decision making of pharmaceuticals. The country profiles were supplemented by information from a structured survey among relevant persons in the field of HTA in the selected countries (n = 44/180).

Results: All countries have undergone major healthcare reforms and are in the process of undergoing further changes in healthcare. Most countries have a mix of public and private insurance systems but differ in the share of public and private insurance, the degree of decentralisation and populations covered (e.g., urban/rural population). All countries require market authorisation for pharmaceuticals to be sold and most countries have a national plan defining which pharmaceuticals can be reimbursed. However, the use of HTA in reimbursement decisions is still in its early stages with varying levels of HTA guidance implementation.

Conclusion: The study provides evidence on the development stages and use of HTA in coverage decision making in selected middle-income countries. It seems that increased healthcare spending and the resulting access to modern technology gives a strong impetus to HTA. The assessment and regulation of drugs are advanced in relation to other technologies. At the same time, the HTA processes are new and are not very robust. Sharing of expertise, experiences and (further) institutionalisation of HTA is therefore essential.

O8.5

Evidence-Based Coverage Decision Making of Genetic Tests: An Experience from the Brazilian Private Health Insurance Sector

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Background: Scientific advances have made possible the development of an escalating number of molecular genetic tests for the identification of disease-causing inherited mutations. Nevertheless, there is considerable limitation in the range of genetic tests available in Brazil and other developing countries. In addition, a number of tests are offered on a research setting and others are obtainable through private genetic services that send samples across national borders for testing.

Objective: To evaluate the appropriateness of incorporating in the healthcare system the genetic tests that are currently offered by health services in Brazil based on their ability to improve health outcomes of affected individuals and families.

Methods: Nineteen molecular genetic tests offered by a national reference research centre were considered as a proxy of the maximum availability of these tests in Brazil. The criteria of clinical utility, epidemiological burden and accessibility were applied to identify test relevance to the private healthcare system.

Results: Out of the 19 tests, seven excluded from the required coverage by private health plans were selected. Four tests for heredodegenerative diseases fulfilled the criteria of clinical utility. Except for the genetic tests for sensorineural hearing loss in children, the tests were intended for rare or ultra-rare diseases. The diffusion of all the tests in the healthcare services was judged as limited.

Conclusion: The performance of all the evaluated tests seemed to be dependent on the capacity of attending physicians to select patients who fulfilled established clinical criteria. The diagnostic pathways necessarily included other conventional tests such as electromyography and biopsy. Most of the genetic tests were still restricted to a research setting in Brazil. Moreover, the access to genetic tests without the simultaneous availability of reference centres, where patients could receive the appropriate medical guidance, could bring more harm than benefit.

O8.6

Evaluating "Immature" Technologies: Grading Uncertainty and Informing the Coverage with Evidence Development Option

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Background: Methods for the timely evaluation of health technologies equipped with an insufficient body of knowledge are still being developed. We propose a method attempting to deal with the scientific uncertainty and the optimistic enthusiasm that accompany immature technologies, developed within a research project on robotic surgery. The objective is to inform adoption's plans capable of combining use in clinical practice with building of further evidence.

Methods/Findings: A 5-step evaluation process was carried out by a multi-disciplinary panel of experts:

1. Definition of relevant clinical outcomes and systematic review of scientific literature,
2. Evidence mapping differentiating research results in steady, plausibly stable, uncertain and unknown results,
3. Definition of the acceptable level of uncertainty for the devolving of resources to research activity,
4. Analysis of local context aimed at identifying high profile professional competence, excellence structures and adequate volumes of activity,
5. List of clinical indications of promising clinical return for which the hosting context can provide adequate infra-structure and professional expertise for knowledge furthering research.

Results of the process consist in distinguishing viable clinically promising use of the technology from excessively hazardous employment. Outputs of the 5-step evaluation process for the da Vinci robot are described.

Conclusion: Taking the scientific literature as a starting point, this method attempts to grade levels of uncertainty in order to map out a research course of action and define the experimental use of an immature health technology. Decision makers wishing to tie coverage policies to the development of scientific evidence could find this method useful for the governance of innovations.

O8.7

Utility of Short Term Register Data in Health Technology Assessment Where the Evidence Base is Poor

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Background: Bridging the gap between introduction of new technologies with poor evidence and their dissemination continues to present a challenge. Registers remain controversial as a method for 'use with evidence development'. In 2003, the UK NICE published guidance on safety and efficacy of minimally invasive pectus bar placement for pectus excavatum (Nuss procedure), recommending submission of all cases to a new Register.

Methods: Completeness of the Register between 2004 and

2007 was assessed by comparison with routinely collected Hospital Episodes Statistics (HES) for England. Safety and efficacy data were compared with the contemporaneously published literature.

Results: Data on 144 patients were spontaneously submitted to the register from 11 units. The only available comparator code from HES data included both Nuss and conventional open procedures, of which 254 were recorded in 27 hospitals. Responses from 12 of the 16 non-submitting hospitals (69%) showed that two had not submitted data (n = 23), 5 were doing open procedures only (n = 30), and 5 were coding errors (n = 10). The literature review found 88 publications since 2003 (mostly case series) with 5,400 patients. Most reported only technical and safety outcomes. Excellent or good cosmetic outcomes were reported in 81% to 100% (94% in the Register). Clinically significant adverse events included bar displacement (2% to 10%, Register 3%), wound infection (1% to 2%, Register 6%) and pleural effusion (1% to 17%, Register 6%). The register exposed no adverse events not reported in the literature.

Conclusion: This study has shown that a new register, with recommended (but not automatic or mandatory) submission can produce useful data to supplement the available literature on both safety and also on patient reported efficacy outcomes. Improvement of routine coding for new procedures is needed in the UK. 'Active surveillance' and validation of register data are important.

O9 – HTA IN CANCER

O9.1

Rehabilitation of Breast Cancer

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Objective: Breast cancer is the leading female cancer world wide, and the chance of surviving initial treatment is high. Breast cancer treatment however, is associated with long-term side-effects. To support programmes for breast cancer rehabilitation we assessed the efficacy of single- or combinations of rehabilitation interventions on physical functionality and psychological well-being.

Methods: Systematic literature searches were performed in 8 databases. Studies were selected according to predefined inclusion criteria established by expert group and HTA methodologists. Included interventions were physiotherapy, physical exercise, psychosocial intervention, nutrition, complementary intervention and complex intervention. Main outcomes assessed were Quality of life, mood, cancer related stress, fatigue, lymphoedema, hot flushes and coping. After critical assessment, moderate or high quality RCTs was included.

Results: From 9,617 hits, we assessed 204 publications in full text and included 46 RCTs. Due to variation in interventions and outcomes, it was impossible to perform meta-analyses. Furthermore, small studies and large standard deviations made interpretation of data from the studies difficult. The overall results showed that both cognitive behaviour therapy (CBT) and physical exercise increased overall QoL (short-term). Physical activity reduced fatigue. There is insufficient evidence to show whether physiotherapy or manual lymph drainage was more beneficial than standard care for lymphedema or shoulder function.

Conclusion: The overall conclusion is that breast cancer patients may benefit from physical activity and CBT may enhance QoL and that physical activity may reduce the burden of fatigue imposed by cancer treatment. Given the large number of women surviving breast cancer treatment, research on physiotherapy, psychoeducation, social and emotional support, nutrition, and complementary interventions should be given priority to support future programmes for rehabilitation following breast cancer treatment.

O9.2

The Application of HTA to the New Oral Oncologic Drugs in Italy: The Case of Lapatinib in Metastatic HER2 Positive Breast Cancer

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Introduction: The application of Health Technology Assessment (HTA) to oncology could represent a way to evaluate innovative drugs like the new target therapy lapatinib, an oral Human Epidermal Growth Factor Receptor 2 (HER2) tyrosine kinase inhibitor used, with capecitabine, for HER2 positive metastatic breast cancer (BC) beyond anthracycline, taxane and trastuzumab treatment.

Methods: Through systematic review, meta-analysis and database research, epidemiological and clinical aspects were analysed, while cost-utility and budget impact analyses were performed to evaluate the economic impact for the National Health Service (NHS). Ethical involvements were assessed with a question scheme drawn from literature while a focus group discussed the organisational implications of oral agents

introduction. An external advisory board was involved in results assessment.

Results: In 2008, the estimated incidence rate of BC was 134/100,000 for Italian women until 84 years, 20% to 30% of new cases were HER2 positive. About 2,200 women progressed after trastuzumab treatment and, currently, continued it off-label with or without other cytotoxic agents: literature data pooling yielded a median time to progression (TTP) of 24.55 weeks. Median TTP of lapatinib/capecitabine was 27.1 weeks. With cost-utility analysis, lapatinib/capecitabine was cost-saving compared to trastuzumab/capecitabine but dominated by capecitabine, while showing an incremental cost of €40,168/QALY versus current treatment. Assuming lapatinib at trastuzumab price, the NHS budget impact of introducing lapatinib (4 cycles of 21 days) would be €1,320/patient. Regarding organisational aspects, patients' quality of life and compliance, as well as the need for restructuring oncology services through a patient centred ambulatory devoted to manage oral oncologic drugs were considered relevant. From the ethical viewpoint, potentially different regional rules could limit a fully ethical use of lapatinib.

Conclusion: HTA allows considering all the aspects of a new drug introduction and provides comprehensive information to decision-makers in order to best allocate resources and plan health services.

O9.3

Safety and Efficacy of Human Papillomavirus Vaccines: A Systematic Review and Meta-Analysis

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Introduction: A persistent infection by human papillomavirus (HPV) is related to cervical cancer. Prophylactic HPV vaccines for cervical cancer prevention are currently available.

Objectives: The aim of this systematic review was to assess safety and efficacy of HPV vaccines.

Methods: We conducted an exhaustive search for all randomised controlled trials (RCTs) in a wide range of electronic databases: Ovid Medline, Ovid Medline in-process and other non-indexed citations, Embase, Cinahl, Pascal Biomed and the Cochrane Central Register of Controlled Trials. We assessed the quality of the included studies and extracted relevant data to conduct a pooled meta-analysis.

Results: Nine out of the 323 screened reports met the criteria to be included: 6 for efficacy and 9 for safety assessment. The meta-analysis of the per-protocol-population data showed that the incidence of any cervical intraepithelial neoplasia (CIN) was lower in the vaccine group than in the control group. Likewise, high-grade CIN was less frequent in the vaccine group. In addition, the incidence of persistent infection at 6 months was also lower in the vaccine group. Modified intention-to-treat and intention-to-treat analyses were also undertaken and the results supported this trend. With regard to the safety analysis, the incidence of local adverse events as well as systemic events was higher in the vaccine group, although most adverse experiences were mild. There was not significant difference in terms of the severe adverse events.

Conclusion: There is evidence from RCTs that there is a decreased incidence of low or high-grade CIN with the HPV vaccine. In addition, there is evidence of higher incidence of adverse events in the HPV vaccine group although most were mild. Data from this meta-analysis will be used for cost-effectiveness analysis.

O9.4

The Role of HTA in Priority Setting in Healthcare: A Case Study of the Introduction of HPV-Vaccination in Norway

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Background: Priority setting has remained high on the policy agenda in Norway for the last three decades. Explicit criteria were not included in legislation until 2001. Priority should be given to interventions according to: 1) Severity of the condition, 2) The magnitude of expected outcomes from the intervention, 3) A reasonable cost-effectiveness ratio. In 2007 the Department of Health established the National Council (NC) responsible for priority setting. In November 2007 the NC was asked to consider whether vaccine against the Human Papillion Virus (HPV) to protect against cervical cancer ought to be included into the national vaccination programme for young girls. Persistent HPV infections (Types 16 and 18) have been found to cause about 70% of all cervical cancers. About 300 cases of cervical cancer are detected yearly in Norway.

Objective: To analyse how Health Technology Assessment (HTA) may provide decision making support for national advisors in complex cases of priority setting.

Method: A case study of the decision-making process of whether or not to introduce HPV-vaccination in Norway was performed. Particular attention was paid to how HTA-documents can underpin evaluations of the priority setting criteria.

Results: HTA-documents on efficacy, cost-effectiveness, ethical aspects and organisational consequences were presented to the Council. The documentation provided the basis for the Council's priority discussions. The council did not explicitly address the question of severity. Regarding the expected outcomes of the intervention, the Council concluded that sufficient evidence existed on the protective effect of HPV

vaccines on cervical cancer. It also emphasised that the costs were high, but not too high to not recommend the vaccine.

Conclusion: The majority of the Council supported the recommendation to introduce HPV-vaccination in the national programme. Based upon the Council's recommendations the Norwegian Parliament decided to fund the vaccination (€6 million) in a school-based programme for 12-year old girls. The programme will start in 2009/2010.

O9.5

Cost-Effectiveness of the THINPREP® System for Population Screening in Australian Women

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Introduction: This research explores the cost-effectiveness of replacing the conventional Papanicolaou (CP) smear with the ThinPrep® System (TPS), a computer-assisted, liquid-based cytology (LBC) method for population screening in Australian women. Currently in Australia routine cervical screening is carried out every 2 years in women without symptoms or history suggestive of cervical pathology. At this time only the CP smear is publically subsidised in Australia.

Methods: A cost-effectiveness analysis using microsimulation was developed to determine the cost-effectiveness of TPS versus the CP smear for population screening in Australia. The structure of the economic model was informed by the recently published National Health and Medical Research Council Guidelines for the Management of Asymptomatic Women with Screen Detected Abnormalities (NHMRC, 2005). Data on the comparative performance of TPS and CP were taken from a comparative cohort study comparing the two testing modalities in 53,000 Australian women. The model was validated against Australian-specific cervical cancer incidence data.

Results: The incremental cost-effectiveness ratio (ICER) for TPS versus CP was approximately $16,700 per additional quality-adjusted life year (QALY). When the screening interval for TPS was extended to 3 years, and was compared to 2 year screening with the CP test, the ICER of TPS decreased to approximately $4,500 per QALY. In this analysis, 3-year TPS screening remained more clinically effective than 2-year screening with CP.

Discussion: Population screening with TPS appears to be a cost-effective alternative to the CP smear when used for population screening in Australian women (at 2- or 3-year screening intervals).

O9.6

Benefit-Cost Analysis of Heavy Ion Medical Accelerator in South Korea

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There is a plan to develop and introduce a heavy ion medical accelerator in South Korea. This study aims to conduct benefit-cost analysis of the heavy ion accelerator from a societal perspective. The accelerator provides medical benefits such as reductions in death of patients with various cancers and reductions in patients going abroad for treatment of cancer. It also produces benefits from related research and development (R&D). Treatment effectiveness of each cancer was obtained from clinical data of Japan and Germany where carbon ion radiation therapy has been conducted. By comparing with each survival rate of conventional radiotherapy or surgery, the number of excess survivals from heavy ion therapy was estimated. The value of life was estimated to be $0.37 million per life saved. R&D benefit was calculated based on a reported social rate of return from R&D. For calculating costs, equipment costs, R&D costs and operating costs were considered. Benefits and costs were evaluated over a 30-year time frame and discounted to their present value using an annual discount rate of 6.5%. The present value of benefit and cost were $578 million and $362 million, respectively, implying $216 million of net benefit. Benefit-cost ratio was 1.596. Sensitivity analysis supported that the heavy ion medical accelerator would be potentially beneficial in South Korea as well.

O10 – MEDICAL DEVICES AND INFORMATION TECHNOLOGY

O10.1

A Case Study of the Implementation of an Oncology Information System in Two Hospitals in Sydney

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This case study examines the processes of introducing an oncology information system to two Radiation Oncology Departments at two hospitals in Sydney, Australia. The aims of the study are to understand how the processes of clinical IT adoption in these two radiation oncology departments have occurred and whether and why the same clinical IT system was used differently in these two departments. Semi-structured interviews were conducted among 12 radiation oncologists, who account for 80% of the consultants in these two radiation oncology departments. The data was transcribed and analysed using NVIVO software. The investigation suggests that the

oncology information system was used in one hospital to a larger extent than the other one. The critical factors accounting to this difference in usage include the differences in leadership, senior management commitment, project management, usage policies, end user ownership and engagement, training and support of end users and environment. Our investigation suggests that the more software functions the clinicians use in supporting care delivery, the more potential functions they are keen to explore. On the contrary, without exposure to any software functions that support clinical need, the clinicians also loose desire in exploring the potential of the software in supporting clinical care. The most critical factors for success are strong leadership, clinician engagement, project management, usage policy and end user support.

O10.2

The Effectiveness of Digital Hearing Aids and Assistive Listening Devices for Adults with Hearing Loss: A Systematic Review of the Literature

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Objective: To summarise and critically appraise evidence on the effectiveness of digital hearing aids and assistive listening devices for adults with hearing loss.

Methods: The study research questions were:

- What is the effectiveness of digital hearing aids for adults with hearing loss?
- What is the effectiveness of assistive listening devices for adults with hearing loss?

We used a systematic method of literature searching, study selection, data extraction and critical appraisal to assess the effectiveness of various styles and types of digital hearing aids. Databases searched were MEDLINE, EMBASE bibliographic databases, the Cochrane Database of Systematic Reviews (CDSR), the Database of Abstracts of Reviews of Effects (DARE), and Health Technology Assessment databases. Searches were limited to English-language material published from January 2000 through February 2008.

Results: Most of the 8 studies included relied on subjective measures to assess satisfaction in using hearing aids, rather than objective measures of hearing ability. For patients with high-frequency hearing loss, open canal fittings were preferable to non-open canal devices. For patients with asymmetric severe-to-profound hearing loss, contralateral routing of signal digital hearing aids may improve satisfaction. The cost effectiveness of digital hearing aids relative to no hearing aids is unclear. The cost-utility result is highly dependent on the magnitude of improved quality of life (utility).

Conclusions: Although hearing aids do not restore hearing to normal, studies in this systematic review indicate that various styles and fittings of digital hearing aids may benefit adult patients with hearing loss. Users gained satisfaction from these devices. This systematic review could not identify relevant evidence to support the routine use of the one-to-one communicator (assistive listening devices).

O10.3

Early HTA to Model Cost-Effectiveness of Future Point-Of-Care Applications

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Introduction: The impact of highly innovative (bio) medical technological applications in healthcare were investigated and quantified. Using AHP and Markov modelling an early assessment was made for emerging point-of-care chips. After identifying potentially attractive product-market combinations, two models [for patients with chronic kidney disease (CKD) and heart failure (HF)] were developed to predict future cost-effectiveness.

Methods: Point-of-care (POC) applications operate using capillary electrophoresis with conductivity detection (CE-CD). Using CE-CD, many other particles can be detected and consequently, many other product-market combinations (PMCs) can be developed. Therefore, a quantitative decision-support model is requested to assess the clinical benefit and costs of introducing a PMC before the actual R&D phase. To first select an attractive PMC from the very wide range of potential PMCs, a roadmap of attractive PMCs was constructed using an elimination method and the Analytical Hierarchy Process (AHP). For estimating future cost-effectiveness, a Markov health state transition model was developed.

Results and Conclusion: The elimination procedure yielded six PMCs to be potentially attractive. AHP identified clinical gain as being the most important criterion to assess the attractiveness of a PMC, followed by the other four criteria (market potential, attitude of professionals, R&D barriers and implementation barriers). Using AHP we decided to focus on a potassium chip for CKD and HF patients.

Subsequently, a Markov model was constructed. Heath state transition probabilities and health state utilities were derived from the literature and additional interviews. Markov model cohort simulation yielded incremental cost-effectiveness ratios (ICERs) of approximately €1,000,000/QALY for CKD patients and €14,000/QALY for HF patients. Considering these results, further analysis of the CKD model was discontinued. A potassium chip for HF patients could be cost-effective and provide a valuable addition to the treatment.

O10.4

Machine Perfusion versus Static Cold Storage in Kidney Transplant

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Static cold storage (CS) is the most widely used organ preservation method for deceased donor kidney grafts. We performed an economic evaluation of the use of hypothermic machine perfusion (MP) versus CS alongside a multi-centre RCT and present the preliminary results of the long-term cost-effectiveness (CE) analysis up to 20 years posttransplant. 336 consecutive kidney pairs were included, one of which was assigned to MP and one to CS. The economic evaluation combined the short term results based on the empirical data from the study with a Markov model with a 20-year time horizon. Patient survival (life years, LYs) and quality adjusted life-years (QALYs) were the clinical outcomes. Direct medical costs of hospital stay, dialysis treatment and complications were included. Data regarding long-term survival (5% annual mortality for functional graft, 15% annual mortality after graft failure) and quality of life (0.66 utility for graft failure), and long-term costs were derived from the literature. Costs and LYs were discounted at 5% and 2%, respectively. Short term results showed that MP reduced the risk of delayed graft function and graft failure in the first year post transplant. The base-case long-term analysis based on the crude odds ratio (OR) in the clinical study resulted in an incremental CE ratio of minus €51,200 ($64,500) per LY gained in favour of MP. The corresponding incremental cost utility (CU) ratio was minus €111,800 ($140,800) per QALY gained. An alternative scenario with the multivariate adjusted OR increased incremental LYs, QALYs, and cost savings by 33%. Further scenarios, including the impact of re-transplantation and multivariate sensitivity analyses will be added. We conclude that MP has a favourable short-term effect on post transplant outcome compared to CS. Preliminary CE results suggest that MP is also superior to CS in the long-term. MP results in more LYs and lower costs than CS. The favourable CE- and CU ratios, suggest that LYs and QALYs can be gained while reducing costs at the same time, when kidneys are preserved by MP instead of CS.

O10.5

Automated Anaesthesia – An Emerging Health Technology: Hope or Hype?

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Background and objective: Automated delivery of anaesthesia is being intensively researched with the hope of improving safety and efficacy of providing anaesthesia in day to day clinical practice. However, as this is (i) cost, (ii) Technology and (iii) Resource intensive, it is pertinent to examine and appraise current knowledge on the subject.

Methodology: A systematic review of randomised trials, quasi-randomised trials and case series examining safety and/or efficacy of automated anaesthesia using closed loop anaesthesia systems, with objective measurement of depth of anaesthesia was undertaken. An exhaustive literature search through PubMed and The Cochrane Library (Cochrane Reviews, DARE, CENTRAL, Technology Assessment), using standard search terms and procedures were undertaken in December 2008. Quality Assessment using the Risk of Bias Tool was performed, with the intention of performing meta-analysis of data.

Results: Nine studies (six RCTs and three case series) comparing automated versus manual delivery were identified in a variety of surgical procedures among adult patients. All but one RCT compared propofol anaesthesia. All but one used bispectral index to measure depth of anaesthesia. All the RCTs demonstrated statistically higher median absolute performance error (MDAPE) with manual control of anaesthesia. Automated anaesthesia resulted in tighter control over depth of anaesthesia as measured by real-time BIS. None of the studies evaluated cost, cost-effectiveness, learning curve characteristics, clinical impact of statistical significance and patient preference.

Conclusion: Currently available data, albeit limited in quantity and quality suggest that automated anaesthesia delivery is safe and efficacious, both appearing to be better than manual anaesthesia. However, other issues have not been explored. The stage is ripe for undertaking formal health technology assessment on this intervention.

O10.6

Supporting Decision-Making When Evidence is Poor: The Use of Class 3b and 4 Lasers and Intense Pulsed Light (IPL) Sources for Cosmetic Purposes in Non-Medical Settings

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Background: Today, the search for beauty can be fulfilled with high-power technologies such as lasers and IPL sources, which are relatively easy to use. In the province of Quebec

(Canada), their use in non-medical settings is widespread and dermatologists raised many concerns about the risks for people undergoing these cosmetic procedures. However, there is a lack of evidence and information about the safe use of these technologies by non-physician operators and without medical supervision.

Objective: To analyse international experience and local context related to the regulation of this practice in order to support the decision-making process for improving its safe use.

Method: Web-based search of the grey literature for legal and regulatory provisions framing the use of lasers and IPL by non-physician in various jurisdictions, interviews of local experts to validate the contextual data and the applicability of recommendations, validation of qualitative data through an inter-judge technique, meeting with key stakeholders to share final recommendations and help them coordinate future actions.

Results: Overall analysis of regulation in other jurisdictions showed that laser and IPL use is a controversial topic characterised by a grey area between what is strictly cosmetic and what comes under the purview of medical practice, and by the divergent positions about authorised activities and their operating conditions. In Quebec, there were neither regulated professions governing this practice in non-medical settings, nor legal provisions or regulations to protect clients' health and safety. A regulatory gap in the required conditions for good practice in terms of training, qualification and audit was identified. Consulted experts were unanimous about the necessity of defining non-medical cosmetic procedures, establishing mandatory training and qualification and informing population about the risks.

Conclusion: In spite of poor scientific evidence, feasible recommendations could be derived, using international information and contextual data, and were well received.

O11 – HTA IN HEPATOLOGY AND GASTRO-ENTEROLOGY

O11.1

Cost-Effectiveness Analysis of Screening Test Plus Treatment of the HBV Positives versus Treatment of Patients with Cirrhosis and HCC After Chronic HBV Infection.

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Background: Individuals infected with HBV can develop the following health states: inactive carrier, or with chronic hepatitis, asymptomatic infection with only serum evidence, acute hepatitis, chronic hepatitis and lethal hepatitis. Nowadays, disease guidelines recommend using vaccine but the screening test among not vaccinated individuals is useful to define people that have clear presence of virus without signs and symptoms of disease. Thanks to the test patients infected with HBV virus who are administered traditional therapy in order to stop chronic HBV infection progressing to cirrhosis, liver failure and hepatocellular carcinoma. These diseases cause the decrease in QoL and are more costly for the health system. We seek to determine whether the test approach plus the treatment of the HBV positive is more cost effective with respect to the no test approach plus treatment of the individuals progressed to cirrhosis or HCC.

Objective: Cost-effectiveness analysis of screening test plus treatment of the HBV positives versus treatment of patients with cirrhosis and HCC after chronic HBV infection.

Design: We created a Markov model to evaluate the cost-effectiveness of two strategies. We created the Markov model following the natural history of disease and considering the antigen HBeAg status. Perspective: Third-party payer. Data source: Medline literature, Italian DRGs, Italian Pharmaceutic Manual 2005. Population: Cohort of 100000 European individuals of 40 years. Time horizon: 40 cycles of 1 year. Half-cycle correction was included. Treatments: Patients positive to test are administered either peg-interferon treatment or lamivudine, adefovir, entacavir (consistently with international guidelines) Patients included on no test arm are administered treatments after cirrhosis symptoms or HCC. Outcome measure: Incremental cost per quality adjusted life year (Qaly) gained.

Results of Base case analysis: Patients who follow test strategy compared with patients of no test approach have an incremental cost of €16,806 per Qaly gained. Results of sensitive analysis: Sensitive analysis points out that the ICER is sensible to the variables of model. Montecarlo simulation points out the sensibility of ICER to every variable of model. We created a cost-effectiveness plan for the results of Montecarlo simulation and defined a cost effectiveness acceptability curve of no test strategy. Limitations: We do not consider health states such as fulminanting hepatitis, acute hepatitis, moreover we supposed a coefficient to consider the reactivation of viral replication. This coefficient is 0.0001% of transitions probabilities. We assumed patients can take every treatment.

Conclusion: Test strategy is cost-effective; the results of this study can be used to advise hospitals to administer anti-hbv test to patients considered at risk.

O11.2

Cost Differences in Liver Transplantation Between the US and Other OECD Countries

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Large cost variations of liver transplantation are reported in literature. The purpose of this study was to analyse cost differences of liver transplantation between the US and other

OECD (Organisation for Economic Cooperation and Development) countries by using the framework of Goeree et al on transferability of economic evaluations. The cost difference was explored by looking at characteristics of the recipient, indication for transplantation, transplant centre experience, methodology used to determine costs, and healthcare system differences.

From 8 databases, 2,000 citations published after 1990 were included. Eventually 30 articles were included with a total of 5,975 liver transplantations. Mean US liver transplantations cost $174,490 compared to $108,934 in other OECD countries. All costs related to the liver transplantation and clinical follow-up were compared.

Recipient characteristics were similar with no difference between adult and pediatric recipients and similar disease severity. Patient indication could not explain the difference in costs since the US had less fulminant liver failure than the other OECD countries, an indication known to have higher costs. Also, transplant centre experience could not explain the difference in costs with similar 1-year patient survival and the vast majority of transplantations being performed in high-volume centres. Even though the preferred methodology to determine costs was different between the US and other OECD countries, the cost difference could not be explained. Only the healthcare system could explain a large part of the cost difference between the US and other OECD countries. By correcting for gross domestic product per capita or purchasing power parities, cost of US and other OECD countries' liver transplantations would be more similar.

By using the framework by Goeree et al, it is concluded that the cost difference in liver transplantation between the US and other OECD countries may be primarily attributed to differences in health systems.

O11.3

Which Proton Pump Inhibitors Provide the Greatest Clinical Benefit?

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Objective: The main action of proton pump inhibitors (PPIs) is marked and long-lasting reduction of gastric acid production. PPIs have largely superseded H2-receptor antagonists, a group of drugs with similar effects but a different mode-of-action. The consumption of PPI's is high in France (19 tablets/patient per year), and increased by 88% between 2000 and 2005.

The French Ministry of Health and National Health Insurance asked HAS to assess the clinical benefit and added value of five PPIs (esomeprazole, lansoprazole, omeprazole, pantoprazole, and rabeprazole) for medical treatment of gastro-duodenal ulcers and gastro-esophageal reflux disease (GORD).

Methods: A systematic review of the efficacy and safety of five PPIs was performed (*Databases*: Medline, Cochrane Library, National Guideline Clearinghouse, HTA Database, Pascal, pharmaceutical company reports; **selected documents**: HTA reports, guidelines, and well-designed randomised controlled trials on the indications of the marketing authorisation; **search period**: from 2007 (date of last French Healthcare Product Safety Agency (AFSSAPS) guidelines) to December 2008. The systematic review was submitted to gastroenterologists for discussion and reviewed by the HAS Committees.

Results: No PPI was superior to any other in the symptomatic treatment of GORD, long-term treatment of reflux oesophagitis, eradication of Helicobacter pylori, peptic ulcer disease, long-term treatment of duodenal ulcers, treatment of gastroduodenal lesions caused by non-steroidal inflammatory drugs (NSAIDs), prevention of gastroduodenal lesions in high-risk patients taking NSAIDs, and Zollinger-Ellison syndrome.

Esomeprazole (40 mg) was slightly more effective than omeprazole (20 mg) on healing rate in the short-term treatment of erosive reflux oesophagitis in a subgroup of patients, but the clinical significance of this observation is unclear.

There was no difference among the PPIs with regard to the overall incidence of adverse events.

Conclusion: The clinical benefit afforded by these five PPIs is high. However, there is no difference in the clinical benefit or added value that they provide. These conclusions were the subject of a leaflet distributed to the medical community in order to promote the proper prescription and use of PPIs.

O11.4

Mini HTA: Enhancement of Detection of Colorectal Polyps and Dysplasia Using Endoscopic Tri-Modal Imaging (ETMI)

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Introduction: Early detection and removal of colonic polyps through endoscopic examination is currently the "gold standard" for reduction of colorectal cancer risk. However, conventional colonoscopy has a number of limitations including missing polyps (with this risk as high as 30%) and difficulty in detection of flat dysplastic lesions. Technology Endoscopic Tri-Modal Imaging (ETMI) combines high-resolution white light endoscopy (HR-WLE), auto-fluorescence imaging (AFI) and narrow-band imaging (NBI) and has been proposed as being superior in identifying minute alternations in mucosal patterns compared to conventional colonoscopy alone.

Methodology:

Population – Normal and high risk patients for colorectal polyps and dysplasia Intervention – ETMI
Comparators – White-light endoscopy (WLE)
Outcomes – Diagnostic yields, detection rate
A systematic literature review was performed using PubMed,

NHS Centre for Reviews and Dissemination and National Guidelines Clearinghouse databases as well as the Cochrane database of systematic review.

Results: One meta-analysis, three randomised controlled trials (RCTs), seven primary studies and two case series were found. Only one RCT directly compared ETMI with WLE. No clinical practice guidelines and economic analysis were found. Meta-analysis showed that NBI was accurate with high diagnostic precision for diagnosis of neoplasia, area under curve was 0.96 (standard error 0.02) and relative diagnostic odds ratio was 7.78 (95% CI: 2.01 to 30.05, $P = 0.009$) using NBI compared to WLE alone. Overall, sensitivity and specificity were 94% and 83%. RCTs examining NBI and AFI individually suggest that both improve diagnosis of malignancy and pre-malignant lesions. Neoplasia miss-rate for AFI and WLE were 0% and 50% ($P = 0.036$). Most studies appeared to support NBI and AFI having higher efficacy of detection rate of colorectal polyps and dysplasia compared to WLE.

Conclusion: ETMI technology appears superior to WLE in detecting early stage lesions in colorectal mucosa. However, more studies are needed to evaluate its cost-effectiveness.

O11.5

Sentinel Lymph Node Navigation Surgery in Early Gastric Cancer

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Objective: The first possible sites of metastases along the route of lymphatic drainage from the primary lesion are known as sentinel lymph nodes (SLN). Our purpose is to assess the effectiveness and safety of procedures in treating patients with early gastric cancer by using SLN navigation surgery.

Methods: MEDLINE, EMBASE, The Cochrane Library, CancerLit, CINAHL, CiNii, Koreamed, and Kmbase were searched from 1990 to 2007. In the study design, up to case series of which patients received SLN biopsy or SLN navigation surgery were included. Two reviewers screened all references independently, and the article's quality and extracted data were included for assessment. Descriptive analysis and meta-analysis were conducted.

Results: A total of 21 studies were included. Adverse effects were not reported in included studies. SLN detection rate was greater than 90% and skip metastasis ranged from 0% to 24% in 19 articles. Sensitivity ranged from 50% to 100% compared to haematoxylin and eosin as reference test, and specificity was 100% for SLN biopsy. Pooled diagnostic odds ratio was 340.50 (95% CI: 161.26 to 718.98) and homogeneous between studies ($X^2 = 9.42$, d.f = 18, p = 0.949). Diagnostic accuracy of SLN identification by sentinel node navigation surgery was high. However, false negative was also high with a rate of 0% to 50%.

Conclusion: We conclude that the data are insufficient to determine whether SLN navigation surgery will reduce surgery for early gastric cancer by its various sensitivities. Further research is needed to validate the SN concept at the micrometastasis level.

O11.6

Transient Elastography for Diagnosis of Liver Fibrosis: A Systematic Review and Meta-Analysis

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Background: Transient elastography (TE) is a new non-invasive diagnostic technology that uses low frequency vibration and ultrasound to measure liver fibrosis. Until now, biopsy was the only method to quantify liver fibrosis. Patients with a fibrosis stage of F $\geq$2, according to the METAVIR scale, would receive medical treatment.

Objective: To study the effectiveness and safety of TE in the diagnosis of liver fibrosis.

Method: Systematic review and meta-analysis. All studies published before March 2008 were reviewed. Selected studies included patients with liver pathology who received TE to quantify liver fibrosis and biopsy as the gold standard method to confirm the diagnosis. QUADAS was used to assess methodological quality. Evidence tables were generated from each study. Diagnostic parameters, with their 95% confidence interval, were extracted. 2x2 contingency tables were estimated. The F $\geq$2 stage was chosen for the analyses. Threshold effect was examined by plotting sensitivity (Se) and 1-specificity (1-Sp) of each study in the ROC plane, and calculating the Spearman correlation coefficient.

Heterogeneity was assessed using forest plots and the Cochrane Q test and I2 index. Summary receiver operating characteristic (SROC) curves were fitted, and pooled indexes were calculated using a random effects model. Meta-regression and subgroup analyses were made to explore heterogeneity.

Results: From 70 potentially relevant studies, 26 case-series were selected. The quality of studies was high. Eighteen studies with data for a fibrosis stage F $\geq$2 were analysed. There was no threshold effect (correlation coefficient of 0.161). A great heterogeneity ($P < 0.001$) was found. After excluding three outliers, pooled Sp was 0.85 (0.82 to 0.97), pooled positive likelihood ratio, 4.7 (3.87 to 5.77) and pooled diagnostic odds ratio, 20.36 (14.37 to 28.84). The area under the SROC curve was 0.89 and Q* point was 0.83. Adverse effects were not reported.

Conclusion: TE is an effective and safe technology to diagnose liver fibrosis and could replace liver biopsy.

O12 – HTA IN CARDIOVASCULAR DISEASES

O12.1

Are Lipid-Lowering Drugs Really Equivalent? A Bayesian Analysis

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Background: As of January 1st 2009, Dutch GPs and clinicians are expected to preferentially prescribe low-cost statins in patients with dislipidaemia. This policy, based on presumed equivalence of drugs, has been fiercely criticised, since it fails to take into account differences between various subgroups of patients.

Objective: To estimate the probability that the hypothesis, that lipid-lowering drugs are, in fact, equivalent, is true for the subgroup of patients with familial heterozygous hypercholesterolaemia. Methods A Bayesian analysis was performed. Empirical priors were elicited from GPs, cardiologists and internists, using questionnaires. Likelihood estimates were based on a meta-analysis of available evidence. Posterior probability estimates were calculated for three different end-points: the probability of a specified reduction of plasma LDL-C, the probability of patients achieving the LDL-C target level, the probability of patients sustaining a cardiovascular event in case of inadequate lipid control.

Results: Thirty-six out of 101 clinicians (36%) completed the questionnaires. Mean posterior estimate of LDL-C reduction was 37.0% (±10.3) and 45.4% (±10.6) with simvastatin and atorvastatin, respectively. Mean posterior estimates of the probability of patients achieving target levels were 0.07 and 0.26 with simvastatin and atorvastatin, respectively. Respondents estimated the probability of inadequate lipid control (as defined in our study) not having a relevant clinical impact at 0.41. No posterior probability could be calculated for this end-point because of the lack of empirical evidence.

Interpretation: In patients with familial heterozygous hypercholesterolaemia, the probability that atorvastatin is *not* superior to simvastatin, is estimated at 0.3. This would suggest that, for this particular subgroup of patients, the two drugs are *not* equivalent. It should be noted, however, that this conclusion is based on the surrogate end-point of lipid control. More robust conclusions regarding (in) equivalence of these drugs awaits evidence on clinical end-points.

O12.2

Prescribing High Dose Lipid-Lowering Therapy to Individuals with ACS: Is this a Cost-Effective Strategy

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Background: Meta-analyses have shown that intensive statin therapy reduces cardiovascular events compared with standard therapy when prescribed immediately after an acute coronary syndrome (ACS). In the UK, many patients with ACS currently receive sub-optimal treatment. We explore the cost-effectiveness of atorvastatin 80mg/d, and rosuvastatin 40mg/d compared with simvastatin 40mg/d in individuals who have experienced a recent ACS event.

Methods: Effectiveness data was obtained using Bayesian mixed treatment comparison (MTC) methods involving 28 RCTs and a published relationship linking changes in LDL-c and relative risk of vascular event. A state-transition Markov model was used to quantify the costs and benefits of the treatment regimens using baseline transitions from UK RCTs or registries.

Results: The MTC demonstrated a clear dose response in terms of reductions in LDL-c with rosuvastatin 40mg/d achieving the greatest percentage reduction (56%) from baseline, followed by atorvastatin 80mg/d (52%), and simvastatin 40mg/d (37%). Using a threshold of £20k per QALY, if it is assumed that the benefits and adherence rates observed in the clinical trials are generalisable to a clinical setting, or if it is assumed that individuals who do not tolerate the higher dose statins are prescribed simvastatin 40mg/d, then atorvastatin 80mg/d and rosuvastatin 40mg/d would both be considered cost-effective compared to simvastatin 40mg/d. While our results show rosuvastatin is currently the optimal treatment for individuals with a recent history of ACS, this is based on the assumption that the additional reductions in LDL-c will produce corresponding reductions in cardiovascular events. If the cost of atorvastatin decreases in line with those observed for simvastatin when the patent ends in 2011, atorvastatin 80mg/d will be the most cost-effective treatment for all thresholds. If the cost reduces to 25% of the current value, atorvastatin 80mg/d will be the most cost effective treatment for thresholds between £5,000 and £30,000 per QALY.

O12.3

Does Unrecorded Cardiovascular Disease Prevalence Increase with Increasing Deprivation?

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Introduction: This research has arisen from a national study to assess variation in the use of statins in the context of cardiovascular (CVD) disease prevalence.We commissioned the generation of national prevalence estimates of CVD. The prevalence estimates were generated synthetically using national health survey data (Health Survey for England). Estimates were weighted for ethnicity, deprivation, age, sex and smoking status. Prevalence estimates were generated for Primary Care Trusts and for all 8,300 general practices in England.

Method: We compared synthetically derived estimates of

CVD (expected) with recorded prevalence data (observed) obtained from the Quality and Outcomes Framework national prevalence data. A CVD observed prevalence was obtained by applying proportional component disease prevalence data obtained from the lipid modification costing model derived by the National Institute for Health and Clinical Excellence (NICE). Using both data sets we calculated the level of 'unrecorded' prevalence at both practice and at PCT level. Negative binomial regression was used to assess how unrecorded prevalence varies with increasing deprivation. The measure of deprivation used was index of multiple deprivation (IMD).

Results: Our results suggest that unrecorded prevalence (i.e. the difference between observed and expected as defined above) does not appear to increase as deprivation increases.

Conclusion: These results are good news for public health and suggest that the primary care system in England is effective in detecting cardiovascular disease even in areas where the inverse care law may be expected to exert a greater influence.

O12.4

Cost-Effectiveness of Add-On Early Stress Myocardial Perfusion Imaging for Asian Patients Presenting to the Emergency Department with Chest Pain but Non-Diagnostic Electrocardiography – The Acute Chest Pain Treatment and Evaluation Study (ACTION)

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Objective: Existing triage strategy is suboptimal in risk stratifying Asian patients with chest pain. Hence, we aim to determine the cost-effectiveness of an add-on stress myocardial perfusion imaging (MPI) in improving risk stratification in a single-centre randomised controlled trial involving Asian patients with chest pain and non-diagnostic ECG presenting to an emergency department (ED) in Singapore.

Methods: Consenting patients were randomly assigned to with or without MPI add-on. Patients who developed ST segment changes, elevated CKMB/ Troponin during the 6 hour observation were admitted without receiving the assigned interventions. 1-year cost-effectiveness of the two strategies (MPI vs. no MPI) was analysed from the institution's perspective. Inpatient costs were obtained from electronic database. Outpatient costs were estimated with expert input. Effectiveness was measured as percent patients accurately risk stratified at 1 year (i.e. high/medium risk patients experiencing a cardiac event and low risk patients not experiencing any cardiac event within 1 year). The incremental cost-effectiveness ratio (ICER) and confidence intervals (CI) were constructed by bootstrap analysis (percentile approach). Sensitivity analysis was conducted for outpatient costs.

Results: Cost data were available from 1,418 patients (83.9% of randomised patients). The ICER of MPI vs. no MPI was -$6334 (-$13,474 to -$40). 97.6% of bootstrapped replicates fell below the $0 per accurate risk stratification level, indicating that the scan strategy dominated the no scan strategy. All bootstrap replicates fell in the north- and south-east quadrants on the cost-effectiveness plane, confirming that the negative ICER was due only to negative cost differences. Coefficient of variation (CV) of the effect difference is 0.19. Small bias to standard error ratio (0.013) justifies not making bias correction in estimating CI. Results were insensitive to outpatient costs.

Conclusion: Add-on MPI is cost-effective in risk stratifying patients with chest pain. Given the small CV, bootstrap estimates are likely to be robust.

O12.5

Can We Trust Patient-Reported Outcomes in Health Technology Assessments? A Systematic Review of the Efficacy and Safety of Transmyocardial and Percutaneouslaser Revascularisation for Refractory Angina Pectoris

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Background: As interventions for angina pectoris, percutaneous laser revascularisation (PMR) and transmyocardial laser revascularisation (TMLR) create shallow channels in the myocardium which are thought to encourage revascularisation. Both procedures are practised worldwide although the mechanisms of effect are poorly understood and debated.

Methods: A systematic review of safety and efficacy of each intervention was undertaken at the School of Health and Related Research in the UK. This review informed UK National Institute for Health and Clinical Excellence (NICE) patient safety guidance. Randomised controlled trials were reviewed for effectiveness and non-randomised studies identified adverse events as a result of either intervention.

Results: From the 155 publications retrieved from the initial search, 29 studies were included in the review (16 RCTs and 8 observational studies). The review has shown that for those outcomes where there is an objective measure of heart function, ie myocardial perfusion and left ventricular ejection fraction no effect is seen with treatment. Where measures become more subjective, such as exercise tolerance tests, angina score, and quality of life more of the trials see a statistically significant effect. This effect is, however, lost or much reduced where patients are blinded.

Conclusion: A major contribution of this work is the identification of no treatment effect for objective measures for

both interventions. However, perhaps due to lack of blinding and poor methodological rigour, patient reported outcomes used widely in this type of research appear to be significant. Placebo effect may distort the actual effect of interventions since trial patients have severe angina symptoms and had exhausted all forms of conventional therapy. As a result, they may be more likely to overestimate and over report on health-related quality of life measures. Patient-reported outcomes can only be trusted when blinding has taken place, but for some studies blinding is not feasible.

O12.6

Appropriateness Explicit Criteria for Carotid Revascularisation

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Background: Carotid stenosis has a prevalence of 0.5 to 10% and is a risk factor for ischaemic stroke. In addition to pharmacological therapy, carotid revascularisation can prevent ischaemic strokes in some patients. Selection of these patients should be based on individualised assessment of risks-benefits. Evidence from randomised controlled trials is often insufficient to do this. The RAND/UCLA appropriateness methodology complements this evidence with expert judgement to develop detailed appropriateness criteria.

Objective: To develop appropriateness criteria for carotid endarterectomy and endovascular treatment.

Methods: RAND/UCLA Appropriateness Method was applied: 1) Systematic review about safety and effectiveness of carotid revascularisation procedures, 2) Elaboration of clinical scenarios, from variables relevant to the decision of carotid revascularisation, 3) A multi-disciplinary panel of experts assessed the appropriateness of the interventions in each clinical scenario following the Delphi modified method, and 4) Each scenario was classified as appropriate, uncertain or inappropriate, taken into account the median score and the level of disagreement among experts. Influence of variables on the final appropriateness score was assessed by multiple linear regression. Results were summarised by classification and regression tree analysis.

Results: Among variables considered for influencing the indication of revascularisation (symptoms, stenosis degree, age, gender, life expectancy, comorbidities and surgical complexity), stenosis degree and life expectancy best explained the panel scoring.

Of the 480 scenarios for carotid endarterectomy, 4% were appropriate, 19% uncertain and 77% inappropriate. For endovascular treatment, 5% were appropriate, 15% uncertain and 80% inappropriate. Disagreement was present in no more than 5% of the scenarios.

Misclassification of decision trees was 7% in endarterectomy and 4% in endovascular treatment.

Conclusion: Appropriateness criteria can be used in health services research and clinical practice guidelines development. They provide useful information for decision making for the indication of carotid revascularisation (endarterectomy, endovascular treatment). However, their application to individual patients should be made cautiously and they must never replace medical judgment.

O13 – STAKEHOLDER INVOLVEMENT

O13.1

EUnetHTA Strategy for and Initiatives with Stakeholder Involvement

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Objectives: The objectives of EUnetHTA were to produce practical tools to be used for preparing health technology assessments (HTA), adapting existing HTA reports into new settings, informing on emerging technologies, for providing information on timely access to promising health technologies, for capacity and institution building and to improve the Policy-HTA links. Work was organised with EUnetHTA partners in 8 Work Packages. Developing stakeholder involvement was a specific objective.

Methods: EUnetHTA recognised the interest of stakeholders in its work. Stakeholders were identified to be a number of social and interest groups with legitimate and major interests in the innovative work and practical tools developed in EUnetHTA. Criteria for inclusion and a number of stakeholders were identified and several tools and initiatives in practical terms were used to provide stakeholders with opportunities to impact on work. A EUnetHTA stakeholder policy was developed and communicated to stakeholders.

Results: Results of the policy for stakeholder involvement were an Open Stakeholder Forum on the EUnetHTA website, a Discussion Topic Catalogue. A meeting with stakeholders took place with presentations on EUnetHTA experience and ambitions and of stakeholders' interests and critical questions. The results of these activities provided input to a strategy for involvement of stakeholders in future EUnetHTA Collaboration.

