9th HTAi ANNUAL MEETING

"HTA in Integrated Care for a Patient Centered System"

Bilbao, 23rd-27th June 2012

PANEL SESSIONS

Monday 25th June

METHODOLOGICAL ISSUE OF HTA STUDIES IN INTEGRATED CARE

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Background: In recent years, Integrated Care (IC) as well as economic evaluation and HTA, have increasingly received attention. The number of published HTA studies in the field of IC has augmented substantially. Due to the nature of IC it stretches the current methodological framework of HTA, as we cannot use without adaption the HTA methods which are often developed for stand-alone clinical interventions. The aim of this panel session is to give an overview of the current state of affairs when looking at HTA and IC, the methodological challenges, and potential solutions for these challenges with respect to costs and effects.

Panel session

This panel session consists of 4 presentations: First, Silvia Evers presents a trend analysis of economic evaluation studies in integrated care. This presentation is based on a systematic literature review focused on economic evaluation in the field of integrated care. Second, Aggie Paulus discusses methodological challenges with regard to costing research in integrated care. She argues that using Activity Based Costing and integrated care pathways provides the best information possible for decision-making by health care managers, insurers, care suppliers and governments. Third, Janneke Grutters focuses on the methodological challenge of measuring effectiveness in integrated care. She discusses the use of quality-adjusted life years in assessing integrated care, and presents and discusses other potential solutions. Fourth, David McDaid concludes the session by reflecting on crossing the boundaries of HTA and integrated care. He briefly discusses the preceding presentations and anticipates future opportunities and challenges with respect to methods, policy and practice.

METHODOLOGICAL CHALLENGES FOR ASSESSING CO-DEPENDENT HEALTH TECHNOLOGIES

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Background: Consumers and clinicians alike have applauded recent government initiatives to address the issue of timely assessment of co-dependent technologies. These initiatives acknowledge that the management of disease requires optimal utilisation of a suite of technologies used in an integrated rather than piecemeal fashion. In February 2010, the Australian Government accepted a recommendation from its Health Technology Assessment Review relating to "ensuring timely assessment and appraisal of co-dependent technologies and coordinating the provision of advice to the Minister". To date much of the experience in assessing co-dependent technologies have involved test and drug packages, usually for "personalised" cancer medicines.

Panel session

To present experience from Australian and English perspectives To examine some early lessons and their implications, including: the disparity between the evidence base supporting drugs and medical tests, where it is unusual for tests to undergo rigorous evaluation which leaves uncertainty if a test and drug must be linked in order to deliver a substantial health outcome; the frequent use of multiple test strategies to identify a target patient group which may involve onerous, invasive or potentially harmful test strategies for patients, but which serve as the gatekeeper to the new medicine. To discuss examples of the HTA process for a number of cancer medicines and their associated tests to illustrate the methodological, practical and policy challenges of evaluating targeted therapies. To illustrate why product innovators, regulators, HTA practitioners and policymakers should consider the merits of bringing together clinical development pathways for tests and drugs

WHAT ARE THE BEST HTA PRACTICES TO ASSESS THE RELATIVE VALUE OF THERAPIES FOR RARE DISEASES?

Alicia Granados[a], Nilay Shah[b], Gerd J van der Wilt[c], Gordon Guyatt[d], Alric Rüther[e], Karen Facey[f] and Carlo Incerti[g]

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Background: Rationale: Rare diseases are what they say they are: rare. Many countries define rare diseases according to disease prevalence. In the United States, for example, rare diseases are defined as those that affect less than 200,000 persons in the United States. In Japan, the legal definition of a rare disease is one that affects fewer than 50,000 patients in Japan. In the European Union, a rare disease is defined as one affecting not more than 5 in 10 000 persons. EURORDIS, the voice of rare disease patients in Europe, estimates that there are between 6000 to 8000 rare diseases Prevalence is but one distinct

feature of rare diseases. Unlike other, more common diseases, rare diseases are most often genetic in nature. EURORDIS estimates that at least 80% of rare diseases have identified genetic origins. There are also health system challenges associated with rare disease. From the provision of care, to the financing of care, rare diseases pose unique hurdles. For example, limited awareness of rare diseases leads to delayed or missed diagnoses. In addition, developing medicines to treat rare diseases is costly. Lastly, given the small number of patients, data collection on disease prevalence and progression as well as treatment effectiveness is difficult. Objectives Session will examine the challenges of rare diseases for HTA and rare disease treatment's researchers and the potential solutions to best assess the value of orphan drugs. From the patient, the methodological, the ethics, the rare disease treatment's researcher and HTA perspective. The panel will also provide a broader discussion about whether it is possible to establish a collaborative approach to developing appropriate and fair assessment options

Objectives: Panel session will examine how to best assess the relative value of orphan drugs, highlighting the challenges of rare diseases for HTAs, rare disease researchers and the potential solutions.

ASSESSING THE VALUE OF GENOME-BASED TECHNOLOGIES IN A PERSONALIZED HEALTH CARE SYSTEM: IS THERE A NEED FOR A NEW ANALYTIC FRAMEWORK?

Karla Douw[a], Iris Paternack[b], David Veenstra[c], Patrick Bossuyt[d] and Lieven Annemans[e]

[a]University of Twente. Denmark. [b]Finnish Office for Health Technology Assessment. Finland. [c]University of Washington. USA. [d]University of Amsterdam. Netherlands. [e]University of Gent. Belgium.

Background: In the context of an EU funded project, Public Health Genomics II, existing guidelines and best practices have been explored for assessment of genome-based information and technologies to support the translation and application for the purpose of combating diseases of public health significance and to produce guidance on assessment for the Member States. Different frameworks exist, and the question is which of these are most adequate.

Panel session

The Public Health Genomics European Network (PHGEN) is a cornerstone in the development of Public Health Genomics in Europe. It is funded by the General Directorate for Health and Consumer Protection (DG SANCO) under the Health Program. In PHGEN II, existing guidelines and best practices have been explored for assessment of genome-based information and technologies to support the translation and application for the purpose of combating diseases of public health significance, in order to produce a best practice guideline for the Member States. Among these frameworks are the ACCE framework, the HTA core model for diagnostics and screening, Constructive or Early HTA, and risk-benefit analysis for genetic testing. The question is whether the available frameworks are fit for purpose to support the adequate translation of the most significant genome-based technologies into a personalized health care system, and what framework should guide assessors in practice? Another question is how to appraise the synthesized evidence? In this panel session different speakers will provide insight in whether genome-base technologies are any different from other health technologies and warrant specific guidance, and what consequences this has for the development of guidance for assessment and appraisal of these technologies.

