9th HTAi ANNUAL MEETING

"HTA in Integrated Care for a Patient Centered System"

Bilbao, 23rd-27th June 2012

WORKSHOP SESSIONS

Saturday, 23rd June 2012

INAHTA/HTAi ETHICS INTEREST SUB GROUP: EDUCATIONAL SESSION ON ADDRESSING ETHICAL ISSUES IN HTA

Christa Harstall[a], Björn Hofmann[b], Annette Braunack-Mayer[c], Gert Jan van der Wilt[d] and Ken Bond[a]

[a]Institute of Health Economics. Canada. [b]University College of Gjøvik. Norway. [c]University of Adelaide. Australia. [d]Radboud University Medical Centre. Netherlands.

Background: Participants will be shown how to identify ethical issues in HTA, methods for handling ethical issues, and different ways of communicating results. Then they will be asked to practice these skills using specific cases and to compare and contrast the different approaches considered.

Workshop session

The workshop aims to introduce methods for identifying and analyzing ethical issues and different ways in which the results of ethics analysis may be communicated.

Objectives: Explain the importance of considering ethical isssues, recognize potential ethical issues, formulate research questions, describe methods for analyzing ethical issues, describe alternative ways of synthesizing and communicating results.

Introduction: Participants will be asked to share and discuss their experiences of conducting HTAs where value issues arose since a formal ethics analysis was not done; there was no framework for considering the issues.

Methods: Using examples introduce the main methods for identifying and analyzing ethical issues. Participants will be asked to formulate ethical questions for investigation and apply some of the concepts.

Communicating results: Several ways to present the results will be shown including how to assess the "quality" of ethics analysis. Using examples, to show the benefits and challenges with summarizing and communicating results.

USING ONLINE COLLABORATIVE TOOLS IN HEALTH TECHNOLOGY ASSESSMENTS

Chantelle Garritty, Lucy Turner and Adrienne Stevens

Ottawa Hospital Research Institute. Canada.

Background: The ability to innovate, and to tap into new technologies to facilitate the management and production of HTAs is key to progress. In recent years, several internet-based technologies have been emerged that assist the ways in which knowledge synthesis are conducted. It's important to know what technologies exist and how best to make use of them as they have the potential to improve the speed, quality and audibility of collaborative research initiatives such as HTAs. We advocate leveraging available IT resources and progressively incorporating more technology into the HTA process. The availability of an array of inter-based technologies opens the possibility to expand beyond the traditional paper-based approach to conducting technology assessments serving to increase efficiencies in production and enhancing collaborative efforts.

Workshop session

Objectives: To inform participants of the online tools available to manage the systematic review (SR) process involved in HTAs; and to promote application of these tools with regards to planning, coordinating, and conducting such research online versus using the traditional paper-based approach.

Description: This session will cover the panorama of tools (commercially and non-commercially available) that can be incorporated throughout the HTA process, and the value this brings. The following internet-based SR software will be compared and contrasted: Abstrakr, DistillerSR, EROS, EPPI-Reviewer, RevBase, and Sumari.

Further, participants will be divided into groups where they will receive hands on experience screening, extracting, and generating data reports and tables using one of the available internet-based technologies (DistillerSR). This will be followed by a general discussion of the benefits and/or drawbacks to using an online approach. We will also discuss common meta-analysis programs; real-time exchange tools; virtual learning environments; and document sharing tools.

THE IDENTIFICATION AND REVIEW OF EVIDENCE TO INFORM COST EFFECTIVENESS MODELS

Eva Kaltenthaler, Paul Tappenden and Suzy Paisley

ScHARR. University of Sheffield. UK.

Background: The development of a cost effectiveness model is a key component of health technology assessment. Methods for the acquisition, selection and review of evidence to inform cost effectiveness models are not well developed. However there is a recognised need for the development of methods in this area. Research in this area has been important in informing methods for NICE technology appraisals in the UK and has been the focus of a recent technical support document produced by the NICE Decision Support Unit. The purpose of the proposed workshop is to explore some of these important issues and generate an understanding of appropriate methods and procedures in this area.