Discussion and Conclusion: The presentation will discuss which dilemmas, risks and opportunities the involvement of stakeholders were faced with and brought into EUnetHTA's work. Special emphasis will be on describing the involvement of industry and what impact this had on structural challenges that EUnetHTA Collaboration may face when balancing the

needs of stakeholders for involvement and at the same time maintaining transparency and objectivity in work.

O13.2

How Should HTA Agencies Use Stakeholders? An Example from the United States

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The US Agency for Healthcare Quality and Research (AHRQ) generates and communicates unbiased evidence on healthcare interventions to decision-makers through its congressionally mandated Effective Healthcare Programme (EHC). The EHC has established an external Stakeholder Panel of 18 individuals to support extramural programmes and to provide strategic input and guidance to the EHC. The focus of this workshop/ panel is to discuss the EHC's experience using this broadly representative stakeholder group. The Stakeholder Panel represents participants in the US healthcare system, including pharmaceutical and device manufacturers, patients, practicing physicians, health plans, pharmacy benefit management plans, and medical directors of Medicaid, an insurance provider of the very poor. The role of the Stakeholder Group is to: 1. Provide input on critical research information gaps for practice and policy and on identifying and developing key research questions, 2. Provide input on implementation issues for EHC Programme reports and findings, 3. Define information needs and identify types of products that will be most useful, 4. Provide feedback from report users, 5. Provide guidance on the programme as a whole for quality improvement, and, 6. Provide guidance on how the programme can have more of an impact with users. Involving the insight of a diverse group of stakeholders in a comparative research/health technology assessment programme has provided an on-going mechanism for identifying priorities for both methodology perspectives and processes and has enabled the EHC programme to remain relevant, timely, and transparent by being user driven. This model of a stakeholder driven technology assessment programme may be especially relevant to countries in the formative stages of creating a HTA agency or programme. The EHC Director and a current member of the stakeholder group will share their perspectives on how the group has worked and provide examples of issues that the group has addressed.

O13.3

The Role of the Pharmaceutical Industry in HTA in the Asia-Pacific Region

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Health technology assessment is receiving increasing interest from governments as a tool of health policy, especially in the Asian region, and there has been much dialogue within and between governments, academia, health experts and the like about HTA systems, how they should work and what is required to make them function in an efficient and transparent way. However, to date there has been much less engagement from government with the pharmaceutical industry in the development stages of HTA systems in the region. This is problematic, given that the pharmaceutical industry is a key sector affected by the introduction of HTA and a legitimate stakeholder. This presentation will discuss some of the issues that pharmaceutical industries have experienced with the development of HTA systems and the issues that government and industry need to discuss where a country has decided to introduce HTA. The presentation will argue that in cases where a government has decided to develop an HTA system, engaging the pharmaceutical industry early, constructively and meaningfully in the development of such systems leads to a better HTA system. The presentation will suggest some of the particular structural, policy and methodological issues that industry identifies in HTA systems, and will present lessons from Australia and other countries in the region about industry engagement in the development of the HTA system.

O13.4

Improving Decision-Makers' Response to Guidance that an Interventional Procedure is 'Safe and Efficacious'

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Objectives: The Interventional Procedures Programme (IPP) hosted at the National Institute for Health and Clinical Excellence (NICE), issues guidance on the safety and efficacy of new interventional procedures. When choices need to be made as to whether procedures should be routinely available in the health services, decision-makers need to make a judgement about the benefits of the new procedure, as well as its appropriateness, effectiveness and cost-effectiveness, and these are not considered directly by the IPP. This study was designed to investigate the nature of evidence (explanatory or pragmatic) underpinning the guidance and to assess the ability to extrapolate effectiveness outcomes that are more relevant to health services and people affected, such as serious morbidity and quality of life.

Methods: Procedures evaluated by the IPP made up the sampling frame. Data in NICE overviews were re-categorised as explanatory (can it work?) or pragmatic evidence (does it work?) A system was developed to score procedures according to the type and adequacy of the evidence. Descriptive and quantitative analyses were carried out.

Results: A total of 198 procedures were evaluated by the IPP between July 23rd, 2003 and February 24th, 2007 of which 88 were eligible. Preliminary results suggest that evidence on

patient-based outcomes is less abundant but available for some procedures. Moreover, the types and balance of evidence available varies considerably between procedures for which the same category of guidance had been issued.

Conclusion: Decision-makers should look beyond safety and efficacy when guidance is issued, as the evidence available may be broader. Types and patterns of evidence supporting guidance, and the relationship between the types of evidence of benefit and safety and the category of guidance issued is used to develop a more useful approach for guiding policy-makers.

O14 – HTA IN NON-COMMUNICABLE DISEASES

O14.1

A Systematic Review of Psychological Interventions for Pathological Gambling

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Objective: Pathological gambling is a prevalent impulse control disorder that significantly disrupts a patient's functioning in personal, familiar, or social spheres. Our aim was to review available scientific evidence on the efficacy/effectiveness of different psychological interventions for pathological gambling as a basis for clinical practice guideline (CPG) recommendations.

Methods: Systematic review of the literature. Inclusion criteria: 1) CPG, systematic reviews and primary studies, 2) Psychological interventions for pathological gambling in adolescents and adults, 3) Main outcomes: abstinence and controlled gambling. Comprehensive search strategy included: NGClearinghouse, UK NELH, NZ Guidelines Group, TRIPDatabase, G-I-N International Guidelines Library, GuiaSalud, Medline, PsycINFO, Cochrane Library, CMA-Infobase, ISI Web of Knowledge, Scopus, IME, ISOC to May 2008, reference lists of selected publications, specialised websites and contact with experts. Study selection, data extraction and quality-assessment by standardised tools were done in duplicate, discrepancies resolved by discussion. Evidence classification was based on SIGN system.

Results: Of 361 identified publications, 124 were eligible and screened for inclusion. No evidence-based CPG was found. One systematic review, one meta-analysis (2005) and 21 primary studies (randomised controlled trials, controlled studies and case series) met the inclusion criteria. Specific psychological interventions found were: cognitive, behavioural, cognitive-behavioural, brief interventions and self-help therapies. Findings showed that cognitive-behavioural therapies can be effective on short and mid-term. Still, the majority of the studies contained methodological flaws (small sample size, heterogeneous samples of gamblers, indirect outcome measures, lack of standardised treatments, absence of baseline data, or big number of lost to follow-up) that limited firm scientific knowledge about gambling treatment.

Conclusion: The scientific evidence on the efficacy/effectiveness of psychological therapy for pathological gambling is of variable quality and still insufficient to support strong recomendations. There is a need of further investigation based on established methodological criteria and standardization of treatment management in the clinical practice.

O14.2

Vitamin D Supplementation to Prevent Fracture in Older People Living in Residential Care

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Purpose: The purpose of this project was to review the effectiveness and safety of vitamin D supplementation to prevent fractures especially hip fractures in older people, and to provide information to develop an injury prevention programme aiming to reduce injuries in residential care facilities in New Zealand.

Methods: Search strategy including hand searching was developed to search for randomised studies in different databases and other sources. Forty two randomised controlled trials (RCTs) were found, among them thirty three RCTs were included in a systematic review and meta-analysis. Epidemiological analysis on fracture incidence and related cost was also performed to quantify the disease burden at a national level. The dose-response relationship between 25-hydroxyvitamin D [25(OH)D] and hip fracture was also analysed.

Results: Vitamin D > = 700 IU/day with calcium showed statistically significant protective effect on hip fracture [7 studies, 10,552 participants, OR (fixed effect model) 0.79, 95% CI: 0.66 to 0.95]. No statistically significant effect was found for vitamin D supplementation <700IU/day with or without calcium. Vitamin D supplementation with calcium appeared to have statistically significant protective effect on the older people who lived in institutional care facilities [Two studies, 3,853 participants, OR (fixed effect model) 0.73, 95% CI: 0.58 to 0.90]. The dose-response relationship analysis also indicates that a 25(OH) D level of 80 nmol/L or higher may be needed to prevent hip fracture.

Conclusion: There is evidence to support the use of vitamin D doses > = 700 IU/day with calcium to prevent hip and non-vertebral fractures. There is no evidence to support the use of low doses of vitamin D (<700 IU/day) and the use of vitamin D alone (without calcium) to prevent the fractures. 25-hydroxyvitamin D needs to be measured before and monitored during the intervention. An injury prevention programme of vitamin D supplementation for the residential care facilities in New Zealand has been developed.

O14.3

Cost-Utility of Insulin Aspart Compared with Recombinant Human Insulin in Treatment of Type 1 Diabetes Mellitus in Poland

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Objectives: To evaluate cost-utility of insulin aspart (IAsp) compared with recombinant human insulin (RHI) in Type 1 diabetes mellitus.

Methods: A cost-utility analysis based on The CORE Diabetes Model was conducted, resulting in estimation of total direct costs incurred by the National Health Fund, life years gained (LYG) and quality-adjusted life expectancy (QALY). The CORE Diabetes Model is a complex tool allowing for evaluation of long-term health and economic outcomes of different treatment options in diabetes mellitus. It is designed as a Markov model using Monte Carlo simulations and based on a series of interconnected sub-models representing diabetes complications. Cohort baseline characteristics and baseline distribution between states in the model were derived from published literature. Differences with respect to treatment results (IAsp vs RHI) were defined as change in HbA1c level and hypoglycemia rates calculated on the base of a systematic review of RCTs. Default settings were used regarding transition probabilities and utilities of health states. Assumed time horizon in the model was 50 years. In order to estimate the probability of IAsp being cost effective in Polish settings (threshold about 91 000 PLN), bootstrap simulations were performed.

Results: Both treatments were comparable in terms of LYG (11.40 for IAsp and 11.37 for RHI), but IAsp yielded higher QALY (5.41 vs. 4.91 for RHI). Costs generated by IAsp were 76 125 PLN and 78 765 PLN for RHI in the horizon of the analysis. Incremental costs for IAsp compared with RHI were -81 936 PLN per LYG and -5 317 PLN per QALY. The probability of IAsp cost effectiveness over RHI was 60% for LYG and 100% for QALY.

Conclusion: IAsp is the dominating option, generating higher utility outcomes and lower costs in long-time horizon.

O14.4

Health Economics Evaluation on Percutaneous Coronary Intervention (PCI) in China

S LIU, X XIONG
China

Objectives: In China, increasing CHD patients accept PCI treatment, with about 40% GR annually from 1984 to 2005, however, some have alleged that it was abused. Further, the China Basic Medical Insurance (BMI) Authority also felt financial pressure due to escalating use. Therefore, the China Health Insurance Research Association (CHIRA) decided to evaluate the value of coronary stenting as the evidence for appropriate regulation.

Study Design: This observational, prospective study involved 20 sites (13 cities). 630 of 720 planned cases were recruited from July 2005 to July 2006 with 1 year follow-up. The study evaluated clinical and economic value of stenting by collecting clinical, cost and QoL data. Retrospective data collected included reimbursement policy and actual claim data in 2005 and first half of 2006, to estimate the economic burden and budget impact and to analyse the cost-influence factors.

Results: 1) There was generally no evident abuse in PCI/ stenting in the available data, 2) The effectiveness of PCI/ stenting is favourable, with 1.43% complication, 0.98% death, 0.82% incidence of MI, and 1.79% of revascularisation. All SEs are significantly lower than those published. The QoL scores improved significantly (+20, SF-36), 3) Stenting can gain $7,100 per incremental QALY, 4) PCI fees are influenced considerably by the number of diseased vessels, co-morbidity, and reimbursement policy, 5) The price of PCI is lower than its cost, and thus it's mainly reimbursed by pharmaceutical and device use, 6) The economic burden of PCI was heavy in 2006. The out-of-pocket part of PCI was equal to an employee's average annual salary or twice that of a retiree's pension.

Conclusion: Stenting is cost effective with favourable QoL improvement. Therefore, it's worthwhile to further improve reimbursement regulations to release a patients' economic burden.

Limitation: Insufficient comparison data relative to BMS.

O15 – HTA IN CARE OF THE ELDERLY

O15.1

Frailty Predictors in the Elderly

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Introduction: The population's ageing is a complex problem. Nowadays there are important knowledge gaps on the group called 'frailty elderly people' who could be delivered primary prevention in order to avoid age-related deterioration. There is agreement neither on the definition of 'frailty', nor on diagnostic tools, predictors or strategies to manage the elderly frail. We carried out a systematic review of literature in order to extract frailty predictors from which consensus can be looked among experts through the Delphi methodology.

Objective: To define the frailty concept and to develop diagnostic criteria and management strategies.

Method: A systematic review had been conducted on the databases: MEDLINE, CINAHL, PsycINFO, EMBASE and COCHRANE LIBRARY up to December 2007, and sources

such as: INAHTA, Blue Cross and Blue Shield Association-TEC, ICES, NICE and Spanish scientific societies. The quality had been assessed using CASPe score.

Delphi methodology was applied, sending two rounds by mail. Experts from different specialties were involved: internist, geriatrist, family physician and nurses. The predictors from the review were asked about their prediction capacity (YES or NO), and then they were ranked using a 1 to 9 scale (1 was inappropiate and 9 was fully appropriate).

Results and Conclusion: The most frequent concept used in the literature were those proposed by Fried (2001) and Rockwood (1994). Consensus was reached (100%) in the following predictors: falls, cognitive deterioration, limitations to daily, basic activities, psychological problems, presion ulcers, mobility disorders, and visual/hearing deficit.

Moderate agreement was reached (<100% to 70%) in: incontinence, nutritional state, age, socio-demographical data, and limitation to daily, instrumental activities.

The worst frailty predictors were: poly-medication, bad health self-rate, clinical parameters, marital status and gender.

There are differences depending on professional specialty in clinical practice where frailty is identified by internists as deterioration risk and by the remaining specialists as vital risk.

O15.2

A Cost-Effectiveness Analysis of Vitamin D and Calcium Therapy to Reduce Falls and Fall-Related Injuries in Community-Dwelling Elderly Women in Ontario – Results from the Falls/Fractures Economic Model in Ontario Residents (FEMOR) Aged 65 Years and Over

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Objective: To assess the incremental cost-effectiveness of vitamin D + calcium therapy vs. no intervention in reducing falls and fall-related injuries in community-dwelling female seniors from the Ontario Ministry of Health perspective.

Methods: A Markov model represented the recurrent nature of fall-related health states. States reflected how community-dwelling seniors transit between healthcare settings once they experience a fall. After a patient experienced a clinically important fall, they were admitted to the hospital or visited an emergency department. Hospital admissions were permitted for hip fractures, other fractures and non-fracture injuries. Following hospital care, patients were either discharged to the community, a rehabilitation centre or long-term care (LTC) facility or remained in the hospital for palliative care. Patients could die at any point in time. Costs and outcomes were discounted 5% annually within a lifetime horizon. Outcomes measured were: number of falls avoided, life years, total cost, LTC and hospital costs. Costs were reported in CAD$ 2008. Vitamin D + calcium therapy efficacy was estimated from a meta-analysis of randomised controlled trials.

Results: Vitamin D + calcium therapy produced dominant results. The potential lifetime cost avoided per patient to the public system was $174.55 LTC dollars and $22.80 hospital dollars for elderly women vs. no intervention. Results were robust to univariate sensitivity analysis. The lifetime savings from vitamin D + calcium in female Ontario residents aged ≥65 was 70.8M.

Conclusion: A combination of vitamin D + calcium supplementation in elderly women is cost-effective in reducing falls and fall-related injuries in Ontario's elderly female population.

O15.3

The Efficacy of Coenzyme Q10 on Parkinson's Disease: A Systematic Review

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Background: Mitochondrial dysfunction has been implicated in the pathophysiology of certain neurodegenerative disorders such as Parkinson's disease and Progressive Supranuclear Palsy (PSP) whereby coenzyme Q10 is also found to be reduced. A few studies have shown efficacy of coenzyme Q10 in slowing the progression of disease, however conflicting evidence exist. This study aims to determine effects of coenzyme Q10 on clinical outcomes in this population.

Methods: Systematic searching was performed through multiple computerised databases such as PUBMED, EMBASE, Cochrane CENTRAL, CINAHL, AMED and PsyInfo. Only randomised, placebo controlled clinical studies were included. All articles were reviewed independently by two investigators. Outcomes measure was the total Unified Parkinson's Disease Rating Scale (Total UPDRS). When sufficient data were available, the weighted mean difference (WMD) and 95% confidence interval were calculated comparing the outcomes in coenzyme Q10 and control groups. The meta-analysis was performed using the DerSimonian and Laird method under a random-effects model.

Results: Five studies met inclusion criteria. Coenzyme Q10 supplementations were different in several aspects including dose, frequency of administration and formulation. Patients were also varied in terms of disease severity and concomitant medications. Effects of coenzyme Q10, both low dose (1000 mg) were assessed in two time frames, short-term (<3 months) and long-term (>12 months). For short-term outcome, the WMD of total UPDRS was not statistically significant for both low dose (-0.18, 95% CI: -1.30 to 0.94) and high dose regimens (0.20, 95% CI: -2.80 to 3.20). For long-term assessment, only

high dose supplementation was reported. The WMD of total UPDRS was not statistically significant for low dose (-1.68, 95% CI: -8.02 to 4.66).

Conclusion: These results demonstrate that coenzyme Q10 has no clear benefit in patients with neurodegenerative disorders such as Parkinson's disease and Progressive Supranuclear Palsy (PSP).

O16 – SURGICAL TECHNOLOGIES

O16.1

Cost-Utility of Bariatric Surgery in the Treatment for Severe Obesity in Finland

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Introduction: The number of bariatric surgical operations is low in Finland, but the demand is increasing rapidly. About 400 bariatric operations were carried out in Finland in 2008 while the corresponding figure in Sweden was 3,000.

Objectives: To evaluate the cost-utility of bariatric surgery (gastric bypass, sleeve gastrectomy and gastric banding) versus conservative treatment.

Methods: Analysis was done from healthcare providers' perspective using a Markov cycle tree and a time horizon of 10 years. Events during the first year, including mortality and primary complications resulting in reoperation, were modelled in a decision tree. Then the patient cohort moves into a stage transition model including four states: alive (no reoperation or abdominoplasty), reoperation, abdominoplasty, and death. The parameter values were taken from a large representative population survey measuring quality of life (QoL) and health service use, registers or literature, and if necessary, expert opinions were used. Different types of sensitivity analysis, including probabilistic sensitivity analysis were conducted.

Results: In CUA bariatric surgery dominated the conservative treatment. The mean cost was €30,298 and €41,785 and the mean number of QALYs 8.841 and 8.252 for bariatric and conservative treatment, respectively. Surgery remained a dominating strategy after excluding gastric banding. Comparing only gastric banding with conservative treatment resulted in an ICER of €2,970.

Discussion: The model takes into account all the major events and the uncertainty around the parameter values is tested comprehensively in sensitivity analysis. Strengths of the model include the actual cost data on bariatric surgery and inclusion of abdominoplasty, which seems to be neglected in previous analyses. Also, a unique set of data on mean healthcare costs and QoL for both alternatives was available. The time horizon is rather short and may underestimate the effectiveness of bariatric surgery, but it is based on available survival data.

O16.2

Appropriateness Criteria for Vertebral Arthrodesis: Thoracolumbar, Lumbar and Lumbosacral Spine

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Spain

Objective: To develop appropriateness criteria for thoracolumbar, lumbar and lumbosacral vertebral arthrodesis' indications in degenerative spinal pathologies.

Methodology: Systematic review of literature by searching on the main databases. Inclusion criteria: 1. Randomised clinical trials or prospective studies with comparison group and 1-year-minimum follow-up, 2. Adult patients with degenerative stenosis, spondylolisthesis, or discopathy in toracolumbar, lumbar and lumbosacral area, 3. No prior surgery. The studies should compare arthrodesis versus alternative therapies/ decompression alone, and 4. Outcomes: disability and pain measures, quality of life, reoperation's incidence, and adverse effects from surgery.

Relevant variables were selected from the systematic review, and different scenarios were designed to assess arthrodesis' appropriateness. Modified-Delphy method was applied. 9-experts-panel scored the degree of appropriate criteria for every indication from 1 (very inappropriate) to 9 (fully appropriate). The indications were scored twice. According to the scores' median by the panelists and their agreement degree, every indication was classified as appropriate, uncertain or inappropriate.

Results and Conclusion: Included studies had low or moderate internal validity. There is no evidence on the benefits of arthrodesis in degenerative stenosis or discopathies. In discopathies the assessed alternative treatments presented benefits unlike spine fusion except for the non-intensive and unstructured conservative treatment. There is weak evidence backing spine fusion versus decompression alone in degenerative spondylolisthesis, although it is based on low quality studies.

Of 864 assessed indications, there were scored: 44 (5.09%) as disagreement, 381 (44.1%) as agreement, and 439 (50.8%) as uncertain. There were considered: a total amount of 101 indications (11.7%) as appropriate, 309 (35.8%) as uncertain, and 454 (52.5%) as inappropriate.

Appropriate use standards for spine arthrodesis were developed and they may be applied to patients with degenerative stenosis, spondylolisthesis and discopathies. The standards would be employed prospectively as help in decision-making in order to foster the appropriate use of arthrodesis.

O16.3

Investigating the Belief that Contact Between Consultant Teams Could Influence the Clustering of Relatively Novel Surgical Procedures: A Cross-Sectional Survey Using Hospital Statistics Data

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Objective: To investigate the hypothesis that contact between individual clinicians influences variations in the uptake of surgical innovations recommended or supported by the UK's National Institute for Health and Clinical Excellence (NICE).

Methods: Records relating to two relatively newly recommended procedures – breast conserving surgery and laparoscopic hernia repair – were extracted from the Hospital Episodes Statistics (HES) system for England for the financial year 2006/07. The rates of usage of these techniques by different consultant teams were calculated during subsequent data processing. To measure how much clinician networking might influence the use of these techniques, network "connections" were imputed between consultant teams if the system recorded them as working together at one or more site. Beta co-efficient values from linear regression analysis were used to assess the impact of personal contacts on the usage of each procedure.

Results: A significant predictor of procedure use by teams was the average level of use by the "colleague teams" they worked alongside. The association between colleague teams was moderately strong but highly significant [b = 0.22 for breast conserving surgery (P <.001), and b = 0.24 for laparoscopic hernia repair (P <.001)]. These results were calculated in the context of regressions that attempted to control for consultant workload characteristics, and also any local variation in patient demographics, patient clinical characteristics, and local health service provision.

Conclusion: Guidance from NICE and similar HTA organisations can set standards, but dissemination of new techniques is likely to be influenced by other factors. Contact between individual clinicians has been suggested as a potent factor, and our analysis supports this mechanism, based on national analysis.

O16.4

Robotics Applied to Surgical Techniques: Effectiveness of Da Vinci Surgical System® on General Surgery and Gynaecologic Indications

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Introduction and Objective: Robotic surgery is an emerging technology for minimally invasive surgery. Da Vinci Surgical System® is the most extended platform. The surgeon performs the operation from a console next to the patient, guided by stereoscopic vision and moving the instruments using joysticks. Our objective was to assess effectiveness of Da Vinci Surgical System®.

Methods: A systematic review was conducted. EMBASE, MEDLINE and CINAHL were searched for primary studies. Controlled studies of surgical procedures assisted with Da Vinci Surgical System® were included. Outcomes were extracted from studies and pooled on meta-analysis when possible.

Results: We selected 52 articles (61 comparisons), including 7 randomised clinical trials. The most frequent indications in general surgery (total 45) were fundoplication (11), cholecystectomy (5), gastric bypass (5), colorectal resection (5), nephrectomy (5), live-donor nephrectomy (3), Heller myotomy (3) and gastrectomy (2). For gynaecologic surgery (total 16) the most frequently reported procedures were hysterectomy with endometrial cancer staging (6), radical hysterectomy (5) and tubal anastomosis (2). We found that robotically-assisted Heller myotomy was associated with lower oesophageal perforation risk. In addition, robotically-assisted hysterectomy for cervical cancer and benign disease showed less bleeding and shorter hospital stay. Hysterectomy with endometrial cancer staging or tubal anastomosis seems to contribute advantages opposite to open surgery. In contrast, on fundoplication, cholecystectomy, gastric bypass, gastric banding, gastrectomy, rectopexy, splenectomy, pancreatic resection and tubal ligation advantages may exist in laparoscopic or open compared to robotics technique. For the rest of studied indications no clear advantage was found with any technique.

Conclusion: Only patients undergoing Heller myotomy and those submitted to hysterectomy for either benign or malignant disease seem to benefit from the use of the Da Vinci system. These results must be interpreted with caution since there are not many randomised clinical trials and the studies did not include long-term outcomes such as survival rate.

O17 – ORGANISATION OF HTA IN EUROPE

O17.1

Adaptation of HTA Reports from Different Contexts: Identification of the Need for a Toolkit to Aid the Process

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Objectives: There are numerous Health Technology Assessment (HTA) agencies across Europe, each producing their own HTA reports. Reports on the same HTA are often required by a number of agencies around the same time. The preparation of these reports is both time consuming and costly, if HTA reports prepared for different contexts could be adapted, this could reduce the need for multiple reports on the same health technology with resultant saving of time, and resource. The aims of this study were to examine and understand the process of adaptation, to investigate whether the adaptation of HTA reports could be useful to agencies across Europe, and how this might be achieved in practice.

Methods: The methods employed were (in chronological order): a review of the literature, a survey of 28 European HTA partners, one round of a Delphi survey, a face to face meeting of 21 EUnetHTA representatives and a second round of the Delphi survey.

Results: Descriptions of previous examples of adaptation in the literature are sparse. The majority of respondents had previous experience of adapting reports and all felt that adaptation was useful. There was strong support for the development of an adaptation toolkit.

Conclusion: Consensus of opinion from 28 European organisations/networks has indicated that the adaptation of HTA reports would be desirable and beneficial, and that there is a need for the development of a toolkit to aid in the adaptation of HTA reports, in order to maximise resources and save costs.

O17.2

Internal Evaluation of EUnetHTA Project 2006 to 2008 (European Network for Health Technology Assessment) - Structure of Evaluation and Overall Results

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Objective: To present the method of carrying out the internal evaluation and the overall achievement of the EUnetHTA project being conducted from 2006 to 2008. An internal evaluation was a prerequisite by the EU Commission.

Methods: The prospective plan was made at the start of the project period in 2006. At closure of the project 64 organisations were included. The work was organised into eight Work Packages (WP), and the internal evaluation was a separate WP. Data was collected by three yearly participant surveys. WP leaders were contacted for five biannual interviews. Relevant documents produced during the project were an additional source of information.

Results: The overall experiences from the network were analysed according to specified criteria in view of the general aim of the project of establishing an effective and sustainable network:

1. Production of deliverables in a timely manner,
2. Effective working collaboration among WPs,
3. Degree of participation within WPs,
4. Effective communication,
5. Sustained commitment to the project,
6. User and stakeholder satisfaction with new routines and practice,
7. Perceived added value.

In general, the evaluation showed that the deliverables including new tools were produced as planned but some were being delayed. Collaboration between WPs was challenging due to the large number of partners involved. Participation within the WPs varied. Different means of communication were used. The new tools need to be tested in real life situations and evaluated. The participants believed in EUnetHTA having an added value for the organisations and the increased use of HTA as a working method.

Conclusion: The results were overall positive with an expressed wish for an effective and a sustainable EUnetHTA collaboration. Nine recommendations were formulated for the establishment of the future network.

O17.3

Internal Evaluation of the EUnetHTA Project 2006 to 2008 (European Network for Health Technology Assessment). Results of the Participant Surveys

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Objective: To internally evaluate the EUnetHTA project's goal of establishing an effective and sustainable network for

Health Technology Assessment (HTA) through telephone interviews with Work Package leaders, a documentary analysis of the key project documents, and surveys of the project participants. This paper focuses on the survey methods and results.

Methods: A questionnaire was e-mailed annually to project participants: 193 questionnaires in 2006, 181 in 2007, and 243 in 2008. The questionnaire consisted of 51 queries of the individuals' experiences in the project's work groups, their general views of the project, an evaluation of EUnetHTA's strengths, weaknesses, opportunities and threats, and their vision of the network's future. The annual surveys were analysed as independent samples, producing data on the project's evolution.

Results: Questionnaires were returned by 45 participants (response rate of 23%) in 2006, 41 (23%) in 2007, and 63 (26%) in 2008. These response rates are infra-estimated because some responses represented groups of participants. The majority of participants (61.9%, 63.4%, 72.6%, respectively) believed that using HTA as a working method was beneficial on a national level. Confidence that EUnetHTA will not override decisions by national HTA organisations increased during the project (72.1%, 97.6%, 96.8%, respectively). A primary concern of participants was economic resources, consistently throughout the project period (15.4%, 20%, 21.4%, respectively). Other concerns included the large number of participants in each working group, the heavy participant workload, and language barriers. Despite these issues, commitment to the project was sustained, and participants expressed a strong and increasing belief that the network will improve the quality of HTA reports.

Conclusion: There was a positive attitude towards the establishment of an effective and sustainable European network for HTA. The participant surveys have been useful to provide regular feedback during the project and to detect new challenges for the future network.

O17.4

Ranking of Expensive Drugs Based on Cost-Utility Ratios Prior to Coverage Decision-Making on Therapeutic Programmes of the National Health Fund in Poland

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Therapeutic programmes in Poland have been lunched by the National Health Fund (NHF) for very costly drugs, to be used in a small numbered populations (number of patients lower than 7,000 in the 40 million Polish population). From 2003 to 2006 about 180 new submissions for coverage were received by NHF. To the majority of these submissions the HTA reports had been required and attached. The NHF goal was to develop and apply transparent procedures compliant with the Transparency Directive of EU to deal with the submissions and HTA reports in coverage decision-making. The decree no 17/2007 of the President of NHF and the code of procedures of the Drug Policy Department regulated the process. The HTA reports gave direct cost-utility ratios or indicated measures to be translated to such. Validity of HTA reports was checked due to the HTA guidelines issued by the HTA Agency in Poland. After cataloguing submissions and evaluation of quality of HTA reports, drugs were divided in 4 categories: with potential to cut costs of NHF in a given condition, increasing total costs of NHF but with good quality HTAs, with HTAs but with missing piece of information and rejected due to lack of proper information. The drugs had been ranked due to cost-utility ratios in the two first areas mentioned. Not only cost-utility ratios were taken into account in ranking but also grades of uncertainty around the cost and utility estimates, orphan status and other factors of minor impact. That was the first experience when transparent and rational rules based on HTA were applied in coverage decision-making process in Poland.

P1 – ORGANISATION OF HTA SYSTEMS AND COUNTRY EXPERIENCES

P1.1

Competitive Bindings on Health Technology Assessment

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Objective: To describe the priority setting process for themes to competitive bindings as well as the employment method for resources destined to health technology assessment (HTA).

Method:

(1) The Department of Science and Technology (DECIT) of the Ministry of Health (MH) organised a "Health Research Priorities Workshop" in order to identify priority themes which could be carried out with the mechanisms and the resources at disposal. The themes were set according to the five priority criteria established by DECIT: epidemiologic relevance, services/policies relevance, state of the art, operational feasibility and social demand.

(2) A 2 million reais budget (around $870,000) from MH was destined to Competitive Bindings so as to foster studies.

Results: DECIT, together with the specialized areas of the Ministry of Health and ad hoc consultants, identified 11 themes to encompass the competitive binding. The judgement committee granted merit to 40 projects. 28 out of 40 were ranked as top priority and 12 were ranked as high priority. Due to the limited budget, 12 projects were sponsored, reaching 1.9 million reais ($825,000).

Conclusion: This is the second experience of the MH regarding a competitive binding to sponsor HTA projects. There has been a substantial improvement in quality of the presented projects in relation to the prior binding. To that extent, a considerable number of high level projects could not be sponsored due to the lack of resources. A repressed demand was created, which encompassed 16 top priority projects, reckoning 1.1 million reais ($475,000), and 12 high priority projects, reckoning 1.4 million reais (over $600,000). Thus, based on the last two experiences, we believe competitive binding is not the best way to financially support this kind of research.

P1.2

Inclusion of Innovative Non-Medicinal Technologies into the Benefit Catalogue of Solidary Healthcare Insurances

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Background: Many countries have introduced procedures to regulate the inclusion of innovative non-medicinal technologies into the benefit catalogue of solidary healthcare insurances.

Objectives: This report describes the procedures for the adoption of innovative non-medicinal technologies by solidary healthcare insurances in Germany, England, Australia and Switzerland.

Methods: A systematic literature research, a broad hand search and a written survey were carried out.

Results: All countries in this report require that some innovative non-medicinal technologies undergo evaluation by a central governing body. Similarities do exist, such as the size and composition of the governing bodies or the overreaching criteria according to which institutions must make their recommendations but a large number of non-medicinal technologies make it into the medical care system via other decision-making processes. Often, these innovations are not evaluated and differ from region to region.

Conclusion: There is no uniform international standard in how to regulate innovative technologies. Many innovative technologies are applied across the board without evaluation from the central governing bodies. Decentralised decision-making bodies can decide whether or not to introduce a particular technology in a particular area. This leads to regional differences in all the countries. In principle, the starting point for improving regulations of innovative non-medicinal technologies lies in the extension of transparency, the shortening of decision-making time (especially the central decision-making processes), the further development of evaluation methods, more flexibility and increased capacity in the governing bodies' decision-making processes and also, if needed, in the creation of a single authority to act as a contact person for people who are interested in introducing an innovation into the benefit catalogue.

P1.3

Outline of the Researches Accomplished by the Research Centres of the Brazilian National Clinic Research Net at University Hospitals (RNPC) from 2005 to 2007

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Objectives: To outline the initialised research by the centres of the RNPC from 2005 to 2007.

Methods: In 2008 the Department of Science and Technology (Decit) from the Ministry of Health of Brazil accomplished an inquiry to establish the centre's situation and information about the researches achieved in the RNPC. A questionnaire was sent to 19 centres regarding their structure and the researches accomplished. The variables considered were: title and type of research, starting date, partnerships, budget and

financing source.

Results: Sixteen institutions responded. In total, 1,604 research began during this period. Considering the type of research, the clinical research corresponds to 868 cases. In 2007, an amount of 596 research were started, meaning a 20% increase when compared to the year of 2006. In 26.9 % of the cases the partnership occurred with other universities. The financial resource addressed to the researches was about $15 million coming from different sources. More than half of the researches, or 852, did not have its value declared. The name of the financial source was not provided in 38.7% of the cases, those institutions received $800,000. Decit was responsible for $2.5 million. However, there is also data that 120 research are financed by the Brazilian Public Health System and the MH. The private sector is responsible for financing $3.8 million.

Conclusion: An increase in the number of research accomplished during the analysed period was observed. However, considering that this period corresponds to the implementation of the RNPC it will be necessary for a broader analysis to evaluate the impact of the Net. The absence of some data did not contribute to a complete analysis. That reinforces the idea to establish a monitoring and evaluation system to measure the results of the Net.

P1.4

Brazil's Unified Health System Qualification: High Pattern Hospitals Partnership

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Objective: Describe the first submission of proposals from High Pattern Hospitals (Hospitais de Excelência - HE) according to Ministry of Health's (MH) Act n°3.276/GM from December 28th, 2007, which disposes about the Philanthropic non-Profit Organisations Certificate. Thus, the HE get social tax exemption to develop MH approved projects as a compensation equivalent to the triennial amount foregone. That Act creates a partnership between MH and the HE, aiming Brazil's Unified Health System institutional development by projects on technology assessment and incorporation, professional training, public interest research (PIR) and health services management development.

Method: Study case of Ministry of Health data.

Results: The Secretariat of Science, Technology and Strategic Inputs (SCTIE), by its Department of Science and Technology (DECIT), analysed 25 projects from six High Pattern Hospitals. Twenty-three out of 25 were approved totalling R$32,639,417.19 (corresponding around US$16 million). Among these projects, it should be noted those related to training programmes in clinical trials and evidence-based medicine. In addition, Systematic Review Centres were created, in which studies according to MH demands will be carried on. Another positive aspect is related to medical technology development, such as the artificial heart and implantable blood pump, creating an innovation perspective to the funding application.

Conclusion: During the last years, MH has accomplished many actions aiming at public management qualification. The Health Technologies Assessment (HTA) usage has been identified as a strategic action for this purpose. Therefore, by including HTA and PIR areas, the Act has much to contribute to health management improvement, since it undertakes High Pattern Hospitals expertise into Brazil's Unified Health System institutional development.

P1.5

Brazilian Net in Health Technology Assessment: Bases to Consolidate HTA in Brazil

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Objectives: To describe the construction of the Brazilian Net of Health Technology Assessment (REBRATS). The structure of HTA in Brazil is recent. It involves a conjunction of academic and research institutions with postgraduate courses in this area and policy makers of the Brazilian Public Health System.

Methodology: Construction of a base document discussed in the first meeting of the Net creation with 55 participants and also by sending the document to the stakeholders for their opinion in a 2 month deadline. The working process of INAHTA and EunetHTA contributed to the construction of REBRATS base document.

Results: 30% (19/55) of the participants of the meeting contributed with suggestions for the REBRATS and 7% (4/57) sent written contributions. The consensus relevant points were: a) Aim: to broaden the capacity to produce knowledge, to make possible to dispose technical and scientific information, that are important in the decision making process, b) Strategic vision: quality and excellence in the connection between research politics and management to subside the decision process considering the incorporation fazes, monitoring and abandoning technologies in the Public Health System context; c) Scope: organising system, where its members considering a common objective - to promote and disseminate HTA in Brazil - have convergent and specific functions working in a dialogued way, d) Operating the Net: divided in five working groups coordinated by members of the Net. The groups correspond to the key areas of the Net: priority setting and financing studies in the HTA field, development and methodological evaluation in HTA, professional training and continued education, horizon scanning and dissemination/information.

Recommendation: To complete the aim to create a platform

of knowledge management, it is necessary to have a mechanism of continuous evaluation and to establish national and international partnerships to promote de sustainability of the Net.

P1.6

Brazilian Health Technology Assessment Network (REBRATS): Implementation Strategies

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Introduction: REBRATS aims to produce and to disseminate priority research and studies in the HTA field, to standardise methodologies, to validate the studies quality and to train human resources. It also includes horizon scanning and a new educational vision toward HTA. All of those factors facilitate the incorporation or removal of technologies or the decision to maintain the existing ones in the Brazilian Public Health System. The network is composed of government, educational and research institutions as well as actors from different society sectors.

Methods: To facilitate the Network's construction and implementation, five permanent working groups (WG) were created according to the affinity of the proposed themes. Each group chose, by common sense, a coordinator who was responsible to stimulate the discussion of the objectives, activities and results expected in each theme.

Results: The WG created were: (1) Priority and development of studies in HTA, (2) Methodological, development and evaluation in HTA, (3) Professional training and continuous education, (4) Horizon scanning, and finally (5) Information and dissemination. The short-term activities accomplished in the second semester of 2008 were:

- Guidelines to elaborate mini-HTA reviewed, Partnership with the Brazilian Sentinel's Hospital in order to train human resources in Evidence Based in Public Health using the distance course tool.
- Proposal to organise book and articles about the research accomplished by current students who are finishing the professional Master in Health Technology Management.
- Assemble groups and nets who work with monitoring technologies.
- Create form to request studies in HTA, available in the REBRATS site.

Conclusion: The REBRATS is based on the exchange of information, political and institutional articulation for the implementation of a common project - to promote and disseminate HTA in Brazil, as well as strengthen the collaboration between international institutions who traditionally work in this field.

P1.7

HTA in Developing Countries: A Special Issue of the International Journal of Technology Assessment in Healthcare

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Background: It has long been recognised that HTA is relevant for both developed and developing countries. For example, in 1995, a special issue of the International Journal of Technology Assessment in Healthcare (IJTAHC) included a selection of 40 articles that had been published on HTA in developing countries in the period 1988 to 1994.

Objective: To illustrate the actual and potential role of HTA in developing countries by means of a second special issue of the IJTAHC, covering a selection of articles on HTA in developing countries published in the period 1994 to 2008.

Methods: Based on title and abstract, all issues of the IJTAHC in the period covered were screened for relevant articles. In addition, the sponsor of the special issue, WHO, asked us to include examples of articles discussing educational programmes in HTA in developed countries (in addition to those in developing countries), articles from developed countries that demonstrate the potential of HTA to inform policy making, and articles on primary care and integrated care that demonstrate the potential of HTA at the health systems level. The selection of articles was prepared and discussed by the authors and agreed with by the sponsor.

Results: 35 articles on HTA in developing countries were selected (all but a few of the articles identified), ordered and presented in seven categories. Articles in two added categories were produced in developed countries. The total number of articles included is 47. Two introductory articles precede this collection, one introduces the field of HTA and the other summarises the articles in each category.

Conclusion and Discussion: The ISTAHC journal has published a number of articles relevant to HTA in developing countries. We hope that the special issue will contribute to increased attention of the international HTA Community to the issues presented in this volume.

Terms for indexing: health technology assessment, developing countries, health policy

P1.8

A Decade to the Updating Process of the National List of Health Services in Israel

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Background: There is a perpetual imbalance in healthcare systems – demands are infinite and resources limited. Exponential development of emerging technologies and the policy of supplying them within the framework of public funding, raise the need for wise decision-making. Values also play a paramount role, therefore, priority-setting becomes a necessity to ration skillfully.

Since 1999, Israel has implemented a structured mechanism of annual updating of the National List of Health Services (NLHS = "Basket") on the basis of the National Health Insurance Law (1998). Broad perspectives are incorporated in the process embracing clinical, economic, ethical, legal and social aspects. Decisions are made by the National Basket Committee including physicians, insurers, clergy, ethicist and representatives of the public.

The Process - Stages in Priority Setting: This complex decision-making requires consistent, thorough, systematic evaluation through several stages.

Stage 1 – Basic regulatory approval by the Ministry of Health authorities, based on safety and efficacy criteria for drugs and devices.

Stage 2 – Internal prioritisation process focusing on effectiveness, consulting relevant professional National Councils (i.e. for Oncology, Cardiology, Gynaecology etc.)

Stage 3 – "Technology Forum" determining technology benefits (life-saving, prolongation of life, quality of life) to establish policy decisions ad-hoc.

Stage 4 – Auxiliary committee with a professional subcommittee focusing on pricing.

Stage 5 – National "Basket" Committee, a supreme authority, extensively discusses and analyses data gathered in prior stages. By consensus decision, the Committee prepares a final recommended list of technologies for public funding. The list is presented to be approved by the statutory Supreme Health Council.

Stage 6 – Government approval of this final list presented for authorisation within annual budgetary limits.

Conclusion: Reviewing the past decade reveals a structured mechanism enabling a variety of issues for debate such as orphan drugs, preventive medications, quality of life and social values. This dynamic process results in a comprehensive national publicly-funded healthcare basket.

P1.9

Queensland Establishing a HTA Process from Scratch: Achievements and Difficulties.

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Queensland is the fastest growing and the third largest populated state in Australia, with an estimated 4 million people spread over a land mass roughly equivalent to that of Indonesia. As citizens continue to flock to Queensland, it can no longer ignore the demand for world class health technologies. In the absence of a statewide health technology assessment (HTA) process, funding applications for new technology in Queensland follow the traditional business case process. Where current funding arrangements cannot incorporate new, high-cost technologies or clinical practices, direct applications are made in an ad hoc manner to the state health system. Using modern health systems' guiding principles of effectiveness, equity and efficiency, this current process is not ideal to optimally serve the population. Queensland is now developing a new state-wide HTA process drawing on the experiences of other Australian states and international jurisdictions' work to date. The aim is also to make better use of the expertise of clinicians on the national Medical Services Advisory Committee (MSAC). To date, this body of expertise has been largely under-utilised, with information shared only through a underdeveloped clinical network system and individual hospitals. Persuading bureaucrats and clinicians that the surveillance of technology by field evaluation is a necessity, and additional funding is warranted to implement the technology has been the easy part. Securing the funding and finding a workable process for the state and individual districts requires a comprehensive communication strategy and developing relationships statewide, nationwide and internationally. Queensland intends in the future to not only have a proficient HTA process, but to help steer Australia to hold a global position of expertise in successful HTA. Its close proximity to Asia also puts Australia in an ideal position to support developing countries in the future with health technology assessment.

P1.10

Budget Impact Analysis in the Statutory Health Insurance System of Germany

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Background: Like many other nations, Germany struggles with increasing expenditures in the healthcare sector. The most recent laws passed by Germany's parliament (Bundestag) aim to reduce expenses and increase efficiency. In this context the Institute for Quality and Efficiency in Healthcare (IQWiG) can

soon be commissioned with cost-benefit assessments of interventions. Thereby, information about the projected impact on expenses of the largest budget holder in Germany, the Statutory Health Insurances, can be of additional value for decision makers. The principle and application of budget impact analysis in the German context are described in detail.

Methods: Budget impact analysis from the perspective of the statutory health insurances in Germany means that the direct financial consequences of a decision by a committee to reimburse a certain treatment in the healthcare system at a certain price are estimated for the expenses of a particular statutory health insurance or for the statutory healthcare system in total. Thereby these analyses can support the decision making process regarding the setting of ceiling prices for interventions or the limitation of reimbursement to a certain group of patients. Based on information about incidence and prevalence, size of the target group, anticipated market shifts and the costs of applying the innovation, budget impact analysis allows, by modelling, the projection of the longer-term financial effects in the context of various scenarios.

Discussion: Budget impact analyses in complement to cost-benefit assessments can contribute to a more transparent decision-making process and provide support to sustainable decision-making policies in the German healthcare system.

P1.11

HTA: Development and Institutions in Germany

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The idea of Health Technology Assessment (HTA) was born in the USA. It reached Europe in the eighties. After other European countries, like Spain, Sweden, the Netherlands and so on, Germany was "infected" in the middle of the nineties. In 1994 the Office of Technology Assessment at the German parliament did the first steps in research and technology assessment. Then in 1995, the German Federal Ministry of Health formed a project to evaluate the usefulness of HTA for Germany and how it could be implemented. The project was done by the University Medical School of Hannover. Methodological standards of the HTA process were developed, adapted to the German healthcare system and tested in some pilot HTA projects. The next important step took place in 2000. The German agency of HTA at DIMDI (DAHTA@DIMDI) was established. It still manages the German HTA programme including the development of standards of practice following international standards. In 2004, the main supporting institute of the Federal Joint Commitee (G-BA) was founded: the Institute for Quality and Efficiency in Healthcare (IQWiG). The IQWiG gives recommendations on the basis of evidence based medicine studies to the G-BA as decision maker. Preferentially HTA provides information to the decision maker in healthcare - politics and the G-BA, but also to the statutory health insurance organisations, for the ambulatory, hospital, dental and nursing care providers as well as to the public, to industry and others. The main involved actors in HTA today in Germany are DAHTA@DIMDI and IQWiG. Both institutions complement each other in tasks and goals, cooperate in some points, have few similarities but basically have different target groups, focus and methods in the proceeding of HTA. Moreover, the National Association of Statutory Health Insurance, private institutions, and others, are active in the field of HTA, too.

P1.12

Current Situation of Health Technology

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The Government of Mongolia has implemented the National Health Technology Programme from 2003 to 2008. The main purpose of the Programme was to improve quality of health services through selecting and introducing cost effective and accessible technologies at each level of care in the health promotion, protection, diagnosis, treatment, rehabilitation and health information fields.

In order to assess the current health technology situation in Mongolia, we have conducted a survey, "Health technology assessment", involving 64 health facilities of four aimags, three districts covering 900 medical professionals and 900 clients.

The survey result generally concludes that even though there are some progress in the development of health technology in Mongolia, health technology reform is slow resulting from number of factors, namely, inadequate financial resource, health professional's ability, availability and selection of equipment.

Diagnosis and treatment technology has been developing in the specialised hospitals of Ulaanbaatar city. However, most of the equipment are deteriorated and out of date which negatively affects the improvement of diagnostic and treatment technologies.

There is a lack of appropriate standards at each level of care for preventive, health promotion, diagnostic and rehabilitative services especially in almost non-modern technologies in the early detection of diseases. Annually, 13.6% of health professionals attend the postgraduate continuing education trainings, even though health technology related trainings have not been conducted due to reasons such as heavy workload, training fee, information inaccessibility and lack of managerial support.

