HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG)
E-Bulletin, June 2020

Enhanced quality and relevance of HTA through patient and citizen involvement

http://www.htai.org/interest-groups/patient-and-citizen-involvement.html

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Welcome to our June E-Bulletin!

From our Chair

As June came to an end many PCIG members reflected on the missed opportunity for shared learning, catching up with old friends and making new friends following the cancellation of HTAi Beijing. Regrettably, it may be some time before we can meet again face to face - HTAi 2021 is scheduled for Manchester, 19-23 June - for those informal chats that are so essential to good relationships. We are determined to do what we can to keep the shared learning going.

Last week, the Patient Preferences Project Sub-Committee kicked of the first of four webinars aimed at putting patient preference studies for HTA in the spotlight and gaining a wider understanding in the HTA community of its strengths, limitations, and potential. The team have made sure their program is full of practical examples and well-integrated with other initiatives in this area. You can watch the first webinar or register for the second in the series which will be held on 24 July 2020.

Additionally, PCIG panels planned for Beijing on patient participation at the organizational level (not individual assessments), stakeholders' perspectives of impact, the international template for summary information for patients and patient involvement in low- and middle-income countries are being adapted into webinars over the coming months.

While the HTAi COVID webinar series is open to anyone, most HTAi webinars require HTAi membership. If you've let your membership slip, do check out the options. If you are interested in membership options for patients and patient organisations, please email me.

Finally, on behalf of PCIG I'd like to congratulate Grace Huang and Franz Waibel on their appointments to the HTAi Board. Grace and Franz have been generous contributors to PCIG work. I'd also like to acknowledge the huge contribution of PCIG founder, Karen Facey, who has just completed her term on the Board.

Stay safe

Ann Single, Chair – HTAi Patient and Citizen Involvement Interest Group
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NOTE: Present and past issues of the E-Bulletin can also be accessed on the website https://htai.org/interest-groups/pcig/e-bulletins/

PCIG Matters

Brian O'Rourke retires as CEO of Canadian Agency for Drugs and Technologies in Health (CADTH)

This month saw the retiral of Brian O'Rourke as CEO of CADTH. We owe him thanks for his sustained and meaningful support to the development of patient involvement in CADTH over the past decade that has benefitted the international HTA community. I have always said that effective patient engagement needs real leadership support, not just nice words, but actions and a change in culture and that's what Brian gave. In the early days, CADTH carefully reviewed how other HTA bodies were implementing patient involvement initiatives and I supported discussions at Board away days and staff development to explore the possibilities for patient involvement in Canada. Brian was always supportive and aware of the great work of his staff, but also challenging all to think about implementation and sustainability. Over the decade we've seen development of the CADTH patient involvement team and their processes. They were the first to implement the HTAi Values and Quality Standards for Patient Involvement in HTA and are one of the few bodies that now employ qualitative researchers. This requires investment, change in process and recognition of value, which Brian gave. We thank Brian for his support and wish him a very Happy Retirement.

Prepared by Karen Facey

We may be facing difficult circumstances with COVID-19 but PCIG members continue to do good work:
For information on HTAi webinars, log in as member and go to the introductory webpage.
https://htai.org/?CFID=2244825&CFTOKEN=cc5e0cbe520f6d9a-F7E6050D-B0CC-CD69-EB3E4EEEDF869FEA

Information on the HTAi Patient Preferences Webinar Series
https://register.gotowebinar.com/register/7320216772546285840
HTAi Patient and Citizen Involvement Interest Group has created an exciting new webinar series, from June to October 2020. This webinar series includes four 60-minute webinars providing an introduction to patient preference research that over the series will explore its use in HTA.

Patient preference studies could help identify the outcomes and improvements that are most important to patients, while potentially addressing some of the perceived challenges with patient participation approaches, including the robustness, quality, partiality and consistency of input. However, the role of patient preference evidence in HTA is as yet undetermined and remains a subject of continued interest and debate: how can we best embrace new forms of patient-based evidence alongside more traditional forms of input, and will patient preference evidence redefine the future of 'the patient voice' in HTA?

HTAi Global Policy Forum - Panel Session
https://bit.ly/3cE9Lgw
In January 2020, the HTAi Global Policy Forum met in New Orleans, USA to discuss Deliberative Processes in HTA. Their panel session on the topic was held on 22 June. A recording is available to members. Hear Valentina Stramiello, Vice-Chair of PCIG ably represent patients.

