HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG)
E-Bulletin, November 2015

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

Welcome to this month's E-Bulletin

HTAi 2016 – Informing Health Care Decisions with Values and Evidence, May 10-14, 2016, Keio Plaza Hotel Tokyo, Japan

Today is the last day to submit abstracts for poster & oral presentations: November 30, 2016

Registration: Early Bird Deadline March 4, 2016
Annual Meeting: Pre-Conference Workshops May 10-11, 2016; Annual Meeting: May 12-14, 2016

Travel Grants – for not-for-profit patient organisations and people from low and middle-income countries with an interest in health policy and health technology assessment
Application Deadline: January 8, 2016
http://meeting.htai.org/events/toky02016/custom-115-4023afce0ec04ab387500e87f0a6a42d.aspx
Please let us know if you would like help with your application.

Ethical issues for patient groups to consider when collecting and reporting information for HTA submissions
In collaboration with the HTAi Ethics Interest Group, the PCIG has prepared advice on ethical issues specifically for patient groups who are collecting and reporting patient information in patient group HTA submissions without the aid of formal researchers and scientists.
We seek your comments about the following:

- Name of the guide. Is it meaningful and appropriate or can you suggest another title?
- Content of the guide. Does it contain the information you need?
- Language used in the guide? Is it easy to read and understand?
- Format of the guide? Does this format work for you or can you suggest an alternative?

The draft documents can be downloaded at:
www.htai.org/fileadmin/HTAi_Files/ISG/PatientInvolvement/Short_Guide_September_2015.docx
www.htai.org/fileadmin/HTAi_Files/ISG/PatientInvolvement/Long_Guide_September_2015.docx
Please submit your feedback by **31 January 2016** to Ann Single, singlehaworth@gmail.com.

You may like to read our commentary on the project in The Patient http://link.springer.com/article/10.1007/s40271-015-0143-y
Single AN, Scott AM, Wale J. Developing Guidance on Ethics for Patient Groups Collecting and Reporting Patient Information for Health Technology Assessments. Patient. 2015 Oct 17. [Epub ahead of print] PMID: 26476960

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INTEGRATE-HTA

Two lay stakeholders co-presented at the INTEGRATE-HTA project's final conference that was held in Amsterdam on 12-13 November. The INTEGRATE-HTA project (2013-2015) developed new concepts and methods for integrated HTA and applied some of these in a palliative care case study. George Wood and Jacqui Gath both from England shared their experiences of being involved in the project. The presentation was very well received by the international audience which included representatives from HTA agencies, policy makers, researchers, health care professionals and students.

Jacqui and George shared their rationale for becoming public involvement representatives in palliative care research. Jacqui took part in stakeholder meetings that assisted project scoping in 2013. She has continued to work closely with the INTEGRATE-HTA project team in Sheffield, participating in the monthly project meetings to provide a public involvement perspective on the project. The Sheffield team have valued her input which has assisted decision making about stakeholder involvement throughout the project. Both Jacqui and George took part in various meetings as part of the evidence assessment for the project. One of these was a face-face group meeting with other lay people and a researcher who had travelled from Germany to assess socio cultural issues related to palliative care; others were face-face meetings with other lay people and professionals involved in palliative care led by researchers based in Sheffield to assess costs of palliative care. George also took part in a Skype meeting with a mixed lay and professional group of stakeholders to assess patient preferences and moderators of treatment effect. At the conclusion of the case study, George and another lay stakeholder also took part in a 'mock' decision making meeting with end of life care commissioners and a researcher from Germany who moderated the meeting. George and Jacqui recounted their experiences and the project team concluded that stakeholder involvement is invaluable throughout the HTA process. Stakeholder input not only assists in the identification of priorities from stakeholder perspectives, the information provided can complement and enrich traditional forms of evidence without creating heavy workload demands for researchers or stakeholders themselves. It was noted that various approaches can be used to involve stakeholders throughout the HTA process but consideration should be given to a number of methodological, ethical and practical issues to ensure success. Jacqui and George emphasised the value of their continued experience on the INTEGRATE-HTA project (as opposed to one off involvement). They reflected that this provided learning and experience that will be of value to future projects that require public involvement.
The project comes to a close in December 2015 and the presenting team thanked stakeholders and their colleagues who participated in the project in seven European countries (England, Germany, Italy, Lithuania, The Netherlands, Norway and Poland).
For more information, please visit www.integrate-hta.eu.