Based on this survey we recommend:

- To reform health sector financial system and implement appropriate policy

- To develop essential health technology package for each level of care
- To improve capacity of human resource through conducting trainings and sending teams in oversees trainings in high technology countries.
- Build a policy support to institutionalise essential health technology introduction through selecting and implementing appropriate high modern technologies in the health sector.

P1.13

An Assessment of the Utilisation of High Technology in Health Facilities: Implications for the Healthcare Providers and Decision Makers in Saudi Arabia

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The Kingdom of Saudi Arabia (through the Ministry of Health) has imported the high technology for its health facilities in order to improve the quality of health services provided to patients in Saudi Arabia. This provision of technology - with no doubt - will promote the quality and the effectiveness of health provided to the Saudi population.

This study is still in progress and aims to assess the current perceptions of both decision makers and healthcare providers about the current situation of health technology utilisation at the various health facilities (Hospitals and Primary Healthcare Centres). Moreover, the study aims to determine whether the technology resources currently available in these facilities are appropriately used and sufficient for the care of the patients in Saudi Arabia.

To satisfy the research objectives, the authors propose to use both qualitative (depth-interview) and survey data collection from a convenience sample of healthcare providers and decision makers from all parts of health regions in the Kingdom.

We expect our findings to benefit 1) Patients in terms of providing them with necessary healthcare though the availability and the use of the necessary technology, 2) Healthcare providers in terms of ensuring the appropriate utilisation of high technology available in the health facilities and 3) Ministry of Health and other health agencies in terms of providing them with recent and appropriate information about the actual needs of health technology and measures to assure proper use of technological resources and information that are necessary to achieve the objectives of the Saudi Healthcare System.

P1.14

Handbook on Health Technology Assessment Capacity Building

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Objective: The goal of Work Package 8 of the EUnetHTA (European Network for HTA) Project (2006 to 2008) was to promote HTA in EU Member States with limited institutionalisation of HTA. Among other activities, a handbook on HTA capacity building was developed to assist in the process of creating HTA Agencies and to support their sustainability. The presentation provides an overview of the main contents and recommendations of the handbook.

Methods: International survey of HTA agencies, organisation of workshops to collect HTA expert opinion on the issue of capacity building and a literature search.

Results: The basis for the task of establishing effective HTA programmes that guide key policy decisions is a solid commitment from politicians and key decision makers in the health system to integrate HTA findings and/or recommendations into this process. Further, a regulatory framework, an appropriate organisational structure and an efficient institutional setup for HTA need to be identified. Collaboration either nationally or internationally also plays an important role as a way of creating a platform for information exchange on HTA, ensuring multidisciplinary of HTA, and establishing some kind of formal links with health policy. Success depends also on the quality and relevance of the HTA reports and an efficient information dissemination system. Funding for the recurrent operational costs of the established HTA structure should be identified and secured on a long-term basis.

Conclusion and Discussion: Setting up organisational structures and establishing effective HTA programmes that guide key policy decisions is a challenging task. The Handbook may guide countries in the process of establishing new HTA agencies since it takes into account the obstacles that the countries are facing in the institutionalization process. In addition, the information presented may serve as a guide for the improvement of processes and structures of existing HTA agencies. The EUnetHTA project was supported by a grant from the European Commission (Grant agreement: 2005110 - project 790621)

P1.15

Regional Healthcare Structures Consortium: A Proposal for HTA Methodology

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Aims: Thanks to experience, research and international collaboration, HTA doers all around the world are achieving a high degree of expertise, and a firm and well-defined methodology for assessing is becoming clear and easily available. Whenever a regional agency is being established, however, its organisers and overseers are called to the effort to adapt that methodology to the peculiarities of the health service the HTA agency will have to serve.

The aim of our work has been to produce a procedure and a guideline that, adjusting the state of the art to Tuscany HS distinctive features, will assist both the institutions and the HTA doers, respectively, in setting up an operative service and in performing effective and telling assessments.

Methods: The organisation and structure of a "regional" agency has been studied, and the peculiarities that differentiate it from the National Health Systems leading the HTA paradigm evolution have been individuated. Main elements of the procedure have been defined (decision-makers, team, policy and scientific question, assessment areas of interest, report and criteria for expert advice acquisition). Besides, four quality criteria were identified, to function as internal targets of the work produced: reliability, unobtrusiveness, usability and efficiency.

Results: The intermediate result of the study was a detailed procedure that divided the HTA process in four main stages, described how each of them was further split in a definite number of more detailed steps, defined the ideal number, hierarchy and proficiencies of the HTA doers, and assigned each single operation to an appropriate actor and manager.

Conclusion: Besides this geographical and social contextualisation, another criticality had to be taken into view: HTA is still a young discipline and has yet to gain trust from health administrators and practitioners, thus a flexible framework, suitable to sustain a gradual growth of importance and activity, had to be designed.

P1.16

From Models to Practice, the Case of AGE.NA.S. and UVT in Italy. Comparison between HTA at MACRO and MESO Level.

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Introduction: The Unità di Valutazione delle Tecnologie (UVT) active at "A.Gemelli" University Hospital and National agency for Regional Healthcare (AGE.NA.S.) are both involved in HTA although at different institutional levels. UVT has been performing HTA for about 10 years to support the decision making process in the hospital setting. AGE.NA.S. works at the national level and since 2006 has been asked by the "State and Regions Conference" and National Ministry of Health to provide support to decision makers both at national and regional level.

Objective: The aim of this work is to analyse the features of the assessment activities performed by aforementioned HTA agencies/units under a methodological point of view. The analysis of those two experiences can help to point out the differences and similarities, if any, between HTA processes at MACRO and MESO level.

Methods: Starting from an investigation on peer review literature (Drummond 2008, Busse 2002), we performed an examination and comparison between AGE.NA.S. and UVT's different assessment approach considering all the phases of the process: from selection and prioritising of technology to be evaluated to reports writing, in order to identify the right topic that need to be assessed in the different context.

Results: Considering the work flow of the assessment procedures of each institution, we have outlined different interlocutors and recipients. Moreover we have outlined differences in terms of dedicated staff (both number and skills), needs of time for work's delivery, resources needed (eg. Databases, opinion leader). Another relevant difference regards the working approach: UVT output had to be well-timed and pragmatic in order to answer to needs of hospital top management, instead AGE.NA.S. output had to be complete and rigorous in order to advise regional health police with the aim of equity of care.

Conclusion: Based on the activities of the last two years, the proposed models (methods and resources) can be generalised in a context different from the Italian one.

P1.17

Health and Economic Effects of Improving Treatment of Hyperlipidemia in Korea

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Background: In light of the burden imposed by cardiovascular disease (CVD), the treatment of cardiovascular risk factors, and hyperlipidemia in particular, is a key health strategy in Korea. However, many Koreans remain under-treated. We sought to quantify the extent of under-treatment of

hyperlipidemia in Korea, and the health and economic effects of improving treatment coverage.

Methods: A microsimulation, Markov model with yearly cycles and cardiovascular health states was developed and populated with 5,198 subjects representative of Koreans aged >18 years without CVD. Annual probabilities of first-onset CVD were estimated for individuals using an Asian-specific multivariate risk equation. Age-and-sex-specific annual probabilities of death, CVD cost estimates and utility values were based on national health data. Lipid-modifying efficacies and costs of statins were drawn from a meta-analysis and current pricing schedules, respectively. A 5% annual discount rate was applied. Decision analysis was applied to compare the consequences of currently-observed patterns of lipid-lowering therapy to those of a hypothetical scenario whereby all patients who met current treatment-eligibility criteria (set by the Korean National Health Insurance, NHI) would be treated.

Results: In the sample, 11.9% of Koreans aged >18 years without CVD met current NHI criteria for lipid-lowering therapy, but only 1.2% (10.1%) were receiving it. Compared to currently-observed patterns of treatment, treatment according to NHI guidelines would reduce the rate of incident CVD in this population from 12.0% to 11.6% over 20 years. The estimated incremental cost-effectiveness ratios (ICERs) were 52,502,360 KW per life year saved and 30,898,054 KW per QALY saved. Among subjects aged >45 years, for whom eligible treatment coverage was 11.7%, the estimated ICERs were 34,338,795 KW per life year saved and 20,632,746 KW per QALY saved.

Conclusion: Hyperlipidemia is significantly under-treated in Korea. Treatment according to current guidelines represents an effective and cost-effective strategy for the primary prevention of CVD.

P1.18

Exploring Study on Professional Human Force for the Community Medical Department in Taiwan

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Objectives: The study discusses the staffs in community medical departments shown how to make decisions on establishing their own self-professional team instead of an outside support team.

MethodsThis research adopted interview and questionnaire designs, and the subjects were sampled from the hospitals with community medical departments. This study was using Logistic regression to explain the correlations among the contents of job design, the staff's characteristics, the opinion of medical specialists and non-medical specialists on establishing their own self-professional team.

ResultsThe demand assessment scores for medical service support in the local hospital are higher than the regional hospital. The scores in the unit had been established above 6 years is higher than 6 years and below. The demand assessment scores for medical service support in the organisation with volunteers is higher than the organisation without volunteers. The scores in 300 hospital beds and above is higher than 300 hospital beds below.

ConclusionIn Taiwan, hospitals hold debates with themselves on the issue of community medical recruit their own major clinical manpower separate. To discuss more on the benefit for hospital recruited the specific clinical team in the community medical department, it needs more studies. (More studies are needed on the benefits for hospital community medical departments that recruit specific clinical teams.)

P1.19

Light or Heavy HTA Agency?

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The idea of the performed feasibility study on HTA Agency in Serbia was aimed to help decision-makers to answer the following question:

"What kind of HTA Agency would be best suitable to address Serbian needs?"

The answer to that question, however, should be based on the rational, so a feasibility study has been performed. An interactive tool has been designed; the results were the base for the feasibility study. The interactive tool sets two extremes: light and heavy model HTA agencies that were described by various features. The features that were selected are the ones that must be taken into account in business plan of any selected form of HTA institutionalisation. Therefore, the interactive tool that has been developed is actually a business plan of the HTA Agency in Serbia but with limitation to the most important features, relevant to the decision-making on the agency model. Detailed business and implementation plans may and should be developed after the decision regarding the type of HTA Agency is made. Input data to the interactive tool were taken from a Serbian setting and from various HTA Agencies in the world which represent full range of features specific for extreme arrangements within limits of heavy and light model agencies. It was shown that if a country has a light HTA Agency, the costs of informed decision-making are smaller for the tax-payers. The main difference between heavy and light HTA agencies refers to the number of employees. Nevertheless,

a light-heavy dimension in describing a HTA Agency proved to be a rather academic one, since most of the established HTA agencies have some mixture of light and heavy features. Shifting a mixed model HTA agency closer to a light than to a heavy model is especially important for developing countries for two main reasons: limited public resources for doing HTA and the great need for economic and financial evaluations.

P2 – IMPLEMENTATION AND IMPACT OF HTA

P2.1

A Conceptual Framework for Implementation Fidelity

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Objective: Implementation fidelity refers to the degree to which an intervention or programme is delivered as intended. Only by understanding and measuring whether an intervention has been implemented with fidelity can researchers and evidence-based practitioners gain a better understanding of how and why it works, and the extent to which outcomes can be improved. The objective of the research was to develop a new theoretical framework for the concept of implementation fidelity.

Methods: The authors undertook a critical review of existing models of implementation fidelity, and of the research literature measuring this concept. This helped to inform the development of the new implementation fidelity framework. The focus of the research was the delivery of health technologies by primary and secondary health services.

Results: The critical analysis of the existing review and research literature led to the development of a new framework for describing and understanding the process of implementation fidelity. It explains and justifies more fully than previous work the function of individual components in the framework and the complex relationships between them.

Conclusion: Implementation fidelity is an important source of variation affecting the credibility and utility of health technology research. The achievement of high implementation fidelity is one of the best ways of replicating the success achieved by health technology interventions in original research. The conceptual framework presented here offers a means for measuring this variable and understanding its place in the process of intervention or programme implementation.

P2.2

Logic Model for Improving Impact on Decision Making of a Governmental HTA Organisation

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Background: The constant growth of literature on HTA impact and knowledge utilisation shows that these concepts are major concerns for HTA organisations. Furthermore, the new public management approach that focuses on achieving results and implementing performance measurement increase the pressure to monitor and measure HTA impact. In Quebec, AETMIS took this governmental requirement as an opportunity to adapt a result-based management framework to a HTA context.

Objectives: To develop and implement a routine monitoring system responding to governmental requirements allowing AETMIS to learn and adjust processes and products in order to improve utility, utilisation and influence of HTA on macro decision-makers and organisations targeted by the recommendations.

Methods: HTA impact, knowledge-utilisation and results-based management literature were reviewed. Raison d'être, activities, outputs and outcomes were clarified in order to develop AETMIS' logic model. A set of results indicators, a questionnaire and a method to collect qualitative information were developed. A routine performance monitoring system was institutionalised. Managers and researchers were actively involved in the whole process.

Results: User satisfaction, utility, utilisation and influence of 15 distinct HTA reports were measured and documented. It allowed a better understanding of the decisional context, its opportunities and constraints and gave indications to enhance knowledge exchange strategies. It also provided invaluable information on how decision-makers perceived the HTA processes and methods and how it influenced their decisions.

Conclusion: The implementation of this monitoring system has resulted in improvements of HTA design, processes, products and services to sustain appropriation and utilisation of results by decision makers and stakeholders. In particular, the beneficial role of ongoing, iterative interactions with decision makers has been highlighted and addressed.

P2.3

HTA Impact Study at Ministry of Health, Malaysia

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The HTA Unit in the Ministry of Health, Malaysia has been involved with the process of producing assessment reports and technology reviews for its stakeholders usage such as policy makers, researchers and specialists for more than a decade. Nevertheless the impact of the HTA products such as report and technology reviews on its stakeholders was hardly undertaken. Thus, the objectives of this preliminary study were to determine the impact of HTA products in influencing the decision of public health providers, policy makers, and researchers considering the Unit operations' length. In studying the impact, this study will determine the degree of user awareness on the product, user satisfaction, level of HTA products utilisation and finally the extent of HTA impact in influencing its stakeholder's decision related to medical technologies. The

results of the study indicated that most of the respondents were aware of the existence of the Unit, the functions and objectives, and had access to the agency website. In terms of user satisfaction, most of the respondents agreed that the HTA product had succeeded in contributing to the benefits of the stakeholders. Most of the respondents used the HTA products for decision making, meeting technology specific programme requirement, incorporating into policy or administrative documents, referencing material. The impact of HTA products on the respondents were as follows: to make decisions about programme funding, continuation, delivery elements, evidence to make decision for changes in clinical practice guidelines and concerning health technologies. The implication of the study was an improvement in the dissemination of the report and technology reviews would be recommended as well as the exposure of the Unit to the personnel of the Ministry of Health.

P2.4

The Introduction of New Interventional Procedures in the British National Health Service – A Qualitative Study

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Objectives: To investigate how interventional procedures are introduced into the British National Health Services and identify areas for improvement in the current process.

Methods: Qualitative study using one to one semi-structured interviews. Using the framework approach, the data generated from 14 participants were analysed with coding of emergent themes. Data were analysed separately for providers and commissioner organisations.

Results: Variations were observed in how interventional procedures are introduced from both the provider and commissioner perspectives. Patterns of approaches allowed the development of models reflecting practice at each type of organisation: very structured in some places to, unstructured or almost non-existent in others. Factors affecting the decision to introduce a procedure include: immediate costs and benefits, numbers of people affected, training requirements, NICE guidance, nature of procedure, support from colleagues, incentives, public or policy-maker pressure, and aims of the institution. Monitoring was seen as a key area for improvement by many.

Conclusion: These variations indicate that the process of introducing new interventional procedures in the NHS and similar organisations internationally can be improved. Factors affecting decision-making and problems have been identified. The results of our study could inform and help shape future processes of managing and the introduction of new procedures into the NHS.

P2.5

Brazilian Competitive Binding for HTA Clinical Trials

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Objective: To describe the Brazilian process of priorisation and the involvement of Brazilian Ministries of Health (MH) and of Science and Technology (MST) for resources allocation on competitive binding for Brazilian HTA clinical trials.

Methods:

(1) The Department of Science and Technology (DECIT) of the MH carried out a "Health Research Priorities Workshop" to identify potential HTA clinical trials topics with the available resources.

(2) To support the research, the MH allocated US$4,347,826[1] and the MST funded US$2,173,913[1] count up US$6,521,739[1] for competitive binding.

Results: DECIT, in partnership with Brazilian health policy-makers and the Brazilian Network for Clinical Trial (RNPC), identified potential topics for HTA clinical trials. This action provided the details of call for research proposals and the enlargement of the RNPC, once the competitive binding enabled the linkage of new units for clinical trials. The judgment committee suggested eight proposals, summing US$8,695,652[1] (the enlargement of resources was possible due to other grants). Of these proposals, four will evaluate the efficacy of continuous positive airway pressure for the treatment of obstructive sleep apnoea-hypopnoea syndrome, with 25% of the total funding.

Conclusion: The top quality research proposal did not attend to policy makers' priorities in calls for research in Brazilian settings such as pharmacological and no-pharmacological treatment for neuropathic pain in leprosy, development of clinical radiological score for tuberculosis, etc. On the other hand, competitive binding contributed to the local development of new and emergent academic initiatives and resources decentralisation. The funds relationship from other settings reveals the increase and the acknowledgment of Brazilian HTA activities.

[1] US$1.00 = R$2.30 (January 2009)

P2.6

Brazilian HTA as Public Policy: Are We on the Way?

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Objectives: Analyse 3 years of the implementation of actions in Health Technology Assessment (HTA) in the Department of Science and Technology (Decit) from the Ministry of Health of Brazil.

Methodology: Description of the HTA policy adopted in the Ministry of Health by the experience of the coordination of the HTA sector in Decit and documental analysis of the managements reports. The analysis was based on the key principles recommendations publicised by Drumond et al about the routes to transform healthcare based on Dougherty and Conway PH.

Results: The actuation lines for the HTA implementation are: i) Form academic, research and service Nets, ii) Priority setting and to produce studies, iii) The use of HTA to support the decision making of the steakholders of the Public Health System. The routes proposed by Dougherty and Conway are being used since 2004 with the National Agenda of Priorities in Health Research directed to care, prevention and promotion in health. The 15 key principles (Drumond et al) are aggregated in structure dimensions in HTA, methods and processes to construct and use HTA to allocate resources. In Brazil, we adapted the implementation to the reality and context of a public health system. Ten principles recommended by the authors are being practiced. Priority setting is defined and an evaluation process is made in a transparent way using public calls as instrument. We also have institutional committees for the incorporation process of technologies in the public health system. The challenge is to improve the capacity to carry out economic analysis and to introduce the society and patients in the process.

Recommendation: Creation of an executive agency, public of HTA, as a way to institutionalise HTA as state policy.

P2.7

"SBU Comments" – A Way to Make More Health Technology Assessments Available to Swedish Healthcare

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The national Swedish HTA agency, SBU, has introduced a new publication series, SBU Comments, to meet the increasing demand for technology assessments in healthcare. The aim is to make more HTA reports available to Swedish healthcare professionals and decision-makers, by summarising and commenting on foreign assessment reports. The publications are produced in close collaboration with experts within each medical field. After review by external experts, the final results are presented to the SBU Scientific Advisory Committee. The SBU Comments series are published in Swedish on the SBU web site. The target groups include healthcare professionals, administrators, and decision-makers. The publications may also be of interest to patients and patient organisations. We have developed a procedure in which a) Relevant reports are identified, b) The reports undergo quality assessment using AMSTAR (assessment of multiple systematic reviews), c) Comments and supplements relevant for Swedish conditions and healthcare are made, and d) The documentation is presented in an easy and accessible web format. The SBU Comments series has increased the number of assessments available for strategic decisions in the Swedish healthcare system. In addition, the working process has led to enhanced contacts with other healthcare authorities and catalyzed the formation of a Nordic collaboration network. Examples of SBU Comments will be presented, as well as lessons learned in creating this new product.

P2.8

The SBU Enquiry Service

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SBU, The Swedish Council on Technology Assessment in Healthcare, comprehensively assesses healthcare technology from medical, economic, ethical and social standpoints. SBU's health technology assessments are extensive and often take years to complete. To meet the growing demand for technological assessment in healthcare and to increase the efficiency of SBU, we have launched a new product, The SBU Enquiry Service. The purpose is to provide support for strategic and practical decision making by giving rapid answers to defined medical questions. Help from the Enquiry Service is offered mainly to decision makers within the Swedish healthcare community. They submit their questions via an online request form on the SBU web site. Our answers, in the form of short reports, are mainly based on identified health technology assessments, systematic reviews and subsequent randomised and controlled studies. The aim is to reply within 2 months, depending on the characteristics of the question and on the availability of scientific literature. Answers of general interest will be published on the SBU web site. The SBU Enquiry Service identifies relevant scientific literature through the standard medical databases. However, in contrast to full SBU health technology assessments, the literature searches are very narrow and no formal appraisal of the identified literature is performed. The answers are reviewed by external experts but not by the SBU Board of Directors or the Scientific Advisory Committee.

P3 – ETHICS IN HTA

P3.1

A Practical Method for Addressing Ehical Issues in HTA

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Background: Since the heyday of HTA it has been claimed that ethics is an integral part of HTA. However, few HTA

reports have addressed moral issues, and there has been little agreement on methods for implementing ethics in HTA. Therefore, there is a need to develop a standard methodology for addressing ethical issues in HTA in the same manner as there is a methodology for systematic reviews and economic analysis.

Method: Descriptive ethics and normative ethics.

Objective: To present a method that has been developed to address ethical issues in HTA.

Results: On the background of an analysis of existing theories and positions in ethics, TA and HTA, a method for addressing ethical issues in HTA has been developed. It consists of six steps and a core set of 32 questions, covering general moral issues, moral issues related to the specific technology and to stakeholders, to methodological choices in HTA and research, and to the HTA process itself.

Conclusion: A practical procedure has been developed for ethical analysis in HTA, based on an analysis of existing methods. The procedure is based on six steps and a selection of 32 moral issues to be addressed.

P3.2

Addressing Moral Aspects in Implementing Prophylactic Vaccines Against Human Papilloma Virus (HPV)

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Background: There exist vaccines against HPV 16/18, but there is as yet no evidence that the vaccine is effective against cervical cancer. This has incited fierce debates on whether to introduce the HPV vaccine in national or state wide vaccination programmes.

Objective: This presentation will highlight and discuss the moral aspects that are relevant for the decision-making process with regards to HPV vaccine.

Method: A method developed for addressing moral issues in HTA (Hofmann 2009) is applied.

Results: The benefit of HPV 16/18 vaccination may be substantial, but morally challenging, as the real impact of HPV vaccination on cervical cancer is yet unknown, and the vaccine is costly. Vaccination is an intervention towards healthy people, calling for special attention, especially as there is considerable uncertainty about its effects and side-effects. Assessing future utility of potential prophylactic interventions against the utility of health interventions today is challenging. HPV vaccine of children is also challenging with respect to informed consent. Informing the public and potential persons to receive the vaccine appears to be a considerable challenge. The heated public debate reveals strong interests in favour and against implementing vaccination.

Conclusion: In 50 years, HPV vaccination can potentially reduce the incidence of cervix cancer and the number of deaths by 50%, but the evidence for this is not strong, and vaccination is costly. This raises a series of morally challenging issues that are important to address when deciding whether to implement the vaccine or not (and how to implement it).

P3.3

Ethical Analysis in HTA Processes: The "Triangular Model"

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Objective: The work intends to explain, from a theoretical and practical point of view, the use of the "triangular model" as research methodology for the elaboration of ethical analyses in HTA reports

Methods: The work is conducted with reference to the National Library of Medicine data.

Results: Research methodologies for integrating ethical analyses in HTA reports are several. The "triangular model" represents one of them.

From a theoretical point of view, this methodology is based on a cognitivist Aristotelic-Thomistic ethical approach and founded on the human person as a whole, as reference-value in the reality, towards which all the ethical considerations should be steered.

From a practical point of view, this approach gets ethical evaluations through a triangular process of analysis: 1. Data collection (gnoseological level), 2. Ethical/anthropological analysis (justifying level), 3. Ethical evaluation (normative level).

Its peculiarity consists in referring to an anthropological view whose lack would make the process of analysis incomplete.

Conclusion: The "triangular model" could be used as possible approach for integrating ethical analysis into HTA reports.

P4 – HORIZON SCANNING AND EARLY ASSESSMENTS

P4.1

Horizon Scanning with an Ear to the Ground

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Background: CADTHs horizon scanning programme alerts decision makers to new and emerging health technologies that

are likely to have a significant impact on the delivery of healthcare in Canada. Horizon scanning has been an important part of CADTH's health technology assessment programme since 1997. During the last 12 years the horizon scanning service has continued to evolve and it is now a leaner, fitter version of its former self.

Method: To better address the concerns of our stakeholders the horizon scanning programme has complemented its existing literature-based identification model with a robust environmental scanning process. While ongoing literature scanning continues to be an important tool at CADTH for identifying health technologies that are in the early stages of development and adoption, environmental scanning now plays an equally significant role in our identification and prioritisation process.

Results: Through the strengthening of relationships with key healthcare stakeholders, environmental scanning provides us with a grass root insight into potential threats and real-time issues that are impacting the Canadian healthcare environment. CADTH's current horizon scanning products consists of: Health Technology Update - a newly revised newsletter that is published three times a year; 1) Issues in Emerging Health Technologies - peer-reviewed and MEDLINE indexed 2) Horizon scanning database - that captures technologies that have been identified by CADTH and other horizon scanning organizations.

Discussion: As we continue to nurture relationships with our expanding network of connections that comprise of clinical experts, decision makers, health organisations and industry, it is our aim to better inform decision makers about emerging medical technologies, upcoming policies and practices, and research on the horizon.

P4.2

A Comparative Analysis of Early Awareness and Alert Systems

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Background: EuroScan is a collaborative network of nineteen member agencies that carry out early awareness and alert activities (also referred to as horizon scanning and early warning). The aims of the collaboration are to exchange information on new and emerging health technologies, optimise identification of these technologies, develop applied methods for early assessment and disseminate information on these activities.

Aims: Although the collaboration has common aims, the aims and objectives of the individual agencies and the way in which each operates differ. This study aimed to determine whether agencies differ in their approaches to early awareness and alert activities and compares the results with previous studies.

Methods: A comparison of member agencies has previously been carried out in 1999 and 2001. This comparison was revisited in 2008 and is being expanded in early 2009 in light of four new members joining EuroScan. Member agencies were sent a questionnaire comprising questions on structure, aims and coverage, customers, partnerships and collaborations, methods, output, dissemination, related activities and future developments.

Results: The initial results indicate that the agencies have a number of similarities but also differ in the way in which they operate whilst still having common aims. Similarities include source of funding, definitions employed, sources used for identification and filtration and prioritisation criteria. Differences include the host organisation, size of agency, use of clinical experts, types of technologies considered, outputs and the principal target group.

Conclusion: The similarities demonstrate a shared understanding of early awareness and alert activities that have developed through the collaborative efforts of EuroScan. The variations in systems are inevitable in an international collaboration where healthcare systems operate differently and the end products feed a diverse group of customers with varying needs. Methods in this discipline continue to develop and differences between agencies enrich these developments.

P5 – HTA TRAINING

P5.1

Survey on Educational Health Technology Assessment Programmes

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Objective: To provide an updated overview of the most relevant educational programmes on health technology assessment (HTA) and HTA related areas worldwide. The study was conducted as part of Work Package 8 of the European Network for Health Technology Assessment, 2006 to 2008, (EUnetHTA) project which was commissioned by the European Union.

Methods: A cross-sectional web-based survey sent in April 2008 to 80 organisations (INAHTA members, selected members of the HTAi, Cochrane Centres and selected non-EU WP8 partners). Additionally, a follow-up search of the educational programmes in the programme's websites was carried out. Standard descriptive analyses were conducted and the programmes were classified into three categories: MSc on HTA, Postgraduate courses related on HTA and other HTA related postgraduate courses.

Results: Forty-eight questionnaires were received with an overall response rate of 60%. Five MSc in HTA were identified, one MSc programme was international in scope whereas

national MSc programmes in HTA were provided in Brazil, Canada, Italy (distance learning course) and the United Kingdom. Five HTA related MSc programmes were identified in Canada, Israel and Spain. A total of 11 courses that were part of a postgraduate HTA related course (HTA programme, systematic reviews/meta analysis, evidence based medicine, health economics clearly targeted on HTA) were identified in Argentina, Australia, Canada, Romania and in the United Kingdom. Other HTA related short courses or courses provided on ad-hoc basis were reported in different countries as well.

Conclusion: Although the supply of education and training programmes in HTA in Europe has increased rapidly, only a minority of all European countries was involved in this development at the beginning of the present decade. The existing training programmes in the majority of European Union Countries focus predominantly on the different disciplines contributing to HTA. Also short courses in HTA, provided on an ad-hoc basis and aimed at a postgraduate audience, are common. The EUnetHTA project was supported by a grant from the European Commission (Grant agreement: 2005110 - project 790621).

P5.2

How to Train Decision Makers and Their Technicians on Elaborating and Interpretation of Rapid-HTA: Brazilian Experience

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The training courses for elaborating rapid-HTA were an initiative of General Coordination of Health Technology Assessment of the Department of Science and Technology (DECIT) of the Ministry of Health of Brazil, from demands of technical areas of the Ministry, State and County Secretariats of Health. The training courses aim to disseminate the "Methodological Guideline for Appraisals on Health Technology Assessment" to encourage the utilisation of this guideline in decision practice, to promote concepts concerning evidence search, analysis and synthesis, counting on Evidence Based Medicine and Epidemiology lessons. In 2008, DECIT had promoted seven training courses for elaborating rapid-HTA, two in Brasilia/DF, and one in Joao Pessoa/PB, Belem/PA, Rio de Janeiro/RJ, Belo Horizonte and Sao Paulo. Altogether, 104 people participated in the courses, including pharmacists (40%), physicians (27%), nurses (5%), lawyers (4%), and librarians (3%), between others (21%). The participants were representatives of the technical areas of the Ministry of Health, State and County Secretariats of Health, universities and health-insurance plans. At the end of the courses, an evaluation questionnaire was applied. 73% of the participants answered the questionnaire, and between them 96% considered the training course excellent or good in criteria about content relevance, themes presentation, educational material quality and proposed debates. One positive point of the trainings was that the participants begun to use quality scientific evidence in their daily practice about management and attention to health concerning Health Technology Assessment. Nowadays, the challenge we face is the weak HTA institutionalisation in government structures, which lead to an absence of guarantee of continuity in rapid-HTA elaboration, even though the courses have been requested by decision makers.

P6 – DISINVESTMENT IN TECHNOLOGIES

P6.1

GuNFT: The First Guideline for Not Funding Health Technologies in Hospitals

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Introduction: There is a lack of methods for technological disinvestment in healthcare. The aim of this study was to develop a guideline for hospitals to help them in technological disinvestment.

Methodology: The nominal group technique was used. Eight questions were formulated to ten people working in areas related to disinvestment. Proposals were discussed by teleconference and participants had to select and score by relevance ten ideas (from 10 to 1) for each proposed question. The ideas receiving at least five votes with six or more points were selected. The structure of previous existing GANT and GEN guides was also taken into account to elaborate the GuNFT draft, which was revised by two external reviewers, translated into English and revised again by other two international reviewers.

Results: 35 ideas were finally selected. Basically, a technology should not be funded if there is evidence about global health worsening, potential risk is not assumable or it produces a high discomfort degree or has a negative impact for the patient. To facilitate the acceptance of disinvestment, good information about the reasons for the decision should be given to the patient, and the professionals using the technology should be correctly informed and implicated into the process. The guide was divided into different sections: information about the guideline development, general recommendations, how to do a request and assess its adequacy and how to obtain the final recommendation for the proposed technology.

Conclusion: This is the first guideline developed to help hospital professionals and decision-makers to decide to fund or not to fund health technologies already in use. In a future, the applicability of the guideline should be tested to improve the process.

P6.2

Scanning the Horizon for Obsolete Technologies: Possible Sources for Their Identification

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Introduction: HTA has mainly focused on the identification and assessment of new and emerging technologies. In this case, we wanted to explore what happened with potentially obsolete technologies (POT), starting with the identification of the sources that could be used in their detection.

Methodology: A questionnaire about POT identification was sent to the HTA-IRG members. Secondly, a previous questionnaire about the sources used to identify new and emerging technologies was adapted to POT and sent to INAHTA and EuroScan members. They had to select the sources, giving a relevance score from 1 to 9. The number of votes and total and median score obtained for each source were taken into account in the ranking.

Results: Seven HTA-IRG members answered the first questionnaire. Some of the proposals were taken into account in the elaboration of the second questionnaire, answered by only 4 of the 15 members of EuroScan and 3 more members of INAHTA. One of the agencies used only experts: 6 agencies voted for devices, diagnostics and procedures, 5 for settings and programmes and 3 for drugs. The Canadian Agency for Drugs and Technologies in Health (five votes, median = 2 points), The Cochrane Collaboration (5 votes, median = 3), NICE (4 votes, median = 1), the FDA (4 votes, median = 1, 5) and EuroScan (4 votes, median = 2) were the most voted sources for devices and diagnostics, for drugs, the BMJ and JAMA and for procedures, the Cochrane Collaboration and the Canadian Agency for Drugs and Technologies in Health.

Conclusion: Not many agencies are working in POT identification and used sources are mostly indirect. Based on this research, case-studies will be developed to improve and refine these sources.

P7 – CLINICAL QUALITY IMPROVEMENT

P7.1

Development of an Evidence-Based National Healthcare Performance Measurement Framework for Singapore

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Introduction: Many countries have developed performance measurement frameworks for measuring and managing health system performance to ensure effectiveness, quality, efficiency and equity, to identify gaps for improvement, and monitor changes over time. This describes the development of a locally relevant healthcare performance framework for evidence-based health system performance assessment, to guide policy decisions while enabling national and international benchmarking.

Methods: In developing a National Healthcare Performance Framework, a review of similar frameworks in other countries was conducted. This process also involved consultations with key stakeholders and international partners.

The locally relevant Healthcare Performance Framework links the tiers of 'Determinants of health' and 'Health system performance' to 'Health status and outcomes', reflecting different domains of quality of care (effective, appropriate, patient-centred, accessible and safe care) at national, institutional and specialty levels. From this framework, priority areas for indicator development were selected based on national goals, disease burden/costs, improvability, and known variations in quality. Potential measures for priority areas which met well-accepted criteria for scientific reliability, comparability, acceptability and feasibility were then established as initial performance measures.

Results: This framework is currently being implemented, beginning with the public sector, with measures being operationalised. For example, for ischaemic heart disease (IHD), measures cascaded from a national level (e.g premature mortality from IHD for 'Health status and outcomes', prevalence of smoking, obesity, diabetes for 'Determinants of health'), to institutional and specialty-specific levels (e.g. for 'Health system performance', measures include percentage of acute myocardial infarction patients who were given aspirin on discharge).

Conclusion: The development of an evidence-based Healthcare Performance Measurement Framework for Singapore allows the alignment of performance measurement across the healthcare continuum, helping create a regulated performance environment and stimulating a culture of improvement. Our framework and indicators are a 'living set' in terms of future development and refinement to ensure relevance.

P7.2

Development of Key Performance Indicators for Cardiac Care in Singapore

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Introduction: Reliable Key Performance Indicators (KPIs)

are needed to provide feedback on the performance of a healthcare system over time, to enable standardised comparisons with overseas benchmarks, and to identify current gaps in the processes and outcomes of care for improvement purposes. Many countries have been developing Key Performance Indicators in priority areas of healthcare, particularly in light of rising consumer expectations and concerns over quality gaps and variations in care provision. Cardiovascular disease has been selected as a priority area for quality measurement, in view of its disease burden and significant contribution to mortality, data availability and feasibility for benchmarking internationally. This paper describes the development and establishment of key performance indicators for cardiac care in Singapore.

Methods: In developing locally relevant quality measures, an extensive review of current cardiac care process and outcome indicators used internationally was conducted. Indicators were selected for their widespread use, high level of consensus, reliability and feasibility for local application. In the development process, external (international) reviews were obtained and key stakeholders were consulted where relevant.

Results: Ten initial key performance indicators were developed for local measurement. A combination of process and outcome indicators was selected to provide a holistic view of care provision. Process indicators ascertain the delivery of care deemed appropriate for patients with Acute Myocardial Infarction (AMI) and are used for identifying and remedying variations in quality of care, and are complemented by measures of mortality outcomes. For process indicators, we leveraged on measures developed by the US Hospital Quality Alliance and later adopted by the Centre for Medicare and Medicaid Services and Joint Commission for Accreditation of Healthcare Organisations in the US (CMS-JCAHO Aligned Measures). The process indicators were aspirin at arrival and discharge, beta-blocker at arrival and discharge, lipid-lowering therapy at discharge, angiotensin-converting enzyme inhibitor/ angiotensin receptor blocker for those with left ventricular systolic dysfunction, adult smoking cessation advice and primary Percutaneous Coronary Intervention (PCI) within 90-minute of arrival. For outcome indicators, we used the hospital standardised mortality ratio methodology to compare risk adjusted 30-day mortality for AMI and PCI to enable 'like-for-like' comparison of hospital performance.

Conclusion: The development of initial performance indicators for cardiac care in Singapore aims to identify gaps and stimulate a culture of continuous improvement. Results for the indicators are currently being discussed and validated with the respective hospitals. These indicators and their definitions will continuously be reviewed and refined to ensure relevance with time.

P7.3

Reduction in Hospitalisations due to Ambulatory Care Sensitive Conditions: A Meta Review from the NZ Perspective

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Ambulatory care sensitive conditions (ACSC), are defined as hospital admissions due to medical conditions that could be avoided by provision of adequate primary care. ASH rates are used as a measure of access to primary care. The primary care interventions aimed at reducing ASH include programmes for primary prevention, community interventions, screening and diagnostic services, and specific treatments for individuals in different age groups. We conducted a meta-study of the literature and secondary data sources to identify emergent themes and interventions that would potentially lead to a reduction in ASH related hospitalisations in New Zealand. The conditions selected were (1) All ASH conditions, (2) Bronchial Asthma, (3) Chronic Heart Failure, (4) Diabetes, and (5) All other conditions. The focused review of the literature and other data sources resulted in six clusters of interventions that we found had potential to reduce ASH admissions in New Zealand and in countries that had health infrastructure comparable to New Zealand. These were (1) Comprehensive Disease Management Programmes, (2) Educational Interventions, (3) Telehealth Applications, (4) System Level interventions, (5) Specialist clinic based interventions, and (6) Individual drug or non-drug based interventions. Briefly, we found evidence that combination of interventions based on the six emergent themes were successful in reducing overall ambulatory care sensitive conditions in New Zealand. In particular, multi-disciplinary, comprehensive disease management programmes might reduce ASH admissions in the elderly with chronic heart failure, and combination of educational interventions within comprehensive care was effective in reducing ASH due to Asthma. This meta-review was based on 30 component reviews, and we used a novel mixed approach of quantitative and qualitative data analyses to identify and categorise the emergent themes in the management of ASH conditions. In this presentation, we describe our novel approach, key findings, its limitations, and implications of our study.

P7.4

LASIK Surgery Outcomes

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Objective: To assess the outcomes of LASIK surgery for mild to moderate myopia in 4 centres in Singapore with respect to success, predictability and safety.

Methods: Three public centres and 1 private centre providing LASIK surgery volunteered to participate in the study. All the centres provided aggregate level data collected retrospectively over a 1 year period in 2005. Results for patients undergoing standard LASIK procedure with a microkeratome, standard LASIK with a femtosecond laser, wavefront-guided LASIK with a microkeratome, and wavefront-guided LASIK with a femtosecond laser were provided separately. The criterion for success used in this study was the percentage of patients achieving unaided visual acuity of at least 6/12 or better 3 months postoperatively. The criterion for predictability was the percentage of patients achieving final visual acuity to within 100 degrees of targeted refractive correction. The criterion for safety was the percentage of patients who had an uneventful recovery.

Results: NUH performed standard LASIK with microkeratome only, JTES peformed LASIK with wavefront guidance only, while SNEC did not perform LASIK with femtosecond laser in 2005.

The centres achieved success rates ranging from 98.86% to 100% for the four types of procedures. Predictability rates and safety rates ranged from 98.66% to 100% and 99.29% to 100%, respectively, for the 4 types of procedures.

Conclusion: The success, predictability and safety rates of LASIK in the participating centres in mild to moderate myopia patients compare favourably with international studies. Nonetheless, it is important for patients to discuss thoroughly with their ophthalmologist the benefits and risks of the procedure as well as their expectations from the surgery before making a decision to undergo this procedure.

P7.5

Quality Measurement in Integrated Alcoholism Treatment Models

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In addiction medicine the implementation of clinically effective concepts in economically efficient structures are especially challenging since treatments are often characterised by relapses, fair levels of therapy adherence and other problems of discontinuity. Thus, definition of quality parameters and steady monitoring are essential preconditions for clinically and economically effective services. Based on a systematic literature review and the analysis of international evidence in nine different industrialised countries, three models of good practice have been analysed regarding their quality indicators. Evaluations of the United Kingdom Alcoholism Treatment Trial, the Jellinek Centre Amsterdam and the integrated alcohol addiction therapy model in Oldenburg-Bremen/Germany are combining in- and outpatient technologies, and work on clinical outcomes, structural parameters as well as on questions of efficiency in the use of economic resources.

Methods: Comparative organisation analysis based on systematic literature research and expert interviews.

Results: Next to common therapeutic concepts for all settings, management and communication at gateways (e.g. transfer between treatment settings) are critical points for quality assurance. Firstly, these points in the treatment pathway express the choice of the effective therapy. Secondly, at these points of transfer, the risk of therapy abandonment is significantly high. Retention rate is seen as the main quality indicator for addiction treatment. Besides, information management concerning clinical data and operative procedures and the implementation of clinical theory is considered as highly relevant in quality assurance tools of integrated care models.

Conclusion: The comparative analysis reveals that the quality parameters' values of service systems can be considerably improved by working on the directness and unambiguousness of information and the reducing of barriers at gateway points. Clinical outcomes of addiction treatment can be improved by further developing systemic parameters which are crucial elements for providing economically sustainable services on a high clinical level.

P7.6

A Study on the Reporting Systems and Occurrence of Adverse Events in Philhealth-Accredited Tertiary Hospitals in the National Capital Region, Philippines

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There is a need to document the different measures being done by Philippine Health Insurance Corporation (PhilHealth)-accredited hospitals to deliver quality healthcare and ensure patient safety in order to target interventions towards improvements of care. This study aims to describe the existing quality improvement and patient safety activities among tertiary hospitals in the National Capital Region (NCR), Philippines. Specifically, it aims to determine 1) Different mechanisms employed in ensuring patient safety, 2) The most commonly reported adverse events, and 3) How the hospitals address these events. A cross-sectional study of randomly selected hospitals was done from September 2006 to March 2007. Key informants (medical director, chief nurse, quality assurance officer, hospital legal counsel) were asked to participate in an informal, semi-structured interview. The data collection tool used a combination of closed- and open-ended questions pertaining to the occurrence of adverse events in the hospitals and how they were reported and addressed. The study included 56 randomly selected tertiary hospitals from the NCR (28 government, 28 private). Majority of the hospitals reported the availability of an adverse event reporting system (91 %). The most common means of reporting adverse events is through incident report forms (79 %). The reported adverse events are investigated, then discussed in committee meetings, where recommendations, sanctions or penalties are formulated. The five most common adverse events reported include medication errors, falls, IV therapy related incidents, nosocomial infections and procedure errors. The most common quality assurance activities are Clinical Practice Guidelines, Complaints Analysis, Medical Audits, Morbidity and Mortality Meetings and Credentialing and Clinical Privileging. It is a fact that the current system needs a lot of improvement. The challenge for the Philippines now is to establish a national reporting system and promote quality healthcare which is as safe as possible as soon as possible.

P7.7

Healthcare Risks Management in the Intensive Care Medicine – For a Quality and Safety Medical Practice

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Brazil

Intensive Care Medicine (ICM) consumes the largest amount and types of hospital supplies and medicines, and employs the largest number of equipment and health technologies, therefore is the place with greater risk of adverse events. In 2007, the Brazilian Association of Intensive Medicine (AMIB), with support from the Brazilian National Health Agency (ANVISA), developed a pilot training course on Healthcare Risks Management (HRM) in ICM, aiming at doctors and nurses and had as main objectives: a) Training professionals on the knowledge and care of materials and technology used in hospital services, b) Promote the exercise of surveillance about drugs, blood components, equipments and technologies, c) Promote the rational use of hospital supplies and health technologies, based on professional ethics and evidences. It is a 2- day course and it consists of theoretical and practical modules covering issues related to searching, monitoring and preventing adverse events in the ICM, and also on professional ethics. It had a participation of 40 professionals (28 doctors and 12 nurses). A preliminary subject assessment was performed before the course and another at the end, when the participants also underwent an evaluation about the course. In assessing pre-course, on a scale from 0 to 10, the overall average was 3.5, while for the final evaluation, the average was 7.8, with two 10 notes and only one disapproval. The evaluation of participants with regard: a) Topics covered, 83% excellent and 17% good, b) Knowledge acquired, 59% excellent, 25% good and 16% regular, c) Applicability, 84% excellent and 16% good, d) Degree of course satisfaction, 58% excellent, 25% good and 17% regular, e) Course duration, 40% excellent, 52% good and 8% regular.

It was found that the vast majority of participants, whether active in ICM, did not have the habit of risk management regarding the recognition of possible adverse events.

P7.8

Patient Safety Initiative: A Reinforcement of Adverse Drug Reaction Monitoring and Reporting System in a University-Based Hospital in Thailand

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National Spontaneous reporting system of adverse drug reaction has been established in Thailand for decades. The adverse drug reaction monitoring and reporting system (ADRMRS) has not been well implemented in a new University-based hospital located in the north of Thailand. Several medical errors such as repeated allergic reactions to known drug allergy have been reported and resulted in hospitalisation. A patient safety initiative was therefore developed by reinforcing the importance of ADRMRS. This article is to describe a process undertaken to reduce preventable adverse drug reactions. First, we

conducted a brain-storming to standardise algorithm, documents and processes for the ADRMRS. Next, pharmacist's awareness and attitude regarding ADRMRS were raised. Everyone will be convinced that no one is exempt from being involved in the system and their findings will be taken into account in order to prevent future ADR. Effectiveness and problems of the system were monitored. Variables measured are cumulative ADRMRS and repeated allergic reactions to known drug allergy. Patient Safety will be improved by obeying the standards of system. The ongoing ADRMRS was a part of risk management systems that could reduce costs and ADR-associated morbidity and mortality.

P7.9

A Study on Medical Staffs' Perceptions and Attitudes Toward Patient Safety Culture in the Medical Centre Operation Room in North Taiwan

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Objectives: World Health Organisation has emphasised patient safety as an important topic since 2002. The management system of high quality and patient safety culture should be done by using preventive measures inside the hospital, rather than focus on personal responsibility of patient injuries through the medical executions. Whether Taiwan or overseas, the studies on the patient safety culture in the operating room unit lack references with related literature, therefore this research would discuss the status quo for the unit.

Method: Subjects were sampled from the surgical doctors, nursing staff, and anesthesiologists in the Medical Centre operation room in North Taiwan, and adopts from the American Professor, Dr. Bryan Sexton, who developed the Safety Attitudes Questionnaire (SAQ) to describe and explain the relevance, individual characteristics and job characteristics between teamwork climate, safety climate, job satisfaction, perceptions of management, and working conditions.

Results: In the dimension of teamwork, the safety climate and working conditions, the nursing staff are ranked the highest (49.2%, 46.0%, 41.6%) compared to surgical doctors (43.5%, 17.4%, 21.7%) and anesthesiologists (38.5%, 15.4%, 15.4%). In job satisfaction, the surgical doctors hold the highest agreement (47.8%), followed by nursing staff (36.8%) and anesthesiologists (23.1%). In perceptions of management, the surgical doctors scored the highest (34.8%), nursing staff were second (19.2%) and anesthesiologists last, with nil (0.0%).

Conclusion: The medical staff in the operation room must prepare for surgery with comprehensive procedures and pre-confirmation. Furthermore, we have to strengthen the education and training assignments of staff attitudes based on the reasonable workload distributions. Moreover, team members should be committed to cooperate and communicate for achieving the high quality patient safety culture. Eventually, all levels of staff should mold the patient-centred environment by implementing the patient safety care properly on the continuous improvement practices.