Workshop session

Objectives: The workshop will have three objectives: 1. Explore methods used in model structuring including the identification and specification of relevant parameters within the model. 2. Explore appropriate methods for the systematic identification of evidence to inform models including relevant sources and types of searching. 3. Explore appropriate methods for the reviewing of evidence to inform models including rapid review methods and the reviewing of non-standard sources of evidence.

Methods: The workshop will consist of three sessions, each consisting of a half hour presentation to illustrate the issues and a half hour structured small group discussion working through a set of related questions. Sessions: 1. Practical conceptual modelling methods. 2. Identification of evidence to inform models. 3. Reviewing of evidence to inform models. The workshop will be delivered by researchers experienced in health technology assessment in the UK including a cost effectiveness modeller, information specialist and systematic reviewer.

(THE DEATH OF RCTS) WELCOME TO A NEW WORLD OF DATA! FINDING YOUR WAY ACROSS EVIDENCE TO INCREASE PATIENT PERFORMANCES

Edith Frénoy[a], Guido Rasi[b], Lars Klareskog[c], Matic Meglic[d], Nils Behrndt[e], Luca de Nigro[f] and Thomas Müller[g]

[a]EFPIA. Belgium. [b]EMA. UK. [c]Karolinska Institutet. Coordinator ARTIS Registry. Sweden. [d]CIO of Slovenian National Institute for Public Health and PARENT Coordinator. Belgium. [e]European Commission. Belgium. [f]Drugs Monitoring Registers. Italian Medicines Agency. Italy. [g]Head of the Pharmaceuticals Department at the Joint Federal Committee. Germany.

Background: Discuss with experts of the regulatory and HTA community the validity of evidence beyond RCTs.

Workshop session

HTA is a tool to support efficient healthcare decision-making, aiming at realizing good patient performances whilst ensuring value-for-money for the system and encouraging continued innovation. In a world of evolving science toward increasingly targeted medicines, how can technology developers and assessors ensure that the performance of the individual patient rather than the average is measured and cascaded into medical practice? The session will explore how collecting evidence along medicines' life-cycle can support this new paradigm and increased efficiency of healthcare systems.

DIABETES: UNDERSTANDING THE ECOSYSTEM OF THE PATIENT WITH DIABETES AS THE BASIS FOR BETTER INTEGRATED CARE SOLUTIONS

Elisabeth Paternostre[a], Rafael Rotaeche del Campo[b], Victor Villagra[c], Ed Fisher[d], Tehseen Salimi[e] and Bernard B Charbonnel[f]

[a]Sanofi. France. [b]Coordinator for family medicine in UAP Alza (Gipuzkoa Ekialde district). Spain. [c]Health & Technology Vector. Inc. Spain. [d]University North Carolina. USA. [e]Global Medical Affairs. Sanofi. USA. [f]Unniversity of Nantes Professor of Endocrinology and Metabolic Diseases. France.

Background: Improving the management of diabetes is vital for improving the lives of affected patients and for reducing the burden that this disease places on resource-strained healthcare delivery systems. The majority of healthcare costs associated with diabetes derive from the management of diabetic complications, particularly when these require treatment in-hospital. This aspect of diabetes care is expected to become even more apparent as the global diabetes pandemic progresses. The concept of integrated solutions including novel disease monitoring device technology will be shared.

Panel session:

Moderator: Rafael Rotaeche del Campo.

1. The perception and need of the patient with diabetes. Ed Fisher

What are the main concern that patients report from their treatment&care? What are they expecting from their physicians? What they perceive about the progress of their condition? What are the key levers, usefull to improve behaviors & treatment?

2. The patient ecosystem and its linkage with the quality of care. Victor Villagra

What are the influences of socioeconomics, genetics, environment, attitudes? How to integrate the co-morbidity component in en evidence-based emdical approach? What expected outcomes could be anticipated on quality and cost of care?