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

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CADTH Lecture Series (Canada) — Dr Michael Burgess
The CADTH Lecture Series provides prominent scholars and opinion leaders with a forum to discuss pressing issues facing health technology assessment (HTA) and health care today.

Join the CADTH Lecture Series for the last session before the holidays. The lecture, **Is Deliberative Public Engagement Worth the Trouble?** will be hosted by Dr Michael Burgess, Professor, W. Maurice Young Centre for Applied Ethics, School of Population and Public Health.
Deliberative public engagement is expensive, labour-intensive, and produces knowledge that is limited in scope and extensibility. That said, if decisions about drugs are to be informed by diverse public perspectives, with citizens considering how they would balance fair decision-making with persistent substantive disagreement, then deliberative engagement is the only approach to consider.

The lecture will take place at 1:00 p.m. EST on December 8, 2015 in Ottawa and online via webinar. While there is no charge for attending, you do need to **register by December 4th at 5:00 p.m. EST** at www.cadth.ca/lectures.

Sent in by Elaine MacPhail

Patient and Public Involvement and Engagement in Horizon Scanning
by Kathryn Miles and Ali Cook

A short article about how the NIHR Horizon Scanning Research and Intelligence Centre (http://www.hsric.nihr.ac.uk/) have involved and engaged with patients and public in their work has been published in the Autumn 2015 INVOLVE newsletter (http://www.invo.org.uk/news/involve-newsletters/ found in 'What's happening across the National Institute for Health Research, pg. 11).

Some case studies:
In 2014 we wrote a brief report on a new drug for a condition called alpha-mannosidosis . As this is a rare condition, we sent an early report to the UK charity that supports people with this condition so they could comment.
In 2015 we published a report about a new type of medical device called a closed-loop artificial pancreas that is being developed for people with type 1 diabetes. We asked members of the public with type 1 diabetes to comment on the benefits they think this new technology might bring.
In 2015 we identified a technology called Reza Band® to treat acid reflux (where stomach acid rises back up into the mouth). The Reza Band® applies pressure to the neck to stop this happening at night while patients are asleep. We contacted two key charities who support people with this condition to ask their view on whether they thought we should investigate this technology further. As a direct result of their comments we wrote a report on Reza Band®, which is available on our website.

If you have an interest in patient involvement in horizon scanning and would like to discuss further, please contact Kathryn Miles (K.Miles@bham.ac.uk)

Some of the literature

"Adaptive licensing" or "adaptive pathways": Deregulation under the guise of earlier access
Several non-profit organisations have prepared a position paper on Adaptive Pathways to patients.
http://english.prescrire.org/en/79/207/46302/4548/4089/SubReportDetails.aspx
http://english.prescrire.org/Docu/DOCSEUROPE/20151019_AdaptiveLicensing.pdf

Health Action International (HAI), The International Society of Drug Bulletins (ISDB), The Medicines in Europe Forum, The Mario Negri Institute for Pharmacological Research, The Nordic Cochrane Centre, WEMOS are the organisations involved.

New York Times article, November 26, 2015: Pfizer's Plan to Leave U.S. Unsettles Drug Lobbyists
http://www.nytimes.com/2015/11/26/us/politics/drug-lobbyist-discomfort-over-pfizers-leaving-us.html?_r=0
The Company announced plans to move to Ireland following its merger with Allergan.

21st Century Cures Act and similar policy efforts: at what cost?
Zuckerman DM, Jury NJ, Silcox CE.
BMJ. 2015 Nov 23;351:h6122. doi: 10.1136/bmj.h6122. PubMed PMID: 26597099.

A Foreign Affairs article on expensive medicines: A Bitter Pill. Can the Access to Medicines Movement Score Another Victory?
https://www.foreignaffairs.com/articles/south-africa/2015-10-18/bitter-pill
The World Health Organization and other international bodies are increasingly referring to medicine access as a basic human right.

Sent in by Kathi Apostolidis

Six 'biases' against patients and carers in evidence-based medicine
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.

Six potential 'biases' in EBM that may inadvertently devalue the patient and carer agenda are: 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.

Patient Engagement Practices in Clinical Research among Patient Groups, Industry, and Academia in the United States
Smith SK, Selig W, Harker MH, Roberts JN, Hesterlee S, Leventhal D, Klein R, Patrick-Lake B, Abernethy AP. Patient Engagement Practices in Clinical Research among Patient Groups, Industry, and Academia in the United States: A Survey.
http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0140232

This study set out to gain a better understanding of attitudes and practices for engaging patient groups in clinical trial design so that actionable recommendations may be developed. A literature review was carried out to inform survey questions.
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. Patient group respondents placed higher value in open communications, clear expectations, and detailed contract execution than did non–patient group respondents. Industry and academic respondents more often cited internal bureaucratic processes and reluctance to share information as engagement barriers than did patient group respondents. 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.