P7.10

Economic Benefit of a Programme for Surveillance, Prevention and Control of Surgical Site Infection (Hip Arthroplasty) from a Hospital Perspective

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Objective: To assess the economic benefits of a programme for surveillance, prevention and control of surgical site infection (SSI) following hip arthroplasty.

Methods: Economic evaluation was carried out to determine the net economic benefit of an infection surveillance, prevention and control programme (i.e. the Programme) following hip arthroplasty from a hospital perspective. The marginal cost and benefit to SGH of instituting the Programme was evaluated. Cost categories included in the analysis of the marginal cost for the Programme were antibiotic prophylaxis and the manpower cost. The marginal cost of the Programme was compared to the savings in preventing 12 to 13 surgical site infections following hip arthroplasty using the number needed to treat 17. The savings in costs categories include costs attributable to SSI following hip arthroplasty: (a) Extended hospital stay, (b) Readmissions, (c) Outpatient visits, and (d) Outpatient antibiotics. The costs attributable to a surgical site infection following hip arthroplasty were computed using data on patients that developed hip arthroplasty SSI in 1999 and 2000. The probability of the cost category to occur was calculated using the following event rate: extended stay, readmission and outpatient visits among the patients that developed SSI following hip arthroplasty. Charges and staff salaries were used as surrogate measure for costs and are all expressed in 2000 dollars using the CPI for health.

Results: Two hundred and seventeen patients underwent hip arthroplasty in SGH in 2000. The economic benefit of the Programme to SGH in 2000 was the net benefit of $183,854 (i.e. $201,877 in cost savings less programme cost of $18,023). The marginal benefit to marginal cost ratio was 10.20.

Conclusion: The study results validated that it is in the interest of hospitals to invest in quality, as the downstream economic benefits can be substantial.

P7.11

A Scoping Review of Health System Report Cards

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Objective: An extensive body of literature on health system report cards has yet to be characterised. Scoping reviews are a methodology for systematically assessing the breadth of literature in a research area. Our objective was to showcase this methodology, while describing the literature on health system report cards.

Methods: Using the scoping review methodology proposed by Arksey and O'Malley[1], 14 peer-reviewed and grey literature databases were searched for relevant studies. A focused search of 80 government and organisation websites was conducted and reference lists of key papers were scanned to retrieve additional studies. Articles included contained: original research on effectiveness, stakeholder views, or a focused discussion of ethical considerations or report card methodology. Information from relevant studies was abstracted to generate an indexed database of literature on health system report cards.

Results: Of the 11,402 articles identified through database searching, 960 were included. An additional 227 articles were identified through Internet searches and scanning of reference lists, for a total of 1,189 articles charted on a range of clinical areas and topics. Articles were categorised as: effectiveness (n = 192), stakeholder views (n = 122), ethical considerations (n = 46), and methodology (n = 829). Methodology papers were subdivided into: dissemination methods, data display/framing, report card framework, data sources, statistical methods and quality indicator development and/or validation. While report cards are well developed in some clinical areas, primarily cardiac and hospital care, there appears to be a lack of consensus on the effectiveness of report cards in improving quality of care.

Conclusion: This scoping review facilitated the cataloguing of an extensive body of literature pertaining to health system report cards, indicating where systematic reviews and/or original research would be of benefit. Scoping reviews are tools that can be used by both decision makers and researchers to guide future applied and academic research in this and other domains.

P7.12

Priority-Setting Tools for Improving Access to Medical Specialists

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Background: While access to surgery and associated long waiting times occupy the attention of policy makers and the public, access to medical specialties is no less challenging and long waiting times are the norm in Canada. We collaborated to improve access to four specialties, each of which had a triage system, single point of entry and a high urgency clinic.

Purpose: To formulate and test standardised referral tools for use by primary care providers for improving access to Rheumatology, Nephrology, Geriatrics and Gastroenterology.

Methods: Clinical panels were assembled in each specialty consisting of five specialists of academic/community balance. Additionally three to five family physicians and one nurse-practitioner were included in the deliberative process lasting 4 to 5 days, in two to three meetings. Case scenarios (25 to 33), drawn from referral letters, were developed for each panel. A comprehensive literature review preceded the deliberative process and informed it of any existing scores or priority-setting tools. In a highly iterative, facilitated process, clinicians discussed cases and developed a wide set of elements indicative of urgency and reason for referral. These divergent elements were coalesced into mutually exclusive criteria (6 to 8/ tool), each with two or more levels, broadly representing current state of patient, threat of disease progression and potential for benefit. Using pair-wise comparisons and discrete choice simulation software (1000 Minds®) weights were developed for all criteria/levels leading to a 100-point score, the highest scores representing most urgent need for referral. Tools are at various stages of testing for inter- and intra-rater reliability and validity by the four specialties and family physicians.

Summary: Priority Referral Scores for rating relative urgency for referral from primary care providers to Rheumatology, Nephrology, Geriatrics and Gastroenterology are formulated and are being tested and implemented as a means of improving access from primary care providers to medical specialists.

P8 – PUBLIC HEALTH

P8.1

Implementation of Integrated Home Care in EU

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Objective: WHO put the fragmented delivery of health and social services for large groups of chronic conditions on the research agenda in 2002 as implemented in the call EU-FP7-HEALTH-2007-3.1.6. This granted project (www.integrated homecare.eu) aims to develop a strategy for better clinical continuity in EU.Data.

Method: A systematic literature review on integrated care forms the base for design of an HTA of integrated home care (IHC) for chronic conditions in such a state of disablement that patient schools are not enough. The EUnetHTA Core Model for interventions focusing 9 domains is applied. Further, a SWOT-analysis of IHC determines a strategy for implementation of IHC in EU.

Preliminary Results: 1) The efficacy of IHC for rehabilitation

of frequent chronic conditions as stroke, COPD and heart failure (HF) has a common neuroeconomic explanation in the finding that the blood pressure declines 5 to 7 millimeter in your own home compared to a hospital environment which benefits limbic activity, 2) In order to complement the evidence base for IHC a research programme of 7 trials and surveys is scheduled. This includes an EU-country-specific survey on financial and organisational barriers to IHC due to a fragmented administrative organisation, 3) The SWOT-analysis indicates in accordance with an empirical study that a feasible strategy of implementation is a meso-strategy combining the advantages of the goal-directedness of a centralised approach with the adaption to local conditions in a decentralised approach. This means that a regional level with direct cooperation between the administrative/financial and functional/specialist levels is focused. This meso-level is addressed by an international network of national specialist groups.

Conclusion: For improvement of clinical continuity in EU for chronic conditions as stroke, COPD and HF by IHC a HTA with a meso-strategy for dissemination seems to be an appropriate framework.

P8.2

The Impact of "Healthy Mongolian" Mass Media Campaign on Knowledge, Attitude and Behaviour Change in Healthy Lifestyle Among Population Aged 15 to 65

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One year nationwide "Healthy Mongolian" mass media campaign aimed at prevention of risk factors of communicable and non-communicable diseases and to promote healthy lifestyle among the population aged above 16 was organised in 2008. The present meta-analyses evaluates the campaign, which was aimed primarily at increasing knowledge attitude and behaviours on healthy lifestyles of population in Uvs and Orkhon aimag. Mass media campaign exposure was assessed in the post intervention surveys. Subjects collected by questionnaire among 1% of domestic population aged 15 to 65 (total number = 1,189).

Results after the campaign showed that about 85.3% of the respondents knew about the campaign. The current study found that 91.7% of the respondents mentioned positive change in their attitudes. For example, 39.5% of participants indicated that they obtained new information and 31.5% of participants reported that they started seeing their doctor early. Nineteen per cent of respondents mentioned that the campaign helped them to change their unhealthy behaviour, 18 % of respondents became able to evaluate their own health conditions. The campaign achieved significant improvements in healthy behaviours and about 54.5% of respondents who were trying to change their unhealthy behaviour showed improvement in hand washing patterns, while 43.5% of participants engaged in healthy eating behaviour. Also 43.5% of participants reported that they started doing physical activities.

Conclusion: The results suggested that the first nationwide "Healthy Mongolian" mass media campaign reached a large proportion of the population and initiated some positive attitudes and achieved significant improvements in healthy behaviour. Furthermore, it will be more effective if other national health programmes aimed at preventing communicable and non-communicable diseases are organised through mass media campaigns using theoretical models associated with publicity.

P8.3

A Systematic Review of the Effectiveness of Multiple Risk Factor Interventions in the Primary Prevention of CVD

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Background: In 2005, over 40% of deaths in the UK were caused by CVD. CVD costs the UK £30 billion annually. Within the context of the development of NICE CPHE guidance, a systematic review of the effectiveness of multiple risk factor interventions in the primary prevention of CVD was undertaken.

Methods: Standard systematic review methodology was followed. Eight major bibliographic databases were searched. Inclusion criteria specified a target population comparable to PCT size and interventions targeting a minimum of 2 CVD risk factors.

Results: Thirty-eight relevant programmes were identified of which 22/38 were implemented in the UK or Europe and 21/38 before 1990. Thirty-one programmes were multi-faceted interventions, evaluated using controlled before-after studies. Seven were screening programmes, evaluated using RCTs. Only 3 programmes reported CVD mortality or morbidity. There was a trend to favourable net changes in cholesterol, blood pressure and BMI. For behavioural outcomes, there was a trend towards favourable effect for dietary variables, but for smoking prevalence and changes in physical activity, a trend to favourable effect was less apparent.

Discussion: Information from a large body of research suggests that population level programmes demonstrate a favourable trend for CVD risk factors. Considerable uncertainty is left about effect size and health outcome effects across all programmes. The applicability of programmes conducted many years ago to the current UK population is not clear. The feasibility of meta-analysis based on *P* values and modelling the effects of risk factor changes on CVD mortality and morbidity in the present UK population is currently being explored.

P8.4

Identification on Occupational and Environmental Hazards of Informal Gold Mines

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An observational study was conducted for identifying and evaluating occupational and environmental hazards and some social risk factors related to informal gold mining activities.

A total of 15 informal gold mines and 399 miners were selected in the study. Checklists on occupational and environmental hazards and questionnaires were used. Noise level (Sound level meter – TES 1350A), total dust concentration (weighing method), vibration, air temperature and velocity were measured at the 33 workplaces. Total mercury in river, barrel and well waters in two big mines were analysed by AAS. LOD for total mercury was 0.002. MilliQwater used for field blank of water sampling. Statistical analysis and data entering were conducted on SPSS 11.0 and ISSA.

The main hazards of occupational safety and health in the informal gold mines were identified as an extremely high total dust concentration, noise, mercury and injury risk, ergonomically problems and lack of basic sanitation and hygiene facilities. 14 area samples for total dust were taken. Mean concentration of total dust was 71 to 380.7 mg/m^3. It was highest at the stone crushing and grinding machine. Noise level ranged from 52.4 to 195dbA which is higher than the Mongolian standard (85dbA). Gold miners were exposed to extremely low temperatures. They were working in the range of air temperatures from -5 to -40 ^{0}C. Informal gold miners and their family members are exposed to mercury when amalgam was processed and preserved at home. Total mercury in the river and barrel water was 0.002mg/L.

Total dust concentration and noise level in the work places is much higher (2 to 43 times) than Mongolian Standards. It shows that informal miners are at high risks of getting pneumoconiosis, noise induced hearing loss and musculoskeletal disorder because of low temperatures, high vibration and ergonomical problems. Also their family members are exposed to mercury in their workplace, home and environment.

P8.5

The Impact of Alcohol Drinking on Household Expenditure in Thailand

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This study aims to examine the impact of drinking status of individual household members on the household expenditures. The data on household spending and drinking status of the individual members were derived from the Socioeconomic Survey and a special survey, which is part of the study on the economic costs of alcohol consumption in Thailand. Both data were collected by the National Statistical Office of Thailand in July 2007, by interviewing 4,836 individuals from 3,031 households throughout the country.

It was found that an average monthly household expenditure was 12,640 Baht. The top three expenditures of the household having a drinker and none-drinker were food and beverages, dwelling and traveling, respectively and the expenditure on alcohol was ranked 6th amongst 17 types of expenses or approximately 516 Baht per month in households having at least one drinker. A household with one drinker with low-, median- and high-risk of drinking increased the total household expenses by 696, 1,149 and 1,153 Baht/month, respectively. In addition, spending on alcohol beverages, travelling, non-consumer, foods and beverages, and personal care also significantly increased in households with drinker(s). In contrast, the out-patient expenditures and house rent were considerably lower for households with drinker(s). Amongst households with former drinker(s), the expenses on foods and beverages, travelling, household operation/maintenance, and healthcare were significantly higher. For households without drinkers, expenditures on non-consumer, recreation/sport/entertainment, and personal care were significantly higher.

This study clearly illustrates the relationship between drinking status and the pattern of household spending in Thailand. Findings from this study are important to create the awareness amongst decision makers, public health planners and the general public on the potential consequences of alcohol to the expenditures and/or poverty at the household level.

P8.6

Geographical Accessibility to Cancer Hospitals in Japan

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Background: Since 1981, cancer has been the top cause of death in Japan. The government has launched several actions to control cancer, however a lot of problems still exists. One of the major problems was mal-distribution of cancer hospitals. To promote even distribution, the government designated 351 hospitals as centres of cancer medical services across the country. We evaluated the geographical accessibility of cancer hospitals by using geographical information system.

Methods: The 351 designated cancer hospitals were plotted on a digital map. The areas within certain travel distances (10km, 20km and 30km by way of roads) from each facility were computed as polygons. The population inhabited within

three travel distance areas was estimated for each prefecture. ArcGIS9.2 (ESRI) was employed to process the geographical data.

Results: Designated cancer hospitals were located in densely inhabited areas throughout the country. Of the whole population, there were 71.2%, 89.2% and 95.2% of inhabitants living within 10km, 20km and 30km from the cancer hospitals, respectively. The proportions of the covered population were different by prefectures. In urban regions, Tokyo and Kansai areas, almost all of the population inhabited areas within 20km from the cancer hospitals. On the other hand, in the northern and southern areas, Hokkaido, Tohoku and southern Kyushu areas, more than 20% of the population inhabited areas further than 30km from the cancer hospitals.

Conclusion: Geographical accessibility to cancer hospitals was good. We are planning further analysis to evaluate the accessibility to certain services and their quality.

P8.7

Impact of Family Presence during Resuscitation

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Introduction: Family presence during cardio pulmonary resuscitation (CPR) is always a debatable issue among healthcare professionals. However, family plays a very critical role in providing medical care and has the most stakes in the patient's survival, progress and outcome. Family presence during CPR first emerged in the 1980s from the Foote Hospital in the United States, and since then the concept has gained momentum.

Objective: The study aims to explore positive and negative outcomes of family presence during CPR.

Methods: Systematic review of published literature from year 2000 to 2007 was done. A total number of 22 articles were reviewed from international journals.

Results: Most of the literature revealed that 60% to 80% of the public believe that family should be permitted to be with their loved one during resuscitation (Snoby, 2005). Positive effects of family presence are: it enhances the patient's preference and dignity, helps family in the grieving process and reduces medico-legal divergence. However, literature also highlight consequences of family presence as it neglect the patient's right of autonomy, breaches confidentiality, emotionally traumatise the family and leads to a lawsuit.

Conclusion: In conclusion, if we consider the risk benefit ratio, evidence suggests that family presence during CPR should be encouraged by healthcare professionals as it eases the patient's soreness by providing psychological support through family contribution.

Limitations and Recommendation: There is no research available on the impact of family presence during resuscitation in the developing countries. Therefore, further studies are required on the impact of family presence during resuscitation in developing countries.

P8.8

The Effects of General Practice Size on Quality of Care

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Aim: The aim of this review was to determine if there is an association between general practice size and quality of care.

Methods: A systematic review was done. Five databases (CINAHL, Cochrane database, CRD databases, Embase and PubMed) were searched to identify primary quantitative studies that examined the relationship between practice size and quality of care. The following search terms (with some variations across databases) were used: 1) MeSH terms: family practice, practitioner, primary healthcare, quality of healthcare, outcome and process indicators, 2) Keywords: solo, single handed, practice size, list size, caseload and patient volume.

Results: The initial search resulted in 240 articles. Following the selection criteria and assessment for methodological quality, only 8 studies were included in this review. In all 7 studies looked at clinical effectiveness, larger practices generally showed either similar or better performance compared to smaller practices, though the differences were usually small. On the other hand, the only study on patient satisfaction reported that larger practices were associated with poorer patient satisfaction.

Conclusion: There is some evidence to support the hypothesis that larger general practices perform better in terms of clinical processes and outcomes. However, patient satisfaction may be compromised.

P8.9

Predictors of Vaccination Uptake and Course Completion: A Systematic Review

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Background: To inform targeted strategies to improve vaccine coverage and thus reduce the morbidity and mortality associated with vaccine-preventable diseases, a systematic review was conducted to develop an understanding of the predictive factors of vaccine uptake and of the completion of vaccination schedules.

Methods: Electronic bibliographic databases were searched to identify relevant studies. Reference citations and abstracts from all literature sources were reviewed against the pre-specified selection criteria by two of the authors. Each study was assessed by a prognosis quality appraisal tool adapted

from the New Zealand Graphic Appraisal Tool for Epidemiology Checklist. Given the diversity of vaccine types and the heterogeneity in study design, target population and predictors examined across the studies, a narrative synthesis was provided.

Results: **Thirty-six** articles were assessed as meeting the criteria for inclusion, of which 20 investigated predictors of vaccine uptake and 18 examined predictors for completion of a vaccination course. The only factor that was found to have a statistically significant positive impact on the uptake of vaccination across the studies was prior vaccination history. From the studies investigating predictors of completing a vaccination course, it was found that children born with a very low birth weight (<1,500g) had higher odds of incomplete immunisation. The studies also found that children born at home and those not living with a grandmother were less likely to be fully immunised.

Conclusion: The results of this review suggest that efforts should be directed to increase the uptake of the first or earlier vaccines in an attempt to establish a culture of vaccination. Strategies should also be considered to provide support to mothers with newborn babies, and to allocate resources to educate parents regarding the value of vaccinations. Particular attention should be given to mothers of babies born with a very low birth weight and/or at home.

P8.11

Utilisation of Health Services in Primary Care by Patients with Prior Myocardial Infarction in Spain

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Objectives: To describe socio-demographic, clinical, and attendance characteristics as well as other factors associated with the utilisation of primary care health services by individuals with prior myocardial infarction (MI) in Spain.

Methodology: Cross-sectional study. Patients with the diagnosis of MI from the National Health Survey of 2006 (NHS 2006) in Spain were studied. Poisson regression models were developed to determine the relationship between the number of family physician consultations by MI patients within the past 4 years and socio-demographic, economic, health status, and historical attendance variables. Models were developed for men and women combined and each individually. In order to produce a statistical representation of the Spanish population, the sample was analysed after being weighted. Results are given in the form of odds ratios, with associated 95% confidence intervals and statistical significance.

Results: Of the 731 individuals with the diagnosis of MI in the NHS 2006, 435 were men and 296 were women. In the model including both sexes, the individuals with prior MI who presented to their family physicians less frequently had a good or very good self-perception of their health status, the most recent measurement of their blood pressure was more than 12 months ago, and their number of prescribed medications was low. In men, the variables with greatest statistical significance with respect to family physician visits were number of prescribed medications, self-perceived health, and blood pressure measurement. In women, the variables with greatest statistical significance were current economic status and number of prescribed medications. Fittings of the models (pseudo-R^2) were considered acceptable for the statistical methodology employed.

Conclusion: The utilisation of health services in primary care by patients with prior MI in Spain is fundamentally determined by patients' self-perception of their health, the number of medications prescribed by family physicians, and the follow-up of blood pressure control.

P9 – CLINICAL PRACTICE GUIDELINES

P9.1

Quality Assessment of Clinical Practice Guidelines (CPGs): Is ADAPTE Adaptable?

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Background: In order to reduce the duplication of resources required in CPG development, the ADAPTE Collaboration has developed a framework for guideline adaptation that is supported by a series of tools. These tools are designed to assess the comprehensiveness of the systematic literature search and study selection (tool 13), the scientific validity of the CPGs (tool 14), and the acceptability and applicability of the recommendations (tool 15).

Method: A systematic review of CPGs on the management of low back pain was conducted. Twenty-seven CPGs met the inclusion criteria and were initially screened using the AGREE instrument (rigour score). Tools 13 to 15 from ADAPTE were applied to each of the nine better quality CPGs to assess their scientific validity and applicability.

Results: The quality of the CPGs, as assessed by the ADAPTE tools, was largely uncertain. The majority of CPGs reported poorly the details of their search strategies and the process of selecting the evidence underpinning the recommendations. This made it difficult to ascertain whether the search for evidence was comprehensive and whether bias in the selection of evidence was avoided. The phrasing of some questions in the ADAPTE tools was also ambiguous. It was unclear whether they were designed to assess the comprehensiveness of the review itself or rather the reporting in the review. Further, some of the questions were inappropriate if the guideline recommendation was negative and therefore questions needed modification to accommodate recommendations in either direction. Finally, 'Not Applicable' had to be assigned to some questions even though it was not among the choices available.

Conclusion: The ADAPTE evaluation tools may need to be modified in order to have utility as measures of CPG quality. Should this occur, however, the quality assessment will still be constrained by the level of detail provided in the relevant CPG evidence reports.

P9.2

Evaluation of Clinical Practice Guidelines in Primary Care

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Objective: Clinical practice guidelines are, systematically developed statementsto assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances. Recently, clinical practice guidelines have become increasingly popular all over the world. The number of national and international organisations that have been labouring about guidelines has been rising. In this study, the clinical practice guidelines for primary care were evaluated according to the AGREE criteria. The aim of this study was to contribute to develop evidence based guidelines and improve the quality of healthcare.

Materials and Methods: In this study, 14 topics among the various disorders that the booklet of "The Ministry of Health, Clinical Practice Guidelines for Primary care" include were selected, to asses quality. "Turkey Burden of Disease Study 2004" was used for the selection of the topics and AGREE Instrument for the evaluation.

Results: The mean scores of the domains of the 14 guidelines were: Scope and purpose, 87.9%; stakeholder involvement, 62.2%; rigour of development, 51.2%; clarity and presentation, 66.4%; applicability, 57.2% and editorial independency, 54.5%. The 6 of the 14 guidelines had the lowest score from the domain of rigour of development, 2 guidelines, from applicability, 2 guidelines from editorial independence, 1 guideline from both applicability and editorial independence, 1 guideline, from both rigour of development and applicability and 1 guideline, from both rigour of development and editorial independence.

Conclusion: Clinical practice guidelines are accepted as an inseparable part of evidence-based medicine. Although there is not enough studies about guidelines in our country, developing the clinical practice guidelines for primary care is one favourable attempt. However, there should be further steps to provide the efficiency and continuity and to developand generalise the application of guidelines.

P9.3

Incorporating Key Questions for Patients in HTA

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Objectives: To describe how to get patient information in evidence-based clinical practice guidelines (CPG) and what type of information should be considered in the final patient's version of these guidelines.

Methods: We have involved patients and their representatives from the beginning of the development process of CPG for anxiety disorders, stroke, autism and insomnia. Before developing the workgroup we performed qualitative techniques with patients: participant observation, focus groups and in-depth interviews. When we had the final drafts of the guidelines, we created subgroups with patients to produce the patient's versions of the mentioned guidelines. These subgroups decided which type of information would be crucial for the patients and they assessed its comprehensibility and applicability.

Results: Patient participation gave us the possibility to develop CPG including their interests and led us to develop necessary information for them. Patient's versions included these main points: explanations of the afforded problems, factors that could affect the disease, diagnosis, treatments options, prognosis, what to know when visiting the doctor, how family and friends could help and more information (patients/ representatives associations, on-line resources and books).

Conclusion: Patient involvement in CPG has contributed to a greater value of these CPG. Also, working with patients has allowed us to get the information that was considered useful for patients with anxiety disorders, insomnia, autism and stroke.

P9.4

Public Involvement in the Development of Cancer Screening Guideline Leaflets

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Background: To improve the participation rate in cancer screening programmes, the target population needs to be appropriately informed. Although cancer screening guidelines have been published, no leaflets for the public that explains these guidelines in an easily understood manner have been developed. We attempted to develop a leaflet for the colorectal cancer screening guideline with public involvement.

Methods: Based on public/patient involvement in other clinical guidelines, an original method unique to the Japanese cancer screening guideline, was established for the cancer screening guideline leaflet.

Results: The leaflet development process is as follows: recruitment through the website, selection of committee members, meeting including a lecture on basic knowledge for cancer screening and specific issues related to colorectal cancer screening, planning the content for the leaflet, having a professional writer write the leaflet, external review by another person through a web-based questionnaire survey, focus interview survey involving the public and a medical professional group, feedback of the results of the survey to the development

committee, re-evaluation and improvement, and publication.

Discussion: Although there are several clinical guidelines targeted at patients, guidelines developed with patient involvement have been limited in Japan. There are differences between the public and medical professionals with respect to the necessary information related to cancer screening programmes that need to be considered. Given our experience, there are several problems that need to be solved for the development of leaflet for cancer screening guidelines with public involvement including: the selection method for committee members, the support system for development of the leaflet, and the gap between the complete version and the public version.

Conclusion: We formed a unique method to develop the leaflet for cancer screening guidelines with public involvement. By virtue of this method, other leaflets based on the Japanese cancer screening guidelines will be developed.

P10 – DRUG REIMBURSEMENT

P10.1

Submission of Pharmacoeconomic Data to the Japanese Government When Negotiating the Price for New Drugs: The Current Situation

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Background: From August 1992, pharmaceutical companies in Japan have been allowed to submit pharmacoeconomic (PE) data to the Japanese government when negotiating the price for new drugs. Although submission of PE data was not mandatory, previous surveys conducted before 2002 revealed that submissions were made for nearly 30% of new drugs. However, it is unknown how often and what kinds of submissions have been made in recent years.

Purpose: To investigate the present situation of submitting new drug PE data to the Japanese government at the time of price negotiation.

Methods: We sent questionnaires to all pharmaceutical companies whose drugs were newly listed on the national fee schedule from January 2003 to April 2008.

Results: The response rate was 97.1% (66 out of 68 companies). The overall submission rate was 4.8% (8 out of 168 drugs). Methods and assumptions used in these eight analyses varied widely. Quality-adjusted life years (QALYs) were used in two analyses. Presentations at academic meetings or publications of the study results were not planned for two submissions. None responded that the submission was thought to have positively or negatively influenced the pricing decision by the government. Among the 160 drugs for which PE data were not submitted, PE analyses were conducted for 20 drugs, but in the case of those drugs, the companies chose not to submit the analysis data mainly because they believed that it would have no influence on the pricing decision.

Discussion: The submission rate had dropped dramatically and was maintained at a significantly low rate during this study period. To promote a value-based pricing decision, standardisation of PE research methods and development of the rule of applying PE results to the pricing decision should be established.

P10.2

Implementation of New Cancer Drugs: How Can HTA Fit in?

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During the past two decades several HTA products have been developed for evaluating health technologies. However, HTA has been criticised for not always being suitable for complying with the short timeframes often needed for decision making. This has led to the development of new ways of using HTA approaches, e.g. for evaluating new and upcoming drugs.

Marketing of new cancer drugs showing clinical effect can lead to considerations whether a drug should be implemented as a standard drug treatment for specific indications. In general, the 5 Danish regions are responsible for the implementation of new treatments, including new cancer drugs (after authorisation by the Danish Medicines Agency, DMA). There has been a lack of consistency in the process following the authorisation leading to the drug being actually implemented. The National Board of Health (NBH) therefore decided to establish a national procedure in order to ensure an evaluation of new drugs before inclusion in the group of standard cancer drugs.

A Committee of Assessing Cancer Drugs was established in 2008 with the task to evaluate applications from administrative regions, scientific societies and so forth, applying for inclusion of a cancer drug among standard treatments. The cancer drugs may have been offered via the system mentioned above, but not necessarily. NBH holds the chairmanship and serves as secretariat for the Committee. By the establishment of the Committee, a forum now exists for setting up structures to increase transparency and consistency. Developing procedures for systematic and structured application processes and for the assessment of evidence is essential. Which tools are most applicable within the short time frame for evaluating the applications, in what ways can HTA be useful, and how can HTA approaches be included? Processes, current experiences and future ideas will be presented and discussed.

P10.3

Toward Transparency in Health Technology Assessment in the Brazilian Supplementary Health System

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Objectives: The practical significance of health technology assessment (HTA) in policy decision or clinical practice has been challenged. In 1999, a federal agency was created, National Supplementary Health Agency ("Agência Nacional de Saúde Suplementar – ANS"), with the aim of both granting adequate and integral care to beneficiaries of healthcare plans. Among the attributions of ANS is the periodical revision of a list of procedures that constitute the minimum obligatory coverage for all health plans. As occurs worldwide, healthcare expenditure is rising at alarming rates in Brazil, due not only to the accelerated aging of the population, but also to the introduction of new and expensive technologies previously unavailable.

Methods: The latest revision of coverage was in 2008, and now we are working on another one. The decision-making process in policy definition was to improve actions on promotion, protection, recovery and rehabilitation in health, integrating a multi-disciplinary team. We analysed documents and the priority-setting processes.

Results: The ANS coordinated a technical group for this revision. From 2008, the work was available in our website and we have received a lot of suggestions. We have reviewed all the contributions.

Conclusion: The new process improves transparency on the classification of the procedures and their techniques. This new list of procedures will guarantee more coverage for the health plans and it will provide high-quality care to the population. The study results will assist ANS which are developing their prioritisation methods. To ensure that future studies on healthcare problems are useful, it is imperative that policy makers consider the problem of definitions of potencial users of HTA.

P10.4

An Analysis of Claims of Irreparable Harm in Lawsuits for Access to Medicines in the State of Rio Grande do Sul, Brazil

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Introduction: In Brazil, patients are increasingly using lawsuits against the government to access medications through the public health system. In 2007, the State of Rio Grande do Sul spent more than US$20 million with the acquisition of court-attained pharmaceuticals. In such cases, plaintiffs virtually always request orders for temporary relief, which provide the requested treatments until the case is resolved. Orders for temporary relief are to be used primarily in the presence of a risk of irreparable harm (article 273 of the Civil Process Code). Because judges virtually always grant such orders, they constitute a significant administrative burden for the state.

Objective: To report the proportion of cases in which judges grant orders for temporary relief and in which the plaintiff's physician or attorney claims irreparable harm, including death, in the absence of treatment in lawsuits for access to medications through the public health system in the state of Rio Grande do Sul.

Methods: A cross-sectional study has been in progress since September 2008, following a sequential, convenience sample of lawsuits contested by the Attorney General's Office of the state of Rio Grande do Sul.

Results: From a sample of 447 cases, judges granted orders of temporary relief in 399 (89.3%). Patients' lawyers alleged risk of death in the absence of treatment in 211 (55.6%) of total cases. However, only 87 cases (21.8%) that contained orders for temporary relief also had medical reports asserting the risk of irreparable harm in the absence of treatment.

Conclusion: Decisions to grant orders of temporary relief might be based more on affirmations of risk by patients' attorneys than by medical authorities. Medical confirmation of the need for given treatment is important to avoid the misuse of public funds in acquiring unnecessary, ineffective or even hazardous treatments for patients.

P10.5

Demanding Treatment Access Through Regular Administrative Pathways and Through Lawsuits in Brazil: A Pilot Study

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Introduction: Brazil is one of the countries that recognise a constitutionally guaranteed "right to health". An important part of the right to health is access to medicines and the Brazilian state and civil society have worked in the past 20 years to ensure pharmaceutical access to citizens with mixed results. High-cost medicines present particular challenges to

access and distribution. They are typically obtained through administrative requests to health authorities, and are granted according to evidence-based guidelines and evaluations concerning safe and effective uses. If a requested medicine is not part of the state's pharmaceutical distribution programme or its evidence-base is contested, then the treatment is not granted. Nevertheless, patients may sue the state to obtain the medicines when they are not made available through the regular administrative pathway.

Objective: To evaluate, among lawsuits for access to medicines, the frequency of previous administrative requests for treatment and to examine whether there is agreement between the final results of administrative and judicial pathways.

Method: A cross-sectional study has been in progress since September 2008, based in a sequential, convenience sample of lawsuits requesting medicines contested by the General Attorney's Office of the State of Rio Grande do Sul.

Results: In a sample of 461 lawsuits, 30% of patients requested medicines through the regular administrative pathway before filing a lawsuit for access. For those who had previous administrative requests there was no significant agreement between the judicial decision and the administrative decision (κ = -0.097, P = 0.29).

Conclusion: A substantial number of patients seek medicines via lawsuits and eschew regular administrative pathways. Our results also show that the judiciary disregards the health authorities' previous decisions about access, which are based on best available evidence concerning safety and effectiveness. New strategies of communication between the judiciary and the health technology assessment community are needed.

P10.6

Claiming the Right to Medicines in Brazil Through Public and Private Doctors and Lawyers: A Pilot Study

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Introduction: Brazil has a public health system based on principles of integrality, universality, equity and gratuity. It exists alongside, and at times overlaps with a private health insurance and hospital system. Public healthcare is free of charge and includes a pharmaceutical assistance programme whose medications are incorporated based on best available evidence concerning safety and efficacy. Nevertheless, regardless of their income, patients may sue the state to obtain medicines and/or procedures not provided through the public system. Plaintiffs may use public or private attorneys or doctors in this process.

Objective: To describe the frequency of patients suing the government for access to treatments not provided through the public health system that have been assisted by public or private healthcare services and public or private judicial services, and their income, and to assess agreement between the utilisation of public or private services.

Method: A cross-sectional study has been in progress since September 2008, based in a sequential, convenience sample of lawsuits requesting medicines contested by the General Attorney's Office of the State of Rio Grande do Sul.

Results: Four hundred and thirty-nine lawsuits were studied and a database was created. The majority of patients were assisted by public doctors (55.2%) and attorneys (66.7%), although a substantial number were not. There was a tendency towards agreement between the utilisation of public healthcare and public attorneys (n = 321, κ = 0.11, P = 0.053). When compared to patients using private medical services, the median declared monthly income was significantly lower in patients using public medical services (US$165.7 *vs* 230.9, P = 0.003) and judicial assistance (US$173.91 vs 238.7, P <0.001).

Conclusion: Users of public health and judicial services have significantly lower declared incomes. Those who choose public services appear to utilise both medical and legal assistance. Our data suggest that public services are probably being used by those who need them most.

P10.7

Lawsuits for Access to High-Cost Medicines Might Disorganise and Reduce Access to Priority Public Health Programmes in Brazil

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Introduction: Last year, approximately 10,000 cases were brought by individuals against the State of Rio Grande do Sul in southern Brazil for access to medicines. The growing number of individual judicial cases for access to high-cost medicines with no evidence of efficacy and without regard for treatment guidelines is forcing an unplanned shift in the destination of public resources and is breaking the financial and organisational structure of state health secretariats in Brazil. Administrative processes for pharmaceutical access and acquisition through health secretariats, such as bulk purchasing and price-bidding, follow principles of legality, efficiency and economy established by Brazilian law. In

contrast, the judiciary employs sequestration of funds to coerce administrative authorities to purchase court-attained medicines for a relatively small number of plaintiffs. In sequestration procedures, funds are taken from State accounts and given to plaintiffs for the purchase of medications.

Objective: To assess the frequency and the amount of money spent by the State in the sequestration of funds due to judicial decisions for pharmaceutical acquisition.

Method: A sequential, convenience sample of lawsuits requesting medicines contested by the General Attorney's Office of the State of Rio Grande do Sul was analysed and economic data were obtained from the Health State Fund.

Results: From a sample of 430 judicial decisions, sequestration of funds occurred in 107 cases (24.9%). In 2007 the judicial power authorised a sequestration of US$12,059,549 from the State public accounts, transmitting the management of public funds directly to the plaintiffs, by authorising them to buy directly in private pharmacies those medicines requested from the State.

Conclusion: Judicial sequestration practices ignore the role of the Public Health State Department in planning and managing public resources according to collective population needs, diverting funds for use by a small number of individuals for medications that need not have proven effectiveness.

P10.8

Most Frequently Requested Pharmaceuticals Through Judicial Claims in Brazil, and Most Commonly Reported Diseases

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Introduction: Judicial claims requiring medicines and health technology are a growing epidemic in Brazil. Every year, there is an increase in the number of lawsuits and in the amount of money spent due to these cases. In 2007, for example, more than US$20 million were spent only in the State of Rio Grande do Sul to cover judicial claims requiring pharmaceuticals. The State Departament of Health, in reason of judicial decisions, has their resources mobilised to fulfill individualised situations, depriving the collective.

Objective: To describe which pharmaceuticals are most frequently requested by judicial pathways and which are the most commonly reported diseases, observing the relations between them.

Methods: A cross-sectional study has been in progress since September 2008, based in a sequential, convenience sample of lawsuits requesting medicines contested by the General Attorney's Office of the State of Rio Grande do Sul.

Results: Four hundred and seventeen lawsuits were analysed. The most frequently requested medicines were sinvastatin (2.6%), budesonide (2.3%), acetilsalicilic acid (2.2%) and formoterol (2.2%). The most frequently reported disease was hypertension (6.6%), followed by diabetes (4.9%) and chronic obstructive pulmonary disease (2.7%).

Conclusion: The finding that the most frequently requested pharmaceuticals are those used in primary care shows the ineffectiveness of programmes of free primary care medicines distributions and reinforces the importance of effective primary healthcare in our country.

P10.9

Early Alert Systems for New Pharmaceuticals: Do They Have an Impact on Pharmaceutical Reimbursement Decisions? A Cross-National Comparison

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Objective: With the successful incorporation of horizon scanning (HS) into HTA it has been postulated that HS of pharmaceuticals may inform pharmaceutical assessment for public reimbursement in Australia. This paper intends to examine the role of HS for pharmaceuticals, the effect that HS may have had on the introduction of new drugs onto the health market, and assess whether HS for pharmaceuticals would improve access to new drugs in Australia and New Zealand.

Methods: The EuroScan database of HS agencies was searched for pharmaceuticals assessed in 2004 by the National Horizon Scanning Centre (UK) and the Canadian Agency for Drugs and Technologies in Health. Time taken to licensing and public reimbursement or access approval, if given, in the UK, Canada, Australia and New Zealand was ascertained.

Results: Of 21 drugs identified by HS in 2004 by the NHSC, 11 received licensing approval and the National Institute for Health and Clinical Excellence has delivered guidance on 5 of these, with 3 being recommended. In Australia, 10/21 of these drugs had licensing approval and 7 underwent assessment by the Pharmaceutical Benefits Advisory Committee. All 7 received approval for listing on the public reimbursement scheme. Similarly, CADTH assessed 16 drugs by HS in 2004. Of these, 10 received licensing approval but only 1 gained approval to be listed by the Canadian Expert Drug Advisory Committee. Of these 16 drugs, 14 had licensing approval in Australia and 12 underwent assessment by the PBAC, with only 2 being declined approval for listing on the public reimbursement scheme.

Discussion: The current process of pharmaceutical assessment appears to give Australian patients timely access to publicly funded pharmaceuticals and that the introduction of HS for new and emerging drugs would neither decrease the time to access for patients or better inform policy makers than the system already in place.

P11 – METHODOLOGY

P11.1

Network Meta-Analysis of Ziprasidone Compared to Olanzapine in the Treatment of Bipolar Disorder

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Background: Network meta-analysis (NMA) is a technique designed to estimate relative treatment efficacy of multiple treatment regimens when direct comparisons are unavailable (Lumley, 2002). Given the absence of direct treatment evidence, NMA was considered as the only analytical tool available to comprehensively assess the effectiveness of ziprasidone compared to olanzapine in the treatment of acute mania associated with Bipolar I Disorder (BD).

Objectives: The purpose of the NMA was to combine two indirect comparisons of ziprasidone and olanzapine involving placebo and haloperidol as a common reference therapy.

Methods: Data were combined from 6 randomised, controlled trials of 1,559 patients with BD randomised to 4 different treatment arms: ziprasidone, olanzapine, haloperidol and placebo. Separate indirect comparisons with haloperidol or placebo as the common reference therapy were performed. NMA combined both indirect comparisons into 1 overall analysis. The primary outcome measure was changed from baseline in mania rating scale (MRS) and MRS responder rates (>50%).

Results: The mean difference in MRS change from baseline for ziprasidone compared with olanzapine was not statistically significant (2.5, 95% CI: -0.3, 5.3). There were no statistically significant differences for MRS responder rates [(RR = 0.8 (95% CI: 0.5, 1.4)]. These results were consistent with results from indirect comparisons.

Conclusion: NMA can be used to synthesise evidence from clinical trials in a broad range of therapeutic areas. The lack of statistical significance is not surprising, given that indirect comparisons are low in power and frequently lead to results with wide confidence intervals (Gartlehner et al, 2008). Since NMA combines results from indirect comparisons, the deficiency of statistical power of this method is to be expected. Although inferences that can be deduced from such analyses may be limited, NMA represents a valuable analytical tool in the absence of direct treatment comparisons.

P11.2

Should Systematic Reviews that Include Non-Randomised Evidence also Include Abstracts of Such Evidence?

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Background: Including abstracts of randomised controlled trials (RCTs) in systematic reviews can help address publication bias, contribute data where none are otherwise available and increase precision in a meta-analysis. Where the question of interest cannot be answered by RCTs then it may be possible to include non-randomised studies. However there is uncertainty as to the merits of also including abstracts of non-randomised studies in such reviews.

Objectives: To examine the effects of including abstracts of RCTs and non-randomised studies on the results of a series of systematic reviews assessing the safety and efficacy of interventional procedures.

Methods: For each review, the amount of data contributed by abstracts of RCTs and non-randomised studies was analysed. Sensitivity analysis examined how excluding abstracts of RCTs and non-randomised studies affected the results of the reviews in terms of primary efficacy outcomes, adverse effects information and direction of effect.

Results: In 14 reviews including a total of 673 studies, 81 (12%) were abstracts, of which 25 (31%) were RCTs and 56 (69%) non-randomised studies. Six reviews contained no abstracts. Across the remaining 8 reviews, the median number of abstracts included was 7 (range 1 to 28). The topics addressed included preventing medication error at hospital admission, mesh/grafts for vaginal wall, uterine or vault prolapse repair, foam sclerotherapy for lower limb venous disease, electrosurgery for tonsillectomy, sacral nerve stimulation for urinary and faecal incontinence, and photorefractive surgery for the correction of refractive error.

Conclusion: The number of abstracts included in the reviews varied considerably. Detailed results will be presented on how abstracts of RCTs and non-randomised studies contributed data to the reviews and the effect that excluding them had on primary efficacy outcomes, adverse effects information, and direction of effect of the results.

P11.3

A Systematic Review of RCT's Reporting NNT

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Backgound and Objective: "Number needed to treat" (NNT) is by some advocated to be a measure of effect which is easier to understand than others (relative risk, odds ratio etc.). Others have pointed out several problems with NNT. The objective of this work has been to find out more about the use of NNT in medical journals.

Methods: We searched Medline for RCT's reporting either "number needed to treat" or "NNT" in their abstract. Abstracts reporting values of NNT were included only if they were real RCT's.

Results: The search resulted in 305 hits, of which 53 was not real RCT's or did not report NNT in their abstract. Of the

remaining 252, 43 (17%) was published in one of the "big Five" journals (BMJ, JAMA, Lancet, NEJM and Annals of Internal Medicine). BMJ have published the majority of these articles, with 29. Annals of Internal Medicine and NEJM seem to have stopped publishing NNT (none after 2004). Of other journals with several reportings of NNT in their abstract, Obstetrics and Gynaecology have 17 (all published in 2004 and after). There has been a steady increase in the use of NNT up to 2002, while after that around 30 RCT's have been published each year.

Discussion: It seems some journals have a clear standpoint of not publishing NNT or at least only to a small extent. This might be because editors are aware of the problems with reporting and understanding this measure of effect. Other journals, such as BMJ and Obstetrics and Gynaecology may have other policies, as these two journals alone have almost one fifth of all RCT's published with NNT in their abstract.

Conclusion: You need 5 RCT's in Medline reporting NNT, to find 1 published in either BMJ or Obstetrics and Gynaecology.

P11.4

Updated Methodological Guideline for Rapid-HTA: What Have Changed

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"Methodological Guideline for Appraisals on Health Technology Assessment" aims to help to standardise, qualify and evaluate rapid-HTA produced by technicians from the Ministry of Health of Brazil (MH) and other instances of the Brazilian Unified Health System (SUS) and Supplementary Health. The first edition of this document was published in 2007. Starting from the training courses for elaborating rapid-HTA, which had happened in 2008, more than 100 people, representatives of the technical areas of MH, State and County Secretariats of Health, universities, and health-insurance plans, evaluated the guideline concerning its utility, validity and applicability. The following issues have been evaluated: a) Usefulness to elaborate a rapid-HTA, b) Easefulness and adjustment of the concepts presentation, c) Adjustment of the proposed methods, and d) Clarity of writing, which should be classified as "adjusted", 'partially adjusted" or "inadequate". There were no issues classified as "inadequate". Issues a and c were classified as "adjusted" by 93%, while issues b and d were considered "adjusted" by 96% and 95% of the participants, respectively. Suggestions were used to help the guideline's updating. Before the new edition's publication, we counted on some researchers and decision makers who worked with HTA, management and incorporation, evidence-based medicine and health economics. Several structural and methodological aspects were discussed and updated for the construction of a more complete and didactic version: absence of items concerning the need of economic analysis results on rapid-HTA, which became related only to efficacy of health technologies, need of more details about the literature evidence search and selection, and classification of databases as free or restricted. Finally, a rapid-HTA objective is to congregate the best available evidence and to supply decision makers with recommendations concerning health technologies utilisation. This kind of study is, nowadays, the more often used and useful tool to support the decision-making process on SUS.

P11.5

Issues in Incorporating Heterogeneous Studies in Meta-Analysis (Case in Effect of Atorvastatin on CVD Prevention)

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Background and objective: Combining the results of clinically and/or statistically heterogeneous studies in meta-analysis and making conclusion based on the integration are one of the main issues in meta-analysis. However, this issue is often neglected in meta-analysis by simply pooling all the studies using the random effect model. This study was conducted to investigate the impact of heterogeneous randomised clinical trials (RCT) included in meta-analysis.

Methods: We performed a systematic review and meta-analysis of RCTs on the effect of atorvastatin on CVD prevention. Outcomes were measured by all-cause mortality, fatal stroke and fatal MI, respectively. Pubmed, EMBASE and the Cochrane Library were used in this systematic review. Clinical and statistical heterogeneity was investigated based on clinical consulting and statistical methodologies such as Q-statistics, I^2-statistics and L'abbe Plot. Finally, we examined the impact of inclusion/exclusion of identified heterogeneous studies on outcome results. REVMAN 4.2 version and Stata 9.0 version were used for this analysis.

Results: The search yielded 540 potentially relevant trials. Of these, 10 studies were finally included in the meta-analysis. Among these 10 studies, ASPEN, MOHIER or SPARCL were identified as clinically and statistically heterogenous in all-cause mortality, ASPEN, MOHIER or WANNER in fatal stroke, and ALLIANCE or SPARCL in fatal MI, respectively. Before excluding heterogeneous studies, pooled outcome estimated by fixed model were 0.93 (95% CI: 0.86 to 1.00) in all-caused mortality. However, when we excluded SPARCL which is the most likely to impact heterogeneity on all-caused mortality, the estimate was changed to 0.91 (95% CI: 0.86 to 0.97) by fixed effect model and 0.92 (95% CI: 0.86 to 0.98) by random effect model, respectively. In the case of fatal stroke and fatal MI, similar tendency was observed.

Conclusion: Our results addressed the issue of the combination of clinically and/or statistically heterogeneous studies in meta-analysis and applying a random effect model could not be solution for this heterogeneity. This study showed that integrated outcomes estimated changed depending on the inclusion of heterogeneous studies. This implies that an inappropriate conclusion may be reached if the papers included in meta-analysis were not carefully investigated.

