

HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG) E-Bulletin, November 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 November E-Bulletin – from our Chair

November began with PCIG's annual two- and half-day face-to-face meeting. This year, the meeting was generously hosted by the Belgium HTA body KCE, which launched its 'position on patient involvement' on the first day of the meeting (6 November 2019). Dr Christian Léonard, KCE's Director General, opened the meeting with a thought-provoking address on the need for the subjective input of patients in HTA. Following this, Dr Irina Cleemput detailed the approach taken by KCE to answer the question: "How can we improve the quality of our research on patient-related issues by involving patients in decisions about the scope, design and execution of research projects". KCE undertook a large research project which included a review of the literature and primary qualitative research among local stakeholders. Of note, is the consideration the research gave to KCE culture - in terms of staff perspectives – to determine organisational readiness and to form consensus statements. The work resulted in 18 position statements which must be considered as a whole.

The meeting allowed members of the Steering Committee, project leads and local HTA bodies and a local patient representative to share recent work before discussing in detail our current projects and developing a wide range of recommendations to enable us to enact the new Terms of Reference adopted last June. Our action list is long. I am very grateful to all those who actively contributed to the meeting and, most especially, to the KCE Secretariat and our Vice Chair, Valentina Strammello, who made us so welcome in Brussels.

Finally, I'm delighted to report that the following PCIG-related panels and workshops have been accepted for Beijing 2020.

Workshops:

Identify Possible Steps to Improve Patient Involvement in HTA By Applying Patient Involvement Frameworks and High-Level Gap Analysis

Conceptualizing Patient-Involvement in Countries with Expanding Healthcare Coverage: Identifying Opportunities in Low- and Middle-Income Countries

Panels:

Patient Involvement Impact Stories - Adapting HTA?

Patient Participation at the Organizational Level in Health Technology Assessment

Involving Patients in Health Technology Assessment in Low- and Middle-Income Countries

Development of a 'Summary of Information for Patients' Template for International HTA Adoption

Gaps in HTA Patient Involvement: Suggestions to Enhance Patient Involvement in HTA and Augment

Existing Patient Involvement Frameworks

How and when to do Patient Engagement in Rapid-Cycle Medical Devices HTAs

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HTAi Matters



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

<https://www.htai2020.org/the-role-of-hta/and-plenaries>

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

Acceptance notification: February 1, 2020

Travel grants <https://www.htai2020.org/travel-grants-2/>

Successful/Unsuccessful Application Notification: February 3, 2020

Follow us on social media and re-post our messages: #HTAi2020Beijing

Twitter: twitter.com/HTAiOrg @HTAiOrg

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HTAi planned accreditation for courses and tools <https://htai.org/about-htai/committees-and-working-groups/scientific-development-and-capacity-committee/>

HTAi Interest Groups sometimes develop tools for use by HTA bodies or courses. The Scientific Development and Capacity Building Committee, led by Alric Ruther, is working on a new accreditation process.

IJTAHC Themed Issue: Patient and Public Involvement in HTA, 2021

Patient and citizen involvement have become an important part of health technology assessment. Patients and citizens have developed active partnership roles helping to ensure the relevance, acceptability and appropriateness of HTA.

The International Journal of Technology Assessment in Health Care invites the submission of papers (original research, reviews and commentaries) on the role of patients and citizens in HTA for a themed issue of the journal to be published in early 2021, guest edited by Sophie Werkö (SBU, Sweden) & Sophie Staniszewska (University of Warwick Medical School, UK). Abstracts were due by 30th November 2019. The next step is invitations to prepare full papers, following an assessment by 20 December 2019. Manuscripts will be due 30 April 2020.

Sophie Werko and Sophie Staniszewska

What's Happening

KCE Belgian Health Care Knowledge Centre – Are we ready for patient involvement?

KCE has released its report on 'Position of KCE on patient involvement in health care policy research'

<https://kce.fgov.be/en/position-of-kce-on-patient-involvement-in-health-care-policy-research>

Included in one of the chapters: To meaningfully involve patients in health policy research, there must be a positive culture towards patient involvement, someone needs to take up the leadership for the patient involvement activities within an organisation and coordinate the activities, and sufficient resources must be

available and training for researchers and patients on how to effectively involve/be involved needs to be provided.

Culture

The effectiveness of the contributions of patients is conditioned by the relationships that are established with the other actors involved. Empowering relationships and partnerships with patients, involving trust from patients and professionals, favor meaningful participation. There is still significant resistance against patient involvement among doctors, investigators, and project managers.

Leadership and coordination

Incorporating patient perspectives into a scientific evidence-based health policy research process is a delicate task and a challenge to researchers. They have to do justice to the voice of patients while remaining neutral and evidence-based. Transparency and clear communication with participants is key for successful and valuable engagement...As is evaluation and measurement of impact of patient involvement

Economic resources

Resources are required to organize and set-up patient involvement activities, both in terms of time and people...

Information and training

Patients and researchers involved in HTA agree that providing information and training to patients and researchers about patient involvement is a requirement for meaningful patient involvement...

FDA guidance document:

Patient-Focused Drug Development: Methods to Identify What Is Important to Patients Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-methods-identify-what-important-patients-guidance-industry-food-and>

This latest draft aims to help stakeholders (patients, researchers, medical product developers and others) identify what is most important to patients with respect to their journey with disease burden and treatment and the benefits and risks in the management of the patient's disease. The purpose of this guidance is to describe best practices on how we can collect and submit patient experience data (through a range of qualitative, quantitative and mixed method designs) from patients and caregivers to be used for product development and influence regulatory decision-making.