3. Impact of new technologies on the integrated care in disabetes: (possibly B Charbonnel, TBC due to new french transparency)

What are the evidences on cost effectiveness of integrated solutions in diabetes? Exemple: beta-test of an integrated solutions telemedicine model for T1D patients in the french system

4. What role for the industry? T. Salimi

An exemple of ecosystem based integrated care will be presented.

The discussion will then be opened by the moderator on the diabetes specific features, the exemple presented in the US context of Accountable Care Organization and the role of industry.

HTA 102 INTRODUCTION TO HOSPITAL BASED HEALTH TECHNOLOGY ASSESSMENT

Marco Marchetti[a], Americo Cicchetti[b] and Lennart Jivegård[c]

[a]HTA Unit -University Hospital "A. Gemelli". Università Cattolica del Sacro Cuore. Italy. [b]Faculty of Economic. Università Cattolica del Sacro Cuore. Italy. [c]HTA_Centrum. Sahlgrenska University Hospital. Sweden.

Background: The objectives of the course are twofold: 1. to identify the main features of health care organization's management; 2. to provide participants with the a general overview of the application of HTA methods and instruments in an health care organizations context. The course gives a particular emphasis on: a) planning, evaluation and control activities of the technology innovation process in the hospital context and b) health technologies needs assessment, biomedical technologies investment plan and medical devices assessment.

Workshop session

Session 1. Basics of health care management. Define management. Identify the basic functions of manager and phases of management. *Session 2. Health care management tools.* Identify management cycle. Strategic planning, organizational design in health care organization. Analyze specific aspects of hospital operation management. *Session 3. Management of health care organization and industry relation.* Technological innovation and cost. Innovation process in health care. Industry and HCOs relation. Managing technological innovation in HCO. *Session 4. HTA and hospital management: the role of administrator and Clinicians.* Technology planning: the role of HTA and interaction with clinicians. *Session 5. Case study of:* HTA_ Centrum, Sahlgrenska University Hospital. HTA Unit, University Hospital "A. Gemelli" Rome, Italy. *Session 6. Exercise and teamwork.* Objective of the exercise is to produce and discuss information useful to hospital management to decide for priorities in technologies investment.

Sunday 24th June 2012

PATIENT AND CITIZEN INVOLVEMENT IN HTA- TAKING THE NEXT STEPS TO PATIENT-CENTRED HTA

Karen Facey[a], Janet Wale[b], Sophie Werko[c], Jackie Street[d] and Durhane Wong-Rieger[e]

[a]HTAi Interest Sub-Group on Patient/Citizen Involvement in HTA (PCISG). UK. [b]Cochrane Consumer. Incoming PCISG Joint Chair. Australia. [c]Swedish Council on HTA (SBU). Sweden. [d]University of Adelaide. Australia. [e]International Alliance of Patients' Organisations. Incoming PCISG Joint Chair. Canada.

Background: The HTAi Patient/Citizen Involvement in HTA Interest Sub-Group (PCISG) seeks to promote best practices and facilitate patient and citizen participation in the international HTA community. This has included development of an HTA glossary for patients, a seminal paper and Themed Section in IJTAHC, regular ebulletins, high profile presentations to various stakeholders, input to national HTA consultations and support for initiatives that engage patients and patient organizations in HTA activities. In 2011, PCISG established three Working Groups that have begun working virtually but need a face-to-face meeting to share workplans, develop mechanisms for collaboration, consider future activities, and engage new members.

Workshop session

This workshop provides an opportunity to expand Working Group (WG) participation to others interested in patient/citizen involvement. Karen Facey will summarise PCISG development, highlighting successes, challenges and opportunities, followed by presentations from WG Chairs on early achievements and challenges. Janet Wale will present the Patient Involvement and Education WG work, including a framework for public involvement potentially relevant across the Interest Sub-Group. Sophie Werko will present the Patient Issues: Methods and Impact WG plans and collaborations with academia and INAHTA. Jackie Street will present efforts to build the Citizen and Community Involvement WG and planned advocacy strategies to explicate the role of citizens in HTA. The Working Groups will convene in parallel breakout sessions to develop operational plans for future work. Durhane Wong-Rieger, incoming joint Chair, will lead a feedback session to gain consensus on future directions. A workshop summary will be developed and shared with all HTAi members.