P11.6

Conjoint Analysis and Analytic Hierarchy Process to Determine Preferences for Health Interventions

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Introduction: Conjoint analysis has methodological advantages compared to other multi-criteria decision analyses techniques, like the Analytic Hierarchy Process, because of its foundation in utility theory and the more realistic approach to imitating consumer decisions. However, an empirical comparison has suggested superiority of AHP to CA in complex decisions. In a previous study we compared conjoint analysis and AHP by analysing the preference for two treatment options in high level spinal cord injury. In the present study, we are interested to see how each of these methods behaves in decisions involving more than two treatments.

Methods: The present study was carried out in 142 patients with a mean age of 61 years. Of all patients, about 50% suffered from a drop-foot due to stroke and about 20% has had a HNP. All patients suffer from ankle-foot impairments and used walking aids (e.g. ankle-foot orthoses). The attributes in the conjoint analysis study were based on a decision tree that was created previously in collaboration with an interest group of physiatrists. Subsequently, patients were given a survey asking for AHP weights of the main attributes, determined by an expert panel.

Results and Conclusion: The first preliminary findings were that the AHP and CA studies gave different ordering of the attributes. According to AHP, "treatment results", "risks" and "comfort of additional devices" were the most important attributes. The CA study, however, showed that the "impact of treatment" (i.e. requiring surgery or not) was most important. The other finding was that the relative difference between attribute weights was much smaller using CA compared to AHP. The rank reversals and the smaller difference in weights between first and last attribute, are consistent with the findings in a previous study where we compared four multi-attribute weighting techniques.

P11.7

The Cervical Cancer Cost Assessment (C3A) Study: A Cross-Linking Data-Based Analysis Designed to Estimate Direct Expenses Induced by the Management of Early Stage versus Locally Advanced Cervical Cancer in Italy

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Background: Currently, early stage cervical cancer (ECC) patients (Stage IB1-IIA <4 cm tumour volume) are treated with radical surgery or radiotherapy, while concomitant radiation plus cisplatin-based chemotherapy is considered the standard treatment in patients with locally advanced cervical cancer (LACC) (Stage IB2-IVA) exclusively. Among different approaches aimed at maximising local control and eventually improving prognosis, the use of chemoradiation followed by radical surgery (CT/RT-RS) has also been investigated. To our knowledge, no data are currently available assessing C3 of LACC patients undergoing RT/CT-RS versus ECC patients.

Methods: A longitudinal, retrospective, cohort study was designed, and clinical and administrative databases were cross-linked. All patients with a histologically confirmed diagnosis of invasive cervical cancer admitted to the Departments of Gynaecologic Oncology in Rome and Campobasso University Hospitals in the period of January 2001 to December 2006 were enrolled. Each admission was associated with a DRG code and each code was coupled with a tariff calculated as a mean value at national level. Analyses were performed on a patient-by-patient basis with a minimum follow-up of 22 months. A multivariate analysis to identify cost predictive factors was performed.

Results: Of 351 patients eligible for analysis, 139 (39.6%) were ECC and 212 (60.4%) were LACC. Disease recurrence/progression was recorded in 67/212 LACC (31.6%) and 13/139 ECC patients (9.3%). The average cost was 28,696 (SD = 24,874) in LACC and 12,329 (SD = 8,726) in ECC patients. Relapse or progression induced an increase of costs corresponding to a value of 43,000 (SD = 37,800) in the LACC and 23,900 (SD 17,100) in ECC group, respectively.

Conclusion: The combined use of administrative and clinical databases allowed a feasible assessment of C3 cost both in LACC and in ECC patients. Multimodal treatments of LACC patients were associated with higher C3, due to the involvement of several therapeutic strategies and more frequent appearance of recurrence/progression.

P11.8

The Time-Trade Off Approach to Measure Patients' Preferences for Health States Associated with HPV-Related Pathologies: A Multicentre Pilot Study Performed in Italy

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Background: The economic evaluation of any Human Papillomavirus (HPV) vaccination strategy requires the measurement of clinical benefits expressed in quality-adjusted life year gained, to reflect both the increase in life expectancy, and the economic convenience associated with effective interventions. The purpose of this pilot study was to investigate the feasibility of a method to quantify patients' preferences for health states affected by HPV-related pathologies in Italy.

Methods: A multi-centre, retrospective study was designed to enroll a cohort of females with a biopsy-confirmed diagnosis of Cervical Intraepithelial Neoplasia (CIN) 2/3 which had been managed in the previous 18 months. The value of utilities was calculated using the time-trade off (TTO) method that rated both the experienced and perceived impact on quality of life of some relevant HPV-related pathology states including CIN 2/3, genital warts, and cervical cancer through standardised descriptions and structured electronic questionnaires (i.e. EQ-5D). Patients could assign to each state a value between 0 and 1, corresponding to death and perfect health, respectively. Several risk factors for HPV infections were also registered and examined.

Results: This pilot study evaluated 20 patients with a mean age of 36.7 (SD = 6.37) years. At the time of administration, the perceived quality of life was defined by patients as generally good with a value equivalent to 0.89 (SD = 0.18). The average and standard deviation of utility results for each pathology state were reported as follows: CIN 2/3 0.71 (SD = 0.20), genital warts 0.56 (SD = 0.45), while the mean value for cervical cancer was 0.0 (SD = 0.0).

Conclusion: TTO is a feasible and appropriate technique for gathering patients' preferences and deserves implementation in larger populations. This pilot study provided early data concerning utilities associated with HPV-related pathologies in Italy. Women who had previously experienced precancerous lesions perceived genital warts as a more severe condition in comparison to CIN 2/3.

P11.9

Issues Involved in Populating an Economic Model with Health Related Quality of Life Data: Moving Towards Better Practice

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Background: There has been a growth in economic evaluations used to inform policy decision making on a societal level. The literature shows that results generated using different preference-based measures of health are not comparable and there is a move towards standardising the methods used. However, there is little research into the practicalities of populating economic models using these data.

Methods: We use EQ-5D data collected from a random sample of the general population to explore the appropriateness and implications of applying different methods to inform health states in a cardiovascular disease model.

1) We assess the consequence of using a baseline of perfect health compared with adjusting the baseline to reflect the observed HRQoL profile for individuals without cardiovascular disease.

2) We compare results generated when estimating scores for combined health states using data from individuals with a single health condition using three frequently used techniques: the minimum, additive and multiplicative method.

Results: We demonstrate that assuming a baseline of perfect health ignores the natural decline in quality of life associated with co-morbidities over-estimating the benefits of treatment to such an extent it could potentially influence a policy decision. We show the minimum method of combining scores biases results in the favour of younger aged cohorts. While the additive and multiplicative mean estimations are similar, the additive methodology assumes a constant detriment across all ages and does not account for differentials in detriments attributable to different health dimensions. Although further research in additional health conditions is required to support our findings, this pilot study highlights the urgent need for analysts to conform to a standard and provides initial recommendations for better practice. We advocate the multiplicative technique to be used to estimate values for combined health conditions.

P11.10

A Social Discount Rate for the Economic Evaluation of Health Technologies: Applying the Social Time Preference Approach to Germany

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Aim: Only recently, cost-effectiveness analysis has been introduced to support coverage decisions of the German

Statutory Health Insurance System on new drugs containing patented active agents. Aim of this study is to apply the social time preference (STP) methodology to calculate the social discount rate for health economic evaluations in Germany.

Methodology: The STP approach requires discounting future costs and benefits with the social rate of time preference (SRTP). We have estimated this rate by using the Ramsey equation: SRTP = p + e´g, with p being the individual time preference rate, e being the income elasticity of the marginal utility of income, and g the rate of growth of per-capita income. There are multiple methods to gain an estimate of *e*, we have used the procedures to derive e (i) from estimating the income price elasticity of a 'preference-independent' good, and (ii) from the income tax scheme, assuming the equal absolute sacrifice principle.

Results: According to our calculations, an appropriate value of the discount rate lies within a range of approximately 2.1% to 3.8%, depending on the approach to estimate the elasticity of the marginal utility of income and on the ethical judgment to what extent individual time preference should be reflected in the social discount rate.

Conclusion: If the Ramsey equation is accepted as an appropriate basis for deriving the social discount rate, for Germany a plausible base case discount rate would be about 3%. However, further analysis is required in order to determine the implications of the usual practice to measure only costs, but not benefits, in monetary terms. Given this practice, discounting both costs and benefits at the same rate may not be justified.

P11.11

Burden of Disease in Patients Entering Secondary Care Treatment in a University Hospital – Is the Threshold to Secondary Care Higher for Depressive Patients than for Patients with Somatic Disorders?

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Background: The threshold to secondary healthcare should be similar for all patients independent of the underlying disease.

Aim: To compare, using a validated health-related quality of life (HRQoL) instrument, whether the burden of disease is similar in six patient groups admitted for treatment into a university hospital.

Methods: Using the 15D questionnaire, HRQoL of patients entering coronary angiography (n = 261), hip or knee replacement surgery (n = 223), or elective operative treatment of cataract (n = 219), cervical or lumbar radicular pain (n = 270), or benign uterine conditions (n = 337) were compared with those entering treatment for depression (n = 85).

Results: Mean (±SD) HRQoL score (on a 0 to 1 scale) was highest in patients with benign uterine conditions (0.908 ± 0.071, P <0.001 compared to all other groups) and lowest in patients with depression (0.730 ± 0.212, P <0.001 compared to all other groups). The four other groups had fairly similar scores ranging from 0.802 to 0.824. On 11 of the 15 dimensions of the HRQoL instrument, patients with depression were significantly worse off than hysterectomy patients. The largest differences, besides on the dimension of depression, were on sleeping, usual activities, distress, vitality, and sexual activity. Following treatment, the greatest mean improvements in HRQoL occurred in radicular pain (0.047), depression (0.046) and hip or knee replacement surgery (0.041) patients.

Discussion: Individuals entering secondary care treatment for depression suffer from greater impairment of HRQoL than patients entering elective treatment for many other common conditions. Yet, in terms of improvement in HRQoL, the outcome of treatment in depressive patients is at least equal, or even better, than that in other conditions.

Conclusion: In the priority setting context many guidelines suggest that priority should be given to those worst off. Our results, however, imply that the threshold for secondary care is higher for patients with depression than for patients with common somatic disorders.

P11.12

The Foundations and Usefulness of Threshold Values for the Incremental Cost-Effectiveness Ratio in Healthcare Policy Making

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Cost-effectiveness analyses (CEA), as part of an HTA, inform policy makers about an intervention's relative *value for money*. When an intervention's incremental cost-effectiveness ratio (ICER) is lower than the "ICER threshold value", it increases the total health outcomes obtained from the limited resources available.

This study examines the meaning and caveats of the ICER threshold value in different healthcare systems and explores how countries currently deal with cost-effectiveness issues in decision making processes.

Our study demonstrates that a fixed budget requires a variable ICER threshold value, whereas a fixed ICER threshold value requires a variable budget.

In a fixed budget context the ICER threshold value is the ICER of the last intervention from a league table still financed from the budget. This value changes over time subject to changes in the budget, the interventions funded and the productivity of healthcare. In practice the ICER threshold value cannot be *identified* nor *applied* because information is lacking and because health policy makers wish to take other elements into account in the decision making process besides health maximisation.

In a flexible budget context, the ICER threshold value could be defined as the maximum societal willingness to pay for a QALY (WTP/QALY). However, its implementation is problematic because the WTP for a generic QALY cannot be measured. Past decisions do not help to define the WTP/QALY because they are rarely - if ever - inspired by the ICER only. Equity concerns always arise in resource allocation decisions: the ICER threshold value suggests which interventions are worth implementing but makes abstraction of societal preferences about health and/or income distributions.

Many countries use the ICER in decision making but few define an explicit ICER threshold value. Alternatives to using the ICER for efficiency evaluation include the opportunity cost and cost-consequences approach.

The main common message of all approaches is that transparent decision making requires explicit decision criteria and economic efficiency should be one of them.

P12 – HTA IN HOSPITALS

P12.1

Organisation for Hospital-Based Rapid HTA by Local Healthcare Professionals to be Used as Decision Support Tool in a Swedish Healthcare Region

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New healthcare technologies do not always cost-effectively improve patient benefit. In order to increase evidence based care, Västra Götalandsregionen, a Swedish healthcare region, in 2006 started a project with regional HTA as a decision support tool. Objectives included improved local ownership and understanding of HTA and increased collaboration between the healthcare and the academic organisations. As a result of the project, the proposed hospital-based rapid HTA process (Mini-HTA, 20 HTA questions, including systematic review) became mandatory where new technologies shall be prioritised for introduction into routine care. A regional HTA support centre (HTA-centrum) within the university hospital started in late 2007 and a network of HTA quality controllers and a HTA quality board were established. The HTA-centrum, including mainly physicians with HTA expertise and information specialists and the HTA quality controllers are educated in collaboration with the The Swedish Council on Technology Assessment in Healthcare (SBU). The role for HTA-centrum is to enable and facilitate HTA work by healthcare professionals and to perform some time consuming steps in the HTA process. The critical evaluation of the relevant medical publications is performed by the healthcare professionals in a standardised process with formalised objective quality control. By early 2009 12 HTA projects were finished, 6 are underway and 8 more nominated. Priority decisions are now regularly based on the HTA reports and prioritised technologies are introduced. Funding of clinical research is possible for promising techniques with demonstrated gaps of evidence. We observe a need also for larger HTA reports although single technology HTA with short lead times, during the budget process, are most often wanted. Our processes for selecting HTA projects, giving support during the HTA and securing quality before the HTA report is given the status of a quality controlled decision support tool will be discussed.

P12.2

The Study of Hospital Performance and Knowledgement Management

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The medical industry is a kind of high knowledge-intensive service industry. For the hospital, knowledge becomes a very important capital of the hospital. In terms of system implementation, personnel are one of the important factors on conducting the knowledge management (KM) in the hospital efficiently. The subject of the study is one KM system in one regional hospital in South Taiwan. This study would describe the understanding and the realisation that in the participation of knowledge management in hospitals refers to medical nursing staff and administrative staff. Furthermore, this study would show that the cognitive variation on a KM system refers to executives. The study would also show that the recognition of knowledge management and the understanding of knowledge management in the hospital refer to the basic level staff and the middle level managers.

According to the empirical results of the study, it shows that there are little differences in the employees' awareness of knowledge management and in the employees' awareness of hospitals' knowledge management between the executives and the staff. After comparing the medical staff's cognition with the administrative staff's cognition, the study shows that there is a significant difference between both cognitions. While discussing the performance of the knowledge management activities, the study shows the relationship among personal characteristics, employees' awareness of knowledge and employees' awareness of the hospital's knowledge management.

The study also shows that the relationship between knowledge function of self-awareness and employees' awareness of knowledge management will interact significantly. In other words, employees know that knowledge's function will affect the employees' awareness of knowledge management based on hospital. The study results might be of interest to hospitals.

P12.3

In Sickness and in Health, for Better or for Worse: The Use of a Surgical (Medical Device) Classification System to Measure and Manage Hospital Costs in the South African Private Sector

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The South African health sector comprises of two sectors namely the Public and the Private sector. This paper focuses on the Private sector in South Africa only. Hospitalisation costs represent 35% of the total benefits paid to providers.[1] Historically, negotiations of hospital costs were based on the 'tariff' component of hospital services which comprised of the hospital accommodation, theatre facility fees and equipment costs. The "consumable" component of hospital services, namely medicines and medical devices (surgical consumables) were excluded from such negotiations.

Medical Devices and surgical consumables are currently unregulated in South Africa both in terms of quality and comprise almost 30% of the hospital bill, the cost of which has increased in excess of other sectors in the industry.

The 'Dossier' Report: This report, compiled in 2005 by Discovery Health illustrated the sharp increases in hospital costs from 2000 onwards. Real costs increased between 40% and 50%.

Medical devices and surgical consumables classification: In 2001, Discovery Health in conjunction with an external vendor embarked on the *development of a surgical classification system* which involved the categorisation of all medical devices and surgical consumables.[2]

Conclusion: Managed Healthcare in South Africa has tried to reduce hospital costs through traditional methods of case management i.e. lowering length of stays and acuity levels, pre-authorisation of admissions and discharge planning. Whilst hospitals internationally compete on price and quality, in the South Africa Private sector, which is dominated by three major players, this has not occurred. Third-party payers and hospitals have started engagement on sharing risk through casemix adjusted agreements or DRG fixed fee based reimbursement models. Medical devices and surgical consumables and medical devices remain widely unmanaged. For Discovery Health, the surgical classification has made it possible to have discussions around price variations with the major hospital groups. It has also enabled Discovery to gain insight of the manner in which the hospital networks manage their hospitals.[3]

1 Source – Council of Medical Schemes Annual Report 2006-7

2 Ethical items (medicines) adopted the WHO ATC classification and therefore required no 'home grown' solution

3 Interaction between Discovery Health and the Hospital Networks on Length of Stay and Level of acuity has always been 'routine'

P12.4

Multidisciplinary Analysis for Hospital Based HTA Methodology

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Aims: Technology assessment in hospital depends on three main factors: clinical activities, technology and users. The study analyses the relationships among these factors in order to develop an "HTA dashboard" with the aim to support decision makers in acquisition and management planning of

medical devices in hospitals.

Methods: Literature review and previous technical analysis on technology were the basis for this study to support a check list definition for medical personnel. It aimed to complete existing HTA information such as technological complexity or destination of use classifications, obtained from the Clinical Engineering Department database at Careggi Florence Hospital during previous studies.

Results: By analysing the check list results, the obtained data pointed out evident relationships between "technology", "criticality" (that is the device importance in medical processes), users' "perceived reliability" in medical devices and the "destination of use". Finally, strong correlation between criticality and users' perceived reliability was demonstrated in the analysis.

Conclusion: The use of this methodology has resulted in a helpful tool for decision-makers. The check list analysis completes the dashboard with clinical and usability aspects. Consideration of multi-disciplinary aspects allows for consideration and verification of many different aspects in a HTA process, such as worker performance aspects related to different technologies, technology appropriateness and management aspects for users. Further data analyses are now being processed in order to evaluate the right Key Performance Indicators to use in the final "HTA dashboard".

P12.5

Pharmacy and Therapeutic Committee Reform: An Initiative of Health Technology Assessment Application for Formulary Management

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Background: Pharmacy and Therapeutic Committee (PTC) is the multi-disciplinary committee that oversees policies and procedures related to all aspects of medication use within the hospital. Typical role of PTC in Thai hospitals is to maintain hospital formulary based on expert opinions. However, the process of adding or deleting a drug from the formulary based on available published clinical evidence especially cost effective analysis (CEA) is rather varied and unclear.

Objectives: To develop and implement formulary management system by incorporated health technology assessment at Naresuan University hospital (NUH).

Methods: Workflow and component of PTC and procedures to add or delete a drug from NUH formulary has been redesigned incorporated a task force composed of pharmacy faculty members. Manufacturers were required to submit relevant information for the formulary considerations. Bioequivalence studies were required and assessed for the consideration of generic products. Available clinical evidences including CEA were evaluated by the task force before recommending the formulary status to the PTC.

Results: The new approved workflow has been implemented at NUH since October 2008. During the first 3 months, 11 drugs were considered through these new policies and procedures. One generic product was denied from the formulary due to questionable results of the bioequivalence. Triglyceride lowering agents were considered based on efficacy and safety clinical studies. Only 2 (out of 3) strengths of a fibrate agent was added to the formulary and restricted to be used in combination with statin. Based on comparative studies, 2 proton pump inhibitors were denied from the formulary while one agent was added with restrictions by expert opinion. CEA studies are to be used for the consideration of drug reimbursement.

Conclusion: Health Technology Assessment is the crucial component of this PTC reform. The initiative can be utilised to promote safe and rational drug uses in the hospital.

P12.6

Parental Stress: A Multi-site Cross-cultural Comparison between Neonatal Intensive Care Units (NICUs) in New Zealand and Japan

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This study compares the medical systems and environments in NICUs in New Zealand and Japan in order to analyse how cultural differences influence parental stress and nursing roles, in particular their role in reducing parental stress and anxiety.

The research questions were: How do the 2 systems handle care of preterm infants and their families? How do the roles of nurses and the family differ across cultures? What does the relationship between parental stress and demographic variables imply for nursing roles?

A cross-sectional, cross-cultural, research design was undertaken. Thirty-one pairs of parents participated in the study from each country (n = 121). Participants were recruited from 2 NICUs – New Zealand and Japan. Measures of parental stress were collected from the Parental Stress Scale: Neonatal Intensive Care Unit (PSS: NICU). The results were analysed using parametric and non-parametric tests including multiple linear regression analysis.

Among the 3 subscales, the Tokyo mothers seemed to be more concerned about *Baby's Appearance and Behaviour* compared

with *Parental Role Alteration.* The Christchurch mothers, however, perceived *Parental Role Alteration* to be more stressful compared with *Baby's Appearance and Behaviour* and *Sights and Sounds*.

The Christchurch fathers most frequently experienced stress in relation to the change in parental role as well as the infant's condition. The *Sights and Sounds* subscale was least frequently rated as moderately or highly stressful. The Tokyo fathers experienced stress in association with the *Sights and Sounds* subscale more often than other areas such as *Parental Role Alteration* and *Baby's Appearance and Behaviour*.

The areas of parental support needing attention were different between the 2 NICUs. These areas were: the establishment of oral feeding, and infants' nursing care-related decision-making for the Christchurch NICU whilst parental information/ involvement in the early stage of hospitalisation, the influence of visiting regulations, and importing Western-based NICU intervention for the Tokyo NICU.

P12.7

Overcoming the Lack of Evidence in the Evaluation of Innovative Medical Device: The Experience Unità di Valutazione delle Tecnologie (UVT) at Gemelli University Hospital

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Background: New medical devices (MDs) have been progressively increasing and are still expanding. MDs are indispensable in the provision of modern, high-quality healthcare. In this context, it is crucial for decision-makers that reliable evidence exists on the effectiveness and cost-effectiveness of the MDs in order to introduce only the more effective MDs into clinical practice. The main concern regarding new MDs has been the lack of high quality and effectiveness.

Aim: In this work we describe the experience of UVT in managing the concerns regarding type and extent of evidence needed in order to guarantee appropriate introduction of MDs into hospitals and in overcoming this lack of evidence.

Methods and Results: UVT assists hospital decision-makers with a transparent, explicit, pragmatic and fair HTA process. UVT has developed a procedure based on standardised methods and products. It foresees the arrangement of a mini HTA report for each MD required by clinicians. In the last year, 34 requests have been processed and 23 mini HTA reports have been completed. Two recommended rejection, 18 recommended restricted use, 3 recommended unrestricted use, and 11 were cancelled by clinicians. Grading of evidence on evaluated MDs is based on an adaptation of a model developed by Shekelle (1999). From our observations, evidence from well-designed RCTs, comparing the clinical and cost effectiveness with current standard care is available for only a few MDs in the market. Moreover, even though RCT are available, the studies had significant methodological limitations (few patients, inadequate randomisations).

Conclusion: In order to overcome the lack of evidence, UVT proposes, in the case of restricted use recommendation, reducing the quantity of the required MD and testing its controlled use through the implementation of a monitoring system by performing in-house clinical trials.

P12.8

Benefit Evaluation on Integrated Information System for Hospital Accreditation in Taiwan

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Taiwan

Objectives: Since enforced the National Health Insurance System in Taiwan, lots of medical institutions had faced the political changes and then innovated the strategies about how to control well on management performances and cost control under the government's hospital accreditation mode recent years. How do hospitals integrate the accreditation datum quickly to monitor every unit's work progress, then establish the process as daily work and strengthen the tracing functional management to save more human enforce costs by systematically methodical and the automated ways to assist hospitals to set up the accreditation management has been the goal for which every medical institutions pursue and strive toward continuously.

Methods: This study adopted questionnaire and semi-structured interview design. The subjects were sampled with 110 of all levels of staffs who operate the Accreditation Management Information System, contrast to 78 who don't operate the system in a district teaching hospital in south Taiwan. The purpose of this study was to describe the correlation between individual characteristics, organization's internal environment, individual information/technology ability, job satisfaction, job completion, and its spent time.

Results: This study revealed since the intervention of Accreditation Management Information System implementation, the staffs' effectiveness in the dimensions of organization's internal environment, individual information/ technology ability, job satisfaction, and job spent time was shown significant differences, further, it can verify the benefit after integrating the system with the accreditation.

Conclusions: Through this management plan on hospital accreditation, which can review the outcome of hospital management at anytime, establish complete documentation and benchmarking samples, and then join all the staffs together to display the team cooperation and communication in organization cultures, eventually set up an accreditation system with safe, effectiveness, efficiency, timeliness, and taking the patients as the central.

P13 – INFORMATION RESOURCES

P13.1

The Brazilian Platform for Registry of Clinical Trials (REBRAC): An Instrument of State Policy

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The Brazilian Platform for Registry of Clinical Trials (REBRAC) is a project initiated in 2008 under the leadership of the Department of Science and Tecnology (DECIT). The project answers to World Health Organisation (WHO) direction. But REBRAC was additionally thought of as an instrument of state for the development of the National Policy of Science, Technology and Innovation in Unified Health System (SUS).

In 2008 an Act of the Brazilian Minister of Health constituted an interinstitutional commission with representatives of DECIT, Oswaldo Cruz Foundation (FIOCRUZ), the Regional Library of Medicine (BIREME) and the National Agency of Sanitary Surveillance (ANVISA).

The commission reached the following consensus:

- The REBRAC will be a primary register developed with an open software platform entirely linked to the ICTRP, the National Council for Ethic in Research (CONEP) system and BIREME and in the future with the regional register that may be developed in Latin America and Caribbean Region.
- The scientific information will be available in 3 main languages - Portuguese, Spanish and English and the access to information will consider security levels in compliance with the principles of ethics in research with human beings.
- The database will be constituted by the completeness of the information set that WHO recommends, complemented by other topics considered strategic in the context of the Brazilian public health.
- The REBRAC will be located in FIOCRUZ Foundation in Rio de Janeiro. The Bireme will be responsible for technical assistance and the general coordination will be under the responsibility of DECIT.
- By 2009 December the REBRAC must be in a fully operational phase.

Conclusion: A worldwide net of platforms to registry clinical trials is a decision that protects scientific and ethical principles. The establishment of REBRAC strengthens the regulatory capacity on research and innovation in health in Brazil.

P13.2

Analysis of the Usage of the Information Resources of the Spanish Health Technology Assessment Units and Agencies

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Introduction: The Spanish Health Technology Assessment units and agencies carried out a study to find out which were their common information requirements. Based on this study, it has been proposed to have a common policy of subscriptions to some information resources.

Objective: To know the usage of the databases subscribed for the AUnETS group of information specialists.

Materials and Methods: Joint subscriptions to different databases were carried out for the AUnETS group members. The databases subscribed to were as follows: Scopus, ECRI, Hayes, Clinical Evidence, Dynamed and Ovid EBMR. An analysis of their usage was performed from the start of each subscription until December 2008. The data collection and provision has been conducted according to the practices of the information providers. The basic indicators that are of interest for us are: search results (number of effective searches made) and texts (number of retrieved articles).

Results: There are different ways of exploiting the information for each database and so, it has made the analysis of the data, and even pooling of the results, difficult. Most of the less used databases were linked to clinical questions (target group clinicians). In the searching statistics for each database, there is a limited use of many of them (such as Ovid EBMR, with 20 sessions and 113 searches in 6 months), except for some important and highly specialised ones that focused most of the searches (as Scopus, with 274 sessions that produced 1,604 searches).

Conclusion: The data collection and the statistics analysis of usage of the databases, platforms, magazines, etc. have become of vital importance because they reveal how the users use information resources. Knowing the usage of the databases by information professionals provides great value in taking decisions (both subscription and planning). From the obtained data, it could be possible to propose cancellation of some of the resources, so you only subscribe what is truly used, gaining efficiency from the beginning of the process.

P13.3

AUnETS: Platform for Knowledge Management and Diffusion of the Information Generated by Spanish HTA Agencies and Units

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Background: The Quality Plan for the Spanish National Health System (2006) set up agreements between the Spanish Ministry of Health and the Spanish Health Technology Assessment (HTA) units and agencies, whose aim was supporting HTA research projects. A web platform, named AUnETS, has been set up in order to manage and monitor efficiently these HTA projects. The functionalities of this platform are: knowledge management, diffusion of the results of these projects (HTA reports, clinical guidelines, methodological support tools, etc.) and dissemination of relevant information in HTA.

Methods: In early 2008, a Beta version of the platform was set up and evaluated for 3 months in order to detect its strengths and weaknesses. A set of improvements was proposed in order to make the platform more intuitive and easy to use. Since October 2008, we have been working on the implementation of these improvements. Each HTA unit or agency loads the information about their projects, their documents and other relevant information. The Health Technology Assessment Agency of the ISCIII manages the platform and supervises and standardises the load.

Results: The platform is web-accessible at http://aunets.isciii.es and provides information about 300 HTA research projects, 200 final documents, seminars, congresses, training courses and links to HTA resources. There is also a private section where the research projects that are being developed by the registered users can be submitted through the web, the platform provides the necessary tools for the coordination, communication and management of that information.

Conclusion: This is an ongoing project, and besides the fact that we are at the first stage it can already be used as a useful device for the coordination and networking among agencies. Moreover, it is meant to become a large repository to gather the Spanish publications related to HTA.

P13.4

Which Database Sources are our HTA-Reports Based on? Assessment of Where Included Articles were Found

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Background: To perform a systematic and comprehensive search for preparing a systematic review or HTA is a usually a laborious process, which challenges the timeliness of such research for decision making. Rapid reviews have emerged as one way to reduce time taken. We wanted to assess the origin of included articles of published HTA-reports from the Norwegian Knowledge Centre for the Health Services, in order to assess consequences of limiting the searches to Medline.

Objective: To assess the contribution from different databases to the final documentation in HTA reports. Method: We chose 6 published HTA-reports from our institution within the timeframe from 2006 to 2009. We thoroughly assessed these reports and summarised where the included references had been localised. The database sources were then categorised in "found in Medline" or "found in other source". The use of sources other than Medline was calculated as percentages.

Results: We assessed 6 published HTA-reports covering drugs and new technologies. These reports had included a total of 124 articles and we found that only 8 (6.4 %) could not be found in Medline. The articles identified in Medline for each report were as follows: HPV-vaccination 11/11, Angiotensin receptor blockers 5/6, Selective serotonin reuptake inhibitors 18/23, Left ventricular assist device 14/14, In vitro maturation of oocytes 17/17, Breast cancer rehabilitation 51/53. Conclusion: For selected Norwegian HTA-reports during 2006 to 2009, approximately 94% of included articles were found through searches in Medline. On this background only minor consequences may be anticipated by limiting our searches to Medline when preparing rapid reviews for decision making.

P13.5

Searching for Effectiveness of Public Health Interventions – A Case Study for Cardiovascular Disease (CVD)

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Background: Searching for information on public health interventions may require extensive searches and complex strategies. We report experience searching on the effectiveness of population-level multi-factor interventions for the prevention of CVD.

Objectives and Methods: The reference standard was a sensitive search strategy (R) used to identify the 34 CVD programmes for a systematic review. Yield, sensitivity, precision and number needed to read (NNTR) were compared across 7 databases searched (MEDLINE, EMBASE, CENTRAL, CINAHL, ASSIA, HMIC, PsycINFO). Two alternative strategies (A1 and A2) were developed with the aim of improving precision while minimising impact on sensitivity. Performance of the 3 strategies was compared in MEDLINE and EMBASE.

Results: Strategy (R) across 7 databases achieved 100% sensitivity with a NNTR of 1,428. MEDLINE alone yielded 31/34 (91%) of relevant programme citations. Four databases were required to identify all relevant programmes. Four

databases provided no unique references. In MEDLINE the alternative strategies achieved a sensitivity of 73% (A1) and 79% (A2) with greatly improved NNTR of 119 (A1) and 78 (A2) compared to (R) (NNTR 500). On EMBASE (A1) and (A2) performed poorly in terms of sensitivity (47% and 50%) but again improved in terms of NNTR (322 and 200) compared with (R) (666).

Conclusion: MEDLINE alone yielded 31/34 programmes which did not improve when searching EMBASE. Searching other databases did improve yield but increased NNTR. An optimum of 4 databases found all programmes, questioning the value of very extensive searching. Precision may be improved by judicious use of index terms for public health interventions and MeSH. However strategies using controlled vocabulary will perform variably when applied to different databases. Whether the medical nature of this topic affected yield across databases requires more research.

P14 – STAKEHOLDER ENGAGEMENT

P14.1

Patient Education Programmes

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Background: Patient education programmes are becoming widespread in the attempt to enable patients with a chronic disease to take increasing control of their condition. Studies have, however, shown inconsistent results on the effect of patient education programmes, and it is unclear how ongoing and future patient education is best organised.

Objectives: The objectives of this ongoing health technology assessment (HTA) are to systematically review the clinical effectiveness, patient-experienced effectiveness and cost-effectiveness of generic patient education programmes and disease-specific programmes for Type 2 diabetes and chronic obstructive pulmonary disease (COPD). Further, this HTA reviews characteristics of patients recruited to patient education programmes. Factors experienced by patients as important for maintaining the intended effects of patient education will be identified.

Methods: A systematic literature review was undertaken based on protocolled searches in several electronic databases (Medline, Embase, Sociological abstracts, Psychinfo, Cochrane library) up to January 2009. The HTA report will be finalised in June 2009.

Results: Results on clinical effectiveness, patient-experienced effectiveness and cost-effectiveness will be presented. Moreover, findings on recruitment of patients to patient education programmes will be presented. Finally, results on patients' experiences of which factors are important for maintaining the effects of these programmes will be presented.

Conclusion: This HTA will provide an important basis for an appropriate organisation of future patient education and raise central issues in relation to future research.

P14.2

An Investigation of the Scottish Medicines Consortium (SMC) Impact on and Engagement with Stakeholders

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Objectives: The SMC advises NHSScotland about the status of newly licensed medicines, new formulations of existing medicines and new indications for established products. An investigation was undertaken to identify how SMC has impacted on NHS board Area Drug and Therapeutics Committees (ADTCs) in their assessment of new medicines, and the views of key stakeholders (ADTCs, public partners and pharmaceutical industry).

Methods:

Impact on ADTCs role and function involved:

- Review of reports and publicly available information describing ADTC processes before and after establishment of SMC and an ADTC workshop.

Engagement with stakeholders involved:

- Public partners survey to organisations (n = 154), with a telephone survey of non-responders, generated 93 responses plus qualitative interviews (n = 15) with a sample.[2]
- Separate workshops for ADTCs and pharmaceutical industry to explore the successes, challenges and potential for improving engagement with SMC.

Results: There was a clear evolution in the evaluation and implementation of new medicines by ADTCs across NHSScotland, with SMC now recognised as a credible source of timely advice. Pharmaceutical industry suggested areas for improvement but viewed SMC processes as robust and transparent, and its decisions as timely and globally recognised. Awareness of SMC by public partners was limited though generally positive amongst those who had engaged.

Conclusion: SMC has engaged effectively with ADTCs and Industry. Engagement with public partners remains a challenge.

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[1] commissioned by the SMC Executive.

[2] commissioned from the Scottish Centre for Social Research (ScotCen).

P14.3

Using Community Views to Inform Health Technology Assessment: A Case Study in Pandemic Influenza Planning in an Aboriginal Community-Controlled Health Service

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Background: The Australian government, like other national governments, has allocated substantial health resources toward pandemic influenza (PI) planning. In deciding how these resources were allocated, the views of stakeholders were considered important. Yet we know little about community views, particularly minority community views, on the acceptability of these plans. Aboriginal Australians are likely to be disproportionately affected during a pandemic due to crowded housing and higher background rates of chronic illness. Aboriginal Community-Controlled Health Services (ACCHS), as primary providers of health-care to rural Indigenous communities, will play an important role in implementation of plans. This study explored PI preparedness in an ACCHS.

Methods: Focus groups and face-to-face semi-structured interviews were conducted with stakeholders (n = 16) including board members, health workers and managers in a rural ACCHS.

Findings: As with mainstream studies, our participants had limited understanding about PI and its implications. There were indications that the ACCHS, because of the separation of Aboriginal health services from mainstream services, was actively excluded from regional planning processes. The nearby regional hospital had well developed PI plans. In contrast, the ACCHS had no personal protective equipment (PPE) stockpile and no staff trained in PPE use. The majority of ACCHS staff were willing to provide services during a pandemic but expected adequate ACCHS support. Participants expressed the need for education of health workers and community, inclusion in regional planning processes, and consideration of cultural, social and historical factors that may impact implementation of PI plans.

Conclusion: Our findings parallel other studies which suggest that national pandemic preparedness plans do not address the social issues associated with the needs and interests of disadvantaged populations even while such groups may face an increased burden in a pandemic. This study supports the importance of including citizen perspectives, particularly those of disadvantaged Indigenous groups in HTA processes.

P14.4

Different Roles Played by Consumers in One HTA Organisation

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The Division of Research, Audit and Academic Surgery (RAAS) in the Royal Australasian College of Surgeons values consumer involvement in all aspects of its research and audit processes. Consumers contribute at varying levels in various projects, from participating in the decision-making process to preparing consumer information.

The Australian Safety and Efficacy Register of New Interventional Procedures - Surgical (ASERNIP-S), the research arm of the division, is a member of the Consumers' Health Forum (CHF). ASERNIP-S also benefits from 2 consumer representatives on its Advisory Committee, 1 from the Health Consumers' Alliance and the other a professional communicator. They comment on systematic reviews produced, help prepare consumer summaries, and establish links with consumer organisations. ASERNIP-S conducts systematic reviews for other organisations with guidance from consumers on decision-making committees. Policy-based initiatives have included CHF as a key stakeholder.

The audit section of the division has 2 main arms, the morbidity and mortality audits. The National Breast Cancer Audit is the largest morbidity audit, peak consumer group Breast Cancer Network Australia (BCNA) is heavily involved in the development of the audit through representation on various committees and provision of funding for key projects. The Australia and New Zealand Audit of Surgical Mortality (ANZASM) investigates deaths related to surgical admission in hospitals. A community representative on the national steering committee provides a wider perspective on this sensitive issue, this is complemented by regional consumer representation.

Consumers can access all reports prepared by the RAAS division on its website (Research and Audit page of www.surgeons.org), together with plain English summaries of systematic reviews. Consumers are encouraged to provide feedback to the office via the website. We will look at the mutual benefits of this involvement to consumers and the organisation, and its influence on future activities.

P15 – HEALTHCARE FOR THE ELDERLY

P15.1

A Cost-effectiveness Analysis of Psychotropic Medication Withdrawal to Reduce Falls in Community-dwelling Elderly in Ontario - Results from the Falls/Fractures Economic Model in Ontario Residents (FEMOR) Aged 65 Years and Over

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Objective: To assess the incremental cost-effectiveness of psychotropic medication withdrawal versus no intervention in preventing falls in community-dwelling seniors from the Ontario Ministry of Health perspective.

Methods: A Markov model represented the recurrent nature of fall-related health states. Health states reflected how community-dwelling seniors transition between healthcare settings once they experience a fall. After a patient experienced a clinically important fall they were admitted to the hospital or visited an emergency department. Hospital admissions were permitted for hip fractures, other fractures and non-fracture injuries. Following hospital care, patients were either discharged to the community, a rehabilitation centre or long-term care (LTC) facility or remained in the hospital for palliative care. Patients could die at any point in time. Costs and outcomes were discounted 5% annually within a lifetime horizon. Outcomes measured were number of falls avoided, life years, total cost, LTC and hospital costs. Costs were reported in CAD$ 2008. Psychotropic medication withdrawal efficacy was estimated from 1 randomised controlled trial.

Results: Psychotropic medication withdrawal produced dominant results in both sexes. The potential lifetime cost avoided per patient to the public system was $76.89 LTC dollars and $10.91 hospital dollars in females, and $60.94 LTC dollars and $10.79 hospital dollars in males compared to no intervention. Results were robust to univariate sensitivity analysis. The lifetime savings from psychotropic medication withdrawal in female and male Ontario residents aged ≥65 years were 1.0M and 0.7M, respectively.

Conclusion: While withdrawal of psychotropic medication may be a cost-effective method for reducing falls in Ontario's elderly population, evidence is limited and long-term compliance has been demonstrated to be difficult to achieve.

P15.2

A Cost-effectiveness Analysis of Long-term Exercise Programs to Reduce Falls in Community-dwelling Elderly in Ontario: Results from the Falls/Fractures Economic Model in Ontario Residents (FEMOR) Aged 65 Years and Over

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Objective: To assess the incremental cost-effectiveness of long-term exercise programs (>6 months) versus no intervention in preventing falls in community-dwelling seniors from the Ontario Ministry of Health perspective.

Methods: A Markov model represented the recurrent nature of fall-related health states. States reflected how community-dwelling seniors transition between healthcare settings once they experience a fall. Once a patient experienced a clinically important fall they were admitted to the hospital or visited an emergency department. Hospital admissions were permitted for hip fractures, other fractures and non-fracture injuries. Following hospital care patients were either discharged to the community, a rehabilitation centre or long-term care (LTC) facility or remained in the hospital for palliative care. Patients could die at any point in time. Costs and outcomes were discounted 5% annually within a lifetime horizon. Outcomes measured were number of falls avoided, life years, total cost, LTC and hospital costs. Costs were reported in CAD$ 2008. Exercise program efficacy was estimated from a meta-analysis of randomised controlled trials.

Results: Exercise programs produced dominant results in both sexes. The potential lifetime cost avoided per patient to the public system was $170.64 LTC dollars and $23.63 hospital dollars in females, and $114.77 LTC dollars and $19.95 hospital dollars in males compared to no intervention. Results were robust to univariate sensitivity analysis. The lifetime savings from a long-term exercise program in female and male Ontario residents were 46.4M and 25.7M, respectively.

Conclusion: High-quality evidence indicates that long-term exercise programs in mobile seniors are cost-effective in reducing falls in Ontario's elderly population.

P15.3

A Cost-effectiveness Analysis of Home Modifications to Reduce Falls in Community-dwelling Elderly in Ontario – Results from the Falls/Fractures Economic Model in Ontario Residents (FEMOR) Aged 65 Years and Over

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Objective: To assess the incremental cost-effectiveness of home modifications (e.g. removal of floor coverings, loose cords) versus no intervention in preventing falls in community-dwelling seniors from the perspective of the Ontario Ministry of Health.

Methods: A Markov model represented the recurrent nature of fall-related health states. States reflected how community-dwelling seniors transition between healthcare settings once they experience a fall. After a patient experienced a clinically important fall they were admitted to the hospital or visited an emergency department. Hospital admissions were permitted for hip fractures, other fractures and non-fracture injuries. Following hospital care patients were either discharged to the community, a rehabilitation centre or long-term care (LTC) facility or remained in the hospital for palliative care. Patients could die at any point in time. Costs and outcomes were discounted 5% annually within a lifetime horizon. Outcomes measured were number of falls avoided, life years, total cost, LTC and hospital costs. Costs were reported in CAD$ 2008. Home modification efficacy was estimated from a meta-analysis of randomised controlled trials.

Results: Home modifications produced dominant results in both sexes. The potential lifetime cost avoided per patient to the public system was $164.74 LTC dollars and $24.34 hospital dollars in females, and $112.78 LTC dollars and $21.30 hospital dollars in males versus no intervention. Results were robust to univariate sensitivity analysis. The lifetime savings from home modification in female and male Ontario residents aged ≥65 were 4.7M and 3.7M, respectively.

Conclusion: High-quality evidence indicates that environmental modifications in the homes of frail elderly persons are cost-effective in reducing falls in Ontario's elderly population.

P15.4

A Cost-effectiveness Analysis of a Gait-stabilising Device to Reduce Falls in Community-dwelling Elderly in Ontario – Results from the Falls/Fractures Economic Model in Ontario Residents (FEMOR) Aged 65 Years and Over

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Objective: To assess the incremental cost-effectiveness of a gait-stabilising device (GSD) versus no intervention in preventing falls in community-dwelling seniors from the Ontario Ministry of Health perspective.

Methods: A Markov model represented the recurrent nature of fall-related health states. Health states reflected how community-dwelling seniors transition between healthcare settings once they experience a fall. After a patient experienced a clinically important fall they were admitted to the hospital or visited an emergency department. Hospital admissions were permitted for hip fractures, other fractures and non-fracture injuries. Following hospital care patients were either discharged to the community, a rehabilitation centre or long-term care (LTC) facility or remained in the hospital for palliative care. Patients could die at any point in time. Costs and outcomes were discounted 5% annually within a lifetime horizon. Outcomes measured were number of falls avoided, life years, total cost, LTC and hospital costs. Costs were reported in CAD$ 2008. GSD efficacy was estimated from 1 randomised controlled trial.

Results: GSD use produced dominant results in both sexes. The potential lifetime cost avoided per patient to the public system was $248.26 LTC dollars and $34.40 hospital dollars in females, and $160.04 LTC dollars and $28.67 hospital dollars in males versus no intervention. Results were robust to univariate sensitivity analysis. The lifetime savings from GSD use in female and male Ontario residents aged ≥65 were 133.1M and 71.5M, respectively.

Conclusion: The use of outdoor GSD by mobile seniors during the winter is cost-effective in reducing falls in Ontario's elderly population. Evidence, however, is based on 1 trial of moderate quality.

P16 – INFECTIOUS DISEASE AND SEPSIS

P16.1

Clinical and Economic Impact of Introducing Polymerase Chain Reaction for Group B Streptococcal Perinatal Screening

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Background: Group B Streptococcus (GBS) is the leading cause of neonatal sepsis and mortality. Prevention is based on prenatal screening by culture in late pregnancy. Positive or unknown results lead to prophylactic antibiotics administration to the mother and biological surveillance of newborns. However, carriage can be transient, resulting in overtreatment of some mothers. Polymerase chain reaction (PCR) is a rapid but expensive detection method that can provide reliable results within a few minutes, and hence be used at the time of delivery. We wanted to assess the clinical and economic impact of introducing PCR for GBS screening at our hospital.

Methods: All pregnant women attending for vaginal birth at 37 weeks of pregnancy or more were included. They had all been prenatally screened for GBS. Lower vaginal/rectal swab was performed in the delivery room and both culture and PCR carried out. Antibiotics strategy was based on CDC recommendations. Resource use was prospectively collected from the patient charts, and costs derived from official tariffs.

Results: Two hundred and thirty-two patients were included. GBS prevalence was 19% by prenatal culture and 15% by PCR. As a consequence, 80 women received antibiotics prophylaxis while only 35 were PCR positive, resulting in 45 overtreatments. On the other hand, 7 patients (3%) were culture negative but PCR positive, and did not receive antibiotic prophylaxis. Laboratory costs increased by €6,736, while antibiotics, personnel, and newborn biological surveillance costs decreased by €383, €966, and €939 respectively, leading to an additional total cost of €4,448, or €19 per patient.

Conclusion: PCR GBS screening in the delivery room slightly increases per patient costs but decreases antibiotics overtreatment and newborn biological surveillance costs, with no apparent additional risk. Perinatal GBS PCR should therefore be introduced to replace GBS culture in late pregnancy.

P16.2

Clinical and Economic Impact of Introducing a Rapid PCR Test for MRSA Screening in Hospitalised Patients

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Background: Methicilline resistant Staphylococcus aureus (MRSA) can cause severe infections that are difficult to treat. Screening is currently carried out by microbiologic culture, and the patient must frequently be isolated while waiting for the result (usually 48 hours). Polymerase chain reaction (PCR) is a rapid but expensive detection method providing reliable results within a few hours in MRSA naive patients. We wanted to assess the clinical and economic impact of introducing PCR for MRSA screening at our hospital.

Methods: The observed number of isolation days, resource used and costs per patient and type of ward (emergency room, intensive care and usual care) in year 2007 were compared with a model using PCR as a screening test. Clinical and costs data were retrieved from the hospital accounting system.

Results: In the emergency room, 96 patients were screened. PCR decreased isolation days from 288 to 96 days and related costs from €17,011 to €5,671, while laboratory costs increased from €768 to €8,064, resulting in net savings of €4,044. Similarly, for the 158 intensive care patients screened, isolation days decreased from 506 to 190 days and related costs from €39,974 to €15,010, while laboratory costs increased from €1,169 to €12,277, resulting in net savings of €13,881. Finally, for the 192 usual ward patients, isolation days decreased from 576 to 192 days and related costs from €34,022 to €11,341, while laboratory costs increased from €1,536 to €16,128, resulting in net savings of €8,089.

