

HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG) E-Bulletin, August 2019

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 the August E-Bulletin – from our Chair

Following our call for project proposals, the PCIG was pleased to receive a wide range of proposals. Some projects began in the PCIG working groups, while others are at an early stage of scoping. In most instances, the PCIG Steering Committee encouraged the projects with recommendations for their development. Steering Committee was particularly keen to ensure that the potential benefits of projects will be experienced by more than one country, that project membership is balanced across our multi-stakeholder membership, and too great a burden is not placed on any individual. I encourage you to read the summaries in this e-bulletin and to contact project leaders or Anke-Peggy Holtorf, PCIG project co-ordinator, if you want to get involved. Please also note the following deadlines:

- 6 September – MDIC white paper consultation (see item below)
- 10 October – Deadline for HTAi 2020 panel and workshop abstracts (note PCIG will once again propose a pre-meeting workshop, so please contact myself or a member of the Steering Committee urgently to discuss views and ideas)
- 21 November – Deadline for HTAi 2020 orals, posters and vignettes

As always can I encourage you to contact myself or our Vice Chair, Valentina Strammiello, if you have any questions, ideas or concerns about the PCIG.

Ann Single, Chair – HTAi Patient and Citizen Involvement Group
singlehaworth@gmail.com

PCIG Matters

The New PCIG Structure Goes Live: eight projects will be pursued

Following the call in the July-PCIG-Bulletin, the Steering Committee (SC) received excellent project proposals. Of these, the following eight will be further developed over the coming year.

Poo1: Patient Participation at the Organizational Level in HTA [PPOL-HTA]

Objectives: Better understanding of patient participation in the organizational domain: Identifying how and when dialogue between patients/ patient groups/ citizens and committees / HTA bodies is occurring and what processes facilitate it.

Leader: Hervé Nabarette

Poo2: Impact of Patient Involvement in HTA

Objectives: Tackle activities related to evaluation of patient involvement in HTA, reflect on what the activities produce, and advance the methods in order to develop good practice that can be shared and encourage reflection on patient involvement processes.

Leader: Karen Facey

Poo3: Summary of Information for Patients [SIP TEMPLATE]

Objectives: Broad adoption of an aligned SiP concept by HTA bodies. Simplify the process for industry to provide this input during their submissions; Simplify the process for patients of their giving input.

Leaders: Heidi Livingstone, Nigel Cook,

Poo4: Patient and Citizen Involvement in the Low- And Middle-Income Country settings [PCI-LMIC]

Objectives: Explore the current routes of patient involvement in LMICs. Collaborate with LMIC stakeholders to define LMIC-specific needs for patient involvement. Develop and adapt guidance and tools to support patient and citizen involvement in HTA in emerging economies.

Leaders: Debjani (Jani) Mueller (DC-IG), Anke-Peggy Holtorf (PCIG)

Poo5: Gap Analysis and Central Resource for Patient Involvement in HTA

Objective: Identify gaps, create resources, and disseminate best practices to patients, HTA agencies, companies and others internationally through three related workstreams: Communications, Conceptual framework, Online patient portal for HTA

Leaders: Janney Wale, Sam Thomas

Poo6: Disease Background Repository

Objective: Develop a framework and guidance for the kinds of disease-area evidence based on a pilot project in rare diseases

Leader: Sheela Upadhyaya

Poo7: Including Individuals and Hard to Find Groups in HTAs

Objective: Process and tools for HTA bodies to engage with individuals as an alternative or an add on to patient groups for hard to find or underrepresented groups; either where there are currently no patient groups or where these patient groups do not have the resource to engage with the HTA body in developing HTA guidance

Leader: Jen Dickson, Heidi Livingstone

Poo8: Patient Preferences

Objective: Share good practice and practical advice to foster the use of patient preferences research in HTA

Leaders: Eric Low, Co-leader to be identified at first meeting

The teams are currently forming and updating the proposals based on the SC feedback. All actively pursued projects will be described on the HTAi PCIG website once the SC has received the finalized proposals, and their progress will be reported regularly through the bulletin or in the conferences. Likewise, project teams (sub-committees) may look for your support or critical input through the monthly bulletin. So, please look out for these reports and be prepared to assist or join the teams in order to advance the involvement of patients and citizens in health technology assessment. Note that each sub-committee is limited to 12 members and, therefore, membership is driven by consideration of skills and experience. However, projects will often include consultation with the wider PCIG membership on this list serve.

