HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG)

E-Bulletin, January 2016

Our vision: ***Patient and citizen perspectives improve HTA***

Welcome to this month's E-Bulletin

From 8 February 2016 this is the year of the Monkey in the Chinese calendar

People born in a year of the Monkey are witty, intelligent, and have a magnetic personality. Personality traits, like mischievousness, curiosity, and cleverness, make them very naughty. Monkeys are masters of practical jokes, because they like playing most of the time. Though they don't have any bad intentions, their pranks sometimes hurt the feelings of others. Monkeys are fast learners and crafty opportunists. They have many interests and need partners who are capable of stimulating them. While some like the eccentric nature of Monkeys, some don't trust their sly, restless, and inquisitive nature. Although they are clever and creative, monkeys can't always exhibit their talent properly. Monkeys like to take challenges and they prefer urban life to rural. http://www.chinahighlights.com/travelguide/festivals/spring-festival/chinese-zodiac-years-of-2011-to-2020.htm

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Evidence generation and patient participation in HTA

The HTAi Tokyo conference reflects the growing interest in evidence generation around patient values and preferences in HTA. For a number of years, patient and citizen involvement focused on the participation of patients and citizens HTA decision-making and set about defining how to create an environment to support patient and citizen involvement in HTA processes. However alongside these initiatives has been an increase in methodological work seeking to elicit, and in some cases, quantify patient values and preference for use in assessment reports. Both approaches fit under the banner of patient involvement, and will be discussed in the upcoming book 'Patient involvement in HTA' edited by Karen Facey and Helle Ploug Hansen. It will be important for the HTAi Interest Group to maintain a presence across these different initiatives to ensure a central role for patient and citizen views in HTA processes.

Sally Wortley, University of Sydney

HTAi 2016 – Informing Health Care Decisions with Values and Evidence, May 10-14, 2016, Keio Plaza Hotel Tokyo, Japan: Pre-Conference Workshops May 10-11, 2016; Annual Meeting: May 12-14

Registration open: Early Bird Deadline March 4, 2016

Preconference workshops

WS05. Introduction To The HTAi Patient Group Submission Template For HTA Of Diagnostic Technologies (10 May 1.30 to 5pm)

Workshop to introduce and obtain feedback on a new HTAi patient group submission template for diagnostic technologies, developed by the HTAi patient and citizen involvement interest group to help patient groups provide information to HTA agencies when assessing diagnostics. The workshop will include patient representatives and HTA agencies to improve accuracy, usefulness and acceptance of the template by users.

This is a PCIG workshop led by Victoria Wurcel of EDMa and involving a working group that includes people from CADTH and NICE

The PCIG is running a full day workshop on Wednesday 11 May:

WS09. East Meets West: What We Can Learn From Each Other About Patient Perspectives And Adding Value To HTA (Wednesday 11 May 9am to 5pm)

This workshop brings together patient advocates to share experiences around access to medical interventions. The Patient and Citizen Interest Group will workshop how its tools can be used both within and outside formal HTA to provide important value-based information for evidence based decisions. Approaches the advocates are comfortable with applying in their own countries will be explored through case scenarios.

Other preconference workshops, spread over both the 10th and 11th May, include:

WS01. Engaging Patients And General Public In Health Technology Assessment: Measuring And Valuing Health (10 May 9am to 5pm)

Measuring and valuing health preference has become a recommended method to capture the impact of a health technology on the patient's daily life. This workshop will provide an introductory to intermediate learning opportunity covering direct and indirect measurement of health preferences and their application in HTA. Measuring and valuing health preference has become a recommended method to capture the impact of a health technology on the patient's daily life. This workshop will provide an introductory to intermediate learning opportunity covering direct and indirect measurement of health preferences and their application in HTA.

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It is led by Mireille Goetghebeur of University of Montreal (who has championed multi-criteria decision analysis) (she also has another workshop on Wednesday afternoon, WS18)

WS02. Incorporating The Patient Perspective Into Health Technology Assessment: A Workshop On Understanding (10 May 9am to 12.30)

Patient preferences are not systematically considered when making funding decisions. The use of econometrics to elicit preferences to better understand the experience of living with a particular disease, including the advantages and disadvantages of the current treatment options is a novel approach which can be applied to HTA to ensure patient values are fully considered in the decision making process.