EUNETHTA TOOLS FOR COLLABORATIVE HTA PRODUCTION

Iñaki Imaz[a], Claudia Wild[b], Kristian Lampe[c], Iris Pasternack[c], Sarah Kleijnen[c], Patrice Chalon[d], Sun Robin[e], Debbie Chase[f], Irena Guzina[g] and Sorin Stanel[g]

[a]MD, PhD, MPH. [b]Priv.Doz. [c]MD. [d]M.Sc, Knowledge Manager. [e]MD, MPH. [f]PhD, Specialty Registrar in Public Health. [g]Haute Autorité de Santé. France

Objective: To increase the participants' knowledge of EUnetHTA tools and gather perceptions about their functionality in collaborative HTA projects.

Workshop objectives and description

European Network for HTA (EUnetHTA) aims at sharing knowledge, work and skills in Health Technology Assessment (HTA) across Europe. It has developed practical tools to identify topics of common interest, produce, report and adapt reliable and transferable HTA information, as well as tools to support efficient international project management and communication. The EUnetHTA tools work on different phases of the health technology life cycle (starting from identification until the generation of additional evidence). Currently EUnetHTA is formalised through a Joint Action of 35 government appointed HTA organisations from 26 European countries and a large number of regional agencies. This workshop is intended to increase the participants' knowledge of EUnetHTA tools and gather perceptions about their functionality in collaborative HTA projects. There will be an introduction providing background and terminology for understanding EUnetHTA's collaborative HTA production. Afterwards, each tool will be presented with emphasis on their inter-related functionalities. There will be hands-on training sessions with computers to allow participants to test tools. Finally, speakers will discuss solutions for their further development, taking into account participants' feedback.

TRANSFORMING INFORMATION SERVICES IN A CHANGING HTA ENVIRONMENT

Catherine Voutier[a], Liz Dennet[b], Dagmara Chojecki[b], David Kaunelis[c], Sigrid Droste[d] and Rocío Rodríguez López[e]

[a]Melbourne Health. Australia. [b]Institute of Health Economics (IHE). Canada. [c]Canadian Agency for Drugs and Technologies in Health (CADTH). Canada. [d]Institute for Quality and Efficiency in Health Care (IQWiG). Germany. [e]Agencia de Evaluación de Tecnologías Sanitarias de Andalucía (AETSA). Spain.

Background: The 2012 IRG workshop will focus on new challenges faced by information specialists working in patient centered health care organisations with reduced financial resources. How can we adapt our role and services to meet these new challenges?

Workshop session

9:00-9:15 Welcome and introduction/Catherine Voutier (IRG Chair).

Session 1

9:15-10:30 Rapid Searches for Rapid Reviews/Liz Dennett – IHE, Dagmara Chojecki – IHE and David Kaunelis – CADTH.

10:30-10:45 Coffee/tea break.

Session 2

10:45-12:00 Searching for Social and System Demographical Information: Providing context in HTA/Liz Dennett IHE and Dagmara Chojecki – IHE.

12:00-13:00 Lunch.

Session 3

13:00-14:15 Costs out of control! Is it the end of comprehensive literature searching and reviewing?/Catherine Voutier - Melbourne Health, Sigrid Droste - IQWiG and [speakers to be determined].

14:15-14:30 Coffee/tea break

Session 4

14:30-15:45 The role of information specialists within patient-centered systems/Rocío Rodríguez López – AETSA and [speakers to be determined]

15:45-16:00 Closing remarks/Catherine Voutier

IDENTIFICATION SOURCES AND PROCESS FOR EARLY AWARENESS AND ALERT (EAA) SYSTEMS

Claire Packer[a], Anna Nachtnebel[b], Derek Ward[a], Brendon Kearney[c], Andra Morrison[d], and Setefilla Luengo[e]

[a]National Horizon Scanning Centre. University of Birmingham. UK. [b]Ludwig Boltzmann Gesellschaft. HTA. Austria. [c]HealthPACT. Department of Human Services. Australia. [d]Canadian Agency for Drugs and Technologies in Health. Canada. [e]Agencia de Evaluacion de Tecnologías Sanitarias. Spain.