If you are interested in joining the project sub-committee of a particular project, or have any questions, now is the time to contact us.

Anke-Peggy Holtorf, HTAi PCIG Project Coordinator

Call for Project Participation in PCI-LMIC Project – by 23 September 2019

We are inviting interested stakeholders from Low- and Middle-Income Countries (LMIC) to join this joint project between the Patient- and Citizen Involvement Interest Group (PCIG) and the Developing Countries Interest Group (DCIG).

The objectives of this project are to (1) explore the current routes of patient involvement in LMICs, (2) collaborate with LMIC stakeholders to define LMIC-specific needs for patient involvement, and (3) develop and adapt guidance and tools to support patient and citizen involvement in HTA in emerging economies. We are looking for individuals from LMICs across the world who are interested in this subject and who bring a background in health technology assessment, as patient advocate, or have experience in this subject from another perspective. After formation of the full team, we will proceed with interactively developing a full project plan, which should help us to achieve our objectives as outlined above.

If you are motivated to work with us on this subject and are member (or are willing to become a member) of the PCIG or the DCIG, please send a letter of intent to the project leads (Jani Mueller and Anke-Peggy Holtorf) which specifies what your specific interests are, why you feel qualified and enthusiastic to work with us on this subject, and what your engagement background is. Altogether, we are looking for a maximum of 12 team members with mixed backgrounds from Latin America, Asia, the Middle East or Africa. If we receive more applications, we will select the team to have the broadest possible geographic, cultural and stakeholder representation. In addition, we are looking for a wider group of interested members, who will serve as advisers, sounding board, and reviewers to the project team.

The project leaders are:

Debjani (Jani) Mueller (DCIG) dbmueller7@yahoo.de

Anke-Peggy Holtorf (PCIG) anke.holtorf@health-os.com

US based Medical Device Innovation Consortium consultation – by 6 September 2019

– on *Best Practices for Communicating Benefit, Risk and Uncertainty White Paper*

https://mdic.org/wp-content/uploads/2019/08/MDIC_Risk_Benefit_Uncertainty_Whitepaper.pdf

PCIG will facilitate the development of a formal HTAi PCIG comment on the paper for consultation by MDIC (below). If you wish to take part, please review the linked document and provide comments to PCIG member Samuel Thomas Samuel.Thomas@roseliassociates.com. Of course, you are welcome and encouraged to submit your own comments on behalf of your organization directly to MDIC.

Public Comment is open: August 12 - September 13, 2019

The paper will be part of its larger Framework for Patient Input in Medical Device Clinical Trials aiming to be published in Fall 2020. MDIC has worked to understand the best methods to assess patient preferences for benefit and risk in new technologies. As the Steering Committee for Science of Patient Input worked to identify the best methods for assessing patient preferences, they realized there was also a significant need to understand the best evidence-based practices to effectively communicate the benefits, risks and uncertainty of medical technologies to patients and providers. This white paper aims to be a useful resource for all of MDIC stakeholders, including researchers, regulators, clinicians, and patients.

<https://mdic.org/program/science-of-patient-input/>

Please visit our Public Comments section of the website <https://mdic.org/news-events/publiccomments/>

HTAi Matters



HTAi 2020 Annual Meeting Beijing
Attaining, maintaining and sustaining healthcare systems in a changing World: the role of HTA HTAi2020.org

HTAi 2020 welcomes all stakeholders – patients/consumers, health care providers, academic researchers, HTA agencies, payers, policy makers, and industry – bringing together more than 1000 delegates from around the globe to discuss the latest advances in this constantly evolving field. More details are available for the main theme <https://www.htai2020.org/the-role-of-hta/> <https://www.htai2020.org/plenaries/>

Abstract submission has opened: <https://www.htai2020.org/abstracts/>

Submission deadlines are different based on submission type. Please note below the important dates regarding abstract submissions and be advised that no extensions to these deadlines will be made.