WS02 is led by Institute for Choice in Australia and Janssen

WS11. Does Discussion Format Influence How Values Inform Evidence-Based Decisions? (11 May 9am to 12.30)

This workshop explores how discussion format (open dialogue, nominal group, multi-criteria decision analysis, and deliberate dialogue) influences HTA appraisal outcomes. Participants, working in simulated HTA committees, are presented with four drug submissions with varying attributes. For each drug, participants make a private recommendation and then a consensual recommendation using one of four discussion modes. Outcomes and experiences will be shared. The workshop is led by Durhane Wong Rieger

WS18. Interactive Exploration Of Values And Ethics In HTA: How Can Holistic MCDA Provide A Pragmatic Means (11 May 1.30 to 5pmWS18)
The workshop will present and discuss how an MCDA framework for HTA, incorporating ethics and values, can provide a solution for tackling ethical issues faced by decision-makers.

PCIG Values and Quality Standards for Patient Involvement in French

Hervé Nabarette of the Haute Autorité de santé (HAS) has translated our Values and Standards as well as the 2 existing Patient Group Submission Templates (medicines and non-medicines) to create a first version. He is now looking for someone fluent in French to work with him to finesse the translations.

Please let me know and I will put you in touch.

EUnetHTA social aspects domain now 'Patient and Social Aspects'

Contributed by Karen Facey:
For the past 18 months we have been working with the European Network for HTA (EUnetHTA) to undertake a major rewrite of the 'social aspects' domain of the HTA Core Model®. This has led to a refocusing of the domain to concentrate on patient aspects and so it has been renamed 'patient and social aspects'. The text has been completely revised to explain the new context and the methods for primary and secondary research into patients' issues have been updated. Finally new assessment elements (HTA research questions) have been created that draw on the HTAi Patient Group Submission Templates. See page 346 in:
http://meka.thl.fi/htacore/model/HTACoreModel3.0.pdf

This work has been led by Alessandra Lo Scalzo and Karen Facey as co investigators with Lisbeth Ortenblad, the lead investigator, in EUnetHTA. Many of you contributed to our consultation response on the original proposals in autumn 2014 and the review of the redrafted domain that emerged. Thank you for your contribution to this important work, which now provides the model for assessment of patient issues in full HTAs across Europe. For those outside Europe, it provides an excellent resource to guide research to investigate patient issues in HTA.

Farewell to Mona Sabharwal, Executive Director of pCODR

Mona Sabharwal is leaving pCODR where she has been executive director at the end of February. Carole McMahon and Jo Nanson are patient members of the pCODR Expert Review Committee and will miss Mona: "She has been a brilliant leader, with an inspiring dedication to incorporating the patient perspective in HTA".

Mona worked closely with members of the PCIG Patient Involvement and Education Working Group to adapt the pCODR Guide for Patient Advocacy Groups: How to provide patient and caregiver input for a pCODR drug review.

INTEGRATE-HTA

The INTEGRATE-HTA project officially ended on 31 December 2015.

Although the project has formally ended, we are planning future activities to disseminate and implement our results further and keep all interested stakeholders informed. The first activities include the delivery of the final issue of the project newsletter and the results of the project.

The INTEGRATE-HTA project developed concepts and methods that enable a patient-centred, comprehensive, and integrated assessment of complex health technologies which were applied in a palliative care case study. This include the following guidances:

- "Assessing effectiveness, economic, ethical, socio-cultural and legal aspects in complex health technologies";
- "Guidance on moderators, predictors and patient preferences for treatment outcomes, and their integration";
- "Assessment of context and implementation in systematic reviews and HTAs of complex interventions";
- "Use of logic models in systematic reviews and HTAs of complex interventions";
- "Guidance on choosing qualitative evidence synthesis methods for use in health technology assessments of complex interventions";
- "Integrated assessment of complex health technologies – The INTEGRATE-HTA model";

and a case study report:

- "Integrated assessment of home based palliative care with and without reinforced caregiver support: 'A Demonstration HTA".

We are in contact with several HTA agencies and collaborations (such as EUnetHTA) about the potential application of the guidances. Please keep up to date on our follow-up activities through our project website: www.integrate-hta.eu, that will remain online for another three years.

Contributed by Wija Oortwijn, on behalf of the INTEGRATE-HTA project team

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Better informing decision-making about cancer drugs

The McMaster Health Forum in collaboration with the Canadian Centre for Applied Research in Cancer Control (ARCC) have been awarded funding from the Canadian Partnership Against Cancer (CPAC) to engage Canadians in order to better inform decision-making about cancer drug funding. Julia Abelson (CHEPA/McMaster Health Forum) is one of the 3 lead investigators.
"This project is an important step towards identifying better decision-making models for cancer drug funding, which will incorporate the best-available evidence as well as the priorities and values of Canadian citizens," said Julia Abelson. The project will involve six public deliberation events in 2016.
https://www.mcmasterhealthforum.org/new-at-the-forum/2016/01/19/mcmaster-health-forum-and-arcc-awarded-cpac-grant

