HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG)
E-Bulletin, February 2016

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

Welcome to this month's E-Bulletin

"Our Journal: Not A One-Woman Show" by Marjukka Mäkelä, Editor-in-Chief, The International Journal of Technology Assessment in Health Care
http://www.htai.org/news-events/news/news-item/article/our-journal-not-a-one-woman-show.html

Stepping down after seven fascinating years as Editor-in-Chief of The International Journal of Technology Assessment in Health Care (or IJTAHC among friends), I wish to express my gratitude to all of you who make our Journal. I continue until September editing this year's issues, and calling for a new EIC is a good point to look back as well as to think what lies ahead.
Warm thanks go to the authors, reviewers, editors, and the Editorial Board of IJTAHC for continued interest in and support to the Journal. This community of HTA doers and users wants to share their experience and develop the field, and IJTAHC is a unique channel for sharing. The new Editor-in-Chief will be positively surprised at the broad expertise and numerous areas of interest she or he will meet in editorial work. In my editorial period, IJTAHC was transformed from paper to bits. Today's challenges include keeping abreast of patient empowerment and personalized medicine as well as new opportunities in digital publishing. The collaboration between HTAi, IJTAHC, and our publisher, Cambridge University Press, will surely bring IJTAHC to members and all readers even more actively.
The link between the Journal and HTAi is strong; Chairs of the Society have always guarded the well-being of IJTAHC. The Society has generously started recognizing the Associate Editor's work by supporting their participation in its scientific meetings, and the stronger editorial team is supported by a clever Editorial Board. A scientific journal is not a one-woman- or one-man-show.
The call for a new Editor-in-Chief aims at finding an HTA field expert with a strong scientific background, an open mind, and good managerial skills, to run a journal with and for the HTA community. I hope many will hear the call, and I promise to support the new EIC in getting a good start.
Marjukka Mäkelä, Editor-in-Chief

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.

Plenaries, including:

Yvonne Bombard Canada

Madeleine de Rosas-Valera Philippines

Kristian Kidholm, Denmark

May 12, 2016
Unlocking the Value Potential of New Technologies in Health Care. Are Evidence-based Decisions Possible? New health technologies such as next generation sequencing, health apps, big data, telemedicine, e-health, m-health and other smart-technology solutions can challenge health care systems. With HTA, in many cases, we try to fill gaps or prevent different factors that can influence health outcomes. To what extent do new generation technologies relate to health status? How should they be measured? How do they change patient and citizen behaviour? Should HTA assess them when in many cases they have been promoted by the health care systems themselves or they are not reimbursed?
Chairs: Guy Maddern, Isao Kamae

Also, panel sessions, presentations, posters and additional symposia
http://meeting.htai.org/events/tokyo2016/event-summary-4023afce0ec04ab387500e87f0a6a42d.aspx

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CADTH Symposium April 10 to 12, Ottawa Canada

The 2016 CADTH Symposium will take place in Ottawa, Canada, from April 10-12. The Symposium, themed "Evidence for Everyone" will have workshops, plenary sessions, and concurrent and poster sessions with relevance for patients, caregivers, and the public. CADTH is happy to announce that the Symposium is "Patients Included". For those not familiar with it, the Patients Included charter provides conference organizers with a means of demonstrating that their events are committed to incorporating the experience of patients, who are experts in living with their condition, while ensuring they are neither excluded nor exploited. The Patients Included information for the Symposium can be found here: https://www.cadth.ca/2016-cadth-symposium/patients-included.

Registration and other information for the Symposium can be found here: www.cadth.ca/2016-cadth-symposium

Ken Bond
Director, Patient Engagement and International Affairs, CADTH

INTEGRATE-HTA Project Update

We are excited to inform you that the INTEGRATE-HTA guidances, as well as the Case Study Report on Palliative Care, in which we applied the developed guidances, are now available on our project website: www.integrate-hta.eu.
We will undertake several activities to disseminate and implement the results of the project. For example, the final edition of our project newsletter has just been released and is available on our project website. We will also present the results of the project at this year's HTAi Annual Meeting in Tokyo, Japan (10-14 May) through an oral presentation "*An integrated perspective on the value of health technology – the results of the INTEGRATE-HTA project*" and a poster presentation "*Why is it difficult to integrate ethics in HTA? The epistemological reasons".* Furthermore, we are in contact with several HTA agencies and collaborations (such as EUnetHTA) about the potential application of the guidances.
To keep up to date on our future activities, please check the INTEGRATE-HTA project website, which will remain online for the coming years. If you have any questions or would like to receive more information, please contact us at info@integrate-hta.eu.