- **Open Call for Abstracts:** August 15, 2019
- **Deadline for Workshop and Panel submissions:** October 10, 2019
Acceptance notification: November 11, 2019
- **Deadline for Oral, Vignette and Poster Presentation submissions:** November 15, 2019
Acceptance notification: February 1, 2020

HTAi members represent the most influential leaders in the field of HTA globally. Each year, our Annual Meeting brings together around 1,000 researchers, policy makers, industry, academia, health service providers, agencies, and patients/consumers to share information and best practices from cutting-edge technologies to system development in order to advance healthcare.

Please do follow us on social media and repost our messages: **#HTAi2020Beijing**

Twitter: twitter.com/HTAiOrg @HTAiOrg

Facebook: www.facebook.com/HTAiOrg @HTAiOrg

LinkedIn: www.linkedin.com/company/htai

Denise Jarrett, Senior Coordinator, Annual Meetings

The HTAi 2020 toolkit

Available on the website with a variety of resources to help you spread the news:

https://htai2020.org/digital_creative/

HTAi 2020 Social Media Banners

HTAi 2020 Promotional Email Signature Banners

HTAi 2020 Printed Materials

HTAi 2020 Style Guide

HTAi is seeking feedback on the Society's draft Strategic Plan for 2020-2025

HTAi is the global, not-for-profit, scientific and professional society for all those who produce, use or encounter health technology assessment (HTA) to support optimal policy and decision making. Its mission is to support the growth of the HTA community by providing a neutral, global forum for the exchange of information, methods and expertise. HTAi represents 82 organizations and over 2,500 individual members from 65 countries around the world.

As we continue to look toward the future of the HTA field and the overall direction of the Society, HTAi has worked over the course of the past year to review priorities and outline strategies to move the Society forward. Currently, we are seeking feedback on the Society's draft Strategic Plan for 2020-2025. The consultation process involves HTAi Active Members including HTAi Standing Committees, HTAi Interest Groups, and Key Stakeholders.

The PDF version of the draft Strategic Plan 2020-2025 is available for review [here](#). A survey has been setup to receive comments from members [here](#). Alternatively, you may send comments via email to info@htai.org. Please complete the survey or send your comments by September 29, 2019. The links are also available on the HTAi website <https://htai.org/htai-2020-2025-strategic-plan-consultation/>. Comments will be collated for review by the Board of Directors in late-October. The anticipated announcement of the finalized Strategic Plan 2020-2025 is January 2020.

Shared by Wija Oortwijn

What's Happening

EUnetHTA 'Clinical utility of Point-of-care Tests (POCT) D-Dimer and Troponin'

<https://www.eunetha.eu/otca22-clinical-utility-of-point-of-care-tests-poct-d-dimer-and-troponin-project-plan-and-comments-from-external-experts-are-now-available/>

Project plan and comments from external experts are now available for the 'Other Technologies Collaborative Assessment OTCA22 (14 August).

The final assessment report will be published on 29th November, 2019.

Please access the project plan and external expert comments at the following links:

[Project Plan POCT_final version](#)

[Project Plan_comments from external experts](#)

Recording from webinar as part of the Cochrane Learning Live and International PPI Network series

The Cochrane Learning Live and International PPI Network held a webinar on 'Patient and public involvement in research: What, why and how?' The recording and accompanying materials are now available <https://training.cochrane.org/resource/patient-and-public-involvement-research-what-why-and-how>

Submitted by María José Vicente Edo of Instituto Aragonés de Ciencias de la Salud (IACS)

Informed Choices Network

<https://www.fhi.no/en/more/research-centres/centre-informed-health-choices/>

This website has been developed by the Centre for Informed Health Choices at the Norwegian Institute of Public Health, InfoDesignLab, and the Epistemonikos Foundation.