IMI PARADIGM
https://lnkd.in/gfZG5cV

As part of the PARADIGM collaboration HTAi PCIG is developing a toolkit for HTA bodies to support patient engagement in Early Dialogue/Scientific Advice under the leadership of our Previous Chair and PFMD Board Member, Neil Bertelsen. Find out more about work in this area at the open forum.

PARADIGM Tools – Public Consultation
https://imi-paradigm.eu/tools-consultation/
PARADIGM tools aim to make patient engagement in medicines Research and Development easier for all. These tools have been created iteratively with all relevant stakeholders involved and they are now at the final stage of co-creation: the public consultation. Help us finalise by reviewing and testing these tools and giving your insight on their usability.

The fourth wave of public consultation is open until July 21st:
Patient engagement agreements explained
The third wave of public consultation is open from June 16th to July 9th:
Tools for the management of competing interests and conflicts of interest; Code of conduct; Community Advisory Board – Guidance document and templates
The second wave of public consultation is open from June 11th to July 8th:
Enhancement of the EUPATI industry guidance; Guidance for Reporting and Dissemination of Patient Engagement Activities

Also see: Patient Engagement Open Forum
https://patientengagementopenforum.org/

HTAi Matters

Beijing Annual Meeting (AGM) sessions are being planned in a virtual format for later in the year, so stay alert.

HTAi COVID-19 Response webinar series
https://htai.org/hta-support-for-covid-19/webinars/
All HTAi COVID-19 Response webinar recordings are available online! These webinars are open access, so no login is required and the content is shareable with your networks. The "all previous sessions" tab is at the bottom of the page.

The most recent webinar explored the role evidence and HTA has played in the decisions made about COVID-19 in developing countries, and what evidence or experiences have been most valuable for the represented countries in guiding decisions. The next on 16 July is on Intensive Care = Expensive Care: How HTA can Support Cost-effective Digitization in Hospital Settings

To register, please follow this link.

HTAi Position Statement on Evidence Standards
https://htai.org/wp-content/uploads/2020/06/HTAi_Position-Statement-Evidence-Standards_20200620.pdf
The HTAi COVID-19 Response Team has released a position statement on Evidence Standards and Quality Assessment in COVID-19 Therapeutic Interventions. A brief introduction:
Confidence in HTA findings, recommendations, and policy decisions is directly impacted by the quality and rigor of the evidence submitted. Researchers around the globe are working tirelessly to assess early evidence on therapeutic interventions to treat patients with COVID-19, with the twin goals of speed and maintenance of the standards HTA bodies have been known for.
At the same time, those designing studies to assess the efficacy and safety of COVID therapeutic

interventions need guidance on study design, outcome definition and measurement, and mitigation of bias that will meet HTA standards. This will reduce uncertainty in HTA reviews and help informing decision-making on effective treatment options....

Message from HTAi Director, Scientific Initiatives
If you're working on COVID-19 related projects, in any capacity, we would like to hear from you. We invite you to respond to this email and submit your concerns, suggestions, bright ideas, general thoughts at this time. All suggestions will be collated and reviewed, and where possible plans formulated to respond to priority needs of our global community.

Lucy Henry

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What's Happening

Association of the British Pharmaceutical Industry has launched a public consultation on a 'new-look, more user friendly' Code of Practice
http://www.pharmatimes.com/news/abpi_consults_on_new-look_code_of_practice_1342614?utm_source=Virdis+Newsletter&utm_medium=email&utm_campaign=virdis+news+alert

The Code is designed to help govern the pharma industry's conduct in the UK through self-regulation, and reflects the sector's commitment to operate in a professional, ethical and transparent manner. Essentially, the ABPI is proposing to update the Code to bring it closely in line with the 2019 European Code of Practice, and also its language to help ensure that it is accessible as possible.

A key change is to arrange the Code into six themed sections according to the activity or audience.
The consultation will run until September 8, with a view to publishing the new Code in January 2021 and making 'live' the following July.

ISPOR 18th Patient Representatives Roundtable-North America
ISPOR welcomed more than 45 key healthcare stakeholders to the Patient Representatives Roundtable-North America. This virtual event brought together perspectives from patients, payers, regulators, researchers, and industry on 15 June, 2020. The theme was: Patient-generated health data for HTA. Building a tool we can all use.