Using Qualitative Evidence in Decision Making for Health and Social Interventions
Lewin S, Glenton C, Munthe-Kaas H, Carlsen B, Colvin CJ, Gülmezoglu M, et al. (2015) Using Qualitative Evidence in Decision Making for Health and Social Interventions: An Approach to Assess Confidence in Findings from Qualitative Evidence Syntheses (GRADE-CERQual). PLoS Med 12(10): e1001895. doi:10.1371/journal.pmed.1001895

Advocacy for Health Equity: A Synthesis Review

Farrer L, Marinetti C, Cavaco YK, Costongs C. (2015). Milbank Quarterly, 93 Issue 2: 392–437. doi: 10.1111/1468-0009.12112
This article brings together evidence from the academic and the gray literature and provides a building block for efforts to advocate for health equity.
It states that randomised controlled trials often cannot provide evidence of process, quality of implementation, and context; data that policymakers value in making decisions. Accumulated evidence summaries hold promise.

Type 2 diabetes patients' and providers' differing perspectives on medication nonadherence: a qualitative meta-synthesis
Brundisini F, Vanstone M, Hulan D, DeJean D, Giacomini M. BMC Health Serv Res. 2015; 15(1):516
We identify 7 categories of barriers: (1) emotional experiences as positive and negative motivators to adherence, (2) intentional non-compliance, (3) patient-provider relationship and communication, (4) information and knowledge, (5) medication administration, (6) social and cultural beliefs, and (7) financial issues. Patients and providers express different understandings of what patients require to improve adherence. Health beliefs, life context and lay understandings all inform patients' accounts. They describe barriers in terms of difficulties adapting medication regimens to their lifestyles and daily routines. In contrast, providers' understandings of patients' poor medication adherence behaviors focus on patients' presumed needs for more information about the physiological and biomedical aspect of diabetes.

From AllTrials, Sense About Science
People from around the world are doing brilliant things to get all clinical trials registered and their results reported. Individuals, teams of people, and organisations are finding clever ways to raise awareness and join the campaign.

Miller JE, Korn D, Ross JS. Clinical trial registration, reporting, publication and FDAAA compliance: a cross-sectional analysis and ranking of new drugs approved by the FDA in 2012. *BMJ Open* 2015;5,11:e009758 doi:10.1136/bmjopen-2015-009758
The FDA approved 15 drugs sponsored by 10 large companies in 2012. We identified 318 relevant trials involving 99 599 research participants. Per drug, a median of 57% of trials were registered, 20% reported results in ClinicalTrials.gov, 56% were published, and 65% were either published or reported results. Almost half of all reviewed drugs had at least one undisclosed phase II or III trial. Per drug, a median of 17% of trials supporting FDA approvals were subject to FDAAA mandated public disclosure; of these, a median of 67% (IQR 0–100%) were FDAAA-compliant. 68% of research participants (67 629 of 99 599) participated in FDAAA-subject trials, with 51% (33 405 of 67 629) enrolled in non-compliant trials. Transparency varied widely among companies.

EPF recommendations for the trilogue on the proposal for regulation on Medical Devices

The trilogue, which started in October, is the final negotiation phase between the Council of the European Union the European Parliament and the Commission to adopt the new Regulation on Medical Devices. There are still important gaps to be addressed by the EU institutions in order to ensure EU patients have access to high quality safe devices.
In November, EPF published detailed recommendations on the Council position on medical devices.
http://www.eu-patient.eu/globalassets/policy/medicaldevices/2015-11-24-epf-recommendations-to-the-trilogue-on-medical-devices.pdf
http://www.consilium.europa.eu/en/policies/new-rules-medical-in-vitro-diagnostic-devices/

The package covers a broad range of products, from plasters and pregnancy tests, to state-of-the-art pacemakers, X-ray machines and genetic tests.

The proposed law would increase the scrutiny of products before they enter the market and tighten surveillance once they are available. It also wants to create a unique device identification system that makes it easier to recall faulty products and helps to fight against counterfeit devices.

Janet Wale, Chair HTAi PCIG
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I am happy to address any questions you may have as a result of this e-Bulletin, and to forward information