Survey results on people's attitudes around dementia to be released

<https://www.alz.co.uk/research/world-report-2019>

Between April and June 2019, Alzheimer's Disease International (ADI) commissioned the London School of Economics and Political Science (LSE) to create the world's largest survey on people's attitudes around dementia, to form the basis for the World Alzheimer Report 2019.

Translations into 32 languages by volunteers from all over the world enabled a truly global reach, which will have a direct impact on the effectiveness of follow-up policy and advocacy opportunities internationally, regionally and nationally. Importantly it will re-stimulate and help shape our conversations around dementia, awareness and stigma.

The survey is now in the analysis stage and the key findings will form the core of the next World Alzheimer Report, which will be launched around World Alzheimer's Day in September 2019. In addition to the survey findings the report will also feature expert essays and case studies from all over the world.

The Promise and Price of Cellular Therapies. The New Yorker

<https://www.newyorker.com/magazine/2019/07/22/the-promise-and-price-of-cellular-therapies>

Jul 22, 2019 - New "living drugs"—made from a patient's own cells—can cure once incurable cancers. An interesting and informative read.

2nd annual Patient Engagement Open Forum

<https://patientengagementopenforum.org/>

In Brussels on September 18th and 19th, an event co-organised by EUPATI <https://www.eupati.eu/>, Patient Focused Medicines Development (PFMD)

<https://patientfocusedmedicine.org/about-pfmd>

and Innovative Medicines Initiative (IMI) PARADIGM <https://imi-paradigm.eu/>.

Publications

Supporting the evaluation of public and patient engagement in health system organizations: Results from an implementation research study

<https://www.ncbi.nlm.nih.gov/pubmed/31373754>

Abelson J, Tripp L, Kandasamy S, Burrows K; PPEET Implementation Study Team.
Health Expect. 2019 Aug 2. doi: 10.1111/hex.12949. [Epub ahead of print]

Evaluating community deliberations about health research priorities.

<https://www.ncbi.nlm.nih.gov/pubmed/31251446>

Goold SD, Danis M, Abelson J, Gornick M, Szymeczko L, Myers CD, Rowe Z, Kim HM, Salman C.
Health Expect. 2019 Jun 28. doi: 10.1111/hex.12931. [Epub ahead of print]

PROM Validation Using Paper-Based or Online Surveys: Data Collection Methods Affect the Sociodemographic and Health Profile of the Sample

https://www.ispor.org/publications/journals/value-in-health/abstract/Volume-22--Issue-8/PROM-Validation-Using-Paper-Based-or-Online-Surveys--Data-Collection-Methods-Affect-the-Sociodemographic-and-Health-Profile-of-the-Sample?utm_medium=email&utm_source=brief+report&utm_campaign=vih+etoc+august+2019&utm_content=prom+validation&utm_term=value+in+health

Rowen D, Carlton J, Elliott J. Value in Health, August 2019

Sociodemographic and health profile of samples of people with diabetes differed depending on whether they were recruited to and completed an online or postal survey.

A total of 2784 participants completed the survey (1908 online, 876 postal). The samples (online versus postal) differed; the online sample was younger, with a larger proportion of women and respondents with type 1 diabetes. There were significant differences in sociodemographic characteristics by type of diabetes across data collection mode. The proportion of respondents who responded again at point 2 was higher in the postal sample (525 postal, 698 online).

An Ethical Analysis of Coverage with Evidence Development (CED)

https://www.ispor.org/publications/journals/value-in-health/abstract/Volume-22--Issue-8/An-Ethical-Analysis-of-Coverage-With-Evidence-Development?utm_medium=email&utm_source=health+policy+analysis&utm_campaign=vih+etoc+august+2019&utm_content=ethical+analysis+of+coverage&utm_term=value+in+health

Carter D, Merlin T, Hunter D. Value in Health August 2019

Coverage with evidence development arrangements induce rather than coerce patients because patients have no right to technologies where value for money is seriously in question.