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Multi-stakeholder symposium on improving patient access to rare disease therapies

Karen Facey is on the programme committee for a 2-day multi-stakeholder symposium 24 to 25 February in Brussels that will discuss how the value of therapies for rare diseases is determined and implications for reimbursement. EURORDIS and partners will bring together industry, patient leaders, academics, regulators and payers to discuss the current state of play and how to shape a more effective way to address value determination, appraisal, pricing and reimbursement of orphan medicines.
Details about the 2-day symposium have now been released and registration is open:

http://www.eurordis.org/fr/publication/multi-stakeholder-symposium-improving-patient-access-rare-disease-therapies

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IAPO 7th Global Patients Congress London, UK 9 to 11 April 2016

This congress, organised by the International Alliance of Patients' Organisations, will bring together 200 patient advocates from across the world to share best practice and gain insight into pressing healthcare issues.
https://www.iapo.org.uk/what-gpc

European Patients' Forum position statement on: Clinical trial results – communication of the lay summary
http://www.eu-patient.eu/globalassets/policy/clinicaltrials/epf-lay-summary-position-final_external.pdf

The new EU Clinical Trials Regulation will be applicable from May 2016 and will increase the transparency of clinical trials, including their results. Lay summaries of all clinical trials will be publicly available.

EUPATI launches a new educational Toolbox on Medicines Research & Development
New online Toolbox on Medicines Research & Development.

The toolbox is available to European patient groups, patient advocates and anyone who is interested in learning more about the medicines research and development (R&D) process. Users can acquire the knowledge to make a meaningful contribution to medicines development and to the broader dialogue around patient empowerment. This online educational resource allows users to freely discover, adapt, and share materials.
"The toolbox is a comprehensive, self-explanatory, educational resource that has been built so that learnings on medicines R&D can be developed and shared by patient advocates. It is the result of a long-term, concerted effort by expert stakeholders including patients, researchers and academics. Our vision is that thousands of patient advocates in Europe will leverage the toolbox to enable more meaningful patient involvement and partnership in medicines R&D. The toolbox is EUPATI's second core product, after the Patient Expert Training Course, designed to support patients with information and knowledge," says Jan Geissler, Director, European Patients' Academy.

DIA manages the creation and editing of all content online.

The online toolbox is available in seven languages (English, French, German, Spanish, Italian, Polish and Russian) and contains over 3000 expert materials on the 'A-Z' of medicines R&D. For example, content includes information-rich modules and best-in-class educational materials on discovery research, clinical development, regulatory affairs, medicinal safety, pharmacovigilance and the principles of health technology assessment. Users can access a wealth of fact sheets, graphics, slideshows, videos, recorded webinars, print-ready materials as well as a full glossary. European patient groups and patient advocates are invited to use the toolbox to discover the latest educational resources, to educate and train patient communities, and to identify opportunities on how to get involved in medicines R&D.

You can access the 'EUPATI Toolbox on Medicines R&D' at www.eupati.eu.
Discover more about the 'EUPATI Toolbox on Medicines R&D' by watching the video.

About EUPATI - The European Patients' Academy on Therapeutic Innovation provides scientifically reliable, objective, comprehensive information to patients and the general public on the research and development process of medicines. It will increase the capacity of patients and the lay public to be effective advocates and advisors, e.g., in clinical trials, with regulatory authorities and in ethics committees. EUPATI is a team of 33 organisations, led by the European Patients' Forum, made up of a unique combination of patient organisations, university and not-for-profit organisations expert in patient and public engagement, along with European pharmaceutical companies working in research. EUPATI wants to offer information and education that will help involve patients and patient advocates throughout the medicines research and development process.

The "European Patients' Academy on Therapeutic Innovation" project is receiving support from the Innovative Medicines Initiative Joint Undertaking under grant agreement n° 115334, resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA companies.

Contributed by Karen Facey

Revision of SIGN handbook for patients and carers

The Scottish Intercollegiate Guideline Network (SIGN) has revised its handbook for patients and carers about how they can be involved in clinical guideline development. There are some great practical explanations of process and research methods in here that could be relevant to HTA, particularly those doing full HTA.
http://www.sign.ac.uk/pdf/sign100.pdf

Submitted by Karen Facey; also:

Patient involvement in formulary committees

In Scotland, local formulary committees make decisions after the national HTA committee (SMC) has made its recommendations. Although there is good patient involvement in SMC, there have been questions about patient involvement in the formulary committees – this new report reviews what's happening in these local committees.
http://www.scottishhealthcouncil.org/publications/research/public_involvement_in_adtcs.aspx#.Vo2UOFKX8Qs