Conclusion: PCR screening reduces ward costs but increases laboratory costs compared with culture. Net savings can be observed as soon as the numbers of isolation days are reduced by more than 1.3 days per patient. PCR should therefore be introduced for MRSA identification in hospitalised patients without previous MRSA history.

P16.4

Rapid Point of Care HIV Antibody Tests – OraQuick HIV Rapid Tests

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Objective: We aimed to assess the diagnostic effectiveness and outcomes such as acceptability, patient preference, counselling and linkage to care and prevention.

Methods: We performed a systematic review of the literature published from 2002 to 2007. We searched MEDLINE, EMBASE, CINAHL and The Cochrane Library and identified 1,258 citations, and included 13 studies that met our eligibility criteria. In addition, searches on Koreamed, Kmbase and the National Assembly Library, as well as other manual searching were conducted till August 2007. Two reviewers independently screened all references, assessing article quality and extracted data. Diagnostic accuracy was conducted through meta-analysis.

Results: Diagnostic accuracy analysis was conducted in subgroups based on specimen type. Whole blood tests had high sensitivity (99.0% to 100%), high specificity (99.0% to 99.0%) and high pooled diagnostic odds ratio (93,267 [95% CI: 19,572 to 444,439]). Serum and Plasma tests had high sensitivity (86.0% to 100%), high specificity (99.0% to 100%) and high pooled diagnostic odds ratio (6,825 [95% CI: 424 to 109,755]). Oral fluid tests had moderate sensitivity (75.0% to 99.0%), high specificity (98.0% to 100%) and high pooled diagnostic odds ratio (15,116 [95% CI: 4,130 to 55,325]). Acceptability of rapid tests and patient preference for rapid tests were higher compared with conventional tests.

Conclusion: We suggest that rapid tests (OraQuick HIV rapid tests) have high diagnostic accuracy. Uptake and preference for these tests are also reportedly high. However, countries such as Korea with lower prevalence tend to exhibit higher false-positive results, therefore confirmation with only rapid test results will bring about unforeseen consequences. Hence, we suggest that Rapid HIV test be quickly used in HIV higher probability infection groups or sites and emergency care in suspected HIV infection patients.

P16.5

Access to Standard Treatment among Thai Patients with Chronic Hepatitis C

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Objective: Cirrhosis and liver cancer resulting from disease progression of chronic hepatitis C (CHC) contributes to high disease burden in Thailand. Pegylated interferon alfa and ribavirin combination therapy is the current standard treatment for patients with CHC. However, access to such treatment is restricted to only 1 reimbursement scheme, the Civil Servant Medical Benefits Scheme (CSMBS) which covers only 10% of Thai population. Whether or not this fact may lead to treatment variations and the clinical outcomes is unknown. This study is the first to address this knowledge gap.

Methods: Medical records of patients who were newly diagnosed with CHC and without co-infection with either hepatitis B virus and/or human immunodeficiency viruses, and who attended at 1 of 5 tertiary-care hospitals during the years 2003 to 2006 were retrospectively reviewed. Patients were included if they re-visited not later than 6 months after first diagnosis and had at least 1 year of follow-up. Data on patient demographics, baseline characteristics, treatments and responses were captured. Multivariate logistic regression was used to indicate independent factors associated with receipt of standard treatment.

Results: Out of 439 patients identified, 368 patients (83.8%) received standard combination treatment of peginterferon alfa plus ribavirin. The majority of the cases were under CSMBS reimbursement scheme (60.1%). Multivariate logistic regression showed that patients who were under CSMBS (OR = 9.47, 95% CI: 4.51 to 19.86), those without any concomitant diseases (OR = 2.12, 95% CI: 1.07 to 4.20) and with elevated liver enzymes (OR = 2.88, 95% CI: 1.43 to 5.79) were more likely to receive standard treatment. Overall sustained virologic response at 6 months after treatment completion for all patients was 75.8%.

Conclusion: Reimbursement schemes contributed to treatment variations among CHC patients in these tertiary-care hospitals. Treatment outcomes were shown to be as favourable as those attained in randomised controlled trials. Public health policy and resource allocations are in need to reduce barriers to treatment for CHC patients in Thailand.

P16.6

Evaluation of the Cost of Treating an Invasive Fungal Infection (IFI) in High Risk Patients with Haematologic Malignancies in Australia

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Background: Due to the significant morbidity and mortality associated with invasive fungal infections (IFIs), antifungal prophylaxis is recommended for patients at high risk of infection, including those with acute myeloid leukaemia undergoing intensive chemotherapy and allogeneic haematopoietic stem cell transplant (HSCT) recipients with graft versus host disease. In order to assess the cost-effectiveness of prophylaxis, the cost of treating a breakthrough IFI needs to be ascertained.

Aim: To determine the cost of treating an IFI among acute leukaemia and HSCT patients in an Australian tertiary hospital.

Methods: The study was conducted in 2 parts: 1) An electronic micro-costing database analysis and 2) A manual chart review. In the first part, adult haematology patients with an IFI were identified from ICD10-AM codes and the mean cost per admission of at least 3 days in financial years 2004 to 2006 was compared with a cohort of matched controls without an IFI. In the second part, additional IFI cases were identified from pharmacy records and 2007 coding data. Controls were case-matched to IFI patients by age, underlying condition (HSCT or acute leukaemia) and duration of hospitalisation prior to IFI.

Results: The database analysis identified 17 patients (24 admissions) associated with an IFI and 171 control patients (414 admissions). Average length of stay for cases and controls was 42 days and 18 days, respectively. The mean cost per admission with an IFI was $215,248 compared with $29,193 for controls reflecting an incremental cost of $186,055. The difference was mainly due to pharmacy (47%), ward (18%) and ICU (9%) costs. The most commonly received antifungal treatments were voriconazole and liposomal amphotericin. Preliminary data from the second part of the study shows a slightly lower incremental cost of IFI but similar cost drivers.

Conclusion: Treatment of IFIs in haematology patients is associated with substantial costs, which may support a cost-effectiveness argument for prophylactic treatment.

P16.7

Cost-effectiveness of Antifungal Prophylaxis with Posaconazole versus Standard Azole Therapy in the Prevention of Invasive Fungal Infections (IFIs) among High Risk Haematology Patients in Australia

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Background: Invasive fungal infections (IFIs) remain a significant cause of morbidity and mortality among immunosuppressed patients with haematological malignancies. The recently published Australian antifungal guidelines recommend antifungal prophylaxis with posaconazole for acute myelogenous leukaemia (AML) patients undergoing intensive chemotherapy and allogeneic haematopoietic stem cell transplant (HSCT) recipients with grade 2 to 4 acute or chronic extensive graft versus host disease (GVHD). It is therefore it is timely to assess the cost-effectiveness of posaconazole for this indication.

Aims: To determine the cost-effectiveness of prophylaxis with posaconazole in comparison to standard azole therapy (fluconazole or itraconazole) for high risk haematology patients in Australia.

Methods: Two decision-tree economic models were developed for: 1) AML patients with chemotherapy-induced neutropaenia and 2) HSCT recipients with GVHD. The rates of IFI, IFI-related mortality, overall mortality and treatment duration were obtained from randomised controlled trials. The cost of treating a breakthrough IFI was ascertained by a chart review in an Australian tertiary hospital. The models were extrapolated to a lifetime horizon using Markov simulation in which mortality risk was determined by underlying disease and age.

Results: Compared with standard azoles, posaconazole prophylaxis was associated with a significant reduction in the rates of IFI among AML and GVHD patients, lower IFI-related death in the AML population and increased life years in both economic models. When the costs of treating breakthrough IFIs are included, posaconazole is cost-saving relative to standard azoles. Sensitivity analyses indicate that when model parameters are varied across reasonable ranges of their base case values, the incremental cost-effectiveness ratio ranges from cost saving to <$50,000 per life year saved.

Conclusion: Prophylactic treatment with posaconazole for high risk haematology patients is likely to be cost-saving compared with standard azole therapy in the Australian setting due to the considerable cost of treating an IFI.

P16.8

An Economic Evaluation of Posaconazole in the Treatment of Invasive Aspergillosis with Refractory Disease in Korea

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Objectives: This study is to conduct the cost minimisation analysis (CMA) of Posaconazole compared with currently licensed antifungal agents including Voriconazole (IV and oral), Caspofungin, and L-AMB in the treatment of confirmed infection of invasive aspergillosis with refractory disease in Korea.

Methods: Through a systematic review of preceding literature, we firstly figure out the factors that determine clinical success and clinical failure for each of the comparators and secondly investigate whether Posaconazole decreases infectious morbidity and mortality of the patients from RCTs with various conditions. Without clinical or observational dataset of Posaconazole and other comparators of the treatment for Korean patients, this study indirectly adopted the determinants and probabilities from the clinical results in all languages to decision tree model for antifungal treatment to estimate the clinical outcomes, and conducted the probabilistic sensitivity analysis and economic analysis. This study also estimated the direct costs associated with invasive aspergillosis treatment.

Results: For the antifungal treatment, the study showed that Posaconazole incurs lower drug costs than Voriconazole depending upon the almost similar effectiveness between the 2 AF agents. Based on the desired drug price of Posaconazole (€61.90/400mg) and average KRW-Euro exchange rate in 2008, the result showed that incremental cost of KRW6,934,591 (€4,387.3) would be saved compared with the expected drug cost of Voriconazole, Caspofungin, and L-AMB based upon their market shares.

Conclusion: Probabilistic analysis on net monetary benefit showed that invasive aspergillosis treatment with Posaconazole is a cost-saving method in Korea compared to Voriconazole and other licensed antifungal agents.

P16.9

Modelling the Cost-effectiveness of Influenza Prophylaxis: The Importance of Viral Resistance

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Objectives: To evaluate the incremental cost-utility of antiviral influenza prophylaxis using amantadine, oseltamivir and zanamivir in children, adults and elderly individuals according to risk status and prior vaccination from the perspective of the NHS.

Methods: We developed a decision-analytic model to estimate the incremental cost-effectiveness of seasonal prophylaxis and post-exposure prophylaxis of influenza. The model comprises 3 related components: the baseline risk of developing influenza and influenza-like illness, the preventative efficacy of antiviral prophylaxis, and the costs and consequences of related complications. The model includes short-term costs and health effects as well as life years lost due to influenza-related mortality. The model structure was informed by clinical input and a systematic review of previous influenza prophylaxis models. The model was populated using a systematic review of clinical effectiveness, recent surveillance data concerning influenza activity and viral resistance, costing sources, health status valuation studies and other related literature.

Results: With the exception of at-risk children, the incremental cost-utility of seasonal influenza prophylaxis is expected to be in the range £38,000 to £428,000 per QALY gained (depending on subgroup). The cost-effectiveness of oseltamivir and zanamivir as post-exposure prophylaxis is expected to be below £30,000/QALY gained in healthy children, at-risk children, healthy elderly and at-risk elderly individuals. Despite favourable clinical efficacy estimates, the incorporation of recent evidence of viral resistance to amantadine led to it being dominated in every economic comparison. The economic analysis suggests that the emergence of viral resistance has the capacity to dramatically influence cost-effectiveness estimates.

Conclusion: The economic model suggests that post-exposure prophylaxis using oseltamivir and zanamivir may be economically attractive in certain subgroups when compared against currently accepted cost-effectiveness thresholds. It is crucial that economic analyses are interpreted in the light of current levels of influenza activity and resistance.

P16.10

Extending FLU Vaccination in Individuals Aged 50 to 64 Years of 4 EU Countries: Social Savings and Budget Impact Analysis

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Influenza (FLU) is a viral infection that causes a high uptake of resources either from a social and a third party payer perspective. Several studies have been performed to provide an economic evaluation of the vaccination programmes against FLU. Nevertheless, there is still a lack of evidence about the dynamic effects on resource consumption resulting from the reduction of the contagiousness. This study considers the impact on contagiousness of alternative strategies against FLU in people aged 50 to 64 years in Italy, France, Germany and Spain. Using Influsim 2.0 dynamic model, we determine the social savings due to different coverage levels compared with the levels currently recommended in every country. We then perform a Budget Impact Analysis to determine whether the currently recommended coverage levels result from an optimal budget allocation and whether a 100% coverage strategy maximises social savings. We show that in Germany, the optimal coverage level would be 38.5%, 32.5% in France, 32.75% in Italy and 28.3% in Spain. Extending the coverage level would increase the social savings up to 100% for France and Germany, and up to 80% for Germany and Spain.

In conclusion, our paper wants to be a starting point for decision-makers dealing with the estimation of the social cost of an influenza infection, aimed to determine the optimal level of coverage of a vaccination strategy, consistently with an optimal budget allocation.

P16.11

Clinical Effectiveness and Cost-effectiveness of a Polymyxin B-Immobilised Haemoperfusion Cartage for the Treatment of Severe Sepsis: A Systemic Review and Economic Evaluation

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Background: Polymyxin B-immobilised haemoperfusion cartage (PMX) is a medical device for the treatment of severe sepsis by adsorbing and eliminating plasma endotoxin. The objective of this study is to assess the clinical effectiveness and cost-effectiveness of PMX versus conventional therapy in treating patients with severe sepsis.

Methods: For a systematic review, we searched OVID, EMBASE and Cochrane central register of controlled trial (CENTRAL). Inclusion criteria of clinical trials were RCTs on "sepsis", "severe sepsis" and "septic shock" patients. We included those studies that reported at least 1 of the 4 specified outcomes: mortality, plasma endotoxin level, days of ICU stay and blood pressure. Relevant outcomes were synthesised using RevMan 5.0. The average medical cost of sepsis was estimated from a National Health Insurance (NHI) claims database, and the PMX-related cost was calculated from the fee schedule of NHI. For economic evaluation, we assessed incremental cost effectiveness ratio (ICER) of PMX compared with conventional therapy. The assessment was performed from a purchaser's perspective.

Results: A total of 11 RCTs were identified with pooled sample size of 802, 477 in PMX and 325 in conventional therapy group. Meta-analysis results showed that PMX therapy had significantly lower mortality risk. The 28-day mortality rate of PMX group and conventional therapy group were 35.4% and 70.4% respectively with risk ratio of 0.51 (95% CI: 0.43 to 0.59). The medical cost for sepsis turned out to be 3,536,000 KRW per patient, which is common in PMX and conventional treatment. The additional cost related to PMX treatment was estimated to be 5,496,984 KRW per patient. Applying this mortality outcome and cost data, we produced an ICER of 15,705,669 KRW per life gained.

Conclusion: Compared with conventional therapy alone, PMX therapy with conventional therapy for the treatment of severe sepsis was found to be clinically superior and cost-effective as well.

P16.12

Economic Impact of a Protocol for Early Diagnosis of Severe Septic In-hospital Patients in a Private and Public General Hospitals in South of Brazil

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Introduction: Severe sepsis is associated with a high mortality rate. Early detection and appropriate treatment are cornerstones for decreasing mortality. We aimed to analyse the economic impact of an early sepsis detection protocol in 2 general hospitals – 1 public and 1 private – in the south of Brazil.

Methods: Data were derived from a 'before and after' study evaluating the implementation of a protocol for early diagnosis of in-hospital septic patients. The sepsis surviving campaign bundle was instituted in the first phase. After 1 year a protocol for active search of potentially septic patients was added to the measures adopted in the first phase. In a cost-effectiveness analysis we compared the following in both phases: mortality rate, time to sepsis detection, cost of sepsis treatment and indirect costs attributed to productivity losses from premature death due to sepsis. Costs are expressed in 2006 US dollars.

Results: Two hundred and seventeen septic patients were enrolled, 34 and 68 (phase I) and 59 and 56 (phase II) in the private and public hospital. In the private and public hospitals, respectively, time to sepsis diagnosis dropped from 34.4 to 13.8 hours and from 33.8 to 6.9 (P <0.05) after the protocol. Mortality rate decreased from 50% to 32.2% and from 67.6% to 41% (P <0.05). The mean number of productive years-of-life lost due to sepsis decreased from 3.18 to 0.80 and 9.81 to 4.65 (P <0.05). There was a mean gain of 2.38 and 5.16 productive years-of-life for each severe septic patient. Considering Brazilian gross domestic product per capita, estimated productivity loss due to sepsis decreased from US$3.25 to 9.74 billions, varying by sepsis incidence. Hospital costs were similar before and after the protocol.

Conclusion: A protocol for early detection and treatment of in-hospital septic patients is highly cost-effective from a societal viewpoint.

P17 – HTA IN SURGERY

P17.1

Efficacy, Effectiveness and Safety of Transcatheter Aortic Valve Replacement

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Objectives: This technique avoids the conventional surgical route for the replacement of the aortic valve. The procedure consists of a catheter-based implantation of an aortic valve prosthesis. This prosthesis is implanted in the native aortic valve position and the access is from the femoral artery (transfemoral approach) or through an anterior minithoracotomy (transapical approach). The aim of the review was to assess the efficacy, effectiveness and safety of transcatheter aortic valve implantation, either the transapical or the transfemoral approach, as therapeutics for severe aortic valve stenosis in high-risk for surgery or inoperable patients.

Methods: A systematic review of the literature about the technique was performed in 2008. The comprehensive search strategy included multiple electronic databases (Medline, Embase, Pascal, Cochrane, HTA Database and clinical trials databases). Health Technology Assessment reports, recommendation guidances and primary studies are reported.

Results: Three Health Technology Assessment reports, 1 recommendation guidance, 1 unrandomised clinical trial, 1 randomised clinical trial protocol and 21 clinical studies were identified. All of the 21 studies had prospective design but without a comparison group and were case series with a small number of patients or with patients who were included in further series. The follow-up of the patients is variable among studies and the patient selection criteria are quite heterogeneous. Although there is an improvement of clinical and echocardiographic variables, results on efficacy and safety provided are short-term outcomes in almost the 21 studies.

Conclusion: Quality of published studies and the number of patients enrolled do not allow a definitive conclusion on efficacy and safety of the transcatheter aortic valve implantation. This technique is considered as an option for treatment in patients with co-morbidities that make them unsuitable for the conventional aortic valve replacement. Randomised clinical trials are needed, besides a longer follow-up of the patients enrolled in the studies.

P17.2

Psychosocial Aspects of Bariatric Surgery – A Systematic Review of Quantitative and Qualitative Studies

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Background: As obesity epidemic is escalating globally, the use of bariatric (weight loss) surgery has also increased notably. Bariatric surgery requires life-long commitment and notable behavioural changes from the patient.

Objectives: To identify and synthesise published quantitative and qualitative research exploring various social outcomes and patient's experiences before and after bariatric surgery.

Methods: Extensive literature search was conducted on databases including Psycinfo, SocINDEX, ASSIA, Sociological abstracts, Medline, Cinahl, Linda, Libris, Bisys and Bibliotek.dk for studies on obese adults (BMI >35) planning or having had bariatric surgery with following outcomes: quality of life, psychosocial symptoms, social relations, body image, return to work, usage of health and social services, and patient experiences. Results from quantitative (prospective controlled designs, case series with at least 500 patient years) studies were tabulated, an aggregative synthesis of the qualitative studies was done using the QARI (Qualitative Assessment and Review Instrument) to create synthesised themes arising from findings reported in the original studies.

Results: We identified 5 controlled studies, 9 qualitative studies and 3 case reports. Outcomes of the controlled studies were typically related to the quality of life and mental health. Qualitative studies identified themes that were not seen in quantitative studies including self-control, trade-off of side effects and positive outcomes of the treatment, and experience of re-birth. Bariatric surgery was often described as a dramatic life-changing process with extensive psychological and social consequences.

Conclusion: Bariatric surgery deeply affects many social and psychological aspects of patients' lives and requires a life-long commitment. The inclusion of studies with qualitative methods in addition to the quantitative studies in the HTA process significantly contributed to the results.

P17.3

Expected Impact of Rapidly Growing Bariatric Surgery on National Organisation of Obesity Care

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Background: Two of 100 adults suffer from severe obesity (BMI >35). Bariatric surgery is rapidly expanding with expected heavy impact on the national healthcare system. Organisational consequences and resource shifts need to be predicted for appropriate planning and management.

Objectives: To explore the expected impact of changing practices of surgical and conservative treatment for severely obese patients (BMI >35) throughout the healthcare system in Finland.

Methods: As part of an HTA on bariatric surgery, questionnaires were sent to chief physicians of 9 surgical and 21 internal medicine departments. The questions were structured with a possibility to open-ended comments and considered the local treatment patterns in 2008 and the views about the available and needed resources during the next 5 years.

Results: The response rate was 81% (9/11) and 47% (10/21) in surgical and internal medicine departments, respectively. The access to bariatric surgery was uneven across hospital districts. Bariatric surgery was estimated to increase from about 400 operations to 2- to 3-fold in 2009 and 3- to 5-fold after 5 years. All respondents expressed the need for more resources of operative treatment and trained personnel throughout the treatment path. All respondents considered it necessary to centralise the treatment to university hospitals as well as a maximum of 5 centres, and to have national criteria for access to treatment, bench-marking, and a national registry for bariatric surgery.

Conclusion: There is a need to rapidly establish the indications and uniform treatment paths for bariatric surgery in order to provide equal treatment. The organisational challenges comprise need for education and allocation of considerable resources. Organisational analysis as a part of an HTA specifies the aspects for planning and decision-making at national level.

P17.4

Ethical Evaluation of Bariatric Surgery: The EUnetHTA Model Experience

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Background: Both obesity and bariatric surgery are expanding rapidly and often uncontrollably. Despite increasing evidence of its effectiveness, obesity surgery is considered controversial by lay people and many professionals. The EUnetHTA model proposes a novel framework for including ethical aspects in HTA. It aims at integrating value considerations into the HTA process in order to increase the relevance of the assessments.

Aims: To describe and evaluate the application of the new EUnetHTA core HTA model for the ethical analysis of bariatric

surgery and to present the results of this ethical analysis.

Methods: Integration of ethical analysis into the whole HTA process succeeded by a) creating a common work group for analysing organisational, social, ethical and legal issues and b) encouraging discussion of ethical issues in the planning phase of the HTA process.

Results: Analysing ethical questions brought up viewpoints that were considered important and could have been overlooked on an HTA concentrating on effectiveness, safety and cost-effectiveness. Obesity is a phenomena associated with social stigma in many societies. It is commonly considered to be associated with negative moral character (laziness, lack of discipline) and interpreted to be a self-inflicted condition (not a disease) that could be cured by changing individual behaviour (less food, more motion). Science, however, increasingly sees obesity as a problem with social origins that are beyond the individual's control. This discrepancy appears to be one of the main reasons behind the controversy caused by bariatric surgery. Self-inflicted nature of a condition, e.g. obesity, might challenge the right to receive treatment in a publicly financed system, especially when rationing of other services is needed in order to fulfil demand.

Conclusion: The assumed self-inflicted nature of obesity emerged as an important ethical question that HTA should address, but which would have been overlooked by traditional assessment. The EUnetHTA model seems to work well in detecting relevant ethical issues.

P17.5

Bariatric Surgery: Safety Issues of EUnetHTA Core Model in a National Health Technology Assessment

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Background: Availability of effective mini-invasive surgical treatments for morbid obesity has led to a high increase in bariatric surgery. Along with growing incidence of obesity and extension of operations to wider patient groups, safety issues have become of increasing interest. EUnetHTA has suggested a core model for assessing the safety of interventions.

Objective: To compare and report the generic EUnetHTA safety topics and issues with the ones found in literature while carrying out a national HTA report.

Methods: Literature search including earlier systematic reviews revealed 55 articles since 2004 that fulfilled the selection criteria. Four meta-analyses reporting safety issues were found and these were included into the analysis as well. Primary outcomes were early and late mortality, and complications leading to re-operations. Secondary outcomes were other postoperative complications including nutritional deficiencies and postoperative symptoms. EUnetHTA safety issues were taken into account in data analysis.

Results: EUnetHTA issues covered the safety questions in bariatric surgery well. However, available literature suggests that procedure-related complication risk varies considerable between the subgroups of patients, which is not among EUnetHTA safety questions. Overall <30-day mortality is reported to be 0.07% to 0.41%, 95% confidence interval was 0.09% to 0.23% for gastric bypass procedure, and 0.01% to 0.11% for gastric banding. Male, diabetic and super-obese patients were reported to have higher mortality than other patients. Frequency of complications leading to re-operation varies from 1.6% to 30%, gastric bypass-procedure having the lowest re-operation rate, and banding the highest. Frequency of reported minor adverse events has varied from 4% to 32%.

Conclusion: Generic EUnetHTA Core model issues cover the safety issues of bariatric surgery raised from literature and clinical experience well. An additional question about variance of risk between different patient subgroups could be justified. Mortality after bariatric surgery seems to be low. Need for re-operation varies according to the operative procedure, and is high after gastric banding.

P17.6

Effectiveness of Bariatric Surgery: Outcome Measures in Comparison to EUnetHTA Core Topics and Issues

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Background: Due to the increase in obesity and obesity-related health problems, bariatric surgery is increasingly being used worldwide. EUnetHTA collaboration has recently developed core elements for 9 domains, effectiveness among others, to be considered when performing an HTA report.

Objectives: To compare and report the results of used outcome measures with the core topics and issues recommended by EUnetHTA collaborators when evaluating effectiveness of bariatric surgery as part of an HTA report.

Methods: The EUnetHTA effectiveness domain includes 18 issues concerning 4 topics, mortality (4 issues), morbidity (6 issues), function/HRQL (6 issues), and patient satisfaction (2 issues). We performed a literature search for systematic reviews on effectiveness of bariatric surgery, and search for original studies was performed from 2004 updating the Cochrane review. Firty-three articles were selected for our systematic review. Primary outcome measures were mortality, health-related (HRQL), disease-specific quality of life and effect on Type II diabetes. Secondary outcome measures were effects

on other co-morbidities, changes in Body Mass Index (BMI) and percent Excess Weight Loss (EWL).

Results: The outcome measures used in our national HTA were well in line with EUnetHTA topics and issues, except for the topic patient satisfaction, which was not used as an outcome measure. Procedure-related mortality ranged from 0.16% to 2.5%. Surgery decreased mortality caused by the target diseases (RR 0.11 to 0.71). Both disease-specific and generic HRQL improved following bariatric interventions. The prevalence of Type II DM following surgery decreased 14% to 92%. The proportion of patients reaching a BMI <35 ranged from 53% to 79 % with 3 to 5 years follow-up, and % EWL ranges from 46% to 84 %.

Conclusion: EUnetHTA helps define the elements of an HTA, and may raise relevant issues concerning the 4 main topics of effectiveness. Our HTA suggests that bariatric surgery is effective on all primary outcomes.

P17.7

EUnetHTA Framework as a Scoping Tool: Identification of Core Domains for HTA on Bariatric Surgery

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Background: Bariatric surgery is rapidly becoming one of the most frequent surgical procedures. It is a complex topic for an HTA due to a multitude of items not directly related to patient's health status or costs to the healthcare system. EUnetHTA collaboration has recently developed a generic format suggesting 9 domains to be considered when planning an HTA report on interventions.

Objectives: To describe the use of recently developed EUnetHTA Core model for identification of the relevant domains when planning an HTA on bariatric surgery.

Methods: A scoping group of 4 HTA researchers used the domains of EUnetHTA framework to identify the Core elements in an HTA on bariatric surgery. Selected issues were presented to 2 bariatric surgery experts, who together with 2 of the initial researchers defined the PICO (patient, intervention, comparator, outcome) and the structure of the HTA, and designed and analysed the literature search before the final HTA workgroup was formed.

Results: When the EUnetHTA framework was utilised, the importance of organisational, social and ethical domains was emphasised. In addition, several study questions were identified. The eventually formed HTA workgroup was divided into 3 subgroups: 1 group looking into description of patients and technology plus safety and effectiveness domains, the second to assess cost-effectiveness, and a third group for psychosocial, organisational, ethical and legal aspects.

Conclusion: The EUnetHTA framework seems to be a useful tool for systematic scoping of an HTA topic. It will help to identify areas of high importance, which are not necessarily in the typical focus of an HTA (safety, effectiveness and cost-effectiveness). Organisational, social and ethical aspects were recognised to be of high relevance in the field of bariatric surgery.

P17.8

Estimation of Risk Factors for Hospital Mortality after Bariatric Surgery in the Brazilian Private Health Sector

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Obesity is one of the major public health burdens currently. In addition to being a risk factor for many diseases, it is also associated with a reduced quality of life. It must be fully addressed to ensure access to prevention, clinical treatment and surgery. The latter, known as bariatric surgery, must be the very last therapeutic option for the morbidly obese. Bariatric surgery is used to achieve and maintain body weight loss, as well to reduce or eliminate obesity related co-morbidities. This study intended to estimate the factors that could influence hospital mortality after bariatric surgery. The study population comprised the patients from the private health sector of Sao Paulo State during the period of April 1999 to February 2008. A total of 10,074 surgery records were identified from a production database in public domain. A logistic regression model was built and its coefficients were estimated taking into account patient's gender and age, length of hospital stay, type of financing, and annual average of surgeries per hospital. Wald and Deviance statistical tests were used to fit the best model. All variables, except type of financing, were significant at the 5% level. Characteristics such as being male (OR = 2.06, 95% CI: 1.05 to 4.03), patient age over 40 years (OR = 4.04, 95% CI: 1.87 to 8.70) and length of hospital stay exceeding 2 weeks (OR = 58.85, 95% CI: 24.65 to 140.50) were identified as risk factors for mortality, while hospital annual average of more than 100 surgeries (OR = 0.31, 95% CI: 0.11 to 0.87) was a protection factor. The results indicate the importance of considering the hospital production and infrastructure when performing bariatric surgery.

P17.9

Robotics Applied to the Surgical Techniques: Effectiveness of Da Vinci Surgical System on Urologic and Cardiothoracic Indications

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Introduction: Robotic surgery is an emerging technology for minimally invasive surgery. Da Vinci Surgical System is the most extended platform. The surgeon performs the operation from a console next to the patient, guided by stereoscopic vision and using joysticks that translate hand gestures into micro-movements of the instruments. Our objective was to assess effectiveness of Da Vinci Surgical System.

Methods: A systematic review was conducted. HTA reports, systematic reviews and clinical trials were searched. EMBASE, MEDLINE, and CINAHL were searched for primary studies. Controlled studies of surgical procedures assisted with Da Vinci Surgical System were included. Outcomes were extracted from each study and pooled on meta-analysis when possible.

Results: We selected 52 articles including 59 comparisons. One randomised clinical trial was included. The reported urological indications (total 47) were radical prostatectomy (23), pyeloplasty (11), radical cystectomy (6), adrenalectomy (4), radical cystoprostatectomy (2) and urological anomalies (1). For cardiothoracic surgery (total 12), reports of atrial septal defect repair (6), mitral valve repair (3), coronary artery bypass (2) and thymectomy (1) were found. Patients undergoing radical prostatectomy had better recovery of urinary and sexual functions when performed with Da Vinci. A single study of robotically-assisted coronary bypass yielded a shorter hospital stay, less pain and less analgesic consumption. Moreover, when compared against the open technique, radical cystectomy, radical cystoprostatectomy, mitral valve repair and thymectomy showed better outcomes for the Da Vinci group. Robotically-assisted adrenalectomy took longer and was more expensive than laparoscopic procedure. For the rest of studied indications no advantage exists with any technique.

Conclusion: Patients undergoing radical prostatectomy and coronary bypass may benefit from robotically-assisted procedures. However, laparoscopic adrenalectomy shows better results than the robotically-assisted procedure. These results must be interpreted with caution since there are not many randomised clinical trials and the studies did not include long-term outcomes, such as survival rate.

P18 – HTA IN ORTHOPAEDICS

P18.1

Effectiveness of Artificial Cervical Disc Arthroplasty (ACDA) Compared to Cervical Fusion – A Systematic Review and Meta-Analysis

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Objective: To qualitatively and quantitatively analyse the literature on the efficacy and effectiveness of ACDA compared to cervical fusion.

Methods: Our HTA unit was commissioned by Alberta Health and Wellness to assess the effectiveness and safety of ACDA. We searched 8 electronic databases including MEDLINE, Cochrane Library and EMBASE, unpublished sources, and reference lists for studies on the efficacy and effectiveness of ACDA compared to cervical fusion, the surgical standard of care for patients with cervical degenerative disc disease (DDD). We conducted a meta-analysis of clinical outcomes, using a DerSimonian-Laird approach for continuous outcomes to calculate weights for the random effects models. A weighted mean difference and its 95% confidence interval were calculated for each clinical outcome (SF-36, neck and arm pain, NDI).

Results: Six hundred and twenty-two studies were retrieved, of which 19 (5 RCTs, 1 non-randomised comparative study and 14 case series) met the inclusion criteria for this review. The 5 RCTs and the non-randomised comparative study concluded that the effectiveness of ACDA is not inferior to that of cervical fusion in the short term (up to 2 years of follow-up). The safety profile of both procedures appears similar. The case series reviewed noted improved clinical outcomes at 1 or 2 years after 1 or multiple-level ACDA. A meta-analysis of clinical outcomes using data from 1 published RCT and 2 sources of unpublished data confirmed the conclusions of the studies reviewed, demonstrating no significant difference in clinical outcomes between ACDA and cervical fusion at 2-year follow-up.

Conclusion: The effectiveness and safety profiles of ACDA appear similar to that of cervical fusion in the short term. The data available show sufficient equivalence of clinical outcomes to conclude that ACDA is a viable alternative to cervical fusion. Several ongoing RCTs will provide data on long-term effectiveness and safety of ACDA.

P18.2

An HTA Report on Dual X-ray Absorptiometry (DEXA) for Primary Osteoporosis

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Introduction: Osteoporosis is a disease that causes a reduction of bone density, resulting in a higher risk of fracture. The most common fractures associated with osteoporosis occur at the hip and spine. These fractures increase with age and can have consequences, such as loss of independent living, social isolation, deterioration of quality of life, surgery and death. In women the rate of bone loss speeds up after menopause when the level of estrogen decreases. Due to the higher risk in post-menopausal women of developing osteoporosis and its consequences, this is the target population chosen in this analysis. The bone mineral density (BMD) can be measured through various techniques, predicting fracture risk. Dual-

Energy X-ray Absorptiometry (DEXA), Quantitative Computer Tomography (QCT) and Quantitative Ultrasonography (QUS) are commonly used to diagnose osteoporosis. Our objective is to identify the first 2 most used techniques for the diagnosis of osteoporosis in the Italian context, and perform a cost-effectiveness evaluation on the 2 selected diagnostic procedures, as part of a Health Technology Assessment report, commissioned by the Italian Ministry of Health.

Methods: We performed a systematic review to identify the available evidence on diagnostic accuracy and economic impact on DEXA and its alternative. Searches were run on Medline, Embase and Cochrane Library and CRD database. The following path allowed the collection of primary data on Italian context: access to the Italian hospital records (SDO) to highlight the volumes of inpatients care for osteoporosis in the last years, access to the available ambulatory care data for chosen diagnostic technologies, selection of representative centers to collect contextual data on procedures and technologies costs.

Results: We reviewed systematically the retrieved clinical evidence and performed a cost-effectiveness analysis.

Conclusion: DEXA, in Italy, is likely to be a cost-effective alternative compared with currently available options.

P18.3

Short-term Cost-Effectiveness Analysis of Celecoxib for the Treatment of Osteoarthritis of the Knee

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Purpose: This study was conducted to evaluate the cost-effectiveness of 2 treatment strategies for osteoarthritis (OA) of the knees, non-selective NSAIDs (etodolac, aceclofenac, meloxicam) and celecoxib. The analysis was performed in the perspective of health insurer who will cover the direct costs of the medications upon approval.

Materials and Methods: We developed a decision model to estimate the cost effectiveness of 2 treatment strategies, which was based on a year of treatment period. The model included 6 indicators of health status, ulcer-hospitalisation, ulcer-outpatient treatment, osteoarthritis, death, being well, and surgery. The probability estimates applied were mostly from the SUCCESS-I study (Celecoxib vs. Naproxen and Diclofenac on osteoarthritis), which was a randomised clinical trial to evaluate the efficacy and gastrointestinal (GI) safety of celecoxib compared with the nonspecific NSAIDs. The utility estimates were derived from a comprehensive literature review on cost-effectiveness analysis. The cost data were obtained from the health insurance reimbursement data. We included only the direct costs, which include medication, consultation, upper GI endoscopy, ulcer treatment and surgery. The indirect costs regarding loss of productivity were not included in this analysis. The main outcome measure was quality-adjusted life years (QALYs).

Results: The expected 1-year total costs for the non-selective NSAIDs and Celecoxib strategies were US$3,250 and US$3,361, respectively. The Incremental Cost Effectiveness Ratio (ICER) of Celecoxib strategy compared with non-selective NSAIDs for 1 year was US$10,887 per QALY gained.

Conclusion: This study showed that treatment of OA with celecoxib is cost-effective compared to non-selective NSAIDs.

P18.4

Assessment of New Approaches to Total Hip Replacement Using Minimal Incisions: Collaboration Between UK and Canadian HTA Agencies

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Objective: The UK HTA programme and the Canadian Agency for Drugs and Technologies in Health independently wished to commission an HTA on the clinical and cost-effectiveness of minimal incision total hip replacement (MI THR) compared with standard THR. The objective was to conduct a single HTA that would meet the needs of both the UK and Canada.

Methods: Following a jointly agreed protocol, a systematic review of randomised controlled trials was performed to assess clinical effectiveness. One economic model was developed using the same effectiveness data for both countries. Additional data from other sources (e.g. healthcare providers) were used to develop costs and health state utilities specific to each country. The results of the model were presented as incremental costs per quality adjusted life years (QALYs).

Results: MI THR had some perioperative advantages (less blood loss and shorter operative and recovery time). Few data were available on long-term outcomes, especially risk of revision. Thus, it was assumed that long-term outcomes were the same but with wide confidence intervals. On average, MI THR was less costly and more effective in the UK, but slightly more costly and more effective in Canada.

Conclusion: The effectiveness results were the same for both perspectives but because of country-specific differences in costs and utilities, the cost-effectiveness results showed some differences. In both the UK and Canadian analyses both procedures had a similar likelihood of being considered cost-effective. Collaboration was facilitated by the HTA organisations and the joint development of the work.

P18.5

Systematic Review of Interspinousposterior Lumbar Dynamic Stabilisation

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Objective: We aimed to accomplish the systematic literature study of interspinous Posterior Lumber Dynamic Stabilisation that included DIAM, X-stop, coflex, etc and apply those concepts to interspinous Posterior Lumber Dynamic Stabilisation that induce thereafter.

Methods: Interspinous Posterior Lumber Dynamic Stabilisation was studied using 8 internal databases including KoreaMed, and foreign databases including Ovid-MEDLINE, EMBASE and Cochrane Library. Using the keywords 'Disc herniation, Spondylolisthesis, Spinal stenosis, Neurogenic claudication' and 'dynamic stabilisation, soft stabilisation, elastic stabilisation', we searched a total of 306 literatures. We excluded literature that reviewed animal experiment and study results that were duplicated. Total 20 literatures were included in the final assessment.

Results: Stability of Interspinous Posterior Lumber Dynamic Stabilisation was evaluated by a complication on 14 literatures. Rate of complication was reported as 0% to 32.3% for 3 to 41 months of observation. The complication rate of decompression with Interspinous device insertion (32.3%) was higher than the complication rate of decompression only (6.5%), but most complications did not require clinical treatment and were not reported as none of them critically affected the medical result. Interspinous Posterior Lumber Dynamic Stabilisation has a possibility to provide favourable surroundings for delay lumber's degradation and helping lumber restoration, but the concept of Interspinous Posterior Lumber Dynamic Stabilisation has still not taken a triangular position including motion adjustment.

Conclusion: Induction of Interspinous Posterior Lumber Dynamic Stabilisation is an adjustment method derived from the existing idea of limiting the movement of lumber. It is meaningful to induct an idea to restore a lumber's movement, but the concept of Posterior Lumber Dynamic Stabilisation has not worked out, and lacks case studies for long-term observation data or comparions with other medical treatments. So we accept the subcommittee's valuation that this medical skill needs well-planned clinic studies.

P19 – HTA IN PULMONARY MEDICINE

P19.1

Sildenafil and Bosentan for Treatment of Pulmonary Hypertension: The Challenge of the Decision-Making Process

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Pulmonary Hypertension (PH) is a rare and severe disease that takes mainly young people. Nowadays, the Ministry of Health of Brazil (MH) doesnot have a clinical guideline for its treatment and only adjuvants drugs are used. Manufacturers of sildenafil and bosentan asked for incorporation of these drugs to treat PH in the Unified Health System of Brazil (SUS) by the Commission for Incorporation of Technologies (CITEC/MS), that take into consideration relevance and pertinence of the technologies in the context of health programs and policies, analysed by technical areas of MH, and the available scientific evidences, synthesised by the Department of Science and Technology (Decit/MH). To support this decision-making process, Decit prepared 2 rapid HTA about treatment of PH that would be presented in CITEC. Despite of short follow-ups and small number of participants, the evidence shows efficacy of sildenafil or bosentan, compared with placebo, in improvement of symptoms, functional capability and haemodynamics parameters in people with PH. Meanwhile, there isn't evidence that justifies their use for long time. Longer studies that compare these 2 drugs with bigger samples are needed to define an appropriate safety profile. Added to that, the outcomes investigated should be clinical significance, including mortality and survival, and some participants should present severe PH. This way, associated with cost-effectiveness and budget impact studies, rapid HTA that synthesise available scientific evidence should support more rational decision-making about incorporation of these drugs in the context of SUS in Brazil.

P19.2

Exhaled Nitric Oxide Measurement Using NIOX or NIOX MINO

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Introduction: Several lung diseases including asthma and chronic obstructive pulmonary disease (COPD) involve chronic inflammation of the airways. Therefore, there is great interest in non-invasive methods of assessing airway inflammation.

Aim: To determine the safety, effectiveness and cost-effectiveness of exhaled nitric oxide measurement using NIOX or NIOX MINO in the management of respiratory diseases especially asthma.

Technical features: Measurement of bronchial hyper-responsiveness (BHR) and exhaled nitric oxide (FE_{NO}) are examples of indirect markers for airway inflammation.

Currently, nitric oxide measurement system (NIOX) or a new NIOX MINO are usually used as NO analysers in many research and clinical use.

Methods: Databases such as Pubmed, OVID Fulltext, ProQuest, Cochrane databases, Food and Drug Administration (FDA) and HTA databases. Additional articles were identified by reviewing the bibliographies of retrieved articles. There was no limitation to language. A systematic review of all relevant literature was done and evidence graded.

Conclusion and Results: In conclusion, there was evidence to show that FE_{NO} measurement is safe and non-invasive. There was good evidence to show that there was good correlation between the FE_{NO} values measured with the 2 devices (NIOX and XIOX MINO). FE_{NO} measurement provides superior diagnostic accuracy compared to conventional tests for asthma diagnosis. It can be used as a predictor of steroid response and loss of control (LOC) in asthma following steroid withdrawal. Limited evidence to establish the relationship between FE_{NO} and compliance with inhaled corticosteroids and its role in diagnosis and monitoring of other respiratory diseases.

Recommendation: Based on the above review, it is recommended FE_{NO} measurement can be used in Ministry of Health facilities with chest physicians (adult and paediatric) particularly for diagnosing and monitoring of asthma.

P19.3

The Relationship of Chronic Diseases and Health-related Quality of Life Based on a National Study in South Korea: Focusing on Asthma and Allergic Rhinitis

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Korea

Purpose: Asthma and allergic rhinitis patients are increasing dramatically in South Korea. However, there is less focus on the quality of life of these patients compared with higher level of treatment of the diseases. Therefore, we examined the relationship of asthma and allergic rhinitis and health-related quality of life (HRQL) in the general population by means of the EuroQol-5D questionnaire.

Methods: The relationship between asthma and allergic rhinitis and HRQL was analysed using a national representative sample from the 2005 Korean National Health and Nutrition Survey. Survey participants from 16 years of age and older were classified according to their diseases. People who had experienced asthma and allergic rhinitis at least once or for over 3 months last year or have the diseases now are classified into an asthma group and an allergic rhinitis group. We analysed asthma/allergic rhinitis-HRQOL relationships by age and gender using mean comparison of each group.

Results: People with asthma/allergic rhinitis were older and had more associated diseases than the population without any diseases. Asthma/allergic rhinitis and HRQL are inversely correlated. Mean HRQL of asthma patients was lower than that of allergic rhinitis patients. The patients who have both asthma and allergic rhinitis showed lower EuroQol-5D index scores significantly than those of with only asthma or allergic rhinitis (0.69 vs. 0.77). Participants without any chronic diseases (0.94) showed much higher EuroQol-5D index scores than asthma/allergic rhinitis patients. Gender did not affect HRQL among asthma/allergic rhinitis patients.

Conclusion: Chronic diseases such as asthma/allergic rhinitis have a negative impact on HRQL regardless of gender, social status and so on. A better understanding of the relationships between asthma and HRQL can make people pay attention to a rising chronic disease and may help develop a new approach for treatment strategies.

P20 – HTA IN UROLOGY

P20.1

Non-surgical Treatment for Women with Stress Urinary Incontinence: A Systematic Review Incorporating a Mixed Treatment Comparison Analysis

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Objective: To evaluate the effectiveness of the different non-surgical treatments for stress urinary incontinence in women.

Methods: Relevant randomised controlled trials (RCTs) were identified from the Cochrane Incontinence Group's Specialised Register and extensive electronic searches of the literature published up to March 2008. Primary outcomes included cure rates and improvement rates. Analysis was performed in 2 stages: (a) Pairwise (direct head-to-head) comparison, and (b) Mixed treatment comparison (MTC), which enabled all treatments to be compared in a single model. The results were presented as the odds ratio for each pair of treatments.

Results: Eighty-five RCTs (9,309 women) were identified. Included trials were of variable methodological quality with small sample sizes and short follow-up periods. Included studies covered 6 interventions and their variations, either alone or in combination, which resulted in 57 pairwise comparisons. The pairwise comparisons showed that pelvic floor muscle training (PFMT) was more successful than no treatment (cure OR 5.41, 95% CI: 1.64 to 17.82, improvement OR 11.75, 95% CI: 3.49 to 39.55) but there was inconclusive evidence about whether it was better than the other treatments. The MTC model yielded similar results. However, it was felt that the level of intensity of PFMT may affect the outcome. An MTC model with PFMT split into 2 treatments showed that "intensive" (at least 2 sessions per month) PFMT and PFMT with biofeedback were more effective than the other standalone treatments.

Conclusion: Pairwise comparisons were difficult to interpret due to the large number of intervention variations. The MTC model allowed the interventions to be compared within a single analysis. It also facilitated comparisons of treatments where there was no direct evidence. Supplementing direct evidence with indirect evidence within MTC models revealed results that would not have been available from the direct pairwise comparisons.

P20.2

The Socioeconomic Costs of Overactive Bladder and Stress Urinary Incontinence in Korea

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Purpose: We quantified and described the economic burden of overactive bladder and stress urinary incontinence in Korea.

Materials and Methods: We calculated costs by identifying public and private data sources that contain population-based data on resource utilisation by patients with stress urinary incontinence and overactive bladder. For estimating indirect costs (productivity loss), the human capital approach was applied. Data were collected from several institutes, including the Health Insurance Review Agency.

Results: The estimated total economic cost in treating overactive bladder was 117 billion Korean won in 2006 and 145 billion Korean won in 2007. The estimated total cost in treating stress urinary incontinence was 122 billion Korean Won in 2006 and 59 billion Korean Won in 2007.

Conclusion: By quantifying the total economic costs of overactive bladder and stress urinary incontinence, this study provides an important perspective of this condition in Korea. Because the average age of the Korean population is rapidly increasing, this study provides important information on the direct and indirect costs of overactive bladder and stress urinary incontinence for an aging society.

P20.3

An Economic Evaluation of Fesoterodine in the Treatment of Overactive Bladder in Korea

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Objectives: This study was conducted to evaluate the cost-effectiveness of Fesoterodine compared with Tolterodine in the treatment of OAB in Korea. The evaluation was performed from the perspective of the statutory health insurer who will cover the direct costs of the drug upon approval and from societal viewpoint, as well.

Methods: Through a systematic review of preceding literature, we firstly figured out the factors that determine the efficacy for Fesoterodine and Tolterodine and secondly investigated whether Fesoterodine decreases symptom of OAB patients from randomised comparative trials with various comorbidities. Since there is no clinical dataset of Fesoterodine along with Tolterodine for OAB patients in Korea, this study indirectly adopted the determinants and probabilities from the clinical results in all languages for OAB treatment in order to estimate the treatment outcomes of the selected comparators, and conducted the probabilistic sensitivity analysis. This study also used to explore the cost-effectiveness of Fesoterodine in the following comorbidities: fracture, UTI, and depression.