We argue that patients have a right to funding for a technology only when the payer can be confident that the technology provides reasonable value for money. Technologies are candidates for CED precisely because serious questions remain about value for money. The separate question of whether the inducement is ethically justified remains. We argue that CED does pose risks to patients, and the worse these risks are, the harder it is to justify the inducement. Finally, we propose conditions under which the inducement could be ethically justified and means of avoiding inducement altogether. We draw on the Australian context, and so our conclusions apply most directly to comparable contexts, where the payer is a government that provides universal coverage with a regard for cost-effectiveness that is prominent and fairly clearly defined.

How and Why to Involve Patients in Drug Development: Perspectives From the Pharmaceutical Industry, Regulatory Authorities, and Patient Organizations

<https://journals.sagepub.com/doi/abs/10.1177/2168479019864294>

Hansen MB, Nørgaard LS, Hallgreen CE. *Therapeutic Innovation & Regulatory Science* 2019;1-9. 1-9. DOI: 10.1177/2168479019864294

A qualitative interview study based on 12 semi-structured interviews with representatives from the 3 stakeholders. Based on the findings, the pharmaceutical industry, patient organizations, and regulatory authorities were labeled as "pioneer/dominant," "unaware/quiet," and "hesitant," respectively. The 3 behavioural descriptors reflect a limited negotiation of the role patients have in drug development. Thus, the pharmaceutical industry appears to be the largest influencer with regard to patients' role in drug development.

Submitted by Sophie Staniszewska and Nigel Cook

Patient empowerment and access to medicines: Insights from a scientist-patient suffering from erythropoietic protoporphyria

Barman-Aksözen J. *Medicine Access @ Point of Care* 2019;1-8. DOI: 10.1177/2399202619865167
<https://journals.sagepub.com/doi/full/10.1177/2399202619865167#>

As I myself suffer from the ultra-rare condition erythropoietic protoporphyria (EPP), I have participated as a patient expert in several discussions on access to afamelanotide, which currently is the only treatment for EPP and was approved in the European Union (EU) in 2014. As a molecular biologist with a PhD in EPP research, I consider myself having the necessary requirements to meaningfully contribute to such assessments. I share my personal experiences with regard to the discussions on access in Germany and England at the respective national competent authorities, the Federal Joint Committee, and the National Institute for Health and Care Excellence, respectively. In addition, I discuss the insights of the International Porphyria Patient Network, a group of highly empowered EPP patients effectively supporting national patient communities in their efforts to enable access to the afamelanotide treatment in their countries.

Submitted by Nigel Cook

Research priorities in health communication and participation: international survey of consumers and other stakeholders <https://www.ncbi.nlm.nih.gov/pubmed/29739780>

Synnot A, Bragge P, Lowe D et al. *BMJ Open*. 2018 May 8;8(5):e019481. doi: 10.1136/bmjopen-2017-019481. The authors set out to identify research priorities of consumers and other stakeholders to inform Cochrane Reviews in 'health communication and participation' (including such concepts as patient experience, shared decision-making and health literacy).

Consumers and other stakeholders want research addressing structural and cultural challenges in health services (eg, lack of holistic, patient-centred, culturally safe care) and building health professionals' communication skills. Solutions should be devised in partnership with consumers, and focus on the needs of vulnerable groups.

Scholz B, Bocking J, Hedt P et al 2019. 'Not in the room, but the doctors were': an Australian story-completion study about consumer representation. *Health Promotion International*. doi: <https://doi.org/10.1093/heapro/daz070>

Pagatpatan CP, Ward PR 2018. Understanding the factors that make public participation effective in health policy and planning: a realist synthesis. *Australian Journal of Primary Health*, 23(6), 516-530. doi: <https://doi.org/10.1071/PY16129>

Kjellström S, Areskoug-Josefsson K, Andersson Gäre B et al 2019. Exploring, measuring and enhancing the coproduction of health and well-being at the national, regional and local levels through comparative case studies in Sweden and England: the 'Samskapa' research programme protocol. *BMJ Open*, 9(7), e029723. doi: <https://doi.org/10.1136/bmjopen-2019-029723>

Janet Wale, for HTAi PCIG
E-mail: pcig.htai@gmail.com