Background: Early awareness and alert (EAA) systems 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 disseminate information to decision-

makers. The first stage in EAA systems is the identification of health technologies in development that are likely to come to the health market. The identification process can include consultation with experts, commercial companies, patients and providers, and scanning of internet and other sources. Identification systems can be reactive and/or proactive, and can involve networks of individuals or EAA systems.

Workshop session

By the end of the workshop, attendees will: Know what questions to ask of funders and/or clients prior to deciding on which sources to incorporate into an EAA system. Understand the different categories of identification sources – primary, secondary and tertiary. Understand how experts, companies, collaborative networks and the internet can be used alone or in combination in the identification process. Know about some common difficulties or pitfalls in using different identification sources. Understand the need for the evaluation of identification sources. Know what the next steps are after the identification of emerging technologies. The workshop will take the form of a panel of speakers with different experiences and using examples of EAA system identification processes, with the opportunity for group discussion. All participants will receive a copy of the EuroScan methods toolkit and a list of commonly used internet and other sources.

QUALITATIVE EVIDENCE SYNTHESIS FOR HTA

Christopher Carroll, Andrew Booth and Susan Harnan

University of Sheffield. 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 the quantitative evidence for clinical and cost-effectiveness only. This is a limited brief. It does not take into account how well or how poorly evaluated 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 is affected by patients' likes and dislikes, and views about a technology. The HTA and guideline process may seek to acknowledge such preferences 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. This workshop will outline an existing, evaluated approach for conducting the synthesis of qualitative evidence for an HTA. The method is "best-fit" framework synthesis. Participants will learn how to apply this method.

Workshop session

This workshop will outline an existing, evaluated approach for conducting the synthesis of qualitative evidence for an HTA. The method is "best-fit" framework synthesis. Participants will learn how to apply this method by: Scoping the problem. Identifying relevant conceptual or theoretical models or frameworks relevant to the technology and health behaviour of interest for generating *a priori* themes for analysis; Identifying relevant qualitative studies; Producing *a priori* themes against which to code relevant data from included studies; Critically appraise included studies; Synthesise the data and produce a new model or theory capturing patients' views, values and preferences relating to of the technology. The workshop will involve brief presentations on each of these six stages, using evaluated examples. Participants will follow these stages by working through an exemplar case study to demonstrate the method. Participants' work will be facilitated by the workshop team. Each stage will be discussed. The strengths and weaknesses of this method, and its relevance and applicability to qualitative evidence synthesis in HTA, will also be considered in a final plenary discussion.

THE COMET (CORE OUTCOME MEASURES IN EFFECTIVENESS TRIALS) INITIATIVE

Elizabeth Gargon, Elizabeth Gargon and Paula Williamson

University of Liverpool. UK.

Background: Selection of outcomes to measure when assessing the effects of healthcare interventions is crucial to trials, reviews and guidelines. For findings to influence policy and practice, outcomes need to be relevant to patients, public, practitioners and others making decisions. Trials in a specific condition often report different outcomes or the same outcome in different ways. Furthermore, measured outcomes may not always be important to patients or health service users. Much could be gained if an agreed core outcome set (COS) of a minimum number of appropriate and important outcomes was measured and reported in all trials in a specific condition.