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From the literature

Suzanne Parsons, Bella Starling, Christine Mullan-Jensen, Su-Gwan Tham, Kay Warner, Kim Wever. What do pharmaceutical industry professionals in Europe believe about involving patients and the public in research and development of medicines? A qualitative interview study. *BMJ Open* 2016;**6**:e008928 doi:10.1136/bmjopen-2015-008928

This study is by academic project partners in the Innovative Medicines Initiative funded European Patients' Academy on Therapeutic Innovations Project (EUPATI) to increase the capacity of patient advocates to become involved in medicines research and development (R&D). The European Commission and the Innovative Medicines Initiative recognise the importance of increasing patient and public involvement (PPI) in and public awareness of medicines R&D, in line with patient-centred health care. The study explored European-based pharmaceutical industry professionals' beliefs about patient and public involvement (PPI) by interviewing 21 professionals from the UK, Spain, Poland, and with pan-European roles.

These pharmaceutical industry professionals had different beliefs about PPI. There were those who were positive about PPI and had ideas about it, others who were positive about PPI but did not have any ideas, and those who did not believe patients should become involved in medicines R&D. Uncertainty about the benefits and value of PPI was greater in Spain and Poland. Interviewees believed that the pharmaceutical industry currently has few plans for PPI, with little agreement and understanding on how to implement and organise PPI. The pharmaceutical industry needs to increase its knowledge and understanding of PPI, although it was not clear who should take responsibility for this. Many of the interviewees had little contact with patients and the public in their daily working lives. Those professionals working in patient advocacy and market research were most likely to have contact with patients and patient organisations. Some attributed a lack of contact to their need to work within existing codes of practice. Furthermore for those who were positive about PPI, they identified that good working relationships are needed between pharmaceutical companies and patient organisations. No examples of joint working with patients could be described by the interviewees although joint working toolkits have been developed for the pharmaceutical industry and academia, healthcare providers and patients. The study identified that revisions to the codes may be needed to facilitate PPI, possibly involving patients, as pharmaceutical companies move from mainly acting as financial sponsors for patient organisations with minor roles in the funded activities or patient organisations providing input into specific aspects of industry-led projects.

Interviewees believed that without experience of working with the pharmaceutical industry patient organisation knowledge of medicines R&D was low, and negative media coverage of the industry played a role. High quality information on medicines R&D is needed, and on how and at what points patients could be involved.

Orphanet Journal of Rare Diseases
The quality of economic evaluations of ultra-orphan drugs in Europe - a systematic review
by Schuller Y, Hollak CEM and Biegstraaten M

Altogether, economic evaluations of ultra-orphan drugs are feasible if pharmacoeconomic modelling is used. The most suitable type of model seems to be a Markov-state-transition model. It should be realised, however, that most ultra-orphan drugs will not meet conventional criteria for cost-effectiveness. Still, ultra-orphan drugs are often reimbursed.

The Value of Considering Cost, and the Cost of Not Considering Value

by Leonard B Saltz, MD, Memorial Sloan Kettering Cancer Center, New York. From the Journal of Clinical Oncology
http://jco.ascopubs.org/content/early/2015/12/24/JCO.2015.64.7867?cmpid=jco_pap_28Dec2015

And to finish, a touch of thoughtful discussion from a Centre for Evidence-based Medicine, University of Oxford blog:

Virtues and Vices in Evidence Based Clinical Practice, a workshop led by Trish Greenhalgh Oxford UK, 27 January 2016
http://www.cebm.net/5395-2/
The impetus for the workshop was the idea that Aristotle's conception of virtues as personal "excellences" and vices as personal "defects" might help explain how, why and to what extent clinical practice is evidence-based. This blog explains why we sought to bring virtue theory alongside evidence-based health care, what we talked about (professional virtues, intellectual virtues and vices, the psychology of guideline adoption and professional vices), and possible next steps for this interdisciplinary field.

There was much discussion on all the above presentations. One theme that seemed to emerge from this discussion was that the distinction between professional and intellectual vices is not so clear-cut as we had originally assumed. Perhaps some virtues and some vices are more 'professional' (moral) and some more intellectual than others, but there are few if any that can be said to occur *only* in professionals.

Another strong theme from the floor discussion was that the implementation (and non-implementation) of evidence based clinical practice (however defined) is intimately tied up with power and conflicts of interests. An analysis of 'virtues' and 'vices' makes more sense when couched in relation to the prevailing power relations among and between the professions and institutions involved.

This preliminary meeting affirmed our view that the study of both virtues and vices promises to throw new light onto the study of adoption of innovation and delivery of evidence-based clinical care.

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