User representation for the first time in the Order Forum, Norway
https://nyemetoder.no/english

The Ordering Forum in Norway, RHF approved during its meeting on Monday 22 June 2020 the recommendation of Øystein Kydland from the user committee in the Health South-East RHF as user representative in the ordering forum RHF. It is intended that the user representative can attend meetings in the Order forums RHF from September 2020. The ordering forum consists of the four professional directors in the regional health enterprises Health North, Health Middle-Norway, Health West and Health South-East, as well as two representatives from the Directorate of Health. The Norwegian Institute of Public Health, the Norwegian Medicines Agency, the Directorate for Radiation Protection and Nuclear Safety and Hospital Procurement have one to two representatives each. These participate to shed light on issues being addressed in the meetings. The ordering forum decides which of the methods reported to 'New methods' should go to national method assessment and what type of method evaluation to be performed. It is the

National Medicines Agency (SLV) or the Norwegian Institute of Public Health (FHI) that conducts the national methodological assessments. These are then reviewed by the Order Forum which decides whether the matter should be forwarded to the Decision Forum, or whether more work is required before it can be forwarded.

Submitted by Roald Nystad

Call for (online) internships at several European HTA institutes - Integrative assessment of the immediate and wider impact of health technologies

A consortium of European research institutes led by Radboud University Medical Center (Radboudumc) has recently developed a novel framework for the integrative and interdisciplinary assessment of health technologies, called VALIDATE (VALues In Doing Assessments of healthcare TEchnologies). https://validatehta.eu

The partners of the consortium now offer a free internship ONLINE for 6 enrollees consisting of: an E-learning module developed in the context of the EU Erasmus+ program (4 weeks), followed by an integrative and interdisciplinary assessment of a novel health technology at three of the six participating research institutes: Norwegian University of Science and Technology (Oslo), Università Cattolica del Sacro Cuore, Rome (Italy), Linköping University (Sweden) (3 - 6 months): https://validatehta.eu/available-internship-projects/

After successful completion of an internship project, you will receive the VALIDATE Advanced Certificate; the VALIDATE course is accredited by HTAi.

The course is targeting those who are familiar with the basic theory and methods of HTA, and who wish to deepen their understanding of the policy and societal context of HTA, the role of stakeholders in HTA, methods for evaluating ethical argumentation, and the interplay between facts and values in identifying the relevant questions and evidence to be addressed. During the course you will analyse a central case study on applied behavioral analysis based treatment for children with autism, making use from insights from biomedical science, policy sciences, ethics, philosophy of technology and social sciences.
As this project is funded by the EU Erasmus+ program, students enrolled in curricula on HTA, health policy and management, health sciences and biomedical sciences, PhD students, researchers and other stakeholders working in the field of HTA in EU member states are cordially invited to participate.
For more information https://validatehta.eu

Wija Oortwijn (w.oortwijn@radboudumc.nl)
Bart Bloemen (Bart.Bloemen1@radboudumc.nl)

3ie Technical report to the citizen engagement in public services
Does incorporating participation and accountability improve development outcomes? Meta-analysis and framework synthesis. 3ie Systematic review 43, 2019

Hugh Waddington, Ada Sonnenfeld, Juliette Finetti, Marie Gaarder, Denny John and Jennifer Stevenson
https://www.3ieimpact.org/evidence-hub/publications/systematic-reviews/does-incorporating-participation-and-accountability

This systematic review examined high-quality evidence from 35 citizen engagement programmes in low- and middle-income countries. These programmes promoted citizen engagement in service delivery through four routes: participation, inclusion of marginalised groups, transparency and/or citizen efforts to ensure public service accountability; and collectively, PITA mechanisms. Interventions that improved direct engagement between service users and providers are often effective in stimulating active citizen

engagement in service delivery, and realising improvements in access to services and service provision quality. However, in the absence of complementary interventions to address bottlenecks around service provider supply chains and service use, citizen engagement interventions alone may not improve key well-being outcomes for target communities. In addition, interventions to improve governance by increasing citizen pressures on politicians to hold service providers to account do not usually influence service delivery.

Submitted by Anke-Peggy Holtorf

New FDA guidance to help guide Patient-Focused Drug Development
Collecting Comprehensive and Representative Input - the first of 4 guidances.
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-collecting-comprehensive-and-representative-input

This guidance (Guidance 1) is the first of a series of four methodological patient-focused drug development (PFDD) guidance documents that FDA is developing to address, in a stepwise manner, how stakeholders (patients, researchers, medical product developers and others) can collect and submit patient experience data and other relevant information from patients and caregivers for medical product development and regulatory decision making.