SOCIAL VALUES INTERNATIONAL PROGRAMME: INTEGRATING RESEARCH AND POLICY TO ENSURE FAIR ALLOCATION OF HEALTH CARE RESOURCES

Peter Littlejohns[a], Kalipso Chalkidou[a], Albert Weale[b], Ruth Faden[c] and Sripen Tantivess[d]

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Background: Combining social values (content and process) to technical assessments of the value of health care interventions.

Panel session

All health care systems are facing the same challenge of ensuring that high quality services are provided to the maximum number of people at a cost that the country can afford. In most countries decisions about resource allocation are based on technical assessments of clinical effectiveness and cost. However, it is increasingly being recognized that priority setting decisions should also involve social value judgments that reflect the ethical values of any particular society. Values such as justice, equity, dignity, non-discrimination, autonomy, and solidarity figure prominently in debates about priority setting. But social values are also implied in the processes by which such decisions are reached: considerations of transparency, accountability and participation are all important. A new research and policy network has been established to undertake a cross-national exploration of the different ways in which values are constructed and incorporated into decisions about healthcare reform and resource allocation.

THE ECONOMICS OF PERSONALISED MEDICINE - WHAT ARE THE EXPECTATIONS FROM DECISION MAKING AUTHORITIES?

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Background: Personalized medicine promises to increase the quality of health care based on the molecular analysis of genes, proteins, and metabolites. From the scientific perspective personalized medicine is demonstrating its potential to ensure that new and existing medical interventions are used more safely and more effectively. Although this approach has generated much excitement, the challenges of economic assessment of personalised medicine as well as operational questions in terms of system integration now seem to be the biggest hurdle.

Panel session

From a policy perspective, HTA is used to inform decisions on the reimbursement, coverage, adoption and uptake of healthcare technologies. Formal assessment of technologies usually occurs at a national level, although HTA is being increasingly applied at regional and local levels. In challenging economic times decision

making authorities such as G-BA in Germany or NICE in UK are mandating national policy guidelines on use of personalised medicine in order to define and to quantify the impact of testing on clinical and economic outcomes. However, most guidelines, although appearing to be general, have been written with pharmaceuticals in mind. HTA in personalised medicine remains therefore challenging and there is urgent need to define the economical requirements. The panelists – representing manufacturers and providers of personalised medicine as well as representatives from two well-known national decision making authorities will discuss the economical and political requirements to promote the use of personalised medicine that is clinically and cost effective.

HOW TO OPTIMALLY ASSESS THE RELATIVE VALUE OF DISEASE MODIFYING TREATMENTS IN MULTIPLE SCLEROSIS

Jaime Caro[a], Meindert Boysen[b], Jan Hillert Hillert[c], Gary Cutter[d] and Carlo Incerti[e]

[a]United Biosource Corporation. USA. [b]National Institute for Health and Clinical Excellence (NICE). UK. [c]Karilonska Institute. Sweden. [d]University of Alabama. School of Public Health. USA. [e]Head Global Medical Affaires Genzyme. Italy.

Background: MS is a complex (and quite unpredictable) disease Heterogenicity of MS patients is well known (HTA review Fingolimod Canada) in terms of profile, evolution and unmet needs Identification of different populations alongside disease progression and impact on outcomes in RCTs (Freeman, 2011) Role of investigator's perception on enrolled patients beyond inclusion/exclusion criteria Drug RELATIVE value may differ according to populations/Value of Subgroups analyses Challenge to support labelling indication/Need for actual data in specific populations. Predefined subgroup analysis requested by regulatory, HTA assessment.

Panel session

Objectives: Discuss approaches to assess relative value of MS drugs. Define acceptable approach to indirect comparisons of DMT in MS (in absence of direct comparisons). Discuss patient populations included in drug development programs and outcomes in these studies

Highlight the various stakeholder perspectives: Patient, Payer/HTA and Provider (lack of treatment).

INTERNATIONAL REGISTERS AND PROSPECTIVE OBSERVATIONAL DATA COLLECTION TO SUPPORT HEALTH CARE TECHNOLOGY ASSESSMENT (HTA) WHERE THE EXISTING EVIDENCE BASE IS INADEQUATE (II)

Hannah Patrick[a], Bruce Campbell[b], Nancy Dreyer[c], Roberto Grilli[d] and Danica Marinac-Dabic[e]

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Background: At HTAi Dublin in 2010, a panel was convened to discuss the need for observational data collection, briefly summarise methodological issues and present relevant international work. This panel will update participants and inform them about international work to collect data across borders and is designed to follow on from the panel proposed by Dr Sun-Hae Lee Robin in which issues around prioritisation of research questions for observational data collection at an international level will be discussed.

Panel session

1) Introduction: brief examination of the obstacles to international collaboration and suggestions for possible ways to take the work forward leading to examples of how this has been achieved. 2) Presentation of the Contemporary postmarket surveillance system for Medical Devices: MDEpiNet. An innovation to strengthen and modernize evidence appraisal through systematic and active data collection. 3) Presentation of case studies fostering international collaboration across Europe inc. Transcatheter Aortic Valve Implantation. 4) The Register of Registers - a framework for a registry that is integrated with clinicaltrials.gov and will be a central resource for finding patient registries. 5) Discussion involving all participants, led by Bruce Campbell.

TOWARDS A PATIENT-CENTRED SYSTEM: THE ROLE OF THE CITIZEN IN HEALTH TECHNOLOGY ASSESSMENT

Jackie Street[a], Yvonne Bombard[b], Julia Abelson[c] and Carole Longson[d]

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Background: Effective HTA often requires an understanding of the personal experience of a technology or the value accorded to the technology by its users. Users are often patients. However, we also see a role for citizens in decision-making particularly as: 1. Users in population-based technologies, such as screening and vaccination programs; 2. Taxpayers for publicly-funded technologies, which may be socially contentious or where use of technologies impinges on strongly held beliefs; and 3. Potential consumers with a vested interest in provision or priority setting decisions for health services and technologies in the context of limited resources.

Panel session

Following an introduction by the Chair (Longson - UK), we explore the role of citizens in HTA by drawing on a range of case studies to illustrate the circumstances under which citizen involvement has contributed to: 1. Incorporating community perspectives into health policy (e.g. pandemic planning, disinvestment, Street - Australia). 2. Eliciting citizen values for contentious public health programs (e.g. storage and use of newborn screening samples, Bombard – USA & Canada). 3.3 Bringing social values into decision-making for public health interventions (e.g. colorectal and breast cancer screening, Abelson - Canada). 4. Reflections from the Chair (Longson - UK) will be followed by interactive discussion among panel members and with the audience. Proposed overarching discussion themes include: i) when and for which technologies and programs to include the citizen voice in HTA; ii) how to balance citizen perspectives with those of other stakeholders; iii) challenges for citizen involvement in HTA.