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

Two of the reports are:
report 7: Guidance on choosing qualitative evidence synthesis methods for use in health technology assessments of complex interventions and
report 3: Guidance for the assessment of treatment moderation and patients' preferences

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"Many Thanks to International Journal of Technology Assessment in Health Care Editor-in-Chief Marjukka Mäkelä", Guy Maddern, HTAi President

After more than six years as Editor-in-Chief of the International Journal of Technology Assessment in Health Care, Marjukka Mäkelä will be stepping down from her post this September. On behalf of the HTAi Community, I would like to thank Marjukka most sincerely for her dedication to the journal and her continued contributions to the society. We wish her well and are thrilled that she will continue to review submissions and provide experienced transition support for the incoming Editor-in-Chief.

Career Opportunity: Editor-in-chief, International Journal of Technology Assessment in Health Care. Closing Date: March 1, 2016

The International Journal of Technology Assessment in Health Care is owned and published by Cambridge University Press in affiliation with HTAi and supported by an international Editorial Board of leading academics in the field.
Cambridge University Press is seeking applications for the position of Editor-in-chief to advance further the Journal's scientific reputation while maintaining its relevance to academia. The successful candidate will take up the appointment at the HTAi 2016 Annual Meeting in Tokyo, Japan.
Review: Employment Posting
Submit Application: jointly info@htai.org & THCeditor@cambridge.org

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Report: What is the patient's role in informing the decision process for approval and reimbursement of new medicines? 7-8 October 2015

Members of the HTAi special interest group may be interested in this report from an international workshop on the patient role in HTA. It was run by the UK group the Centre for Innovation in Regulatory Science.
http://www.cirsci.org/wp-content/uploads/2016/02/CIRS_October_2015_Workshop_Programme.pdf

Submitted by Dr Amy Hunter | Senior Research Manager, Genetic Alliance UK

Publications from the DECIDE project

I just wanted to let you know about the recent publication of one of the articles from work package 3 of the DECIDE project (http://www.decide-collaboration.eu/WP3) on communicating with patients and the public about evidence based recommendations.

Fearns N, Graham K, Johnston G, Service D. Improving the user experience of patient versions of clinical guidelines: user testing of a Scottish Intercollegiate Guideline Network (SIGN) patient version. BMC Health Services Research.2016, 16:37
http://www.biomedcentral.com/1472-6963/16/37

The DECIDE website will be updated shortly to fully reflect the findings of the project. A list of the publications, outputs and upcoming publications can be found at
http://www.decide-collaboration.eu/patients-and-public

Also:
A publication on the lack of clear publications on methods for knowledge synthesis:

Tricco A et al. A scoping review identifies multiple emerging knowledge synthesis methods, but few studies operationalise the method. Journal of Clinical Epidemiology, in press
http://www.sciencedirect.com/science/article/pii/S0895435616000986

Submitted by Naomi Fearns | Health Services Researcher | Healthcare Improvement Scotland

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Other publications

Sally Wortley, Allison Tong and Kirsten Howard. Preferences for engagement in health technology assessment decision-making: a nominal group technique with members of the public. BMJ Open 2016;**6**:e010265 doi:10.1136/bmjopen-2015-010265
http://bmjopen.bmj.com/content/6/2/e010265.abstract

The public's preferences on when to undertake engagement relate to both the content of the HTA itself as well as the processes in place to support HTA decision-making.

This research involved 6 focus groups using a nominal group technique to identify and rank factors relevant to public engagement in HTA decision-making. The purpose was to identify characteristics (factors) about health technology assessment (HTA) decisions that are important to the Australian public in determining whether public engagement should be undertaken and the reasons for these choices. The participants were 58 people, aged 19–71 years.
Members of the public were more likely to think public engagement was needed when trade-offs between benefits and costs were required to determine 'value', uncertainties in the evidence were present, and family members and/or carers were impacted. The role of public engagement was also

seen as important if the existent system lacked transparency and did not provide a voice for patients, particularly for conditions less known in the community.
By understanding these preferences, decision-makers can work towards more effective, meaningful public engagement by involving the public in issues that are important to them and/or improving the processes around decision-making.

Jonathan Boote, Steven Julious, Michelle Horspool, Heather Elphick, W Henry Smithson and Paul Norman, on behalf of the PLEASANT study team. PPI in the PLEASANT trial: involving children with asthma and their parents in designing an intervention for a randomised controlled trial based within primary care. Primary Health Care Research & Development, doi:10.1017/S1463423616000025.