FDA Oncology Center of Excellence new pilot Project Patient Voice, a web-based platform for patients and caregivers, along with their health care providers to look at patient-reported symptom data collected from cancer clinical trials.
https://www.fda.gov/about-fda/oncology-center-excellence/project-patient-voice.
Measurement of the patient experience as it relates to tolerability in cancer clinical trials – workshop 17 July
https://www.fda.gov/drugs/news-events-human-drugs/fda-asco-public-workshop-2020-clinical-outcome-assessments-cancer-clinical-trials-fifth-annual

Artificial intelligence enhances brain tumor diagnosis - Kyoto University DOI: 10.1109/ACCESS.2020.2989193
https://www.eurekalert.org/pub_releases/2020-06/ku-aie060820.php?platform=hootsuite
A new machine learning algorithm can classify glioma brain tumours from MRI scans into low or high grades with high accuracy, researchers report in the journal *IEEE Access*. The Indian and Japanese research team created special software that is designed to detect barely perceptible changes on MRI scans which may have clinical significance. Training their system on a set of 210 people with high grade gliomas and another 75 with low grade gliomas, their system classified gliomas into low and high grade with 97.54% accuracy.

Relevant to COVID-19
The following is an article that had to be written…
https://globalforum.diaglobal.org/issue/july-2020/patient-engagement-in-covid-times-looking-behind-the-numbers/?utm_source=db&utm_medium=email&utm_campaign=globalforum&utm_content=PUB_GF_July_2020-07-04A&mkt_tok=eyJpIjoiTXpZMk9URm1ObVZqTm1ReiIsInQiOiJrbopyMFwvR1NKVFhacEhhNE1FNE81WG1VdlwvRDN2dHhhVjc4UnNSZllDWFQ3SVJXMDBOanlZQ1wvWUtKMWdGTUtWb1dOdmFqSnlZWWhLboRTRlVESTMxYkNNMG9xbE9iOFNkUmVvU2F5RnVmVXVUUnYyeGkoUXZBZGVzNW1wYmRGaCJ9

Patient Engagement in COVID Times: Looking Behind the Numbers, from DIA Global Forum
Commentary by Lode Dewulf, Servier
Patients have been asking to be heard and engaged for decades. More recently, their call has been echoed by academics and providers. Today, Patient Engagement in the development, launch, and use of medicines has become an accepted necessity. Indeed, the historical risk of engaging patients has been surpassed by the future risk of not engaging patients. And then COVID happened…
In some ways, the necessary public health measures taken in the face of the global pandemic have effectively been a slap in the face of Patient Engagement. In the interest of population health, even survival,

decision makers have prioritized treating the statistics. "*We need to flatten the curve*" became the overriding goal in many countries—and decisions were made by scientists and politicians, almost always without involving those concerned. Fortunately, today the numbers show that the science-driven approach, when indeed applied, works and has in fact saved tens or hundreds of thousands of lives. So, I will definitely not argue against those science-driven measures, which I support and implement.
But individual patients have been paying and continue to pay the price…
The real issue is whether Patient Engagement will return. Will it become as essential a part of the new (ab)normal, as it was (becoming) pre-COVID-19? Or will decision makers in governments, payers, and providers find convenience and savings in continuing to work and decide for patients without engaging them?
- I remain optimistic that COVID-19 will ultimately advance Patient Engagement in healthcare and drug development more than it slows or reverses it. ..
- the inevitable digitization of healthcare will also bring with it a better measurement of the true outcomes of that care, both medically and beyond. This will allow us to better capture and understand the long-term benefits of Patient Engagement, which in turn will drive more resources to this important investment.
- any changes implemented (especially telemedicine and virtual study visits) could significantly improve both patient convenience and access, which have been two of the major challenges in healthcare for decades….

Patient and public involvement in covid-19 policy making absent in the early stages of the pandemic, it must now move centre stage
Richards T, Scowcroft H. BMJ 2020;370:m2575 http://dx.doi.org/10.1136/bmj.m2575 Published: 01 July 2020.
https://www.bmj.com/content/370/bmj.m2575
Covid-19 has precipitated a global health crisis, plunged the world into economic recession, put the spotlight on structural inequalities, including racism, and galvanised the call for action on climate change. The knowledge to confront these challenges needs to be co-produced. Patient and public involvement must be taken seriously, embedded robustly, and never sidelined again…
The resources, skills, views, priorities, and preferences of patients, carers, and the communities which support them are not well recognised, valued, or systematically used to improve care.