A GLOBAL INITIATIVE TO DEVELOP EVIDENCE GUIDANCE FROM HTA ORGANIZATIONS AND COVERAGE BODIES TO INFORM CLINICAL TRIAL DESIGN AND PRODUCT DEVELOPMENT - THE GREEN PARK COLLABORATIVE

Sean Tunis[a], Chris Henshall[b], Charles Turkelson, Berit Morland, Finn Borlum Kristensen, Jens Grueger and Karen Facey[c]

[a]CMTP. USA. [b]HTAi. UK. [c]SMC Scottland. UK.

Objectives: Present the rationale and history of Green Park Collaborative. Present the methodology for developing the Alzheimer's

disease EGD. Discuss key issues for future GPC work. Topic Selection. Future structure and governance of the GPC. Ensure adequate stakeholder input. Implementation strategies.

Scientific content: Historically, the clinical development process in the life sciences industry focused mainly on fulfilling regulatory requirements, with the expectation that positive reimbursement decisions would generally follow. Therefore, clinical studies have been primarily designed to address the information needs of regulators with less attention to generating evidence targeted to coverage bodies and the Health Technology Assessment (HTA) organizations that support them. As it has become clear that more and different evidence is preferred by coverage and HTA bodies, these organizations have begun to recognize the importance of clearly communicating to product developers the information that they expect to see in clinical trials. The Green Park Collaborative (GPC) is an international initiative that is exploring the scientific feasibility of developing guidance for the life science industry on the design of clinical studies to meet the needs of (HTA) organizations and coverage bodies. The initiative is being guided by a Steering Group of individuals from HTA organizations, coverage bodies, patient advocates, life sciences companies and regulators, and is co-chaired by HTAi and the Center for Medical Technology Policy. The aim is to produce prototype "evidence guidance documents" (EGDs) which will provide both therapeutic-area specific trial design recommendations and general methodological advice, and will be aligned to the extent possible with related regulatory guidance. The purpose of this guidance is to reduce the uncertainty currently faced by the life sciences industry regarding the evidentiary expectations of HTA groups and coverage bodies, to improve the relevance of clinical research, and to speed patient access to useful innovations. The project's current focus is on developing a pilot EGD that will provide recommendations for the design of clinical studies of pharmacologic therapies for Alzheimer's Disease (AD). In addition to assessing the scientific feasibility of creating such guidance, the development of the pilot guidance is informing deliberations about the process, structure and governance needed to enable HTA organizations and coverage bodies to expand the work to other therapeutic domains, and to apply the approach to devices and diagnostics. By June 2012, the GPC will have completed a draft pilot AD evidence guidance document, a non-disease specific statement of principles concerning evidence preferences of HTA and coverage bodies, and a proposed approach to expanding the work to additional therapeutic domains. At that time, the content of the guidance and the process through which it was developed would benefit from external input. As the GPC matures beyond the pilot phase, it will need a more formalized organizational structure, topic priority setting process, and stakeholder engagement process. The purpose of this panel is to provide an opportunity for a detailed discussion of these issues within the broader HTAi community.

RELEVANCE AND JUSTIFICATION: TWO NEGLECTED ISSUES IN HTA

Gert Jan van der Wilt, Bjørn Morten Hofmann, Tanja Krones and Wija Oortwijn

Objectives and outline: This interdisciplinary session will include four brief (15 minutes) papers: a case-study (cochlear implants for deaf children) will be presented to illustrate the difference between validity claims and relevance claims (Gert Jan van der Wilt). Then, the normative presumptions of health care economic evaluation will be explored by Bjørn Hofmann, and Tanja Krones will address the relation between facts and values in HTA more generally. Finally, Wija Oortwijn will explore the implications of the normative dimensions of HTA for the legitimacy of priority setting on the basis of HTA results. The session has a methodological focus, and aims to explore how normative inquiry can be integrated more fully with empirical inquiry and be made more effective in the context of health care coverage decisions.

HTA KNOWLEDGE TRANSFER STRATEGIES IN LATIN AMERICA: USING DIFFERENT TOOLS FOR HTA CAPACITY BUILDING IN LATIN AMERICA

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Background: The words 'knowledge transfer' (KT) and 'capacity building' are two of the many used to describe scientific partnerships and the movement of knowledge from one place or group to another inside a region or country. Recent data from several Latin American surveys shows the presence of very few scattered groups of decision makers applying HTA for decision making, mostly located in central urban areas, but quite a few others who are eager to do so but lack either trained human resources to retrieve or produce HTA reports or the knowledge of HTA potential use. The pool of trainable HTA researchers exist mainly in the form of health team professionals already working long hours for the health system, so an effective, time-saving, flexible and context adaptable KT approach is urgently needed to reach these two groups in developing countries. Both Argentina and Brazil have developed KT strategies targeted both to decision makers and HTA producers such as Online Learning Environments, which have been applied to HTA dissemination programs. Online 2.0 KT has the advantages of overcoming distance barriers and time constraints as well as opening opportunities for "hands on" practical multimodal and multilingual learning mechanisms. Other experiences have focused on "in site hands on" type of strategies, such as workshops and internships or mixed approaches. On top of this, the collaboration of international organizations such as PAHO has catalyzed networking among KT key points between countries and currently supports many KT initiatives.

Panel session

The aim of this panel will be to share experiences on HTA KT from different perspectives in Argentina and Brazil, to discuss its applicability in developing contexts, barriers faced in the process, ways to cope and strategies for improving HTA KT effectiveness and participants satisfaction.

THE USEFULNESS OF EARLY AWARENESS AND ASSESSMENT SYSTEMS IN FORECASTING FUTURE HTA ACTIVITIES FOR PATIENT CENTERED HEALTH CARE

Marianne Klemp[a], Clare Parker[b], Brendon Kearney[c], Roberta Joppi[d], Inaki Gutiérrez-Ibarluzea[e] and Anne Soless[f]

[a]NOKC. Norway. [b]NHSC. UK. [c]HPACT. Australia. [d]Italy. [e]Osteba. Spain. [f]HAS. France.

Background: New health care technologies are key drivers of health care improvements as well as health care expenditures. Limited resources and financial recession necessitates careful

planning of health care investments to provide effective and cost effective care to the population. The challenge between proper assessment and timely access is well recognized. Yet, the role of different systems for early awareness and assessment to address this challenge has achieved less attention. This panel session aims to present different early awareness and assessment systems, and discuss how these systems may interact with and frame the subsequent HTA assessments.

Panel session

Speakers will present awareness and alert systems that forecast the process of pricing or reimbursement, systems that inform recommendations or guideline processes, and systems that may inform all these processes. The presentations will cover different types of technologies, different time periods of assessment (pre launch, at launch or shortly after launch), and different ways of framing the subsequent HTA- process. The main objective will be to identify key elements of successful early awareness and alert systems, and explore similarities and differences between systems. From the perspective of advising on how to design a new early and awareness system we aim to discuss: What are the key elements of a successful early assessment and alert system? Do these elements vary between different types of early awareness and alert system or for different types of technologies? What is the best balance between "too early" and "to late", for optimal framing of the subsequent HTA and decision process?