Workshop session

This workshop will comprise a mixture of presentations, exercises and participant discussion. A presentation will set the scene for several key issues. Participants will be given example reviews to look at. They will work in groups to identify examples of non-standardised selection, measurement and reporting of outcomes, and to discuss problems this may cause for those attempting to synthesise evidence. Subsequent presentations will focus on existing work to design core outcome sets (COS) for clinical trials, and further group discussion of the methodological issues involved in developing COS. The importance of including key stakeholders in establishing COS, including patients, will be emphasised to ensure consideration of appropriate outcomes. The COMET Initiative will be described (http://www.comet-initiative.org/), the COMET database demonstrated and progress to date presented. The impact and implications of COS for research used to inform policy and clinical decision making will be discussed.

PUBLIC HEALTH GENOMICS AND HEALTH TECHNOLOGY ASSESSMENT

Hindrik Vondeling[a], Jonathan Lal[b], Karla Douw[c], Jean-Jacques Cassiman[d] and Angela Brand[b]

[a]University of Southern Denmark. Denmark. [b]Maastricht University. Netherlands. [c]University of Twente. Netherlands. [d]University of Leuven. Belgium.

Background: The workshop will offer the opportunity to obtain insight in the development of meta-level guidance for the introduction of public health genomics in health care systems. The multidisciplinary approach and the consequences for HTA will be highlighted.

Workshop session

The main objective of this workshop is to inform the audience on (HTA-relevant) results of the second phase of a Public Health Genomics European Network (PHGEN) project, PHGEN II. The first speaker, Dr. Lal, will present the theoretical framework for the project, defining ten essential public health services. He will also present a new model for translation of genome based technologies and information to clinical practice. Then the role of HTA in the process will be discussed, first by Dr. Douw, by means of a comparison of HTA frameworks as developed in Europe and the US, followed by Prof. Cassiman on criteria for the responsible introduction of screening programmes. This paves the way for a final presentation by Prof. Brand on the need for adopting the existing HTA frameworks in the era of personalised medicine. The workshop is intended to be complementry to a panel session on PHG.

HTAi-SMDM JOINT PRESENTATION: HOW COMBINING HEALTH TECHNOLOGY ASSESSMENT AND DECISION PSYCHOLOGY CAN ADVANCE PERSONALIZED MEDICINE AND PATIENT CENTERED CARE

Marilyn Schapira[a], Anne Stiggelbout[b], John Gabbay[c], Durhane Wong-Reiger[d] and Uwe Siebert[e]

[a]University of Pennsylvania. USA. [b]Leiden University. Netherlands. [c]University of Southampton. UK. [d]Institute for Optimizing Health Outcomes. Canada. [e]UMIT - University for Health Sciences. Medical Informatics and Technology. Austria.

Background: Health technology assessment (HTA) is a priority across the globe. The focus of HTA is to assess the relative value of alternative options for preventive, diagnostic, and treatment health interventions using a broad array of methods including systematic reviews, meta-analysis, clinical trials, and decision modeling. Personalized medicine refers to a clinical approach that is individualized from a behavioral, demographic, psychosocial, economic, environmental, and biologic perspective. In order for the results of HTA to advance goals of personalized medicine and patient centered care, studies must be designed with outcomes that are meaningful to patients and clinicians in the clinical encounter. Further, HTA has often been based on studies of summary results across populations without the needed granularity to support an individualized approach in the clinical encounter. Questions remain regarding the level of granularity that is desired and useful in the context of clinical decision making. In order to address these issues, efforts are needed to align methods used in HTA to effective strategies in communication and decision making in the clinical encounter. Two fundamental approaches may contribute to this effort. First, research questions and methods should be designed to lead to findings that are meaningful to patients and clinicians in the practice of personalized medicine. Second, insights from decision psychology should be applied to translate HTA findings effectively into patient-centered care. Questions related to methods in HTA include the following: 1) designing studies to increase the power of subgroup analysis, 2) choosing primary outcomes of analyses that are directly meaningful in the clinical setting, and 3) reporting results in ways that are useful for supporting or informing policies and decisions pertaining to the level of the individual patient. Questions pertaining to the field of decision psychology include: 1) how best to communicate uncertainty in expected outcomes to patients, 2) identifying the degree of differences in outcomes that are meaningful to patients and clinicians, 3) determining the value patients place on various levels of evidence such as randomized controlled trials, decision models, or expert opinion, 4) how to assist patients in balancing risks and benefits and assess their personal values and preferences, and 5) how costs and cost-effectiveness analyses may influence patient and clinician decision making in the context of personalized medicine. A rich literature in the fields of HTA and decision psychology can answer some of these questions while others require future research efforts.