The authors describe how patient and public involvement (PPI) was integrated into the design of an intervention for a randomised controlled trial (RCT) based within primary care. The RCT, known as the PLEASANT trial, aimed to reduce unscheduled medical contacts in children with asthma associated with start of the new school year in September with a simple postal intervention, highlighting the importance of maintaining asthma medication for helping to prevent increased asthma exacerbations.

PPI is a key feature of UK health research policy, and is often a requirement of funding from the National Institute for Health Research. There are few detailed accounts of PPI in the design and conduct of clinical trials in the PPI literature for researchers to learn from. We held PPI consultation events to determine whether the proposed intervention for the trial was acceptable to children with asthma and their parents, and to ascertain whether enhancements should be made. Two PPI consultation events were held with children with asthma and their parents, prior to the research commencing. Detailed field notes were taken by the research team at each consultation event.

At the first consultation event, parents and children endorsed the trial's rationale, made suggestions to the wording of the trial intervention letter, and made recommendations about to whom the letter should be sent out. At the second consultation event, parents discussed the timing of the intervention, commented on the lay summary of the Research Ethics Application, and were invited to join the trial's steering committee, while the children selected a logo for the study. PPI has resulted in enhancements to the PLEASANT study's intervention. A further PPI consultation event is scheduled for the end of the trial, in order for children with asthma and their parents to contribute to the trial's dissemination strategy.

Tarang Sharma ,Louise Schow Guski, Nanna Freund, Peter C Gøtzsche. Suicidality and aggression during antidepressant treatment: systematic review and meta-analyses based on clinical study reports. http://www.bmj.com/content/352/bmj.i65

I am sharing this in case more patient groups are interested in getting involved with this agenda and if interested, they can contact me. [mailto:tarangs@gmail.com]
The article is part of research towards a PhD looking at publication bias and selective reporting of harms data and how it impacts evidence based decision making - making it more unreliable and biased (as part of the transparency movement of clinical trial data).

The objective was to study serious harms associated with selective serotonin and serotonin-norepinephrine reuptake inhibitors. The researchers identified systematic review and meta-analysis of double blind placebo controlled trials that contained any patient narratives or individual patient listings of harms. The main outcomes were mortality and suicidality. Secondary outcomes were aggressive behaviour and akathisia.

We included 70 trials with 18 526 patients. These trials had limitations in the study design and discrepancies in reporting, which may have led to serious underreporting of harms. For example, some outcomes appeared only in individual patient listings in appendices, which we had for only 32 trials, and we did not have case report forms for any of the trials.
The harms could not be estimated accurately because of the shortcomings identified and having only partial access to appendices with no access to case report forms. In adults there was no significant increase in all four outcomes (in mortality, suicidality, akathisia, aggressive behaviour), but in children and adolescents the risk of suicidality and aggression doubled. To elucidate the harms reliably, access to anonymised individual patient data is needed.

In the summary trial reports on Eli Lilly's website, almost all deaths were noted, but all suicidal ideation events were missing, and the information on the remaining outcomes was incomplete.

Greenhalgh T, Snow R, Ryan S, Rees S, Salisbury H. Six 'biases' against patients and carers in evidence-based medicine.
BMC Med. 2015 Sep 1;13:200. doi: 10.1186/s12916-015-0437-x. Free access.

Evidence-based medicine (EBM) is maturing from its early focus on epidemiology to embrace a wider range of disciplines and methodologies. At the heart of EBM is the patient, whose informed choices have long been recognised as paramount. However, good evidence-based care is more than choices.
The researchers discuss six potential 'biases' in EBM that may inadvertently devalue the patient and carer agenda: limited patient input to research design, low status given to experience in the hierarchy of evidence, a tendency to conflate patient-centred consulting with use of decision tools; insufficient attention to power imbalances that suppress the patient's voice, over-emphasis on the clinical consultation, and focus on people who seek and obtain care (rather than the hidden denominator of those that do not seek or cannot access care). To reduce these 'biases', EBM should embrace patient involvement in research, make more systematic use of individual ('personally significant') evidence, take a more interdisciplinary and humanistic view of consultations, address unequal power dynamics in healthcare encounters, support patient communities, and address the inverse care law (those who do not seek and obtain care).