HOSPITAL BASED HTA AND HEALTH CARE MANAGEMENT: THE ROLE OF MANAGER, ASSESSORS AND CLINICIANS

Marco Marchetti[a], Americo Cicchetti[b], Jivegard Lennart[c], Pascale Garel[d], Eric de Roodenbeke[e] and Guido Costamagna[f]

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Background: The role of HTA based at hospital level (HB-HTA) is growthing in the last years. In several countries, like Italy, Denmark, Spain, Sweden… The peculiarities of HB-HTA call for a specific approach to HTA process that must be integrated in the health care management process. In this context, the role and interaction between managers, assessors, and clinicians represent a key factor for the success of HTA.

Panel session

The main objectives of the parallel panel session are: 1. to identify the main features of health care organization's management; 2. to provide a general overview of the application of HTA methods and instruments in an health care organizations context. 3. to analyze how health care management process and clinical processes are affected by the application of HTA tools. The session will try to analyze in a deeper way the role and the interaction between the main stakeholders involved in the HTA process in the health care organizations. In particular discussants participating in the session will present different perspectives according their own competencies and role in the organizations. Final discussion will try to identify an interaction model between different stakeholders (manager, clinicians and assessors) in order to have a practical impact in increasing performances in the health care organizations thanks to the use of HTA.

HOW TO BEST USE LIMITED CAPACITY FOR PRAGMATIC EVIDENCE GENERATION INTERNATIONALLY

Sun Robin[a], Lise Rochaix[a], Sean Tunis[b], Andrew Cook[c] and Guy Maddern[d]

[a]HAS. France. [b]CMTP. USA. [c]NETSCC. UK. [d]Asernip-S and University of Adelaide. Australia.

Background: During the production of their reports almost all HTA agencies identify important gaps in evidence that introduce uncertainty into core conclusions. When this happens, many HTA reports make recommendations for new primary research to inform future HTA and to subsequently provide more robust evidence synthesis to support policy decisions. However, the quality and specificity of the primary research recommendations in HTA reports, and the path from these recommendations to actual new data (from a trial, observational study or other design) vary between health systems. Some agencies are able to fund primary research themselves, others have mechanisms for requesting or demanding evidence generation from other organisations (from the public sector or industry), and some have no formal systems. International collaboration on evidence generation could progress by sharing early information on requested or planned studies to reduce redundancy, best use limited resources and to gather consistent endpoints across studies.

Panel session

Speakers will present practices and challenges from four countries and explore: 1. How different heath systems handle research recommendations for evidence generation to address critical evidence gaps (processes to identify key gaps in evidence, to prioritise research questions and to define design of studies to address the gaps). 2. Any lessons learned (limits and difficulties encountered – funding, methodological, and implementation issues) in each system. 3. How limited capacity for pragmatic evidence generation internationally could be best used, potentially through collaborative primary research around common uncertainties. 4. Specific initiatives to share early information on evidence gaps and on requested or planned studies like the EVIDENT database currently under development by EUnetHTA. This Panel Session proposal is based in part on work underway within the European Network for Health Technology Assessment (EUnetHTA) – Work Package 7.

EXPANDING THE HTA LENS TO CROSS-MINISTERIAL ISSUES, AND THROUGH THE LIFE CYCLE OF HEALTH TECHNOLOGIES

Egon Jonsson[a], Laura Sampietro-Collom[b], Jose Asua[c], Joan Berezanski[d], Tom Noseworthy[e], Carole Longson[f] and Chris Henshall[g]

[a]Institute of Health Economics. Canada. [b]HTAi. Hospital Clínic. Barcelona. Spain. [c]Health Department - Basque Government. Spain. [d]CADTH Policy Forum; Alberta Health and Wellness. Canada. [e]University of Calgary and Alberta Health Services. Canada. [f]National Institute for Health and Clinical Excellence. UK. [g]HTAi. UK.

Background: This panel will present approaches underway in different jurisdictions to support new and evolving roles for HTA; and, to discuss how the field of HTA should 'expand its lens' and adapt to meet these growing demands.

Panel session

HTA is expanding beyond assessment of single technologies to the review of a range of interventions, not only in health and health care, but from many other sectors (education, social welfare, and justice). Also, efforts are underway to explore the role of HTA in early

technology development (in pre-market stages) and there is a growing movement towards reassessment of existing technologies and their scope of use. This panel will present approaches underway in different jurisdictions to support these new and evolving roles for HTA and discuss how the field might 'expand its lens' to encompass these growing demands.

Tuesday 26th June 2012

BRINGING HTA TO PUBLIC HEALTH DECISION MAKING. THE ECONOMIC ASSESSMENT OF NUTRITION AND ITS IMPACT

Irene Lenoir-Winjkoop[a], Mike Kelly[b], Franco Sassi[c], Leonie Segal[d] and Iñaki Gutiérrez-Ibarluzea[e]

[a]Danone Research. Scientific Affairs. France. [b]Director of the Centre of Public Health Excellence at NICE. UK. [c]OECD. Italy. [d]Health Economics & Social Policy Group. Division of Health Sciences. University of South Australia. Australia. [e]Osteba. Basque Office for HTA. Spain.

Background: Personalized medicine offers a new chance for life style and life style interventions to prevent chronic diseases become acute and thus reducing the costs for the health care systems. HTA can provide clear guidance to persons seeking to embark on nutrition trials regarding desirable characteristics to maximise the chance of policy translation. HTA and economic evaluation is increasingly demanded by health agencies in making decisions about what to include in core services. (Examples include National Institute of Clinical Excellent (NICE) in the UK and Medical Services Advisory Committee (MSAC) in Australia). It is not enough to design a clinical trial to meet well known statistical or clinical requirements; trials must also provide useful data inputs to economic evaluation.

Panel session

Public Health interventions on life style (including nutrition) to prevent acute and chronic diseases have offered unequal results. Genomic technologies will help to define which population would benefit most on public health interventions. Four short main speeches followed by an opened discussion with the audience regarding the implication of nutrition in the sustainability of the health systems. Franco Sassi (OECD) will talk about the economics of prevention and the role prevention could play in tailored interventions for health care sustainability. Mike Kelly (NICE) will address the role of HTA for public health decision making and the experience in the UK to inform decisions. Leonie Segal will describe the characteristics ideally incorporated into a well designed nutrition study to inform economic evaluation and nutrition policy. Iñaki Gutiérrez-Ibarluzea will explore the methodological challenges for HTA (including ELSI) to measure nutrition based interventions and their implications in regulation and reimbursement processes.