Panel session

Objectives: The objectives of this workshop are to bring together experts in the fields of HTA and decision psychology to address best practices and directions for future research with regard to translation of HTA methods to support personalized medicine and patient centered care. The outcome of this workshop and subsequent planned collaborations between HTAi and SMDM will be a set of white papers to identify best practices and priorities for future research that can move this field forward.

Format of session: The session will include an expert panel and discussion between the panel and workshop participants. The expert panel will include international leaders in the field of HTA and decision psychology. Experts will present key issues relating to the use of HTA in the context of the clinical encounter, both summarizing existing literature and highlighting priorities for future research. Specific topics to be addressed will include designing HTA to ensure that it yields findings useful for informing policies and clinical decisions for personalized medicine; best practices for dissemination and knowledge transfer to support the use of HTA findings in clinical settings. Extensive time will be allotted for participant input and interaction.

INTRODUCTION TO HANDLING MISSING OUTCOME AND COST DATA IN THE ECONOMIC EVALUATION OF RANDOMISED CONTROLLED TRIALS

David Epstein[a] and Rita Faria[b]

[a]York University. UK. [b]Centre for Health Economics. UK.

Objectives: The course will provide practical solutions to the specific problems arising from missing and censored data on costs and quality –adjusted life years in randomised controlled trials (RCTs). Missing data reduces the effective sample size and can sometimes bias estimates of the treatment effect. Analysis of RCTs must carefully consider the possible reasons for missing data, and take appropriate account of the missing values in the methods of analysis. The course will start with an introduction to the theoretical background on missing data, followed by a brief description of the methods (complete case, mean imputation, conditional mean imputation, multiple imputation and inverse probability weighting (Lin-Willan method). Practical applications of the methods will be discussed, illustrated with examples from published trials.

Workshop session

This half-day course aims to: Illustrate how missing data can bias estimates of treatment effect; Briefly review the assumptions and implementation of simple and more complex methods for handling missing data in economic evaluations alongside RCTs; Propose sensitivity analyses to test the robustness of the results to the assumptions used; Give references and sources of code for further study and application. However, computing facilities will not be available during the workshop.

HTA 101: INTRODUCTION TO HEALTH TECHNOLOGY ASSESSMENT

Clifford Goodman

The Lewin Group. USA.

Background: Basic short course in HTA that has been offered and updated since the 1990s

Workshop session

Presented by Clifford Goodman, current President of HTAi, this course offers a lively introduction to HTA for those who are new to the field, as well as for those who seek a refresher course. Developed for international participants and updated annually, this course has been a popular feature of HTA meetings for many years. Discussion of basic concepts and trends will strengthen understanding and participation in other sessions of HTAi 2012. Time is included for questions and discussion. Attendees will receive copies of the workshop materials. This course will emphasize adapting HTA approaches for all types of health technologies and across international settings. The main topics to be covered include: 1. HTA definitions, purposes, and roles in health care policy. 2. Health technology: types, applications, lifecycle. 3. Factors affecting technology overuse, underuse. 4. Properties and impacts assessed in HTA. Technical performance. Health outcomes. Quality of life. Economic. 5. HTA methods. Primary methods. Secondary/synthetic methods (systematic reviews, meta-analyses,

modeling). Economic analyses: CEA, QALYs, and more. 6. Interpreting strength of evidence. 7. Priority setting, timing of assessment, and the moving target problem. 8. A framework for conducting HTA. 9. Sources of evidence and expertise. Bibliographic databases (peer-reviewed and gray literature). International networks/cooperation. 10. Current HTA trends and emerging challenges. Emerging role of comparative effectiveness research. Pharmacogenomics, personalized medicine, and more.