Results: Based on the computed clinical success at week 12 of OAB treatment, Fesoterodine has higher performance than Tolterodine by 18.44% point (56.50% vs. 38.06%) with a bit more total medical cost though (KRW 306,855 vs. KRW 260,457). In terms of cost-effectiveness ratio (CER), Fesoterodine has lower value than Tolterodine (KRW 5,431 vs. KRW 6,843), which implies that Fesoterodine is more cost-effective than Tolterodine in OAB treatment. Through the one-way sensitivity analysis varying the values of several controversial parameters such as resolution of incontinence, pad usage and frequency, and unit price of pad, we could not find the reversal case in which Tolterodine outweighs Fesoterodine.

Conclusion: Probabilistic analysis showed that OAB treatment with Fesoterodine is cost-effective in Korea compared to Tolterodine.

P20.4

Effectiveness of Protocols Using Portable Bladder Ultrasound to Guide Catheterisation for Patients with Urinary Retention in the Hospital

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Aim: The aim of this report was to determine whether protocols using the portable bladder ultrasound (PBU) to guide decision for catheterisation in hospitalised patients could be implemented locally, with emphasis on the clinical effectiveness of such protocols.

Methods: A systematic review was done to evaluate the clinical effectiveness of protocols using the PBU to guide decision for catheterisation compared to usual care for patients with urinary retention in the hospital. Outcomes of interest were rate of catheterisation, urinary tract infection (UTI), and complications associated with urinary retention (UR) and bladder over-distention. The following databases were searched using the MeSH keywords 'urinary catheterisation' and 'ultrasonography': PUBMED, CINAHL, CRD databases and the Cochrane database.

Results: Systematic review has revealed a paucity of high quality research evaluating the clinical effectiveness of protocols

using PBU to guide decision for catheterisation for hospitalised patients with UR. Three studies were selected for this review. All have shown that using a PBU protocol to guide decision for catheterisation is more effective than usual care without the use of PBU. Main outcomes reported from the studies were rate of catheterisation and UTI. Reduction in catheterisation is likely an effect of the PBU protocol. However, the reduction in UTI rate could not be attributed to the use of the PBU because other factors that might affect UTI rate (such as use of antibiotics) were not considered.

Conclusion: Research evidence, though limited, favours PBU protocols over clinical diagnosis alone to guide decision for catheterisation for urinary retention in post-operative orthopaedic patients and neurosurgical patients. PBU protocols could be implemented to guide decision for catheterisation in hospitalised patients, however, outcome evaluation of protocols would be highly recommended.

P21 – HTA IN HAEMATOLOGY

P21.1

Is Artificial Blood an Alternative to Red Blood Cells Transfusion?

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Introduction: Artificial blood or blood substitutes are solutions intended to replace transfusion of banked red blood cells. Alternatives to red blood cell transfusions are designed to overcome known limitations, short supply of donor blood, risk from contamination and clerical error and the requirement for cross-matching. Artificial blood is also known as volume expanders for inert products (crystalloid-based or colloid-based) and oxygen therapeutics for oxygen-carrying products. The aim of this review is to determine the safety and effectiveness of oxygen therapeutics in substituting true blood for transfusion.

Methodology: Literatures were searched through electronic databases such as MEDLINE, EBM Reviews for controlled trials, Cochrane database on systematic review, Cochrane Clinical Trial Registry, and Science Direct. All primary papers, systematic reviews or meta-analysis pertaining to safety and effectiveness of oxygen therapeutics or oxygen carriers in human were included in this review. The literatures were reviewed by 2 authors.

Results and Discussion: Safety is the main concern related to oxygen therapeutics. The only perfluorocarbons (PFC) emulsion approved by FDA for clinical use was Fluosol-DA®. It was indicated for percutaneous transluminal coronary angioplasty (PTCA). However it was withdrawn in 1994 because it was cumbersome and the efficacy was marginal. Very few products have gone through Phase III trial to assess the efficacy. Many of the studies showed major adverse events and increased in mean arterial blood pressure in patients receiving oxygen therapeutics.

Conclusion: Based on the review, oxygen therapeutics is still in experimental stage. There were sufficient evidences on the harmful effect of oxygen therapeutics products. More research is needed to develop safe products for human use.

P21.2

Screening for Haemoglobinopathies Among Pregnant Immigrants in Denmark – A Health Technology Assessment

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Background: The common inherited disorders of haemoglobin and haemoglobinopathies course a significant health problem. Due to migration they are now encountered in many countries of the world. This rather new healthcare problem in the Northern Europe raises the question of development of screening programmes.

Objectives: The overall objective of the present health technology assessment was to provide a multi-faceted basis for the decision on whether a screening programme among pregnant immigrants should be established in Denmark. The aims were to elucidate the following issues: 1) to characterise and evaluate technical aspects of the program 2) to perform a literature-based evaluation of existing evidence for designing a screening program 3) to uncover and describe logistical and ethical issues from the patients' point of view, 4) to compare different organisational models, and 5) to perform a cost-effectiveness analysis.

Methods: A literature search was performed and a 3-year pilot screening programme (January 2005 to December 2007) was established in a part of Denmark covering about 600,000 inhabitants. Data were systematically collected from the laboratory information systems as well as medical records concerning the pregnant women investigated.

Results: Based on the literature, good evidence exists on how to design screening programs in different population settings, and the technology required is present in the relevant laboratories in Denmark. The prevalence of haemoglobinopathy among pregnant women was 2%. The health technology assessment revealed several organisational challenges as only one-third of the pregnant immigrants were tested. The economical analyses showed that the screening program was cost-effective if 2 cases of serious haemoglobinopathy could be detected annually.

Conclusion: The present health technology assessment provides a basis for a political decision on whether and how a future screening programme should be implemented in Denmark.

P21.3

Rapid Health Technology Assessment of Ankaferd Blood Stopper®

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Objective: A rapid technology assessment was conducted on the use of Ankaferd Blood Stopper® (ABS) as a pharmacological haemostatic agent in patients requiring control of haemorrhage due to external wounds, trauma, dental surgery or other surgical procedures.

Methods: A search was conducted for clinical trials, systematic reviews, HTA reports and clinical guidelines using the search items, ("Ankaferd" OR "blood stopper"). Databases searched were the NHS CRD databases (DARE, NHS EED, HTA), the Cochrane Library on CD-ROM, the EuroScan database and PubMed (MEDLINE). A search was also done in the US National Guidelines Clearinghouse database and on Google.

Results: No controlled clinical trials were found on the safety or efficacy of ABS. The search located 1 case series and 2 case reports on ABS, as well as in vitro and animal studies of ABS's anti-bacterial activity and haemostatic effects. No clinical practice guidelines were found recommending the use of ABS. The single poorly-reported case series involved 25 patients undergoing dental procedures and found that ABS stopped bleeding within 3 seconds and 18 people experienced an oral metallic taste. The case series was poorly reported and it was not obvious if it had been published other than at the ABS website.

Conclusion: No evidence from controlled clinical trials was found to demonstrate the safety or efficacy of ABS. Even at the level of case series and reports, only 1 small poor quality case series and 2 case reports were found. ABS has yet to be licensed in major markets like the US and Australia. More research is required on ABS before claims of safety or efficacy can be established.

P21.4

The Efficacy of Adjuvant Ascorbic Acid Treatment in Erythropoietin-Hyporesponsive, Anemic Patients on Haemodialysis: A Meta-Analysis

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Objectives: Even though there have been several studies evaluating the efficacy of ascorbic acid in patients on haemodialysis receiving erythropoietin treatment, there has not been a clear conclusion. This study aims to determine the overall efficacy of adjuvant ascorbic acid therapy in erythropoietin-hyporesponsive, anemic patients undergoing haemodialysis using meta-analytic technique.

Method: PUBMED, Cochrane library, IPA, CINAHL, EMBASE, clinicaltrial.gov, WHO trial registry, and PyschINFO were searched. To be included in our meta-analysis, studies needed to compare the efficacy of ascorbic acid to control, in participants receiving erythropoietin and haemodialysis, and reported outcomes for haemoglobin or transferrin saturation. The outcome measures were weighted mean differences of haemoglobin and transferrin saturation between the ascorbic and the control group. All analyses were performed using the DerSimonian and Laird method under a random-effects model. The Q-statistics and I-squared for test of heterogeneity are also performed.

Results: Out of 459 studies identified, 4 studies met the inclusion criteria, involving a total of 157 patients. The calculated weighted mean difference between haemoglobin changes in the ascorbic acid treatment group versus the control was 0.86 g/dL (95% CI: 0.76 to 0.96). The calculated weighted mean difference of transferrin saturation change in the ascorbic acid between treatment group versus the control was 7.81% (95% CI: 7.27 to 8.36).

Conclusion: Adjuvant ascorbic acid significantly raises haemoglobin levels in patients with erythropoietin hyporesponsiveness undergoing haemodialysis. The significant rise in transferrin saturation indicates that this positive effect on erythropoietin response may be due to increased iron utilisation. Clinicians may consider using ascorbic acid injection for anaemia management in patients undergoing haemodialysis who are hyporesponsive to erythropoietin therapy.

P22 – HTA IN PERIPHERAL VASCULAR DISEASE

P22.1

Intravascular Brachytherapy for Peripheral Vascular Disease: Medical Evaluation

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Background: Intravascular brachytherapy (IVBT) after balloon dilatation (BD) with or without stenting is supposed to reduce restenosis in the treatment of peripheral vascular disease (PVD).

Objectives: Analysis of the medical efficacy of IVBT after BD with or without stenting in the treatment of PVD.

Methods: A systematic literature search of randomised controlled trials (RCTs) comparing IVBT versus no IVBT in patients with PVD was conducted. After appraisal of methodological quality of the identified RCTs their results were synthesised using meta-analysis.

Results: The literature search yielded 353 hits. Twelve

publications based on 7 RCTs were included in the analysis.

Two out of 3 RCTs comparing IVBT versus no IVBT after successful BD showed a significant reduction in restenosis rate for the IVBT-group at 12 months. In the meta-analysis the relative risk (RR) of restenosis was 0.62 (95% CI: 0.46 to 0.84). The 5-year results were presented for 1 RCT and showed similar restenosis rates for both interventions, time to recurrence was significantly longer for IVBT-group (17.5 vs. 7.4 months, P <0.01).

One from 3 RCTs comparing IVBT versus no IVBT after BD with optional stenting showed a significant reduction in the restenosis rates at 6 months. In the meta-analysis the RR of restenosis was 0.76 (95% CI: 0.61 to 0.95). One study revealed a significant increase in the rate of late thrombosis in the subgroup of patients in IVBT-group and BD with stenting.

The single RCT comparing IVBT versus no IVBT after stenting didn't show a significant difference in the restenosis rate at 6 months, RR was 1.12 (95% CI: 0.67 to 1.87). Early and late thrombotic occlusions were observed in the IVBT-group more frequently.

Conclusion: IVBT can be recommended after successful BD in patients with PVD for the prolongation of the time to recurrence of restenosis. IVBT after BD with stenting in patients with PVD cannot be recommended.

P22.2

Intravascular Brachytherapy for Peripheral Vascular Disease: Health Economic Evaluation

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Background: Intravascular brachytherapy (IVBT) is currently used to reduce restenosis in the treatment of peripheral vascular disease (PVD) after balloon dilatation (BD) with or without stenting. However, its cost-effectiveness is not yet clear.

Objectives: To analyse the cost-effectiveness of IVBT after BD with or without stenting in the treatment of PVD.

Methods: Health economic modeling was performed from a restricted societal perspective with clinical assumptions derived from a meta-analysis of RCTs and current cost assumptions derived from the German Diagnosis Related Groups (G-DRG-2007) using a time horizon of up to 1 year. Since there is no special G-DRG for IVBT in PVD its costs were estimated from the G-DRGs for cardiovascular interventions with and without IVBT-use. The base-case value was assumed to be €2,800.

Results: Additional costs of IVBT were estimated to be 1,655 or €1,767 according to the used G-DRG. The incremental cost-effectiveness ratio per avoided restenosis was calculated to be €8,484 or €9,058 for IVBT use after successful BD, €19,027 or €20,314 for IVBT after BD with optional stenting and €-39,646 or €-48,330 for IVBT after BD with stenting. The incremental cost-effectiveness ratio per avoided revascularisation was calculated to be €14,468 or €15,612 for IVBT use after successful BD, €15,746 or €16,976 for IVBT after BD with optional stenting and €-22,287 or €23,960 for IVBT after BD with stenting.

Discussion: The used methodical approach enables a high evidence level for the determined results and presents a good approximation of the current IVBT related costs for the German healthcare system.

Conclusion: From a health economic point of view the cost-effectiveness of IVBT after successful BD in PVD is not yet clear. The use of IVBT after BD with stenting in PVD cannot be recommended.

P23 – HTA IN CONGENITAL DISEASE

P23.1

Prenatal Diagnosis Technology in China: Current Status and Policy Implications

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Objectives: The objectives of this paper are to examine those factors that affect the implementation and development of prenatal diagnosis and identify the major problems facing the development of this technology in China.

Methods: The study used a cross-sectional survey to capture quantitative data from healthcare institutions accredited for prenatal diagnosis. Focus groups were conducted to generate qualitative information.

Results: The findings showed 6 factors that affected the implementation and development of prenatal diagnosis: 1) regulation and policy, 2) management model, 3) financial support, 4) service condition of institutions, 5) human resources, and 6) research and development. In China, the government has made positive contributions to the development of prenatal diagnosis. But there are several constraining factors: management models have not been developed, financial support is lacking not only for providers but also for patients, research and development is lagging, and human resources fail to meet demand.

Conclusion: The quantitative and qualitative data show that prenatal diagnosis is developing in China, but considerable improvement is still needed. This study has implications for policy-makers, including the development of a '3+1' service network, changes to the compensation system, and so forth.

P23.2

Systematic Review of Effectiveness of Screening Strategy for Down's Syndrome in Chinese Literatures

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Objectives: This paper presents the systematic review of papers in Chinese focusing on effectiveness of screening strategy for Down's syndrome in last 20 years.

Methods: To conduct literature retrievals by the Chinese Biomedical Science Literature Database (CBMDisc) with the key words 'Down's syndrome', 'Screening' and 'Diagnosis', from 1987 to 2007, and to review papers screened by the inclusive criteria.

Results: The main screening strategies were maternal serum screening with α-fetoprotein (AFP) and human chorionic gonadotrophin (hCG) (double test), or AFP, hCG, and unconjugated oestriol (uE3) (triple test) in the second trimester. The diagnosis method was mainly amniocentesis (AC). There were 274,536 screened women included in 54 papers. There were 17,868 people with screening positive value, amounting for 6.5% of total screened. Almost 39% of people with screening positive accepted AC. The interventions detected 176 cases with DS, and didn't detect 22 affected cases. There were 10 cases with DS delivered due to the pregnant women rejecting the AC. In addition, there were 225 cases detected with other chromosome diseases beyond Down's syndrome, amounting for 10.7 per ten thousands screened people, 4.4% of total people accepting the AC. Effectiveness in different facilities varied with the screening method, the amount of services, etc. Most of the papers were of the prospective design, but they didn't clearly demonstrate the dropout rate of the cohort.

Conclusion: Effectiveness of prenatal screening for Down's syndrome in China was evaluated by the systematic review of Chinese papers. It will give useful references for decision makers to improve the effectiveness of prevention strategy for Down's syndrome.

P23.3

Cost-effectiveness of Human Growth Hormone (GENOTROPIN®) in Children with Prader-Willi Syndrome, a Rare Disease

A BROWN

Aims: Prader-Willi Syndrome (PWS) is a rare condition with an approximate incidence of 1 in 25,000. Human growth hormone (hGH) improves growth, bone formation, adipose tissue catabolism and muscle metabolism in children with PWS. This study assessed the cost-effectiveness of Genotropin®, an 'Orphan Drug' for PWS, in the Australian healthcare setting.

Methods: A decision analytic Markov model was developed that comprised 2 parts. **Part A** simulated follow-up of subjects from age 6 months to 17 years with somatropin (rbe) treatment (reflecting 'real-life' practice). The health states were 'Alive with PWS' or 'Dead'. **Part B** simulated follow-up from 18 to 50 years without treatment. The health states were 'Alive with PWS but without diabetes', 'Alive with PWS and diabetes' and 'Dead'. At the point of entry into the model, subjects were stratified by presence or otherwise of diabetes. The risk of mortality due to PWS (Part A) and risk of mortality due to diabetic status (Part B) were sourced from observational data. Due to the rarity of PWS, there was a lack of trial evidence regarding the efficacy of hGH. Therefore, evidence regarding the efficacy of somatropin (rbe) at reducing mortality risk was drawn from a publication by Whittington and associates (2001).

Results: The comparison of hGH against placebo generated incremental cost-effectiveness ratios (ICERs) of less than AUD$55,500 per life year saved and per quality-adjusted life year. These ICERs represent reasonable cost-effectiveness within the context of a very rare condition,

Conclusion: hGH appears to be a cost-effective treatment option for PWS relative to no intervention. The caveat is that being based on data from observational studies, a degree of uncertainty surrounds the results of this study. However, they may be conservative as i) no reductions in disease-associated costs or co-morbidities with treatment were assumed and ii) the model only applied a benefit during hGH therapy.

P23.4

Decision-making Tool to Evaluate the Treatment of Inborn Errors of Metabolism

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Introduction: There have been increasing the situations demanding a brief assessment of specific therapies that are used in Inborn Errors of Metabolism (IEM). Nevertheless, due to both the epidemiology of these rare diseases and ethical issues, the studies on this type of treatments frequently have poor internal validity. The high cost of the treatments and the lack of alternative therapies are other factors that play a part. This gives the grounds for the development of a decision-making tool to evaluate the studies that analyse the specific treatment of IEM.

Methodology: A systematic review of literature was conducted on each of the 2 most prevalent lysosomal storage diseases - Gaucher disease (GD) and Anderson-Fabry disease (AFD), which were focused on identifying clinically relevant endpoints, their magnitude and therapeutic goals.

Results: The tool described the efficacy endpoints of greater clinical significance and the most important objectives to be achieved in patients with GD and AFD. In GD, the main endpoints that were analysed are: anaemia, thrombocytopaenia, changes in liver and spleen volumes, bone crisis, pathologic fractures, joint replacement surgery and quality of life. In AFD, the most important endpoints are: glomerular filtration rate, levels of Gb3, proteinuria, left ventricular function, left ventricular mass index, heart rate, end systolic volume, pain and quality of life.

Conclusion: The results have allowed the development of a decision-making tool, to evaluate the effectiveness of the

treatment by the Pharmacy and Therapeutics Committees.

- The results provide a printout of clinically relevant endpoints that will be useful to monitor treatment and to evaluate individualised effectiveness.
- Most of the studies do not use clinically relevant endpoints like mortality, and end-stage renal failure, stroke, heart failure or heart attack in AFD.

P23.5

Enzyme Replacement Therapy (ERT)

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Introduction: The lysosomal storage diseases (LSDs) are a large group of disorders caused by the deficiency of a lysosomal enzyme or transport protein that results in tissue damage and organ failure. Gaucher disease is the most common glycosphingolipid storage disorder resulting from defects in acid a-glucosidase (GCase), (GBA) locus. Fabry disease is an X-linked, single-gene defect caused by a deficiency of lysosomal a-galactosidase A. Pompe disease is a deficiency or dysfunction of acid alpha-glucosidase (GAA).

Technical properties of Enzyme Replacement Therapy: Ceredase® and Cerezyme® are used in the treatment of Type-I Gaucher's disease. Fabrazyme and Replagal are used in the treatment of Fabry disease. Myozyme has been shown to improve ventilator-free survival in patients with infantile-onset Pompe disease.

Methodology: In general, Medline, Pubmed, Ebsco, Cochrane Library and HTA databases were searched from 2001 to 2007 (inclusive). Reference papers and cross-references were accessed where applicable. A systematic review of all relevant literature was done and the evidence graded according to the modified Oxford scale.

Results: A few selected LSDs are now treatable with haematopoietic cell transplant (HCT) and ERT. The treatment of Gaucher disease with ERT in the United States, ranges from US$40,000 to US$320,000. The treatment of Fabry disease was approximately £86,000 per annum in England and Wales.

Conclusion: There was sufficient evidence to indicate effectiveness and safety of ERT for Gaucher Type 1, Fabry and Pompe (Infantile) disease. ERT has not been shown to reverse neurological symptoms associated with Type 2 or Type 3 Gaucher disease. Although clearly beneficial to patients, ERT treatment is very expensive. Increasing the number of patients being prescribed will result in potential long-term costs, and policy makers will have to consider whether the Ministry of Health, Malaysia, can afford such an expensive healthcare in the public hospital setting in Malaysia.

P24 – HTA IN EMERGENCY MEDICINE

P24.1

Users Views of a Change in the Management of Ambulance 999 Calls

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Background and Aims: There is evidence that some 999 ambulance callers do not need or benefit from the standard emergency ambulance response. We have evaluated the impact of managing non-urgent 999 ambulance calls by transferring to NHS Direct nurse advisers for further clinical assessment. One of the main outcome measures was users' views of acceptability of and satisfaction with the new service.

Methods: We conducted a multi-centre randomised controlled trial in 3 UK ambulance and NHS Direct service sites. Non-urgent 999 callers were randomly allocated to usual care (control) or transfer to NHS Direct for further assessment (intervention) groups. Callers recruited to the study were sent a postal questionnaire 7 days after the incident. The questionnaire was designed to elicit experiences and views on the call process, usefulness of advice, what happened next and satisfaction with the call and service. Up to 2 reminders were sent.

Results: Completed questionnaires were returned from 340/639 (53%) intervention and 261/529 (49%) control group callers. There was a high level of satisfaction with the overall service in both groups but higher in the control group (79% intervention vs. 94% control P <0.001). Eighty per cent of intervention callers were happy to speak to the nurse. Callers found the nurse advice helpful with only 18% reporting that it was not helpful. Reassurance from the nurse was particularly valued. Intervention group callers were given clear advice (83%) and were satisfied with information given (84%) but 67% felt they should have received an ambulance.

Discussion: Transfer of some 999 calls for nurse advice was acceptable to callers and the reported satisfaction was high but there remains an expectation that if callers request an ambulance one should be sent.

P24.2

Management of Ambulance Emergency Calls - A Mixed Methods Evaluation of a New Service

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Background and Aims: UK policy encourages the development and testing of new models of care. There is evidence that some 999 ambulance callers do not need or benefit from the standard emergency ambulance response. We have evaluated the impact of managing non-urgent 999 ambulance calls by transferring to NHS Direct nurse advisers for further clinical assessment.

Methods: We conducted a 3-part study. 1) A randomised controlled trial in 3 UK ambulance and NHS Direct service sites. Non-urgent 999 callers were randomly allocated to usual care (control) or transfer to NHS Direct for further assessment (intervention) groups. Processes and outcomes were assessed at 7 days. 2) A qualitative study of semi-structured interviews with key ambulance service and NHS Direct staff to elicit their views of the service change. 3) An observational study where all calls were transferred to the new service to assess the impact on workload for each organisation.

Results: The RCT study found a high proportion of calls (67%) transferred for nurse advice were returned to the ambulance service. Intervention group calls had a significantly reduced mean 'job cycle time': from 50.36 to 40.35 minutes (P <0.001) resulting in increased ambulance service efficiency. The qualitative study revealed that staff appreciated the potential operational benefit of this method of handling non-urgent calls. Factors identified as key for change included strong leadership, early involvement of staff at all levels, and allowing time for testing, modification and implementation. The observational study showed that only 10% of 999 calls are suitable for this service.

Discussion: Transfer of non-urgent 999 patients to a nurse advisor for further advice is an acceptable approach to managing calls for emergency ambulance services but the impact on ambulance service workload is small. There is scope to improve the service if eligible calls can be better identified.

P24.3

Trend in Attendances and Profile of Patients who Attended the Emergency Departments in Public Hospitals in Singapore

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Background: In Singapore, there has been an overall increase in adult Emergency Department (ED) attendances between 2005 and 2007 across all public hospitals. A 2-phased national study was planned to determine specific factors related to utilisation of ED services by age group and acuity status. Patients triaged as P2 are ill and non-ambulant and the severity of their symptoms requires early attention, failing which early deterioration of their medical status is likely. Patients triaged as P3 are ambulant and have mild to moderate symptoms requiring acute treatment.

Aim: The aim of this Phase 1 study was to describe the factors related to utilisation of ED services in 2007 and trend in attendances between 2005 to 2007, using administrative databases.

Methodology: All adults (18 years and above) P2 and P3 attendances at 5 public hospitals from 1 January 2005 to 31 December 2007 were included, except for police cases. Demographic data, referral type, mode of transport to ED and discharge status were analysed.

Results: There was an increase in overall P2 attendances and a decrease in overall P3 attendances from 2005 to 2007. The highest growth in P2 attendances from 2006 to 2007 was seen among those aged 17 to 24 years old (33%), while that for P3 attendances was seen among those aged 25 to 49 years old (5%). In 2007, the highest proportion of P2 attendances was seen in those aged 25 to 49 years old and in males, 76% came to ED with no referral, 25% arrived by ambulance and 47% were admitted. Among the P3 attendances, it was seen in those aged 25 to 49 years old and in males, 88% came to ED with no referral, 3% arrived by ambulance and 11% were admitted.

Conclusion: Findings from phase 1 of the study provided the background for phase 2 involving on-site interviews with P2 and P3 patients where details on socio-demographic and behavioural factors would be obtained. The results of these interviews would allow formulation of strategies to enable more appropriate utilisation of ED services based on possible service gaps in the community and patients' health seeking behaviour.

P24.4

Assessment of Pre-Hospital Trauma Care

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Background: Basically, 2 strategies exist for the pre-hospital management of severe trauma victims: scoop-and-run, and stay-and-play. In the former, the patient is taken to the hospital as quickly as possible. In the latter, trauma care is delivered to the patient on-scene by a dedicated trauma team, brought to the scene of the accident by helicopter (Mobile Medical Team, MMT). Theoretically, the stay-and-play strategy may be advantageous, since less time may be lost before the patient is appropriately stabilised. However, there is no conclusive evidence of superiority of this mode of pre-hospital trauma care. Producing such evidence is difficult because of the complexity of the intervention, the limited generalisibility of findings, the impracticability of randomisation, and the possibility of residual confounding. In this observational study, we tried to overcome the latter problem by using propensity scores.

Method: Observational study, assessing 6-month survival among consecutive trauma patients.

Results: A cohort of 1,424 consecutive trauma patients was analysed, of whom 264 were attended by the MMT. After correction for confounding by systolic blood pressure, Glasgow Coma Scale, age, and New Injury Severity Scale, patients who

were attended by the MMT had a better probability of survival at 6 months after the accident [Odds Ratio (OR) for mortality of 0.70]. This survival benefit did not, however, reach conventional levels of statistical significance (95% CI: 0.29 to 1.69). The OR for blunt trauma patients was 0.54 (95% CI: 0.21 to 1.39).

Interpretation: Although our data are suggestive of a beneficial effect resulting from MMT pre-hospital care of trauma patients, the possibility that this observation is due to chance cannot be ruled out. Establishing a firm evidence base for pre-hospital care remains a challenge, and the need and opportunities for controlled studies in this area will be discussed.

P24.5

Mini-HTA: The Use of Myocardial Perfusion Imaging (MPI) in the Diagnosis of Cardiac Pathology in Patients Presenting with Chest Pain in the Emergency Department

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Introduction: Approximately 10% of A&E attendances are for chest pain in Singapore. This presents significant diagnostic and resource challenges as the exclusion of cardiac pathology remains fraught with difficulty and current clinical protocols call for admission and observation. We examined the evidence for the use of MPI in an emergency department setting.

Technology: In MPI, a radiopharmaceutical tracer is administered intravenously after stress and at rest. Tracer distribution within the myocardium is imaged using a gamma camera, thus revealing the presence or absence of inducible ischaemia and/or infarction.

Methodology:

Population – Emergency Department patients with chest pain and non-diagnostic electrocardiogram
Intervention – MPI
Comparators – Serial ECG
Outcomes – Diagnostic yields, hospital readmission rate
A literature search was conducted in PubMed, NHS Centre for Reviews and Dissemination databases, Cochrane database of systematic review and National Guidelines Clearinghouse. The key search words used were Myocardial Perfusion Imaging OR Myocardial Perfusion Scintigraphy AND chest pain AND Emergency Department AND electrocardiogram AND diagnosis.

Results: We found 21 articles including 1 HTA report, 1 systematic review, 3 3 cost evaluation analysis, 16 primary articles and 1 guideline. MPI had substantially better diagnostic value with higher specificity (84% vs. 71%) and negative predictive value (98% vs. 77%) compared to serial electro-cardiograms. The number of Emergency Department patients with chest pain admitted following MPI and without MPI was 18.4% versus 32.7%. Economic analyses suggest that MPI usage leads to lower overall mean cost ($5,030 vs. $6,044) mainly through reduction of unnecessary hospital admissions and diagnostic angiograms. American College of Cardiology guidelines recommend that rest/stress MPI should be used in the diagnosis and assessment of myocardial risk in possible acute coronary syndrome in patients with non-diagnostic electrocardiogram and initial serum markers and enzymes.

Conclusion: MPI appears to be promising for ruling out acute myocardial ischaemia in an emergency department setting.

P25 – HTA IN DIABETES

P25.1

Is There a Preferred Glitazone for the Treatment of Type 2 Diabetes?

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Objective: Type 2 diabetes is a chronic disease with potentially serious complications, in particular cardiovascular complications. Two oral glitazones (rosiglitazone and pioglitazone) have been developed for the treatment of the disease, either alone or in combination with metformin and/or a sulfonylurea. In France, their reassessment by the HAS Transparency Committee was scheduled to take place 4 years after marketing, in agreement with the Healthcare Products Economic Committee (CEPS). On first assessment, both products received a favourable opinion for reimbursement, but no clinical added value was recognised over existing treatments.

Methods: The efficacy, safety, and effectiveness of rosiglitazone and pioglitazone were reviewed on the basis of newly generated evidence (pharmaceutical company reports and literature search). The review was assessed by in-house staff and external endocrinologists/diabetologists, and validated by the Transparency Committee.

Results: Glitazones are effective agents for glycaemic control even if the reduction in HbA1c level is not very marked (about 1%). Their benefits in terms of morbidity and mortality have not been established. The new evidence confirmed previously reported adverse events (oedema, weight gain) and identified an extra risk - fractures. Four meta-analyses highlighted a significantly enhanced risk of cardiovascular events (myocardial infarction or cardiac ischemia) on rosiglitazone treatment. It is unlikely that pioglitazone increases the risk of myocardial infarction according to the only available meta-analysis for this drug.

Conclusion: On the basis of the new evidence generated on safety, the Transparency Committee considered the benefit of pioglitazone greater than that of rosiglitazone, but still found no grounds for considering that either drug (whatever the treatment combination) provided any added clinical value compared to other oral anti-diabetics.

P25.2

Facts and Myths: Prevention of Diabetic Ketoacidosis (DKA) and Self-monitoring of Ketone Bodies

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Objective: DKA is associated with significant morbidity and mortality. A growing number of diabetes professionals are advocating home monitoring of b-HB by finger prick instead of using urine ketone testing. We reviewed the most recent developments in the epidemiology and management of DKA and compared the 2 self-monitoring methods.

Methods: Literature review of the current publications addressing the epidemiology, management and prevention of DKA based on a MEDLINE search (articles published up to 2008). Relevant articles were crosschecked for additional, pertinent citations.

Findings: Incidence, prevalence and hospital admission rates have remained unchanged over the past few decades, despite considerable advances in diabetes therapy. Tight glycaemic control, intensive self-monitoring of blood glucose and adjustment of therapy according to measurements taken is a key element for prevention of DKA, especially in sick day management. Measurement of ketone bodies is an important, complementary tool in the evaluation of the metabolic situation during hyperglycaemia, as long as the patient is aware of the limitations of the respective methods. The clinically relevant reliability of urine and blood measurement with self-monitoring devices is comparable and so far there is no published evidence that capillary b-HB determination in a home setting is better than urine monitoring to lower the incidence of DKA.

Conclusion: DKA is still a severe complication of prolonged hyperglycaemic episodes with possible devastating consequences. Education of patients and their social environment to promote frequent testing (especially during sick-days) and to lower their glucose levels, as well as recognise the early signs of hyperglycaemia and DKA is of paramount importance in preventing the development of severe DKA. Self-monitoring of ketone bodies can be performed safely with urine test strips or capillary blood measurement devices. Whether other potential benefits of capillary measurement are worth the 30 times higher cost remains to be seen in upcoming studies.

P25.3

Treatment of Poorly Controlled Type 2 Diabetes (T2DM) Patients with Insulin Glargine – Is it a Cost-Effective Option?

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Background: Diabetes mellitus (DM) is a major public health challenge affecting over 300,000 Singaporeans. Glycaemic control while demonstrated to be the best way to retard onset of complication is difficult to effect in practice and almost 30% of diabetics on drug treatment have unacceptable control. Insulin glargine, a long-acting insulin analogue enjoys a better physiological profile compared to conventional NPH insulin and has been advocated for use in poorly controlled diabetics.

Objectives: This cost analysis examines the cost of DM treatment and related complications over a 5-year time horizon in uncontrolled Type 2 DM (T2DM) patients on NPH insulin versus insulin glargine.

Methods: A state transition model was used to simulate the progression of a cohort of 100 uncontrolled T2DM patients on NPH who were either continued on NPH or converted to insulin glargine over 5 years. Reduction in incidence rates of DM-related complications from improved HbA1c control if switched to glargine was estimated based on UKPDS data. Retrospective financial data of admissions from T2DM related complications from a Singapore tertiary teaching hospital were used in estimating the cost of complications and insulin treatment.

Results: Patients who were uncontrolled on NPH and continued on NPH incurred a higher total cost compared to if they were switched to insulin glargine. While the treatment cost for the 100 patients continued on NPH was $599,909.67 versus $857,033.79, switching to glargine and the consequent lower complications would lead to reduction in costs of complications [$544,508.38 (NPH) vs. $280,494.61 (glargine)]. Therefore, cost of medical care would be $6,889.64 more per 100 patients continued on NPH.

Conclusion: Data from the model suggest that insulin glargine is a cost-effective treatment option for uncontrolled T2DM patients on NPH in the long-term. However, the finding should be validated by further analysis of actual outcomes data.

P26 – HTA IN HYPERBARIC OXYGEN THERAPY AND WOUND HEALING

P26.1

Systematic Review of Hyperbaric Oxygen Therapy for the Treatment of Non-Healing Diabetic Ulcers

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Background: Non-healing lower limb ulcers are a major source of morbidity and resource use in individuals with diabetes mellitus. Hyperbaric oxygen therapy (HBOT) has been suggested to improve oxygen supply to ulcers and improve healing through the inhalation of 100% oxygen at 2.0 to 2.5 atmospheres absolute pressure in a compression chamber. The

objective of this review is to evaluate the role of systemic HBOT in the management of non-healing lower limb diabetic ulcers.

Methods: A systematic search using keywords focusing on 'HBOT' and 'lower limb diabetic ulcers' was conducted. Databases searched included Medline (In-Process and Other Non-Indexed Citations), EMBASE, CINAHL, PubMed (for non-Medline records only), Wiley's Cochrane Library, and Thomson's Biosis Previews. Using 2 independent reviewers, study selection was performed with pre-specified inclusion/exclusion criteria, in 2 phases: title/abstract and full-text review. Randomised clinical trials (RCTs) and observational studies were included and cross-checked against systematic reviews. Quality assessment was completed using the Jadad scale. Using meta-analyses, pooled estimates of outcomes will be determined.

Results: In the initial search, 353 articles were identified, of which 102 articles were included for full-text review and data was fully abstracted from 24 publications. Primary outcomes of major amputation and wound size reduction have been identified. Relative risk of major amputation and wound size reduction in terms of a mean difference were also abstracted and analysed.

Conclusion: RCT evidence on HBOT is limited. Most of the published literature consists of observational studies. Additional RCTs need to be conducted to establish the benefits and harms of treating diabetic lower limb ulcers with HBOT more conclusively. This review adds to the evidence surrounding chronic care management and costs that are currently priorities for the Canadian healthcare system.

P26.2

A Technology with Multiple Indications but Little Evidence: How can HTA Help?

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Hyperbaric oxygen therapy (HBOT) is considered standard therapy for decompression illness. However, it is also used in numerous other indications, for which the evidence base has been questioned. The UK Specialised Services Public Health Network wished to prepare a commissioning policy for NHS England such that funding would only be available for indications with evidence of benefit. To inform this policy, they requested NHS Quality Improvement Scotland to undertake an HTA examining the clinical and cost effectiveness of HBOT for all documented indications. The review aimed to group indications into: those of proven benefit and cost-effectiveness, so should be used in the NHS, of proven benefit but not cost-effective, so should not be used in the NHS, of unproven benefit but with sufficient suggestion of possible benefit to be used in trials, and of proven lack of effectiveness so should not be used. Given the range of possible indications, a large amount of literature was retrieved. To manage this literature, a hierarchical approach to evidence selection was adopted, and the review built upon existing secondary evidence where possible. It emerged that the majority of secondary evidence was based upon a small number of primary studies of generally poor quality and that there were few additional well-conducted studies. Consequently it was only possible to group indications according to those for which: there was clinical effectiveness evidence, or consensual evidence supported by a theoretical basis to support the use of HBOT, there was insufficient evidence to support the routine use of HBOT, the evidence did not support the use of HBOT. The findings have been translated into a commissioning policy based upon a traffic light system of red, orange and green indications. This will aid consistent, evidence-based practice across England, and also by requesting accompanying data collection, enable evidence gaps to be filled.

P26.3

Is 'Super-oxidised' Water Effective as an Antiseptic in Wound Care?

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Introduction: 'Super-oxidised' water is sold over-the-counter as an antiseptic solution with claims that it can inhibit the growth of harmful viruses, fungi and bacteria in wounds. Oxychlorine ions in 'super-oxidised' water are known to rapidly infiltrate the walls of free-living microbes while sparing human cells as they are tightly bound together in a matrix.

Objective: The objective of this rapid HTA is to evaluate the evidence for and against the use of 'super-oxidised' water as an antiseptic agent in wound care.

Population – Patients with acute/chronic wounds, ulcers, cuts, abrasions and burns

Intervention – Spray, immersion or irrigation with 'super-oxidised' water

Comparison – Other antiseptics used on wounds such as iodine compounds, hydrogen peroxide, chlorhexidine, silver compounds

Outcomes – Effect on healing, e.g. days to reepithelisation and healing rate, effect on infection e.g. bacterial counts and infection rates

Methodology: A systematic review confined to in-vivo studies was conducted using the databases of MedScape, CINAHL, Science Direct and Google Scholar. Search terms included: [super-oxidised water] or [Brand names of leading products] and [Healing or Infection or Toxicity].

Results: Five primary studies and 1 grey literature article were found. Four of the primary studies involved human subjects and the fifth involved rats subjected to third-degree burns. Three of the primary human studies were case series while the fourth was a controlled study on infected diabetic foot ulcers

which reported that patients in the 'super-oxidised' water group had shorter median healing time compared with patients in the Povidone Iodine group (43 days vs. 55 days, P <0.0001). No adverse events were reported from the use of 'super-oxidised' water.

Conclusion: Existing studies suggest that 'super-oxidised' water is safe for use as an irrigation and cleansing agent in wound care. However, larger studies are necessary to establish its effectiveness in preventing and treating wound infections.

P26.4

Economic Evaluation of bFGF Spray for Non-Inflammatory Pressure Ulcer Patients

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Objective: Basic fibroblast growth factor (bFGF) promotes wound healing and it can be applied on the clean wound with NPUAP stage II, III and IV patients. bFGF spray was recently approved as a new therapy for fast wound healing in Korea. We evaluated the cost-utility of treatment with bFGF spray.

Methods: We evaluated cost-utility of bFGF spray from societal perspective. We made 2 scenarios to consider current wound treatment pattern. At the base case scenario, effectiveness of bFGF spray was assumed to be added to the dressing effectiveness of polyurethane foam or hydrocolloid, which was the most frequently used moist dressing product in Korean market and its alternative was dressing only. For the other scenario, conventional gauze was chosen as a dressing material and comparator. During 11 weeks of analysis period, a patient undergoes care in the hospital for the first 1.5 weeks and then home-care either from a nurse or from family for the 9.5 weeks in the Korean healthcare setting. Primary endpoint was defined as complete healing and measured as a proportion of patients who were completely healed. Meta-analysis was conducted from the literatures to investigate the effectiveness of dressing therapy. The utility weight of pressure ulcer patient was calculated from the expert survey for nurse practitioners. Sensitivity analysis was performed for major parameters and assumptions.

Results: At the base case scenario, ICER was from 1,066,761KRW to 5,333,803KRW for 1 more patient having healed wound and from 18,080,534 KRW to 90,402,671 KRW for 1 additional QALY gain depends on the effectiveness of bFGF. The second scenario showed that the ICERs were 2,999,052KRW/healed wound patient and 76,247,072KRW/QALY. Sensitivity analysis indicated that most sensitive variable is the effectiveness of bFGF.

Conclusion: Treatment of clean wounds with bFGF spray added to dressing therapy was more cost-effective than the treatment with dressing only.

P27 – HTA IN INFORMATION TECHNOLOGY

P27.1

Software HTA: Proposal of Methodology for Safety Evaluation

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Aims: With the European Directive 2007/47/EC, interest on medical software increased in healthcare. This study aims to explore and to evaluate the "medical software" safety through the application of a HTA methodology for a software failure analysis.

Methods: The analysis has been developed at Florence University Hospital of Careggi, a third level hospital with 1,620 beds and 5,600 employees. Five hundred and fifteen software failure reports have been analysed. They have been classified into 7 categories according to the type and to the cause of the failure. Further, all "medical softwares" have been classified according to their "Destination of Use" and according to software installation: '*Stand Alone*' or '*Hospital Network*' softwares. Finally, the quantitative indicator Failure Rate 'FR' was applied to previous classifications and analysed.

Results: Evident relationships have been found by analysing the 'software failure types' according to different 'destinations of use' and 'software installations'. Furthermore, the FR analysis has shown that 30% of software failures are not dependent on "medical softwares" and it would be avoidable.

Conclusion: The proposed methodology allows the quantitative evaluation of safety and reliability for "medical software" in hospital. The multidimensional approach has been considered by evaluating software applications according to different user skills and clinical area needs. It has been shown that personnel training could reduce one-third of total software failures. The methodology would be suitable for a guideline proposition on "medical software HTA" and management.

P27.2

HTA – Network, not Double Work: Concept for Technological Support

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Background: The fast progress in the field of health technology and the high amount of research as a basic for evidence requires efficient and time-saving conduction of assessment. On the other hand EBM and HTA assessments have to be adapted to different settings of health systems. Crucial factors

for higher work speed are networking, structuring and avoiding double work.

Objective: Based on the *Core model* for HTA of Finohta (Finnish Office for Health Technology Assessment) and on the success of implementing an important step in structured literature processing with LitDb[1] a structured way of working in a network of HTA should be developed.

Concept: A database should support the whole process of developing a HTA report according to the Core model for HTA. The user should be led through the process with different choices (i.e. element cards) and tools (i.e. LitDb). Property rights should be included according to legal rules and installed in the background - the user is led through the system automatically. The property rights could be managed using digital signatures for the data contributed. Users should be able to assign parts of their element cards to other users to allow for concurrent work on specific issues. HTA reports or parts of HTA reports should be exchangeable in order to be adaptive for individual health systems. Every user can take from and give back certain parts into the network. The HTA reports should be exchanged in a standardised way in form of XML documents based on XML schemas.

Perspectives: HTA networking can be fulfilled, HTA can easily be integrated and processed in all health systems if required. HTA developers work in the same direction, one network. The whole process is transparent and fulfils high quality standards. IPR are handled properly and can be backtraced to their initial contributors.

[1] Free for download at www. Hauptverband.at/EBM_HTA

P27.3

Patient Decision Aids for Breast Cancer: A Proposal in Web Format

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Introduction: A website is a tool that gathers all audiovisual and interactive supports. In a health context, information helping make shared decisions on diagnosis and treatment of diseases may be available to patient and medical team through a website.

Objectives: To develop a tool for Decision-making Aid in breast cancer in web format, to improve the quality of decisions for diagnostic and therapeutic options in the disease, to promote shared decision-making between patients and healthcare professionals.

Methods: To develop the website, a systematic review of tools for Decision-making Aid was performed. Medline, Embase, the Cochrane database, and the HTA database were explored as well as websites of institutions working with Patient Decision Aids. Subsequently, semi-structured interviews of patients and healthcare professionals involved in the process, and focus group with patients were conducted.

Results: Previous international experiences showed evidence that application of tools to Decision-making Aid in oncology increases patient knowledge about illness, it generates greater realism on patient expectation of possible effects of an intervention and it reduces passivity in the decision-making process to find the option that best suits their medical and personal preferences. Thus, we are working on a pilot website in Spanish context with the following contents: understanding breast cancer, risk factors and prevention, diagnosis, treatment options, after-treatment resources such as links, educational materials, experiences of other patients and a forum.

Conclusion: The availability of instant information and the easy real-time access from anywhere in the world makes the Web format a comprehensive and complete tool compared to other media (e.g. paper, DVD, CD). Through the Internet, patients and health professionals from Spanish-speaking countries have the opportunity to acquire knowledge, to exchange experiences and to solve questions. The website might allow patients to make shared decisions regarding the treatment of breast cancer as well as to access information.

P28 – HTA IN TELEMEDICINE

P28.1

Home Telehealth for Chronic Disease Management

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Background: Globally, non-communicable diseases account for 59% of the 57 million annual deaths and 46% of disease burden. Home care is an integral part of a chronic disease management model to improve and maintain the health of patients. Home telehealth is an extension of healthcare delivery to a patient's home.

Objectives: The research objectives of this health technology assessment were to: systematically review the literature and perform meta-analyses to assess the clinical outcomes and health service utilisation of home telehealth compared with usual care for patients with diabetes, congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD) or mixed chronic diseases, assess the economic impact of home telehealth, and provide an economic evaluation framework.

Methods: An electronic literature search was conducted on clinical and economic studies evaluating home telehealth for chronic diseases, such as diabetes, CHF and COPD, which

were published from 1998 to 2008 using Medline, BIOSIS Previews, EMBASE, HEED and NHS HEED.

Results: Seventy-nine studies were selected for the clinical review. Overall, the findings suggest that home telehealth is clinically effective. The impact of home telehealth on health service utilisation is less certain. The 22 studies selected for the economic review generally found home telehealth to be cost-saving for the healthcare system and insurance provider, but the overall quality was poor.

Conclusion: Home telehealth appears to be generally clinically effective. There is no conclusive evidence that it will help to reduce healthcare resource use and costs. Additional studies of higher methodological quality may provide better insight into the potential clinical effectiveness and economic impact of home telehealth at the population level. A standardised approach on home telehealth evaluation would help to increase the quality of studies and amount of evidence available to make informed decisions. Policy and practice implications for home telehealth will be discussed.

P28.2

Telemedicina and Stroke

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Stroke outcome is closely linked to fast access to thrombolytic therapy, but this can only be provided under expert supervision. Telemedicine has been proposed as a way to improve the outcome of ischemic stroke.

Objective: To assess the cost-effectiveness of telemedicine for the use of thrombolytic therapy for ischemic stroke and the barriers for its implementation.

Methodology: The modified Rankin scale (mRS) was used to assess the outcome of stroke and it was valued against the cost of telemedicine to obtain the cost-effectiveness ratio (CER). A decision model was built and probabilities were obtained from the literature. Costs were provided by providers. Extensive sensibility analysis was done on key variables.

Results: Under a payer's perspective and certain assumptions, the incremental CER was above €50,000/mRS unit and the probability of being on a favourable mRS (mRS 0-3) is not different in either treatment, only the probability of death is lower. However, if the rate of patients treated increased, the results would improve.

Conclusion: Though telemedicine seems to be an acceptable and favourable technology, it is difficult to capture its efficiency from the payer's perspective, probably due to the inability of outcome measures to discriminate clinically different stages. Other factors such as capacity building must be taken into account before its full implementation.