THE INTERFACE BETWEEN HTA AND REGULATORY PROCESSES: RECENT DEVELOPMENTS, FUTURE CHALLENGES AND ADVANCING STRATEGIC LEADERSHIP FOR INTERNATIONAL COLLABORATION

Logan Mardhani-Bayne[a], Chris Henshall[b], Carole Longson[c], Lloyd Sansom[d], David Grainger[e], Logan Mardhani-Bayne[f] and Guido Rasi[g]

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Background: This session will address challenges and opportunities for the strategic coordination of initiatives at the HTA-regulatory interface to maximize global benefit.

Panel session

There is increasing interest in the relationship between HTA, coverage and regulation. This session will address challenges and opportunities for the strategic coordination of initiatives at the HTA-regulatory interface to maximize global benefit. The HTAi Policy Forum discussed this topic in 2011, and HTAi has subsequently undertaken related initiatives. This panel session aims to present a discussion on developments arising from recent international dialogue (including but not limited to HTAi activities) and to present a forward-looking discussion from the perspectives of different sectors (HTA, regulatory, industry) on the major challenges to advancing international collaboration and how these can be addressed. The session will feature presentations on the following: Summary of 2011 HTAi Policy Forum discussion on this topic and follow-up activities by HTAi; Developing a framework for global leadership and strategic direction; HTA, regulatory, and industry perspectives on challenges/opportunities to advance international collaboration.

ACCESSING UNPUBLISHED EVIDENCE - CAN WE RELY ON TRIALS REGISTERS AND REGULATORY AGENCY SUBMISSIONS?

Sari Ormstad[a], Carol Lefebvre[b], Julie Glanville[c], Tom Jefferson[d] and Beate Wieseler[e]

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Background: HTA seeks to ensure all relevant evidence is considered when assessing new technologies. There is increasing access to records of trials via trials registers. This is a reflection of many related influences in the growing field of HTA: the need to access research evidence to assess new technologies reliably; the desire to improve patient recruitment to trials; and the recognition that patients deserve acknowledgment of their contribution to trials (the results will be made publicly available for the greater good). As access to clinical trials improves, there is also evidence that many trials remain unpublished and identifying them is challenging.

Panel session

The development of trials registers and trials results registers: unstoppable wave? Development of trials registers and newer results registers and the influences and encouragements to register trials prospectively. *Searching key trials registers – best strategies.* Which trials registers should be searched, strengths of the main registers and considerations when searching registers. *Identifying unpublished trials of influenza treatments: the challenges of unregistered trials.* This presentation will report on Cochrane Review Group efforts to identify

unregistered trials of Tamiflu and other treatments for flu, to indicate the skills required and the sources searched. *Who seeks will find, who asks will receive – or is this just our imagination?* This presentation will address the following issues: relevance of unpublished studies for HTA, impact of trial registries on the evidence base and how to achieve a more complete evidence base.

CAN YOU HAVE PATIENT-CENTRED CARE WITHOUT AN EXPLORATION OF PATIENTS' VIEWS, PREFERENCES OR EXPERIENCES? A ROLE FOR QUALITATIVE EVIDENCE SYNTHESIS IN HTA

Christopher Carroll[a], Andrew Booth[a], Vinita Mahtani-Chugani[b] and Sandy Oliver[c]

[a]University of Sheffield. UK. [b]Canary Islands Health Care Services. Spain. [c]University of London. UK.

Background: For health technology assessment (HTA) to be patient-centred requires the inclusion of evidence on the experiences, views, preferences and values of patients. This is qualitative rather than quantitative evidence. HTAs currently focus on quantitative evidence for clinical and cost-effectiveness only. This is a limited brief. It does not take into account how well or how poorly technologies may translate into practice. An intervention may be found to be clinically- and cost-effective, but real-world impact may be moderated by issues such as compliance or adherence, which in turn are affected by patients' likes and dislikes, and views about a technology. The HTA and guideline process may seek to acknowledge this by involving patient representatives on panels, but it can also begin to capture this element more systematically by conducting syntheses of qualitative evidence around patients' preferences and views. Such an approach may offer a broader, evidence-based and conceptual perspective than might be generated by a single patient representative or group.

Panel session

This session will involve presentations by all members of the panel, followed by time for a plenary discussion of the potential role of qualitative evidence synthesis in HTA, and what needs to be done for this aspect of systematic review and synthesis to be taken forward and applied in international HTA. Is there a place for qualitative evidence synthesis in HTA?

Methods of qualitative evidence synthesis for HTA. An example of qualitative evidence synthesis. Integrating qualitative and quantitative data.

INTEGRATED HTA FOR EFFECTIVE AND EFFICIENT PATIENT-CENTRED CARE

Karen Facey[a], Anne Lee[b], Brendon Kearney[c] and Murray Ross[d]

[a]NHS Forth Valley. UK. [b]Scottish Medicines Consortium (SMC). UK. [c]New and Emerging Health Technologies Committee. Australia. [d]Institute of Health Policy. Kaiser Permanente. USA.

Background: HTA is an interdisciplinary process that informs technology-related policymaking in healthcare. It is a complex mix of sophisticated analyses, evidence/opinions from stakeholders and value judgments. However, there is often a disconnect between HTA recommendations and implementation in clinical practice. This often occurs because HTA is not integrated into the health system and so technology decisions need to be made before HTA recommendations are available or because the payers/providers have not been sufficiently involved in the process. This panel discussion will present three examples of how HTA can be better integrated into health systems to create effective and efficient patient-centred care.

Panel session

The SMC process for assessment of medicines evolved from a clinical imperative and wide stakeholder involvement that has proved essential for engagement and implementation. Recent challenges regarding cost effectiveness vs affordability highlight challenges in the provider/payer dynamic that require new ways of working to ensure that goals of efficiency and productivity are achieved. The Australian New and Emerging Health Technologies Committee assesses non drug technologies when their evidence base is sparse and complex HTA assessments are not possible. An interdisciplinary approach involving HTA Agencies, clinicians and industry has been established that uses bespoke processes to ensure managed entry of new technologies including evidence collection processes. Kaiser Permanente uses an organized care delivery system that evaluates evidence about new technologies to improve the quality of care. Evidence is often insufficient, inconclusive, or conflicting, so there is a focus on deployment, real-time monitoring of safety/effectiveness and research to fill evidence gaps.

EMPOWERING PATIENTS TO ACHIEVE MAXIMUM VALUE FROM THEIR INVOLVEMENT: HTA AGENCIES AND PATIENT ORGANISATIONS WORKING TOGETHER ON EDUCATION AND TRAINING

Durhane Wong-Rieger[a], Jean Mossman[b], Liuska Sanna[c], Elaine MacPhail[d] and Lizzie Amis[e]

[a]International Alliance of Patients' Organizations. Canada. [b]Health Equality Europe. UK. [c]European Patients' Forum. Italy. [d]Canadian Agency for Drugs and Technologies in Health. Canada. [e]National Institute for Clinical Excellence. UK.