The BMJ's collection of Patient and Public Perspectives on the pandemic can be found here:
https://blogs.bmj.com/bmj/category/patient-perspectives/

Greenhalgh T (2020) Will COVID-19 be evidence-based medicine's nemesis? PLoS Med 17(6): e1003266. https://doi.org/10.1371/journal.pmed.1003266. Published: June 30, 2020
https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1003266

Publications

DC Lavallee, SO Lawrence, AL Avins et al. Comparing three approaches for involving patients in research prioritization: a qualitative study of participant experiences. Research Involvement and Engagement (2020) 6:18 https://doi.org/10.1186/s40900-020-00196-4
Surveys, focus groups, and online crowdsourcing are increasingly used to obtain input, yet little is known about how they compare for prioritizing research topics. Respondents from Back pain Outcomes using Longitudinal Data (BOLD), a registry of patients 65 years and older with low back pain (LBP), were randomly assigned to one of three interactive prioritization activities: online crowd-voting, in-person focus groups using nominal group technique, and two rounds of a mailed survey (Delphi).
Activities generated similar lists of research priorities, including causes of LBP, improving physician-patient communication, and self-care strategies. Focus group participants rated their experience highest, in both the evaluation and interviews. Common methods for research prioritization yielded similar priorities but differing perceptions of experience. Such comparative studies are rare but important in understanding

methods to involve patients and the public in research. Preferences for different methods may vary across stakeholder groups; this warrants future study.

Liabo K, Boddy K, Bortoli S, Irvine J, Boult H, Fredlund M, Joseph N, Bjornstad G, Morris C. Public involvement in health research: what does 'good' look like in practice?
Research Involvement and Engagement volume 6,
Article number: 11 (2020) https://researchinvolvement.biomedcentral.com/articles/10.1186/s40900-020-0183-x

Submitted by Nicky Britten

Kapiriri, L., Baltussen, R., & Oortwijn, W. (2020). Implementing evidence-informed deliberative processes in health technology assessment: A low income country perspective. International Journal of Technology Assessment in Health Care, *36*(1), 29-33. doi:10.1017/S0266462319003398

Defining Patient Engagement in Research: Results of a Systematic Review and Analysis: Report of the ISPOR Patient-Centered Special Interest Group
Rachel L Harrington, Maya L Hanna, Elisabeth M Oehrlein, Rob Camp, Russell Wheeler, Clarissa Cooblall, Theresa Tesoro, Amie M Scott, Rainald von Gizycki, Francis Nguyen, Asha Hareendran, Donald L Patrick, Eleanor M Perfetto. VALUE HEALTH. 2020; 23(6):677–688
https://www.valueinhealthjournal.com/action/showPdf?pii=S1098-3015%2820%2930141-8
Lack of clarity on the definition of "patient engagement" has been highlighted as a barrier to fully implementing patient engagement in research. This study identified themes within existing definitions related to patient engagement and proposes a consensus definition of "patient engagement in research." A proposed definition is offered based on a synthesis of the findings. In healthcare delivery among the definitions of "patient engagement," the most common themes were "active process," "patient involvement," and "patient as participant." In the research setting, the top themes were "patient as partner," "patient involvement," and "active process"; these did not appear in the top 3 themes of non-research definitions.

Submitted by Dominique Hamerlijnck

Wilson MG, Nidumolu A, Berditchevskaia I. Journal of Health Services Research & Policy. 2019; 25: 1.
Identifying approaches for synthesizing and summarizing information to support informed citizen deliberations in health policy: a scoping review
https://journals.sagepub.com/doi/10.1177/1355819619872221#articleShareContainer
Public deliberations are an increasingly popular tool to engage citizens in the development of health policies and programmes. However, limited research has been conducted on how to best synthesize and summarize information on health policy issues for citizens.
The choice and framing of information to inform citizen deliberations about health policy can strongly influence their understanding of a policy issue, and has the potential to impact the discussions and recommendations that emerge from deliberations. Our review confirmed that there remains a dearth of literature describing methods of the preparation of information to inform citizen deliberations about health policy issues.

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