Greenhalgh T et al. An open letter to The BMJ editors on qualitative research

Seventy six international academics invite *The BMJ*'s to reconsider their policy of rejecting qualitative research on the grounds of low priority. They challenge the journal to develop a proactive, scholarly, and pluralist approach to research that aligns with its stated mission.
BMJ. 2016 Feb 10;352:i563. doi: 10.1136/bmj.i563.
http://www.bmj.com/search/Greenhalgh%20T%202016

Basch E et al. Symptom Monitoring With Patient-Reported Outcomes During Routine Cancer Treatment: A Randomized Controlled Trial. Journal of Clinical Oncology 2016;34(6):557-565.
http://jco.ascopubs.org/content/34/6/557.abstract?ijkey=ea1ede0923oc9aec9492f21821a2e2e6031c2dca&keytype2=tf_ipsecsha

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Atomium: Bridging Research and Policy

Mendeley is partnering with the European Institute for Science Media and Democracy for a citizen engagement campaign on chronic diseases. This is being done in conjunction with the launch of a new digital platform that aims at creating a bridge between researchers, citizens, and policy makers concerning topics linked to scientific research and the challenges Europe and the rest of the world face in the next years.
We are featuring essays by Advisors on our Mendeley Blog on each week to showcase their research

and how it plugs into this global conversation on chronic diseases and public health.
The topics are:

- Prevention is the better cure
- New technologies and Innovation
- Citizens' rights and responsibilities (week of 29 Feb)
- Diabetes and Nutrition (week of 7 March)
- More and better data (week of 14 March)

You can also participate in this conversation by filling out weekly questionnaires on chronic disease at the REISearch forums.

Submitted by Catherine Voutier | Clinical Librarian

FDA's Center for Drug Evaluation and Research (CDER) Workshop for Advocacy Groups

On March 31, 2016, FDA's Center for Drug Evaluation and Research (CDER), is sponsoring a public workshop, "Navigating CDER: What You Should Know for Effective Engagement." The purpose of this public workshop is to help the public and patient advocacy groups gain a better understanding of how to effectively engage CDER. Participation by webcast is available.

For more information and how to register: http://www.fda.gov/Drugs/NewsEvents/ucm472604.htm

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Accelerating Anticancer Agent Development and Validation (AAADV) Workshop 4 to 6 May 2016

Leaders in clinical and translational cancer research from academia, industry, government and the non-profit advocacy sector will convene in Bethesda, Maryland, May 4-6, 2016 for the 13th annual Accelerating Anticancer Agent Development and Validation (AAADV) Workshop.

The AAADV Workshop is the only workshop held in collaboration with the U.S. Food and Drug Administration designed specifically to help participants understand and negotiate the drug development approval process so that effective new cancer treatments can reach patients more quickly. The Workshop is designed for scientists and patient advocates with clinical trial experience interested in developing agents for the diagnosis, treatment or prevention of cancer.

Go to https://www.acceleratingworkshop.org/register-apply/ to register or https://www.acceleratingworkshop.org/ to find out more about the Workshop.

New for 2016: Two pre-Workshop programs cover the basics of drug development

- AAADV Fundamentals for Patient Advocates
- AAADV Scholars for Scientists

SPONSORS
U.S. Food and Drug Administration | Accelerate Brain Cancer Cure | Susan G. Komen | American Association for Cancer Research | American Society of Clinical Oncology
Duke University

Call for HTAi Board of Director Nominations. Closing Date: March 16, 2016

HTAi is currently seeking three candidates for election to the Board of Directors, as these Directors' terms are coming due. If you would like to serve or nominate a fellow HTAi member as Director (2016-19), please complete a Nomination Form and submit it to the Managing Director, together with the candidate's biography and vision statement by the deadline date.

Noted below is a general overview of the role of the Board and the commitment required of its members. Please review HTAi Board of Director Bylaws for more detailed information.

HTAi Board
Four elected Officers and seven elected Directors represent HTAi and its membership on the Board. They administer the affairs of the society and manage its operational and financial performance; and are tasked with overseeing implementation of the strategic plan. Presently, three observers and the past President also sit on the board ex-officio. Participation on the Board is voluntary; there is no remuneration.

Director Commitments
• Attend the AGM, Board Meetings in-person and via conference call, as required
• Participate on various Board Committees, as required

Director Qualifications:
• Be an HTAi member in good standing
• Have expertise within the field of health technology assessment
• Understand and support the mission and goals of HTAi

Election: Current HTAi membership will be called upon to vote electronically prior to the 2016 Annual Meeting this May. Members will be notified upon completion of the election process.

Please note, successful candidates are expected to attend the Board of Directors' Meeting in Tokyo, Japan on Tuesday, May 10, 2016. The new term begins May 12, 2016 at the Annual General Meeting.

Send submission materials to Managing Director Lucy Turner: lturner@htai.org

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Janet Wale, Chair HTAi PCIG
E-mail: socrates111@bigpond.com