Background: Many HTA agencies seek to engage patients and the public in HTA processes but are unsure how to do it. Likewise, patient organisations want to participate in HTAs in ways that add value and have the potential to influence decision making. The Health Equality Europe 'Understanding HTA' Guide provides a useful toolkit for patient organisations. Surveys of agencies, patient organisations and policy makers were undertaken by the European Patients' Forum (EPF) to inform development of additional tools and training. Similarly HTA agencies NICE in the UK and CADTH in Canada offer information and workshops to support patient input.

Panel session

Objective: To promote dialogue on current activities that improve patient group capacity to contribute effectively and build on the ability of patients and HTA agencies to work together. Members of the Patient Involvement and Education Working Group of the HTAi Interest Sub-Group on Patient/Citizen Involvement, highlight areas of existing patient involvement and how training and education needs are being approached. The first two speakers give the patient organisation perspective, describing how the HTA Guide is used by patient organisations in several countries and the findings of the EPF surveys. CADTH introduced its process for patient involvement in 2010 and evaluated it in 2011. Evaluation results and lessons learned, leading to a better understanding of the type of education needed, will be discussed. The Patient and Public Involvement Programme team at NICE has developed master classes and other training, factsheets and informal support to lay committee members and other patient/public stakeholders.

RELATIVE VALUE: A KEY DRIVER FOR DECISION MAKING ALONGSIDE R&D DEVELOPMENT

Elisabeth Paternostre[a], Robert Epstein[b], Karen Facey[c], Jim Cox-Chapman[d], Sean Tunis[e], François Meyer[f] and Jean-Pierre Lehner[g]

[a]Global Medical Affairs. Sanofi R&D. France. [b]Advanced Clinical Science and Research. USA. [c]SMC Scottland. UK. [d]Pro-Health Physicians Chief Medical Officer. Spain. [e]Center for Medical Technology Policy. USA. [f]HAS. France. [g]Sanofi R&D. France.

Background: the industry while its standard approach in R&D has been geared towards regulatory requirements, leaving a gap in evidence required by HTA bodies and payers is transforming. Nowadays, bingring a new drug to market infers its therapeutic value is evidently demonstrated relying on multiple stakeholders assessments as well as real life data. Understanding and integrating the value components from different stakeholders alongside the R&D process are directional. An exemple from industry will be shared and open to discussion.

Panel session

Discussion: Challenge of R&D beyond 'efficacy, safety and quality': Patient perspective. What are the ways for patient to express their preferences? How this could be best conveyed to make meaningful improvement in R&D clinical development and effectiveness research? What is the trend about the patient role in HTA? Provider perspective. How integrated care could impact the relative value of therapeutic intervention and the 'real life' evidences? How the new resources/technologies help capture the real life evidence to feed the R&D process, from comparative efficacy to effectiveness research? HTA bodies' and payers' in the context of US HealthCare reform and European HTA network. What evidence from real life and how such evidence could impact the R&D process as a key component to create added value? An industry perspective/JP Lehner or collaborator. A framework proposal will be presented, highlighting how real life 'Evidence and Value' are integrated into the early R&D process from different perspectives. Open the discussion with key healthcare stakeholders: HTA bodies, Payers, Patients, Providers and industry.

INTERNATIONAL COLLABORATION ON HTA: LESSONS LEARNED FROM THE EUNETHTA COLLABORATION AND OTHER EUROPEAN INITIATIVES OF HTA PRODUCTION

Katrine Frønsdal[a], Tom Jefferson[b], Sarah Kleijnen[c], Claudia Wild[d], Vigdis Lauvrak[a] and Iris Pasternack[e]

[a]Norwegian Knowledge Centre for the Health Services (NOKC). Norway. [b]Agenzia nazionale per i servizi sanitari regionali (Agenas). Italy. [c]Health Care Insurance Board (CVZ). Netherlands. [d]Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA). Austria. [e]Finnish Office for Health Technology Assessment (FinOHTA. THL). Finland.

Background: EUnetHTA Collaboration aims at facilitating sharing of information and efficient use of resources available for HTA in Europe. During EUnetHTA Joint Action 2010-2012 several HTA tools and methods have been developed to promote collaboration, such as the database for planned projects for common topic identification, the HTA Core Model as assessment framework, improved methodological guidance for Relative Effectiveness Assessment (REA) of pharmaceuticals, and communication tools to facilitate project management. Several organizations from EU Member States, EEA and EFTA countries, regional agencies and non-for-profit organizations have already tested the different tools and actual collaboration in HTA production.

Panel session

The purpose of this panel is to share experiences from various collaborative projects among EUnetHTA Joint Action members to discuss lessons learned and point to issues that may facilitate effective and sustainable HTA collaboration in the future. Katrine Frønsdal (NOKC) will present the production of a Joint Action Core HTA emphasizing challenges of selecting and prioritizing a common HTA topic. Sarah Kleijnen (CVZ) will describe experiences from collaborating on rapid assessment of relative effectiveness of a pharmaceutical highlighting methodological challenges and communication issues. Claudia Wild (LBI-HTA) will focus on time and resources through experiences from collaborating on oncodrugs and hospital 'high-tech' technologies. Vigdis Lauvrak (NOKC) will discuss management issues with background in producing a common Core HTA within Nordic countries. Finally Iris Pasternack (FinOHTA/THL) will discuss efficiency gain and loss issues illustrated by how two agencies can share parts of assessment although the scope in the national reports is different.

HTA CAPACITY BUILDING IN DEVELOPING COUNTRIES- EXPLORATION OF DIFFERENT MODELS

Joseph Mathew[a], Tantivess Sripen[b], Andres Pichon Riviere[c], Lazar Mathew Thalakkotur[d] and Tammy Clifford[e]

[a]PGIMER. India. [b]HITAP. Thailand. [c]ICES. Argentina. [d]PSG IAS. India. [e]CADTH. Canada.

Background: Background: Different methods are used around the world for HTA capacity and capability building. Health-care institutions and organizations are interested in determining the optimal approach for HTA capacity building that can yield the best results in the local context. This panel session explores four different approaches. Objectives/Goal: To sensitize the HTA community as well as health-care systems interested in initiating HTA about different models of HTA capacity and capability building, using specific initiatives in health-care systems in different countries.