P28.3

Cost Analysis of a Home Telemonitoring Programme for Patients with Heart Failure and Chronic Obstructive Pulmonary Disease

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Introduction: Patients with chronic conditions, such as heart failure and chronic obstructive pulmonary disease (COPD), are heavy users of the healthcare system. Home-based telemonitoring of such patients offers the opportunity for significant savings and improvements to patient care.

Objectives: The aim of this study is to compare the costs, hospital readmissions and emergency care usage of a home telemonitoring intervention and a control care strategy.

Methodology: A randomised clinical trial with a 6-month follow-up was designed to test the impact of 2 interventions on a sample of 70 patients. The control group received a previously tested multiple strategy of individualised care (MSIC). The telemonitoring intervention consisted of a daily transmission of blood pressure, weight, temperature and O_2 saturation using a home telemonitoring system in addition to the MSIC.

Results: Preliminary results seem to indicate that home telemonitoring reduced the number of hospital readmissions and days spent in the hospital. However, there were no significant differences regarding the visits to the emergency care unit for the 2 study groups. The number of alerts received by medical staff (i.e. telephone calls and SMS messages) was initially higher for the telemonitoring group, although tended to even up the number of alerts of the control group as the study progressed. Based on the data collected during the first 3 months of the study, the costs of the telemonitoring + MSIC programme would be of €9,098.7/patient compared to the €9,513.5/patient calculated for the MSIC intervention.

Conclusion: Based on preliminary data, we hypothesise that home telemonitoring could constitute viable means of providing quality healthcare to patients with heart failure and COPD and could reduce the number of hospital readmissions and the days spent in the hospital.

P28.4

An Adaptation of the Technology Acceptance Model as a Tool to Evaluate Telemedicine Adoption by Physicians

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Introduction: The acceptance of telemedicine by physicians constitutes an important prerequisite for the successful diffusion of this technology on a large scale.

Objectives: Based on the Technology Acceptance Model (TAM) developed by Davis, this study examines the main

factors that could affect physicians' intention to accept telemedicine technology in the healthcare context.

Methodology: A technology acceptance questionnaire was developed following an adaptation of the original TAM to our particular case studies. Five more dimensions were included to the model after the adaptation process. Two questionnaires were developed in order to assess physicians' acceptance of telemonitoring devices and teledermatology. A panel of experts in technology assessment evaluated the face and content validity of the instrument, reviewing the questionnaires and providing feedback on the individual items. Cronbach alpha were calculated to measure the reliability of the model. The construct validity of the model was evaluated using interitem correlation analysis. A web-based version of the questionnaires was e-mailed to 75 clinicians specialised in cardiology, internal medicine and pneumology, 49 dermatologists, and 277 primary care physicians.

Results: Results show that correlation was considerably higher among items intended for the same construct than among those designed to measure different constructs, suggesting adequate validity of the measurements. Based on preliminary results, we hypothesise that 'Perceived Usefulness' will have a significant and strong influence on physicians' intention to use telemedicine technology.

Conclusion: The adapted TAM model provides important information regarding physicians' attitudes towards telemedicine technology prior to the development and implementation of telemedicine programmes in our region. Moreover, the information obtained through the adapted TAM model could determine the success of future telemedicine programmes.

P29 – HTA IN OPHTHALMOLOGY

P29.1

Health Technology Assessment Report on Lucentis

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Background: Ranibizumab (Lucentis™ - Novartis) is a humanised therapeutic antibody fragment inhibiting VEGF-A, a protein involved in angiogenesis. It was approved by FDA in 2006, and by EMEA and AIFA in 2007, for the treatment of neovascular age-related macular degeneration (nvAMD), the most common cause of legal blindness in subjects aged over 50 years in developed countries. The aim of the study was to realise a HTA report on Lucentis.

Materials and Methods: HTA report was realised considering epidemiological, organisational, economic, social and bio-ethical aspects and implications. A bibliographic search was performed on Medline, Embase and Cochrane Library databases to evaluate epidemiological context and risk factors for AMD. An informative electronic form was realised and distributed in the Italian ophthalmological centres to investigate disease burden. To estimate cost-effectiveness, a Markov model was used and Quality Adjusted Life Years (QALY) gained were considered as outcomes, model was based on MARINA, ANCHOR, PIER and TAP studies results and compared Lucentis to best supportive therapy, photodynamic therapy and the other antiangiogenic drugs currently used. To evaluate ethical implications, clinical benefits and patient needs were considered.

Results: In Europe (EUREYE 2006) the prevalence of nvAMD in subjects aged over 65 years was 2.29% (95% CI: 1.73% to 2.86%). Risk factors for AMD are: advanced age, female gender, complement factor H variant and other genetic factors, white race, smoke and cardiovascular disease. Comparing Lucentis with the other therapies, the ICER was likely to be under a threshold of €30.000 per QALY. Sensitivity analysis using Montecarlo simulation showed this result can be accepted in a range between 65% and 89% of cases. Bioethical evaluation is work in progress.

Conclusion: Health Technology Assessment is a useful instrument in healthcare decision making to produce a critical documentation about the real value of a product and its utilisation in the Italian context.

P29.2

Estimating Costs of Age-related Macular Degeneration Treatment with Anti-VEGF Drugs in Brazil

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Brazil

Introduction: Anti-VEGF (vascular endothelial growth factor) drugs are the newest therapeutic option available for the treatment of age-related macular degeneration (AMD). Within the drugs of this class, the present study focused on ranibizumab, recently marketed in Brazil, and bevacizumab, licensed for the treatment of colon or rectal cancer, but which has been widely used off-label in several countries, as well as in Brazil.

Aim: To estimate the costs of the AMD treatment with ranibizumab and bevacizumab in Brazil.

Method: To calculate the costs of the treatment, we used ex-manufacture prices approved by Brazilian Government for the 2 drugs. The cost of bevacizumab was based on splitting up doses of the available medicine into unitary doses for intravitreal injection (100mg/4mL). The costs associated with the medical

procedures and the preparation of unitary doses were not considered.

Results: The total cost of the treatment with bevacizumab, considering the application of 3 intravitreal injections of 1.25 mg each, was US$19.31. The total cost of the treatment with ranibizumab, also considering 3 applications, was US$4,724.73.

Conclusion: The difference of costs between the 2 drugs was quite significant, as the cost of the treatment with ranibizumab was approximately 244 times the cost with bevacizumab. Therefore, choosing one drug instead of the other may lead to an important economic impact on the healthcare system. Furthermore, the use of bevacizumab on the AMD treatment highlights the discussion about the ethical and legal issues associated with the off-label use of drugs.

P29.3

Optical Coherence Tomography for Macular Oedema: Assessment of a Proposed New Gold Standard

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Background: Optical coherence tomography (OCT) is a non-invasive imaging technique for cross-sectional tomographic visualisation of the macula. It has been proposed as a new gold standard test for diagnosing macular diseases. As part of a health technology assessment (HTA) of OCT for a range of ophthalmologic conditions undertaken by the Medical Services Advisory Committee (MSAC, 2009), an evaluation of the effectiveness of OCT as a replacement for fundus fluorescein angiography (FFA) for the diagnosis of macular oedema was undertaken.

Methods: Systematic review of the biomedical literature from 1990 to 2008.

Results: Ten studies reporting the comparative diagnostic yield of OCT and FFA were identified. When the results were pooled, there was no statistically significant difference in the yield of both tests (incremental yield of OCT = 1% [95% CI: -1% to 2%]). A proportion of patients were positive on OCT and negative on FFA (median = 9%, range = 0% to 21%), similarly, a proportion was negative on OCT and positive on FFA (median = 4%, range = 0% to 26%). No studies were identified which reported health outcomes of patients with discordant test results. The accuracy of these results is unknown.

Conclusion: The introduction of new gold standard tests may alter the spectrum of disease. OCT appears to diagnose macular oedema in some patients who would not have had this diagnosis with FFA, and exclude macular oedema in patients who would previously have been diagnosed with the condition. Prognostic studies of patients with discordant test results could provide evidence for whether extra cases detected by OCT represent 'true' cases of disease, and whether disease is truly absent in excluded cases. In the absence of conclusions regarding accuracy, public funding for OCT was not supported.

P30 – HTA IN IMAGING

P30.1

64-Slice CT Efficacy and Safety: A Systematic Review

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Objective: To assess efficacy and safety of 64-slice CT in comparison with other diagnostic techniques and to identify new indications.

Methods: A systematic review of the literature was performed. Comprehensive search strategy included the Cochrane Database, HTA, DARE and Cinahl, Medline, Embase, Pascal Biomed databases. The quality of included studies was assessed.

Results: Most of the publications assessed the 64-slice CT versus coronary angiography (CA) to detect coronary artery disease (CAD). The 64-slice CT was associated with good diagnostic performance in patients with intermediate pre-test probability of CAD. CA may be avoided if coronary artery lesions are not detected with 64-slice CT. The diagnostic value is limited to patients with slow or irregular heart rhythms and when there are important calcium deposits in narrow arteries. There are not studies in asymptomatic patients. Other indications of 64-slice CT are the evaluation of coronary artery stents, bypass restenosis or quantification of coronary atherosclerotic plaques. In the analysis of intracranial aneurysms in patients with nontraumatic subarachnoid haemorrhage the diagnostic performance of 64-slice CT differs widely between aneurysms of 3 mm and 4 mm. In studies of safety, some techniques as prospective electrocardiogram (ECG)-gating or retrospective ECG-gating tube modulation have been assessed for the reduction of radiation burden related to the 64-slice CT use. Standardised guidelines for patient shielding to reduce patient radiation dose are recommended.

Conclusion: The main assessed use of the 64-slice CT is the CAD detection. The 64-slice CT is a technique with a good diagnostic performance to identify patients without severe CAD in population with intermediate pre-test probability of CAD. Other indications are the detection of intracranial aneurysms, coronary artery stents, bypass restenosis or atherosclerotic plaques. It is necessary to assess the diagnostic accuracy in new indications. The implementation of new techniques for reduction of radiation dose is recommended in the clinical setting.

P30.2

Utility of Routine Pre-operative Chest X-Rays in Asymptomatic Surgical Patients

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Objective: To review the available evidence on the value of

routine preoperative chest X-rays in healthy or asymptomatic patients in elective surgery.

Methods: A systematic review of the scientific evidence available was conducted up to October 2008. Clinical guidelines and systematic reviews on the indication of pre-surgical chest x-ray in asymptomatic children and adults were selected. Internal validity and degree of recommendation of the studies were assessed by 2 reviewers using the Appraisal of Guidelines for Research and Evaluations (AGREE) and the Scottish Intercollegiate Guidelines Network (SIGN) criteria. A qualitative synthesis was made.

Results: Three clinical guidelines out of 291 papers were selected. Even though 1 of the guidelines was appraised as 'highly recommendable' (NICE guidelines 2003), it was based on recommendations from the experts' opinion and consensus. All available evidence reports the results of case-series. The 3 guidelines recommended the systematic use of chest x-ray in children and adults (no age limit) undergoing scheduled low complexity surgery. For patients aged 60 years or over, there is some uncertainty on its indication in the case of scheduled major surgery and neurosurgery. Chest x-ray is only indicated when the physical status appraisal prior to the surgery requires it, and in the case of heart surgery at all ages.

Conclusion: The available scientific knowledge regarding the indication of pre-surgical chest x-rays in asymptomatic patients is limited. It is based on experts' opinion and consensus driven recommendations. Thus, it is indicated only when the physical status appraisal prior to the surgery requires it, and in the case of heart surgery at all ages (Grade D recommendation). It is suggested to develop the appropriate indicators to monitor the impact of these recommendations.

P31 – HTA IN CANCER

P31.1

Endobronchial Ultrasound (EBUS)

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Introduction: A good assessment of the wall structure and nearby abnormalities can be important for staging and therapeutic decision-making, especially in the case of malignant airway disorders.

Aim: To determine the effectiveness, safety and cost-effectiveness of using EBUS in the management of lung tumour and other lung diseases.

Technical features: BF-UC160F-OL8 and BF-UC260F-OL8 Ultrasonic Bronchofibervideoscope which is specifically designed for ultrasound-guided TBNA procedures are able to provide clear visualisation of a dedicated echogenic aspiration needle under ultrasound imaging, confirming the position of the needle tip during TBNA procedures. EBUS can reduce the need for more invasive procedures such as thoracoscopy or mediastinoscopy.

Methods: Databases such as Pubmed, OVID Fulltext, ProQuest, Cochrane databases, Food and Drug Administration (FDA) and HTA databases from 1999 to 2007 were searched. There was no limitation to language. Additional articles were identified from reviewing the bibliographies of retrieved articles. A systematic review of all relevant literature was done and evidence graded according to the levels of evidence using Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001).

Conclusion and Results: There was good evidence in the favour of EBUS:

- Safe and effective for diagnosis and staging of lung tumour
- Diagnosis obtained by EBUS-TBNA and EBUS guided TBB averted the need for more surgery.
- The combined approach of EBUS-TBNA and EUS-FNA may replace more invasive methods in evaluating lung cancer patients.
- EBUS improves the safety of therapeutic procedures and can assist in decision-making.

There was no retrievable evidence on the cost-effectiveness of EBUS.

Recommendation: It is recommended that EBUS be used for diagnosis and staging of lung cancer. It can also be used for interventional bronchoscopy. EBUS should be made available in Regional Respiratory Centres in Malaysia.

P31.2

Follow-up in Gynaecological Cancer Patients – A Health Technology Assessment

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Background: After treatment for cancer, patients are routinely included in follow-up programmes to evaluate late complications and to improve survival by diagnosing early recurrent disease. However, the value of these follow-up programmes is based on clinical tradition rather than on evidence. Gynaecological cancers were selected for a first assessment.

Aim: This health technology assessment addresses the value of follow-up for patients after treatment for ovarian or endometrial cancer and seeks to improve follow-up for cancer patients in the Danish healthcare system.

Method: A systematic review of clinical studies, patient surveys and interviews, organisational analyses and cost estimations by a multidisciplinary group of clinicians and researchers.

Results: The diagnostic procedures carried out at follow-up visits do not seem to have an effect on outcome, although good quality prospective comparative studies are missing. It cannot

be ruled out if high-risk patients will benefit from clinical follow-up. Patients have heterogeneous views on and experiences with follow-up, some are comforted by being in a follow-up programme, others are distressed and would rather neglect it. At present, follow-up is organised differently across hospitals in Denmark, raising further concern for patients. Since use of diagnostic procedures and human resources varies, costs of follow-up are hospital-dependent.

Conclusion: Current follow-up for the cancer patients studied is not based on evidence, which gives reason to rethink clinical practice. Follow-up for cancer patients could be more individualised and have a stronger focus on psycho-social support. The findings within gynaecological cancers advocate for assessing follow-up within other cancers.

P31.3

Cost-effectiveness of Bevacizumab Plus Paclitaxel versus Paclitaxel Alone as First Line Treatment for Metastatic Breast Cancer in Norway

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Objective: The monoclonal antibody bevacizumab (Avastin®) offers an alternative first-line treatment for metastatic breast cancer to traditional treatments such as taxanes. However, the randomised controlled trial by Miller et al. (2007) comparing bevacizumab plus paclitaxel with paclitaxel alone suggests that the difference in terms of median overall survival is negligible (1.5 months), whereas the combination treatment resulted in an increase in median progression-free survival of 5.9 months. We have estimated the cost per progression-free life year gained as a consequence of using bevacizumab combined with paclitaxel instead of paclitaxel alone.

Methods: We developed a Markov-model based on the overall and progression-free survival curves reported in the literature. All patients were initially assigned to the disease state 'progression-free' and then, in 1-month cycles, gradually transferred to the states 'progression' and 'death' based on transition probabilities estimated using the survival curves during 5-year follow-up. The included costs were related to pharmaceuticals, pharmacy preparation and nurse time associated with infusion at a hospital outpatient department. The incremental costs associated with adverse events were deemed to be negligible. Costs of other hospital services were considered to be similar in both treatment groups. Costs were calculated from the perspective of the health services and also society as a whole, with the latter involving the deduction of tax and social security expenses.

Results: The cost per median progression-free life year gained was NOK 1.6 million (US$220,000) from the health service perspective and NOK 1.2 million (US$173,000) from the societal perspective. The sensitivity analysis revealed that the price of bevacizumab was by far the most influential variable affecting the results.

Conclusion: The analysis indicates that adding bevacizumab to paclitaxel prolongs progression-free survival but the costs for this gain are higher than suggested pragmatic thresholds for assessment of cost-effectiveness in the healthcare sector.

P31.4

Health-Related Quality of Life in Patients Undergoing Treatment for Breast Cancer

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Background: In oncology, in addition to life length, also the quality of life is of importance when drawing conclusions about treatment success.

Objective: To compare the health-related quality of life (HRQoL) of patients treated for breast cancer with that of the general population, and to study whether HRQoL is associated with certain patient or treatment characteristics.

Methods: One hundred and eighty-nine breast cancer patients (mean age 52.1 years) undergoing treatment in the Helsinki University Hospital were asked to fill in several questionnaires concerning disease symptoms and HRQoL. Clinical data were available from patient records. HRQoL of the patients was compared with that of an age- and gender-matched sample drawn from the Health 2000 general health survey performed in Finland in the year 2000.

Results: The mean ± SD15D HRQoL score of the patients (0.896 ± 0.077) was only slightly, although statistically significantly (P <0.001), worse than that of the general population (0.917 ± 0.079). The most striking differences (P <0.001) between the patients and the general population were seen in the dimensions sleep and sexual activity. In addition, the patients were statistically significantly worse off on the dimensions elimination, usual activities, depression, distress, and vitality. Self-reported presence (n = 130) or absence (n = 35) of menopausal symptoms during the preceding 7 days did not affect HRQoL in a significant manner. HRQoL of patients receiving endocrine therapy or trastuzumab treatment did not differ from those not receiving either of the therapies. Those receiving chemotherapy (n = 171) had a lower HRQoL score than those not (n = 10) (0.893 vs. 0.936) but the difference was not statistically significant. Breast surgery technique, mastectomy or breast-conserving surgery, did not affect HRQoL.

Discussion: Compared with the general population, patients with breast cancer have only a slightly impaired HRQoL.

P31.5

Can Automated Breast Ultrasound Replace Hand-Held Ultrasound as an Adjunct to Mammography? A Mini-HTA

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Introduction: Ultrasonongraphy as an adjunct to mammography in the screening of breast cancers has been established to be more sensitive in women with radiographically dense breasts. However, manual ultrasound is known to be operator-dependent, requiring skilful probe manipulation and lacking reproducibility. Hence efforts have been made to automate ultrasonography and reduce operator reliance. One current modality of automated breast ultrasonography (ABUS) involves an automated transducer arm placed firmly on the supine patient's breast automatically performing a sweeping breast scan with the acquisition process allowing the technologist to select the individual diagnostic planes to be captured.

Objective: Evaluate the evidence for the use of ABUS to replace hand-held (manual) breast ultrasonography (HHUS).

Population - Women presenting for breast ultrasonography screening

Intervention – ABUS

Comparison – HHUS

Outcomes – Accuracy, sensitivity of detection, patient satisfaction

Methodology: A systematic search was conducted through PubMed, Medline, Embase and bibliographies of published articles. Search Terms: [Automated] or [Automatic] and [Breast] and [Ultrasonography] or [Ultrasound]

Results: Six articles were identified. Only 1 study involved a control group. Different models and specifications of ABUS machines were evaluated in the 6 studies impacting comparability. Two articles, based on the same study population, reported that images made with ABUS and HHUS produced images with similar visibility and BIRADS assessments. In the other papers, ABUS was not compared with HHUS but was reported to be a useful adjunct to mammography. One limitation of ABUS was difficulty in achieving complete coverage of the breast. Patient satisfaction with ABUS was extremely high with 83% rating it to be similar or more acceptable than HHUS.

Conclusion: There is lack of high-quality, published, comparative trials between ABUS and HHUS. Current evidence suggests that newer versions of ABUS can give similar image quality as HHUS and complements mammography but ABUS presently cannot replace HHUS.

P31.6

Health Technology Assessment: The Anti-HPV Vaccines

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Introduction: Health Technology Assessment (HTA) is spreading as an important tool for stakeholders in decision-making. The aim of our study is to produce HTA reports on anti-HPV vaccines.

Material and Methods: HTA reports were realised using a multidisciplinary method (epidemiologic, meta-analytic, mathematical, economical, social and ethical approach). The studies were conducted on HPV Vaccines Cervarix (Genotype 16, 18, GSK) and Gardasil (Genotype 6, 11, 16, 18, MERK-Sanofi). Two external Advisory Boards were consulted for preliminary reports and the comments that arose were implemented in final reports. HTA report for Cervarix was published in 2007, report on Gardasil is under review.

Results: From an epidemiological viewpoint, for both vaccines, prevalence rate of HPV genital infection in Italy is of about 20% (95% CI: 10 to 30%) with an incidence rate for cervical cancer of 9.8/100.000 and a mortality rate of 3/100.000 for year. Considering the ano-genital warts, prevalence rate in 2005 was of 6/1000 with an incidence rate of 4.3/1000. In Italy, every year, about 6 million of PAP tests are executed for about €150 million. The 69% of female population (25 to 64 years) was screened in the 2006 (+2.3% respect 2005). Differences were present in north and south Italy.

Meta-analysis showed, for the Cervarix, an efficacy of 87% (95% CI: 80% to 91%) for Genotype 16 and of 78% (95% CI: 62% to 87%) for Genotype 18 into prevention of persistent infections. Referring to Gardasil, the meta-analysis showed an efficacy into prevention of uterine cervical carcinoma in-situ (grade II and III) and of adenocarcinoma in-situ of 98% (95% CI: 93% to 99%) and for anogenital injuries of 95% (95% CI: 86% to 98%).

Both vaccines seem to be cost-effective: incremental cost/QALY vaccination of 12 years old cohort with Cervarix was €26,361.34. Economic evaluation of Gardasil is preliminary.

Conclusion: Evaluation of anti-HPV vaccines using an HTA approach represents an innovative instrument for Italian decision-makers at a central and regional level.

P31.7

Discussion about Incorporation of HPV Vaccine in Brazil

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The Brazilian National Agency of Sanitary Surveillance licensed quadrivalent HPV vaccine (to women from 9 to 26 years old) in August/2006 and the bivalent HPV vaccine (to women from 10 to 25 years old) in February/2008. After the license of quadrivalent HPV vaccine, a Work Group (WG) was created to support the Health Minister on discussion about incorporation of HPV vaccine in Brazilian Unified Health System (SUS). The WG's participants were from National Cancer Institute, Women's Health Program, Department of Science and Technology, Immunisation National Program, STD/AIDS National Program, Oswaldo Cruz Foundation and researchers from this area. The scientific evidence about efficacy and safety of HPV vaccine was analysed by WG, which has recommended the non-incorporation of HPV vaccine as a public health policy nowadays. The reason of this decision was the lack of knowledge about the HPV vaccine's cost-effectiveness on SUS' perspective and the need on making women aware about the importance of screening for cervical cancer and taking other STD prophylactic proceedings, even among the vaccinated ones. Moreover, there is not enough knowledge about specific issues as the duration of immunity, the public health impact of immunisation, the need of booster, the possibility of imbalance between another HPV types' prevalence and the risk in specific groups, like pregnant women and immunodepressive patients. The WG recommends strengthening actions concerning the control and screening of cervical cancer, structuring epidemiologic surveillance laboratories in SUS to monitoring HPV infection, elaboration of epidemiologic studies about HPV types distribution in Brazil and economic analysis studies, national vaccine manufacturing by internal development and/or by technology transfer process assuring autonomy and sustainability of HPV vaccination. The maintenance of discussion about the theme must be done to support future decision-making about incorporation of HPV vaccine in SUS.

P31.8

Intraoperative Radiation Therapy

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Objective: A rapid technology assessment was conducted on the efficacy of intraoperative radiation therapy (IORT) in the treatment of colorectal cancer.

Methods: A literature search was conducted for published systematic reviews and health technology assessments in the NHS CRD databases (DARE, NHS EED, HTA), the Cochrane Library on CD-ROM, EMBASE, PubMed (MEDLINE). In addition, guidelines were retrieved from the US National Guidelines Clearinghouse database, National Library for Health, the Australian National Health and Medical Research Council, and on Google. Search terms used were ['intraoperative radiation therapy' OR IORT] AND ['Rectal Neoplasms' OR 'Colorectal Neoplasms' OR 'colorectal cancer' OR 'rectal cancer'].

Results: No systematic reviews or clinical practical guidelines were found on the use of IORT in colorectal cancer. One randomised controlled trial was found. Retrospective studies found that assessing the use of IORT in the treatment of colorectal cancer showed varying results. Single (IORT with surgical resection) or combined modality therapy (IORT with surgical resection with external irradiation or chemotherapy) generally seemed to provide a therapeutic advantage in patients with locally advanced primary tumours or recurrent rectal tumours. These studies suggested that combined modality therapy was well-tolerated and improved local tumour control and survival rate. Poor local control was noted with low-dose IORT alone. Complications due to IORT included ureteral narrowing with hydronephrosis and peripheral neuropathy.

Conclusion: One randomised controlled trial and a number of observational studies and retrospective studies assessing the role of IORT in the treatment of colorectal cancer were found. Retrospective studies generally suggested that IORT is beneficial. Larger randomised controlled trials would help to better evaluate the effectiveness of this treatment modality.

P31.9

Electrochemotherapy as a New Technology for the Treatment of Tumours

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Background: Electrochemotherapy (ECT) is a new technology that combines non-permeable or poorly-permeable drug chemotherapy (bleomycin or cisplatin) with the application of electrical pulses (electroporation) to increase drug uptake.

Aim: To study the effectiveness, safety, and cost-effectiveness of ECT in tumour treatment.

Methodology: Rapid HTA. ECT was identified by the early-warning system "SINTESIS-new technologies" of AETS. The searched databases were PubMed, EMBASE, CRD, and the Cochrane Library. Clinical studies published in any language until November 2008 were reviewed.

Results: Retrieved studies were case series, including a European multicentre project on skin tumour nodules, which standardised ECT protocol (the ESOPE project). RCTs or comparative studies were not found. ECT was used for treatment of metastasised and primary-site cutaneous and subcutaneous nodules, as well as to treat tumours in other regions such as the head and neck or breast. Different modalities of electrical pulses were used. A total of 1,340 nodules of various aetiologies

in 302 patients were treated. Treatment success, defined as clinical disappearance or decrease in tumour size of 50% for at least 4 weeks, ranged from 46% to 100% of treated nodules. The success rate in the ESOPE study was 85%. ECT effectiveness was similar for bleomycin and cisplatin when delivered by intra-tumour injection. However, bleomycin was more effective than cisplatin when delivered by intravenous injection. Only 1 (non-independent) economic study showed ECT as a cost-effective technology. Minor side effects were reported, the most common was muscle contractions associated with the application of electrical pulses.

Conclusion: ECT appears to be an effective and safe technology for the treatment of cutaneous and subcutaneous tumour nodules, mainly with palliative intention. However, further studies are necessary to better determine this technology's effectiveness. More economic studies would be advisable. Electrical stimulation modalities should continue to be investigated.

P31.10

Do New Treatments for Metastatic Renal Cell Carcinoma Provide any Clinical Benefit?

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Objective: Renal cell carcinoma (RCC) accounts for 90% to 95% of neoplasms arising from the kidney. Immunotherapy (either interferon alpha [IFNa] or interleukin 2) is the standard medical treatment for advanced or metastatic disease but its efficacy is limited and its toxicity is high. The development of new drugs is thus warranted. The HAS Transparency Committee received applications for the assessment of 2 kinase inhibitors (sorafenib, sunitinib), 1 inhibitor of mTOR (temsirolimus) and 1 monoclonal antibody against vascular endothelial growth factor (bevacizumab). The aim was to give an opinion on the benefits provided by these new drugs in view of their reimbursement by French national health insurance (NHI).

Methods: In-house analysis and external review (by oncologists) of the data (dossiers filed by the drug firms and literature search).

Results:

(i) *Efficacy in patients with a good or intermediate prognosis*: With regard to disease-free survival, sunitinib was superior to IFNa as first-line treatment and sorafenib was superior to placebo as second-line treatment after failure of immunotherapy. No difference in overall survival was observed in the comparison of bevacizumab + IFNa versus IFNa alone.

(ii) *Efficacy in patients with a poor prognosis*: Temsirolimus was superior to IFNa in terms of overall survival.

(iii) *Safety*: The most frequent adverse events were gastrointestinal (GI) events and skin reactions on treatment with kinase inhibitors, and proteinuria, bleeding and GI perforations on bevacizumab treatment.

Conclusion: These drugs provide new options for the first- or second line-treatment of advanced or metastatic RCC. All of them are reimbursed by French NHI. The clinical added value provided by the kinase inhibitors and the inhibitor of mTOR is considerable compared to current treatments but minor for the combination bevacizumab + IFNa. Because of the lack of direct comparisons between the drugs, it is impossible to rank them, especially for first-line therapy.

P31.11

What Should We Use as Evidence of Harms to Determine Recommendations? Comparison of Evidence of Harms for the Prostate Cancer Screening Guideline

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Background: To determine the recommendations in clinical guidelines, the balance of benefits and harms should be considered. Since there are several types of harms, including adverse effects and psychological effects, the extent of harms that should be considered when determining the recommendations for cancer screening programs is unclear. We compared types of harms that were regarded as evidence in the prostate cancer screening guidelines.

Methods: Using MEDLINE and other databases, guidelines and evidence reports for prostate cancer screening were identified. Based on the selected guidelines and evidence reports, we selected the evidence of harms and divided them into the following categories: false-negative and false-positive rates (sensitivity and specificity), overdiagnosis, adverse effects of needle biopsy, adverse effects of treatment and others.

Results: Using MEDLINE and other databases, 149 guidelines and evidence reports were identified. We excluded 135 guidelines and evidence reports due to the following reasons: other topics, older version, duplication, and others. As a result, 12 guidelines were selected, and 4 guidelines were added by other approaches. Adverse effects of treatment were limited to localised cancer that could be diagnosed mainly by cancer screening. Basic information differed between the guidelines. Information relating to overdiagnosis was lacking in the guidelines published in 1990s. Although overdiagnosis was considered as an important harm for prostate cancer screening, the basic concept differed between urologists and others.

Discussion: Cancer screening has a potential for harm, the most important aspects of which are over-diagnosis and overtreatment. Although the basic concepts of harms for prostate cancer screening were similar for the false-negative and false-positive rates and the adverse effects of treatment, the definition of overdiagnosis differed. When considering the balance of benefits and harms, we must reconsider the clarification of the extent of harms, including the definition of overdiagnosis.

P31.12

Trends in B-Cell Non-Hodgkin's Lymphoma Treatment and Associated Outcomes in Thailand: A Retrospective Analysis

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Objective: The addition of rituximab (R) to chemotherapy has shown dramatic improvement in outcomes in patients with B-cell Non-Hodgkin's Lymphoma (B-cell NHL) in several randomised clinical trials. The utilisation rate and effectiveness of this combination therapy in the real-world setting had not yet been explored in the Thai population. This study was the first to assess this knowledge gap.

Methods: Medical records of patients who were newly diagnosed with B-cell NHL during 2003 to 2006 were retrospectively reviewed. All cases that were treated with regimens locally adopted at that time were included.

Results: One hundred and twenty-four patients were identified (26 in 2003, 23 in 2004, 37 in 2005, 38 in 2006). The majority of patients (72%) received chemotherapy alone in which 88% received CHOP (cyclophosphamide, doxorubicin, vincristine and prednisolone)-like regimen. A total of 28% received a combination of R-chemotherapy in which 89% received R-CHOP-like regimen. During the study period, the use of chemotherapy had decreased (92% in 2003 and 76% in 2006) while the use of R-chemotherapy had increased (8% in 2003 and 24% in 2006). After a median follow-up of 36 months, the median overall survival (OS) and the median event-free survival (EFS) in the chemotherapy group were 53 and 11 months, respectively, while both median OS and median EFS in the R-chemotherapy group have not yet been reached. In multivariate analysis, the use of R-chemotherapy remained the significant predictor of EFS (Hazard Ratio = 0.485, $P = 0.04$).

Conclusion: Even though rituximab, which has been proved to increase patient outcomes in several randomised clinical trials, was introduced during this period, the majority of patients was still treated with chemotherapy alone. Our study showed the improvement in outcomes when using R-chemotherapy. Future research is needed to see the overall outcomes when this combination therapy is fully adopted.

P31.13

People's Attitudes and Perceptions Relating to Agents for the Chemoprevention of Colorectal Cancer

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Objective: Research has assessed the effectiveness of a range of agents in the potential chemoprevention of colorectal cancer: anti-inflammatory agents (NSAIDs, aspirin), micronutrients (vitamins, selenium, calcium) and dietary supplements generally. The aim of this study was therefore to evaluate people's views and beliefs about taking these agents and supplements so that reasons behind compliance may be understood better, and, consequently, any potential beneficial effect of these agents in chemoprevention could be realised.

Method: A systematic review of UK studies from the last 5 years assessing people's views about the taking of the stated agents or supplements. The following databases were searched for published and unpublished literature: MEDLINE, PreMEDLINE, CINAHL, EMBASE, AMED, ASSIA, IBSS, PsycInfo, Science Citation Index, Social Science Citation Index, HMIC, and the King's Fund database. Studies were appraised and extracted. A thematic analysis was performed. This review and synthesis is currently being extended to non-UK studies and a completely novel sensitivity analysis of qualitative data is to be performed.

Results: The search retrieved 1,806 unique citations, of which 7 were relevant. The analysis identified 5 principal themes describing attitudes towards the taking of the included agents or supplements: perceptions of effectiveness, perceptions of risk, perceptions of necessity, the influence of others, and the attractiveness of supplements in terms of taste, flavour and texture.

Discussion: Various agents have been identified as having a potential effect in the chemoprevention of colorectal cancer. People's perceptions of the balance between risk and benefit, the influence of other individuals, and the attractiveness or otherwise of the agents, all determine levels of compliance and people's willingness to take these agents or supplements as required. Addressing people's perceptions of effectiveness and necessity may enhance compliance and therefore support the chemoprevention of colorectal cancer using these agents.

P31.14

Calcium with and without Vitamin D or Antioxidants in the Chemoprevention of Colorectal Cancer: A Systematic Review

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[1]University of Sheffield, UK

Objective: Calcium has been proposed as a possible agent in

the chemoprevention of colorectal cancer, and has been the subject of a number of recent trials. The aim of this review therefore was to assess the effectiveness of this agent in reducing colorectal cancer or the recurrence of adenomatous polyps (precursors of colorectal cancer) among both at-risk and other populations.

Method: A systematic review of randomised controlled trials comparing calcium alone, and with other agents, with placebo. The following databases were searched for published and unpublished literature: Cochrane Library, MEDLINE, PreMEDLINE, CINAHL, EMBASE, Web of Science, Biological Abstracts and Research Registers. Studies were appraised and extracted. Meta-analysis was performed.

Results: The search retrieved 3,791 unique citations, of which 5 studies (17 papers) were relevant. Two good quality trials comparing calcium with placebo among populations with a history of adenomas found that calcium significantly reduced recurrence of adenomas (RR: 0.82, 95% CI: 0.68 to 0.98, P = 0.03). A third, lower quality, smaller trial evaluating a calcium and antioxidant combination in older people (50 to 76 years) with a history of adenomas also found that the number of patients free of recurrent adenomas was significantly lower in intervention group, but event data were not reported, preventing inclusion in the meta-analysis. A meta-analysis of 4 studies of calcium alone, or with vitamin D, found no effect on incidence of colorectal cancer (RR: 1.04, 95% CI: 0.84 to 1.28, P = 0.74) in either postmenopausal women or populations with a history of adenomas, but the number of events was small.

Conclusion: Calcium with and without antioxidants appears to have some effect in reducing the recurrence of colorectal adenomas in people with a history of such polyps. However, when used alone or in combination with vitamin D, calcium has not been shown to be effective in preventing colorectal cancer in either at-risk or older, female populations.

P32 – HTA IN MENTAL HEALTH

P32.1

Evaluating the Clinical Effectiveness of Group Cognitive Behaviour Therapy for Postnatal Depression

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Introduction: Group cognitive behaviour therapy (CBT) is a potentially effective treatment for postnatal depression (PND).

Methodology: A systematic review was undertaken comparing group CBT with currently used treatments. Three studies contained data suitable for meta-analysis: all 3 contained data on change in depression at treatment cessation, 2 contained data on change in depression at a 6-month follow-up. These studies used either the Beck Depression Inventory or the Edinburgh Postnatal Depression Scale. Six further studies with information on acceptability and adverse events were identified for a qualitative review.

Results: Meta-analysis showed that depression scores were significantly reduced in women receiving group CBT compared with routine primary care at the end of the treatment period (z = 5.93, P <0.001). The estimated standardised mean difference was 0.71 (95% CI: 0.48 to 0.95). This effect remained significant during follow up (z = 3.22, P <0.001) with an estimated standardised mean difference of 0.39 (95% CI: 0.15 to 0.63). Data did not allow a meaningful comparison of group CBT with individual CBT, however, the limited data did not show that group CBT was inferior to individual CBT. Group CBT appeared to be acceptable to the majority of participants, however, adverse effects, such as fear of group failure and unfavourable social comparisons were reported. As these findings were based on women who had volunteered for group treatment, it is likely that the treatment effects are more favourable and the adverse events lower than those typically observed in a general PND population.

Conclusion: CBT appears more clinically effective than routine primary care for consenting women and may be as effective as individual CBT. Qualitative analyses identifying adverse effects revealed that group CBT, although deemed acceptable to the majority of those who volunteered to take part, may not be suitable for all women with PND.

P32.2

Dietary Supplements Therapy in Autistic Disorder: A Systematic Review

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Objective: In this systematic review the efficacy and safety of dietary supplements therapy in autism disorder were assessed.

Methods: A systematic review was performed. We searched studies within the databases HTA Database, Cochrane Database of Systematic Reviews, DARE. Medline, Embase, Cinahl, Pascal biomed, and CENTRAL. Studies assessing these supplements in autistic patients were included: magnesium, taurine, vitamins, zinc, calcium, iron, cod liver oil, fatty acids, melatonin, creatine, dimethylglicine, trimethylglycine, amino acids, secretin, glutathione, carnosine, silymarin, probiotics, folic acid or oxytocin. We analysed the quality of the studies and a narrative synthesis was performed.

Results: We found 1 systematic review including 14 RCT about secretin in autism. It concluded that trials had not demonstrated any inprovement in the main autism characteristics. Another systematic review assessing the administration of vitamine B and magnesium in autism, including 2 RCT, did not find significant differences between treatment and placebo. We also included 19 trials assessing the efficacy of the suplementation with iron, ascorbic acid,

dimetilglicine, inositol, tetrahidrobiopterine, L-carnosine, tiamine, folic acid, omega 3 acid, oxitocine and melatonine. Nine studies were randomised clinical trials, the other were case series. All of them had very small sample sizes and most of them had a high risk of bias. The studies did not find an autistic behaviour improvement after iron supplementation, dimetilglicine, inositol, tetrahidrobiopterine or omega 3 acid. Some studies found an improvement in the results after suplementation with ascorbic acid, L-carnosine, tiamine, folic acid, oxytocin or melatonin, but these studies presented multiple and important methodologic deficiencies such as absence of statistical analysis, absence of control group, very small sample size or a biased method of assessment.

Conclusion: There is no evidence supporting the efficacy of dietary supplements in autism disorder. These kinds of therapies should be assessed within rigorous randomised clinical trials with greater sample size.

P32.3

Music Therapy May Benefit Autistic Children, but Larger Controlled Trials Needed

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Objective: To review existing literature on the benefits of music therapy for children with autistic spectrum disorder (ASD) presenting with significant limitations in verbal and non-verbal communication. Music therapy encourages clients to use instruments and their own voices to explore the world of sound and create a musical language of their own. By responding musically, the therapist supports and encourages this process. Music therapy interventions involve both active, improvisational methods, and receptive approaches.

Population – Children with ASD

Intervention – Music therapy

Comparator – "Placebo" activity - Therapeutic attention without the use of music

Outcomes – Communication, behaviour

Methodology: Ovid Medline, Pubmed and Google Scholar databases were searched using 'music' and 'autism' or 'autistic' as keywords. The reference lists of the articles were also checked. Included in the review are 1 meta-analysis (2004), 1 systematic review (2006), 1 HTA (2004), 1 review article (2005) and 4 primary studies [2 randomised controlled trials (RCTs), 1 counterbalanced controlled trial and 1 case series].

Results: The literature generally suggests that music therapy improves communication and behaviour of autistic children with the meta-analysis concluding that music therapy is effective. However, 9 out of 11 studies reviewed in the meta-analysis were unpublished data and the pooling of the results might not have been appropriate as there was considerable variation in studies included. The systematic review and HTA do not lead to similar conclusions, although 2 of 3 studies used in each analysis were the same. While the intervention effect was statistically significant for studies included in the systematic review and the HTA, the number of subjects involved was small, ranging from 4 to 11 per study.

Conclusion: Music therapy potentially has benefits on communication and to a lesser extent behaviour of children with ASD, but research results were inconclusive. Larger RCTs are needed to demonstrate positive effects of music therapy.

P33 – HTA IN IMMUNE SYSTEM DISORDERS

P33.1

Use of Rapid HTA Results for the Decision-making About High-cost Biological Agents for Psoriasis

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Psoriasis is an inflammatory, chronic, non-contagious and recurrent disease of skin affecting around 2% of general population. Currently, the systemic therapies available in the Brazilian Unified Health System (SUS) for the treatment of severe psoriasis are acytretin and cyclosporin. However there is some pressure for incorporation of the high-cost biological agents in SUS. To support decisions about new technologies incorporation in SUS, the Commission for Incorporation of Technologies of the Ministry of Health (CITEC) evaluates the relevancy of incorporation at the policy context of Brazilian public health and evaluates the available scientific evidence, which is summarised by Decit. Decit worked in 3 rapid HTA about severe psoriasis' treatment. These rapid HTA will be presented to CITEC to support the decision about incorporation of the biological agents available in the Brazilian market for psoriasis treatment: infliximab, etanercept and efalizumab. The same systematic review was selected in the 3 rapid HTA, comparing, in meta-analysis performed independently, each

one of the biological agents with placebo. The 3 biological agents are more efficacious than placebo in improving symptoms of patients with moderate to severe plaque psoriasis, measured by PASI 75 (RR = 17.40, 11.73 e 7.34, respectively). However, there are no evidences proving efficacy and security of these drugs for longer periods of treatment, neither head-to-head trials. Longer-term data from head-to-head trials comparing biological agents with each other and with traditional agents available in SUS are needed. Furthermore, the utility of the score PASI used in trials of psoriasis in clinical practice must be established. Thereby, taken together with cost-effectiveness and budged impact analysis, the evidence come from rapid HTA could rationally support the decision for incorporation of biological agents in Brazilian public health.

P33.2

The Association of Thiopurine S-Methyltransferase Polymorphisms and Leukopaenia in Patients Receiving Azathioprine: A Meta-analysis

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Background: Azathioprine has a narrow therapeutic index and is associated with the development of serious haematotoxicity such as leukopaenia and thrombocytopaenia. Some evidence suggests that the incidence of leukopaenia among patients with mutant Thiopurine S-methyltransferase (TPMT) gene is higher than those with wild-type TPMT. As the conclusion regarding this association remains unclear, this study is undertaken to determine the association of TPMT polymorphisms and leukopaenia among patients receiving azathioprine.

Methods: Multiple computerised databases such as PUBMED, EMBASE, Cochrane CENTRAL, CINAHL, AMED, Psych Info, and International Pharmaceutical Abstract were searched. To be included in this meta-analysis, studies needed to determine the association of TPMT and leukopaenia among patients receiving azathioprine. All articles were reviewed independently by 2 investigators for study design, population, outcomes and quality of evidence. The overall risk ratio (RR) and 95% confidence interval were calculated for mutant TPMT gene compared to wild-type TPMT gene for leukopaenia outcome. All analyses were performed using the DerSimonian and Laird method under a random-effects model. The Q-statistics and I-squared for test of heterogeneity were also performed. Publication bias was assessed using Begg's test, Egger's test and funnel plot.

Results: Eleven cohort studies including 981 patients were pooled for analyses. The summary risk ratios of mutant TPMT gene for leukopaenia among studies involving transplant patients and patients with neurological or rheumatologic disorders were 3.09 (95% CI: 2.10 to 4.56) and 6.86 (95% CI: 3.08 to 15.26), respectively. There was no heterogeneity or publication bias within these 2 groups, however, a significant heterogeneity is found among studies involving inflammatory bowel disease (IBD) population. The risk ratio was 4.39 (95% CI: 0.86 to 22.35) with I-squared value of 64.6%.

Conclusion: These results suggest that leukopaenia is significantly increased in azathioprine users with mutant TPMT gene. Understanding patient's TPMT polymorphisms may aid clinicians in optimising therapeutic use of azathioprine.

P33.3

The Effectiveness of Intravascular Immunoglobulin on Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis: A Systematic Review and Meta-analysis

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Background: Intravenous immunoglobulin (IVIG) has been used in Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN). However, evidence of effectiveness of IVIG on SJS and TEN remains unclear. This study aims to systematically review the effects of IVIG on treatment of patients with SJS or TEN.

Method: We performed a systematic search using computerised databases including PUBMED, EMBASE, Cochrane CENTRAL, CINAHL, Psych Info, IPA databases, www.clinicaltrial.gov and WHO clinical trial registry. To be included in this systematic review, studies needed to compare the effect of IVIG and control on mortality rate. All articles were reviewed independently by 2 investigators. The relative risk of death and the weight mean difference of length of stay with 95% confidence interval were calculated comparing the outcomes in IVIG and control groups. The meta-analysis was performed using the DerSimonian and Laird method under a random-effects model.

Results: Of 127 papers retrieved, 5 cohort studies were included for meta-analysis. All studies compared the effect of IVIG and supportive care on mortality rate. A cohort of 200 participants was included. Mean age varied from 45.8 to 60.0 years. The percentage of male ranged from 30% to 78%. The dosage of IVIG ranged from 0.7 to 1.9 g/kg/d with duration of 2 to 4 days. The summary relative risk of IVIG for death outcome was 0.70 (95% CI: 0.32 to 1.50). The length of stay in the IVIG group was longer than those in the supportive care group but not statistically significant different [the weighted mean difference was 3.95 days with 95% CI: -0.71 to 8.62].

Conclusion: Our findings indicate no benefit of IVIG compared with supportive care in patients with Stevens-Johnson syndrome or toxic epidermal necrolysis based on mortality rate and length of stay outcomes.

P34 – HTA IN NEUROPATHIC PAIN

P34.1

A Systematic Review and Meta-analysis of Health Utilities in Neuropathic Pain

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Background: Although the impact of neuropathic pain (NeuP) on health-related quality of life has been the subject of previous reviews, the range of health utility values associated with NeuP remains unclear.

Objective: To undertake a systematic review and meta-analysis of published literature health utility values of NeuP patients.

Methods: A detailed search of bibliographic medical databases (Medline, Embase, Cochrane Library) and specialist economic databases (NHS Centre for Reviews and Dissemination Economic Evaluation Database and Health Economics Evaluation Database) was undertaken (to September 2008). Reference lists of retrieved reports were also searched. Studies reporting utility single-index measures (preference based) in NeuP were included. Meta-analysis was used to pool utility estimate across studies. Meta-regression was used to examine association of utilities and a number of pre-defined factors (i.e. NeuP indication, patient age, sex, duration and severity of pain and method of utility scoring).

Results: Twenty-three studies reporting utility values in patients with NeuP were included, of which 11 were randomised trials that also reported the change in utility with intervention. There was evidence of substantial statistical heterogeneity across studies (P <0.0001). The pooled mean utility score across studies was 0.48 (95% CI: 0.44 to 0.53) in a random effects analysis. Although increasing severity of pain was found to be strongly associated with a reduction in utility, we found little evidence of variation in utility across other patient characteristics, NeuP indication or utility scoring method.

Conclusion: This study confirms that NeuP patients experience low utility and therefore poor quality of life. Although patient characteristics (age, gender and duration of pain) and NeuP indication may not associated with utility, future technology assessments of NeuP treatments do need to consider the relationship between pain severity and utility.

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