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

E-Bulletin, March 2016

Enhanced quality and relevance of HTA through patient and citizen involvement

Welcome to this month's E-Bulletin

2016 CADTH Symposium, themed 'Evidence for Everyone' April 10 to 12, 2016 - Shaw Centre, Ottawa, Ontario

The CADTH Symposium is officially a 'Patients Included' event, meeting every condition of the Patients Included Charter (Patients Included | CADTH.ca). https://www.cadth.ca/2016-cadth-symposium/patients-included

The program includes plenary sessions, oral and panel sessions: https://www.cadth.ca/2016-cadth-symposium/program

There is also an opportunity for people to connect by webinar for two sessions (https://www.cadth.ca/news-and-events/events)

Oral Presentations on Patient and Public Engagement
Date: Monday, April 11, 2016
Time: 1:30 p.m. to 3:00 p.m. EDT

Panel Discussion on Making Evidence Meaningful: Optimal Use and Adoption of Medical Imaging Equipment

Date: Tuesday, April 12, 2016
Time: 1:00 p.m. to 2:30 p.m. EDT

"There is no fee to participate, but registration is required. For more information on each of the presentations and to register, please visit our website."

Call for Applications for the Position of Scientific Secretary to the HTAi Policy Forum, 2016-17

Deadline: April 3, 2016
To submit an application and for all inquiries, contact: **HTAiPF@southampton.ac.uk**

The HTAi Policy Forum provides a unique opportunity for senior people from public and private

sector organizations using HTA to support decisions or recommendations about product development and coverage to meet one another, members of the HTAi Board, and invited international experts, for strategic discussions about the present state of HTA, its development and implications for health care systems, industry, patients and other stakeholders. The aim of the Forum is to provide an environment where senior people can engage in strategic discussions informed by the perspectives of their different organizations without the constraints associated with discussions of specific products or organizational policies.
Discussions at Forum meetings lead to range of outputs, typically including a short report and/or slide deck of the meeting for Forum members, a peer reviewed journal paper, and presentations and discussions at the HTAi Annual Scientific meeting.
For detailed information on the HTAi Policy Forum, its membership and activities see:
http://www.htai.org/policy-forum/policy-forum.html

HTAi Policy Forum 2017 Topic and Meeting

The HTAi Policy Forum has chosen as the topic for its main meeting in late January 2017: 'From theory to action: new developments in value frameworks to inform willingness to pay (WTP) and decisions on coverage, affordability, price and access'.
The Forum will have a scoping discussion of the topic in the course of its meeting on the morning of Wednesday 11th May 2016 ahead of the HTAi Annual Scientific Meeting in Tokyo.

The duties of the Scientific Secretary 2016-17 are expected to take a suitably qualified and experienced person up to a maximum of 20 days across the twelve-month period from May 2016 to June 2017.

How to apply

Interested applicants should:
-Submit a short Letter of Intent (LOI) no more than two pages in length (single-spaced, 11 point font) stating qualifications and experience and expected level of remuneration, together with a Curriculum Vitae.
-The letter and CV should be sent to the HTAi Policy Forum Secretariat via email to the following address: HTAiPF@southampton.ac.uk. Any questions or queries should also be sent to this email address.
-All applications should be received by 3rd April 2016.
-It is anticipated that shortlisted applicants will be interviewed by telephone between 14.00 and 16.00 (BST) Thursday 12th April 2016. Potential applicants are asked to hold this time in their calendars until we have notified applicants of the outcome of shortlisting.

The INTEGRATE-HTA project

As reported in previous newsletters, the INTEGRATE-HTA project officially ended on 31 December 2015 and the team are busy disseminating information from 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. Both lay and professional stakeholders were involved throughout the HTA process.

The following abstracts have been accepted for the 9th World Research Congress of the European Association for Palliative Care (EAPC) to be held in Dublin on June 9-11th 2016.

The following abstracts have been accepted for oral presentation in a free communication session

1. "Effectiveness of Home-based Palliative Care" by Burns, J.; Polus, S.; Brereton, L.; Ward, S.; Chilcott, J.; Pfadenhauer, L.M.; Rehfuess, E.A.