Panel session

Capacity building in new hta systems. HTA capacity building model used in Thailand (HiTAP). Strengths/limitations of the model. Learning messages for other health-care systems *Online teaching/learning.* 3 distance-learning programmes (HTA and Economic Evaluations). Lessons learned after three years' experience (350 participants; 18 countries). Strengths/limitations of the model. Learning messages for other health-care systems. *Learning-by-doing approach.* Capacity building programme in India (SIGNET Programme). Strengths/limitations of the model. Learning messages for other health-care systems. *HTAi scholarship programme for low and middle income countries.* HTAi Scholarship Programme as a tool for capacity building in developing countries. Progress till date. Strengths/limitations of the model. *Moderator's remarks. Discussion.*

WHEN SHOULD AN INTERVENTION BE RECOMMENDED FOR WIDESPEAD USE ONLY WITH FURTHER EVIDENCE COLLECTION

Peter Littlejohns[a], Karl Claxton[b], Andrew Mitchell[c], Steven Pearson[d] and Chris Henshall[e]

[a]National Institute for Health and Clinical Excellence. UK. [b]University of York. UK. [c]Department of Health and Ageing. Australia. [d]Institute for Clinical and Economic Review Massachusett General Hospital's Institute for Technology Assessment. USA. [e]HTAi Policy Forum. UK.

Background: Introduction and explanation of why NICE commissioned this research. Summary of the study on "Only in Research" and its key conclusions and recommendations. Reflections from the USA approach and experience with Coverage with Evidence Development. Reflections from the Australian approach and experience. (HTAi Policy Forum): Reflections from perspective of the

HTAi Policy Forum discussions of CED and Managed Entry Agreements, and key issues for discussion.

Panel session

Bodies making recommendations on coverage are often faced with an immature evidence base. A recommendation that a treatment should only be available in the context of further data collection may be appealing but experience to date has been mixed and many bodies appear unsure whether and when, to adopt this approach. NICE commissioned research to identify when a decision of "only in research" would be appropriate. The research identified four broad areas to consider: cost-effectiveness and population net health effects; whether the type of research required can be conducted once a technology is approved; whether there are sources of uncertainty which will only be resolved over time; and whether there are significant (opportunity) costs which once committed by approval cannot be recovered. These findings represent a significant advance in the thinking in this area and will be presented and discussed in the light of experience in other countries.

THE FUTURE OF HTA DEPENDS ON THE IMPACT OF HTA

Måns Rosén[a], Brian O'Rourke[b], Måns Rosén[a], David Hailey[c], Ulla Saalasti-Koskinen[d], Denis Bélanger[b] and Alric Rüether[e]

[a]SBU. Sweden. [b]CADTH. Canada. [c]University of Wollongong. Australia. [d]FINOHTA. Spain. [e]IQWIG. Germany.

Background: Demonstrating the value and impact of HTA from different parts of the world

Panel session

As part of an INAHTA initiative for capturing and reporting on the impact of HTA work several examples of measuring the impact will be presented. SBU tries regularly to measure practise before and after publication of HTA-reports. The effects of publishing and disseminating the results of many SBU reports will be presented. CADTH will present the impact of HTA work on self-monitoring of blood glucose, MRI technology, anticoagulants, hip protectors and surgical robotics. Germany has been providing a highly developed, legally based HTA process of decision making in health care since the 1990's. Experiences will be presented. FINOHTA has provided evidence to the Ministry of Health and Social Affairs by producing HTAs on screening and conducting implementation of screening. HTA activity in Australia has included support for the national Medicare program, assessments at state level of technologies for public hospitals, and evaluation of interventional technologies.

HTA AND DISINVESTMENT

Tara Schuller[a], Chris Henshall[b], Laura Sampietro-Colom[c] and Mitch Sugarman[d]

[a]HTAi Secretariat. Canada. [b]HTAi Policy Forum (Chair). UK. [c]HTAi Policy Forum. Spain. [d]HTAi Policy Forum/Medtronic. USA.

Background: "HTA and Disinvestment: Harnessing HTA to reduce lower value or ineffective uses of health technologies" Proceedings of the January 2012 HTAi Policy Forum Meeting

Panel session

The 2012 Policy Forum meeting brought together senior leaders from public and private sector organizations with strategic interests in HTA, members of the HTAi Board, and invited experts for strategic discussions about emerging trends and recent experiences in reducing lower value or ineffective use of health technology. The meeting considered various stakeholder perspectives, and discussed HTA-related disinvestment activities to identify barriers to disinvestment and the characteristics of successful approaches. The discussion was framed by an introduction that reviewed the pressures health system managers face and the range of management and research approaches that they can and do call on and with which HTA may need to interact to achieve maximum impact.

Wednesday 27th June

DEVELOPING PRINCIPLES FOR HTA THAT ARE PATIENT-CENTRED

Karen Facey[a], David Grainger[b], Finn Boerlum Kristensen[c], Chris Henshall[d] and Durhane Wong-Rieger[e]

[a]University of Glasgow. UK. [b]Lilly. Australia. [c]EUnetHTA. Denmark. [d]HTAi Policy Forum. UK. [e]HTAi Interest Group for Patient/Citizen Involvement in HTA. UK.

Background: A CRA report published in May 2011 developed previous work to propose 14 HTA principles covering scope, methods, process and impact. Metrics were defined for each principle and used to assess HTA agencies using information from interviews and HTA Agency websites. In this panel session, four speakers providing international perspectives from different stakeholder groups will review the principles and consider how they should be used to improve the quality of HTA. This session will include short presentations and substantial interaction with the audience to develop shared principles, which will lead to HTAs that are more patient-centred.

Panel session

David Grainger from Lilly will explain how the CRA report sought to develop HTA principles that could be used to align HTA practices and provide a method of accountability to improve HTA standards. Professor Finn Boerlum Kristensen will review the HTA principles on behalf of EUnetHTA, focussing on the perspective of HTA Agencies that inform policy making and consider the difference between national and international HTA initiatives. Dr Chris Henshall, Chair of the HTAi Policy Forum, will consider the challenges of developing the HTA principles for those involved in using HTA directly in decision making, taking account of different contexts, cultures and challenges. Dr Durhane Wong-Rieger, will represent the views of the HTAi Interest Group on Patient/Citizen Involvement in considering which principles are important for promoting relevant patient input ensuring that HTA is relevant and useful for patients.

TREASURE OR TOKEN? THE IMPACT OF INCLUDING PATIENTS IN HEALTH TECHNOLOGY ASSESSMENTS FOR CANADA'S PUBLIC DRUG PROGRAMS. WHAT IS THE IMPACT AND WHERE LIES THE POTENTIAL?

Harlon Davey[a], Bill Dempster[b], Janet Martin[c], Kelly Gorman[d] and Martine Elias[e]

[a]The Ontario Ministry of Health's Committee to Evaluate Drugs. Canada. [b]ThreeSixty Public Affairs. Canada. [c]London Health Sciences Centre. Canada. [d]Cystic Fibrosis Canada. Canada. [e]Janssen-Ortho. Canada.

Background: An expert in Canadian Policy, a patient representative to the Ontario Ministry of Health's Committee To Evaluate Drugs, an

evidence based medidal doctor, a patient advocate and someone from industry will reflect on their experiences with patient engagement in decision making.

Panel session

In May 2007, drug reimbursement decision-makers in Canada have acknowledged that the patient's experience of a condition should be accommodated and considered as criterion for evidence in the funding recommendation process. Few jurisdictions have implemented such a mechanism. How has this input been incorporated? How has it impacted the system and human health? Are the current opportunities achieving their goals? Is this process meaningful and reflective of patient preferences which ultimately enhance the quality and clarity of patient-centred medicine? The panel will review old and new mechanisms that capture patient values: patient input to drug plans, patient panelists as experts on committees, traditional patient advocacy and lobbying, and the role of industry. Participants on the panel represent diverse voices that impact the delivery of health care through policy or practice or through sharing personal perspectives. Each will share unique perspectives on the implementation of patient inclusion and discuss objectives based on personal experiences and knowledge from the trenches.

NO HEALTH WITHOUT RESEARCH. AND NO RESEARCH WITHOUT EVALUATION

Paula Adam[a], José A. Exposito[a], Molly Morgan[b], Maite Solans-Domènech[a], David Kryl[c], Marta Aymerich[d] and Jack Spaapen[e]

[a]Catalan Agency for Health Information Assessment and Quality. Spain. [b]RAND-Europe. UK. [c]Department of Health. UK. [d]Department of Health. Government of Catalonia. Spain. [e]The Royal Netherlands Academy of Arts and Sciences. Netherlands.

Background: "No health without research" is the motto that WHO has chosen for the year 2012. HTA agencies and other organizations oriented to evidence-based decision-making might want to add to this the following: "no research without evaluation". The magnitude of global –and local- investments in health science research is increasing as the research enterprise moves from a small scale conventional uni-centric to a big scale collaborative multi-centric enterprise. Yet, the "science of science", of the scientific assessment of the real world effectiveness of this "investment" is, in many cases, unknown. A pre-condition for the development of studies on the impact of research is a comprehensive repository of data on the research process from inputs, throughputs, outputs and outcomes. Furthermore, the analysis requires a multifaceted approach depending on the assessment question, ranking from top-down macro-economic analysis of the rate of return, to bottom-up economic methods of QALYs gained for implemented innovation, qualitative or semi-qualitative case studies, surveys combined with bibliometrics, benchmarking and peer-review studies. Research impact studies have mainly been developed in a number of Anglo-saxon countries. Nonetheless other countries are more and more encouraged to join in, especially with the development of databases around the world.

Panel session

Objectives: To present ongoing development of databases on the "productive" research process (from a bottom-up approach –from programs or organisations). To present selected results from studies on the impact of research programs using bottom-up databases. Part I: Data collection tools in Spain and the UK. On the inputs of research. The SIRECS project. On the outcomes of research. The RAISS tool. Part II: Evaluation of research programs in Spain, UK and the Netherlands. Assessing the impact of a research call on clinical and health services research. Assessing research impact from the UK Department of Health using RAISS. Social impact through productive interactions in Dutch Health and Health Services research. Discussion.

PRACTICAL EXAMPLES OF INTERACTION BETWEEN HTA AND REGULATORY BODIES: WHAT CAN BE SHARED? WHAT CAN BE LEARNT? WHAT CAN BE IMPROVED?

Mel Walker[a], Katrine Fronsdal[b], Alasdair Breckenridge[c], Carole Longson[d], Brian O'Rourke[e] and Franz Pichler[f]

[a]GlaxoSmithKline; Associate. Centre for Socioeconomic Research. UK. [b]Norwegian Knowledge Centre for Health Services. Norway. [c]Medicines and Healthcare Products Regulatory Agency. UK. [d]Centre for Health Technology Evaluation. National Institute for Health and Clinical Excellence. UK. [e]Canadian Agency for Drugs and Technologies in Health. Canada. [f]HTA Programmes. Centre for Innovation in Regulatory Science. UK.

Background: The interface between regulatory and HTA agencies is developing at a rapid rate. Less than five years ago discussion between these stakeholders was very limited but recently there has been a rapid development of collaborative initiatives in the areas of parallel advice and review. While the experiences are generally positive, there is considerable diversity in these approaches and their outcomes. To help to inform future interactions, HTAi has established a new Interest Sub Group on HTA-Regulatory Interactions for the purpose of identification, comparison and sharing of learnings from the experiences of these early collaborations.

Panel session

The objective of the panel session is to compare and discuss different HTA-Regulatory interactions in relation to the development and review of new medicines. Discussion will focus on the challenges and experiences of existing initiatives, what can be learnt and how these learnings can be used to facilitate more effective interactions in the future. Katrine Fronsdal (NOKC) will set the scene by describing a recent study that compared all the current HTA and Regulatory interaction initiatives around the world. Following this overview, case studies and perspectives of how collaborations are evolving both at product review and during drug development will be given from a regulatory, HTA and decision-maker perspective by Alasdair Breckenridge (MHRA), Brian O'Rourke (CADTH) and Carole Longson (NICE) respectively. Franz Pichler (CIRS) will describe the need for sharing the learnings from these diverse initiatives which led to the founding of a new HTAi Interest Sub Group.

THE SOCIAL VALUE OF THE QALY IN ASIA: SEARCHING FOR THE HOLY GRAIL?

Yot Teerawattananon[a], Takashi Fukuda[b], Takeru Shiroiwa[c], Jeonghoon Ahn[d], Montarat Thavorncharoensap[e] and Asrul Shafie[f]

[a]Health Intervention and Technology Assessment Program (HITAP). Thailand. [b]University of Tokyo. Japan. [c]Ritsumeikan University. Japan. [d]NECA. Republic of Korea. [e]Health Intervention and Technology Assessment Program (HITAP). Thailand. [f]Universiti Sains Malaysia. Malaysia.

Background: The recent attempt made by HTA organization in Japan, Thailand, Korea, and Malaysia to identify social value of the QALY across Asian setttings.

Panel session

In this panel, we will present the recent attempte made by HTA organizations in Japan, Korea, Malaysia, andThailand to identify the social value of the QALY across Asian settings. The panel will discuss the theoretical framework as well as the strengths and shortfalls of the previous attempts made in Asia and Europe. This panel will offer

practical approach in determining the social value of the QALY using household survey.

Sessions: Overview of the concept of the social value of the QALy in health economic evaluation including its current use in policy decisions in Asian countries. Summary of previous attempst made by scholars in Europe and Asia in identifying the social value of the QALY including the results and limitations of the previous works. Proposition of the conceptual framework, tools, plans, and preliminary results for a new survey in Japan, Korea, Malaysia, and Thailand. Suggestion of potential application and impact of this work in allocating resource, program budgeting and decision making in Asian settings.