2. "The Economic Potential of Interventions to Support Carers in Home Palliative Care" by Ward, S., Chilcott, J., Burns, J., Pfadenhauer, L., Clark, J., Goyder, E., & Brereton, L.

The following abstracts have been accepted for print only. The abstract will be published online in a special edition of Palliative Medicine by Sage Journals.

1. "Stakeholder Involvement in Health Technology Assessment: A Palliative Care Case Study Exemplar" by Brereton, L., Ingleton, C., Burns, J., Ward, S., Mozygemba,K., Refolo, P., Oortwijn, W., Lysdahl, K., Tummers, M., Leppert, W., Chilcott, J., Gardiner, C., Goyder, E. On behalf of the INTEGRATE-HTA team.

2. "Complexity in Palliative Care: Implications for Health Technology Assessment" by Brereton, L., Chilcott, J., Lysdahl, K., Wahlster, P., Burns, J., Ward, S., Tummers, M., Oortwijn, W., Sacchini, D., Ingleton, C., Gardiner, C., Goyder, E. On behalf of the INTEGRATE-HTA team.

3. "Contextual Enablers and Barriers to the Implementation of Home-based Palliative Care Interventions" by Pfadenhauer, L.M.; Brereton, L.; Lysdahl, K.B.; Busert, L.K.; Burns, J.; Mozygemba, K.; Gerhardus, A.; Polus, S.; Rehfuess, E.; Booth, A.

Please keep up to date on our follow-up activities through our project website: www.integrate-hta.eu, which will remain online for another three years.

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

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Patient engagement and patient-reported outcome research for people with haemophilia

Mark Skinner would like to share the following information.

I have been leading the PROBE (Patient Reported Outcomes Burdens and Experiences) project. Our first poster demonstrating feasibility was accepted for The European Association for Haemophilia and Allied Disorders (EAHAD) (http://onlinelibrary.wiley.com/doi/10.1111/hae.1_12882/abstract).

Citation: M. W. Skinner, R. Curtis, N. Frick, A. Iorio, M. Nichol, D. Noone, B. O'Mahony, D. Page, J. Stonebraker on behalf of the Patient Reported Outcomes, Burdens, and Experiences (PROBE) Investigator Group (2016). The Patient Reported Outcomes, Burdens, and Experiences (Probe) Phase 1 Study Methodology and Feasibility, Poster Presentations (P039). Haemophilia, 22: 19–111. doi: 10.1111/hae.1_12882.
A poster from the PROBE group has also been accepted for the HTAi meeting in Tokyo.

In addition, we authored a letter (just published in early view on-line) in response to a prior review article on outcomes research. We were concerned the original review article overlooked the importance of patient engagement. http://onlinelibrary.wiley.com/doi/10.1111/hae.12922/full

O'Mahony, B., Skinner, M. W., Noone, D., Page, D. and O'Hara, J. (2016), Assessments of outcome in haemophilia – a patient perspective. Haemophilia. doi: 10.1111/hae.12922.

New President and Vice President for the European Patients' Forum (EPF)

At its Annual General Meeting in March members elected 5 new board members, a new President and Vice President for a two year mandate.

Marco Greco who has been Chairman of the European Federation of Crohn's and Ulcerative Colitis Associations (EFCCA) since 2008 is the new president.The immediate past President, Anders Olauson, was awarded the title of Honorary President.

EPF currently represents 67 members, which are national coalitions of patients' organisations and disease-specific patient organisations working at European level.

Taiwan Alliance of Patients' Organizations (TAPO)

There are different kinds of patient associations in Taiwan, and they offer health education services and do lots of advocacy work for patients. However, with the diversity of diseases and medicament of requirement, it is hard to form a powerful voice in a single association.

In order to pursue a sound national health insurance, Dr Yaung, Chih-Liang, the former director of National Health Insurance, assembled a forum of Taiwan patients with many of the patients associations in 2015. We expect the officials can include the representative of patients' voices through integrated communication with the official unit.

Currently, the role of patients is being left out of the decision making process in National Health Insurance when, in fact, patients should be at the center of health policies. Therefore, we established the Taiwan Alliance of Patients' Organizations, hoping to strengthen the voice of patient non-government organizations (NGOs) in medical institutions.

Who we are

Our membership is growing. We are an official NGO, as a network of patients' organizations working at local, national and regional levels to represent and support patients, their families and carers. The organizations cover a wide range of disease types and conditions, and we will work together to strengthen the patient voice.

What we do

We represent people who suffer from diseases, disabilities, illnesses, impairments or syndromes. We work with communities of patients or associations to get their voices heard by all involved in health care. And, with the help of our members and collaborating organizations, our work will not be complete until patient-centred healthcare is well empowered.

Kevin Yeh

TAPO

Relevant publication by Smith SK, Selig W, Harker M, Roberts JN, Hesterlee S, Leventhal D, et al. (2015)

Patient Engagement Practices in Clinical Research among Patient Groups, Industry, and Academia in the United States: A Survey. PLoS ONE 10(10): e0140232. doi:10.1371/journal.pone.0140232

Patient-centered clinical trial design and execution is becoming increasingly important. No best practice guidelines exist despite a key stakeholder declaration to create more effective engagement models. This study aims to gain a better understanding of attitudes and practices for engaging patient groups so that actionable recommendations may be developed.

Methods

Individuals from industry, academic institutions, and patient groups were identified through Clinical Trials Transformation Initiative and Drug Information Association rosters and mailing lists. Objectives, practices, and perceived barriers related to engaging patient groups in the planning, conduct, and interpretation of clinical trials were reported in an online survey.

Descriptive and inferential statistical analysis of survey data followed a literature review to inform survey questions.

Results

Survey respondents (n = 179) valued the importance of involving patient groups in research; however, patient group respondents valued their contributions to research protocol development, funding acquisition, and interpretation of study results more highly than those contributions were valued by industry and academic respondents (all $p < .001$). Patient group respondents placed higher value in open communications, clear expectations, and detailed contract execution than did non–patient group respondents (all $p < .05$). Industry and academic respondents more often cited internal bureaucratic processes and reluctance to share information as engagement barriers than did patient group respondents (all $p < .01$). Patient groups reported that a lack of transparency and understanding of the benefits of collaboration on the part of industry and academia were greater barriers than did non–patient group respondents (all $p< .01$).

Conclusions

Despite reported similarities among approaches to engagement by the three stakeholder groups, key differences exist in perceived barriers and benefits to partnering with patient groups. This recognition could inform the development of best practices for patient-centered clinical trial design and execution. Additional research is needed to define and optimize key success factors.

The FDA contributed to funding of this manuscript.

More Trials: The public campaign for more, better, randomized trials (http://moretrials.net):

MoreTrials will bring together everybody involved or interested in randomised controlled trials (RCTs) to develop a new modern set of principles of how to do trials well. The aim is to improve the quality of RCTs - there is currently a new proposed update to the ICH guidance for RCTs and this undermines the quality of the trials and potentially could expose patients at greater risk in future trials.

This work was initiated in Oxford. Those groups interested in participating can directly correspond with Tim at: Tim.Sprosen@ctsu.ox.ac.uk (Nuffield Department of Population Health, University of Oxford)

A letter has been sent to the European Medicines Agency (EMA) and International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), which is on the website. The letter concludes with the following points:

Lack of engagement with the broader community: ICH does not include representation from the wider community of academic investigators or funders who have expertise in the design and conduct of clinical trials that address important public health questions. Nor is there evidence of any meaningful involvement of trial participants and the public. By contrast, other groups (most notably the FDA-supported Clinical Trial Transformation Initiative [CTTI]), have demonstrated the value of taking account of the perspectives of all those involved in the clinical trial enterprise (including not just industry and regulators but also academic investigators, trial participants and the wider public) in the development of clinical trial guidance and its interpretation.

A better way forward

It is not appropriate to leave the future development of GCP [good clinical practice] guidelines for clinical trials to a group representing industry and regulatory authorities only that is focussed solely on the registration of new drugs. Instead, a new GCP guideline should be developed that is firmly founded on those key principles that really matter to trial quality (i.e. have a meaningful impact on the rights, safety and wellbeing of trial participants and on the reliability of the results for the subsequent treatment of future patients) and that is relevant for different types of clinical trial. This new guideline should be developed in an open and transparent process that involves everybody interested in clinical trials.

Submitted by Tarang Sharma

The Forum, McMaster University Canada

Publications

The Forum continues to gain momentum in giving diverse groups of citizens a voice in the future direction of the health system. Our recent citizen panel on Improving Pain and Symptom Management in Cancer Care in Ontario helped to inform the discussion and outcomes of the Stakeholder Dialogue.

Citizen Panel - Improving Pain and Symptom Management in Cancer Care in Ontario. Moat KA, Abelson J, Lavis JN. Hamilton, Canada: McMaster Health Forum, 19 September 2015. Citizen brief. Panel summary. Topic overview.

Stakeholder Dialogue - **Improving Pain and Symptom Management in Cancer Care in Ontario.** Moat KA, Wilson MG, Lavis JN. Hamilton, Canada: McMaster Health Forum, 26 November 2015. Evidence brief. Dialogue summary. Topic overview

Improving Pain and Symptom Management in Cancer Care in Ontario

As the number of individuals diagnosed with cancer continues to rise in Ontario, advances in screening, detection and treatment have also increased the number of people living longer after a diagnosis. Many individuals living with cancer experience significant amounts of pain and other distressful symptoms that may negatively affect their lives, and the need for comprehensive, patient-centred and evidence-based pain and symptom management is emerging as a priority issue.

The Forum hosted a stakeholder dialogue to address this challenge, focusing on three potentially viable approaches to improve cancer pain and symptom management in Ontario:

- strengthening knowledge translation efforts to patients, caregivers and providers;
- supporting increased uptake of pain and symptom guidelines; and
- optimizing the integration of best practices for pain and symptom management into cancer care models.

Sign up to receive our curated monthly evidence services that provide links to recently identified evidence on topics covered by our stakeholder dialogues.

Canadian Centre for Applied Research in Cancer Control (ARCC) in collaboration with the McMaster Health Forum was awarded funding from Canadian Partnership Against Cancer (CPAC) to engage Canadians on their priorities for cancer drug funding decisions. Julia Abelson is a lead investigator

ARCC and McMaster Health Forum awarded CPAC grant

https://www.mcmasterhealthforum.org/new-at-the-forum/2016/01/19/mcmaster-health-forum-and-arcc-awarded-cpac-grant

The latter information submitted by Deb Maskens

And another publication

Erika K Cottrell EK et al. Defining the benefits and challenges of stakeholder engagement in systematic reviews. Comparative Effectiveness Research 16 April 2015

Background: Although there is a growing literature on the process of engaging stakeholders in medical research, there are a lack of clearly-defined measures for reporting and evaluation, which limits the ability to learn from past experience, understand the effectiveness of engagement, or identify which approaches work best. Clearly defining the benefits and challenges of engaging stakeholders in the systematic review process is an integral first step toward developing a set of

criteria that can be used to evaluate the impact and effectiveness on the conduct, quality, and dissemination of systematic reviews.

Methods: We utilized two complementary approaches to examine the benefits and challenges of engaging stakeholders in the systematic review process: 1) a literature scan to understand the overall state of the field; and 2) a series of key informant interviews with systematic reviewers, program/policy officials, and stakeholders.

Results: We identified six main expected benefits and five primary challenges of involving stakeholders in systematic reviews. Benefits included: establishing credibility; anticipating controversy; ensuring transparency and accountability; improving relevance; enhancing quality; and increasing dissemination and uptake of findings. Challenges included: time; training and resources; finding the right people; balancing multiple inputs; and understanding how to match the right type of stakeholder to the right time in the systematic review process.

Discussion: The results of this study are an important first step toward developing mechanisms for evaluating the effectiveness of stakeholder engagement in systematic reviews. Future work should seek both to verify the appropriateness of these benefits and challenges and identify concrete criteria for evaluating the effectiveness of different methods, timing, and intensity of stakeholder engagement.

Janet Wale, Chair HTAi PCIG

E-mail: socrates111@bigpond.com