[US FDA CDER \(Drug Division\) Holding a Public Workshop on Incorporating Clinical Outcome Assessments into Endpoints for Regulatory Decision Making](#) (Workshop in Silver Spring, MD on 6 December 2019)

The US Food and Drug Administration (FDA) is hosting a public workshop on 6 December 2019 in Silver Spring, MD to gather input from the broader community of patients, patient advocates, researchers, practitioners, drug developers and other key stakeholders. The purpose of this workshop is to obtain feedback on considerations and issues related to the collection and analysis of clinical outcome assessment (COA) data for drug development and regulatory decision making. Topics such as endpoint development, estimands and analysis models, addressing heterogeneity, and the collection, storage, transmission and analysis of data will be discussed. [Registration is free here at this link](#). If unable to attend in person, registration for a live webcast is available.

Submitted by Sally Wortley and Barry Liden

The U.S. Food & Drug Administration (FDA) has developed a concise 'Biosimilar Basics for Patients' webpage to provide useful resources on the fundamentals of biosimilars.

<https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars>

From the European Patients Forum (EPF) November newsletter

EPF Congress 2019: For Patients With Patients

<https://www.eu-patient.eu/News/News/epf-congress-2019-theres-nothing-for-patients-without-patients/>

Over 300 delegates, including patient advocates, healthcare professionals, health NGOs, academics, members from industry and national institutions, and more than 60 speakers attended.

EUPATI latest addition to their programme: a new one-day training course on patient engagement for professionals. EUPATI Fundamentals is a one-day training course on patient engagement for professionals working in academia and the pharmaceutical industry, to ensure the accelerated uptake of effective patient engagement, and good partners for the patient community to work with.

International Alliance of Patients' Organizations Asia Pacific Patients Congress Taiwan 14 to 14 November 2019

<https://www.iapo.org.uk/asia-pacific-patients-congress>

Learn how patient reported symptoms may be able to assess cancer care quality

Patient Centered Outcomes Research Institute (PCORI) funded PRO-PM study.

<https://innovation.cms.gov/resources/oncology-listening-session.html>

The Centers for Medicare & Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (Innovation Center) is seeking feedback regarding a potential new model for value-based payment to support high-quality oncology care.

We will accept written feedback on the informal Request for Information until Friday, December 13, 2019.

Written feedback can be sent to OCF@cms.hhs.gov

A recording of the Public Listening Session is linked below (please note, that the session recording is divided into two parts):

Part 1: <https://www.youtube.com/watch?v=Nv6okv25-p4>

Part 2: <https://www.youtube.com/watch?v=1R8Afyma4gY>

Presented by the PRO-PM Patient Investigators

PCORI funds research that can help patients and those who care for them make better-informed decisions about the healthcare choices they face every day, guided by those who will use that information.

Patient Reported Outcome (PRO) measurements are any report of a patient's health condition that comes directly from the patient. PROs are reported without involvement by a doctor or anyone else. This study looked at symptoms reported from patients and if they can be used to assess cancer quality of care. How well does each clinic control symptoms for their patients?

The Patient Engagement Management Suite (PEM Suite)

A hub of co-created tools, resources, and practices to help stakeholders adopt PE in a systematic, efficient and meaningful way. The PEM Suite includes not only [Synapse](#), but also our ever-popular [PE Quality Guidance](#), [Book of Good Practices](#), [PE Industry Training](#), as well as the forthcoming [Fair Market Value Calculator](#) and How-To Modules for specific PE activities.

Publications

Co-construction of health technology assessment recommendations with patients: An example with cardiac defibrillator replacement. Pomey MP, Brouillard P, Ganache I, Lambert L, Boothroyd L, Collette C, Bédard S, Grégoire A, Pelaez S, Demers-Payette O, Goetghebeur M, de Guise M, Roy D.

Health Expect. 2019 Nov 5. doi: 10.1111/hex.12989. [Epub ahead of print]

<https://onlinelibrary.wiley.com/doi/epdf/10.1111/hex.12989>

Including the patient voice in the development and implementation of patient-reported outcomes in cancer clinical trials. Addario B, Geissler J, Horn MK, Krebs LU, Maskens D, Oliver K, Plate A, Schwartz E, Willmarth N. Health Expect. 2019 Nov 13. doi: 10.1111/hex.12997. [Epub ahead of print] Review.

<https://onlinelibrary.wiley.com/doi/epdf/10.1111/hex.12997>

Submitted by Karen Facey

Gathering Structured Patient Insight to Drive the PRO Strategy in COPD: Patient-Centric Drug Development from Theory to Practice. Commentary. Francesco Patalano . Florian S. Gutzwiller . Bhavik Shah . Chitresh Kumari . Nigel S. Cook. Adv Ther <https://doi.org/10.1007/s12325-019-01134-x>
<http://link.springer.com/article/10.1007/s12325-019-01134-x>

Submitted by Nigel Cook

Unmet needs in the international neuroendocrine tumor (NET) community: Assessment of major gaps from the perspective of patients, patient advocates and NET health care professionals. Simone Leyden, Teodora Kolarova, Catherine Bouvier, Martyn Caplin, Siobhan Conroy, Phillipa Davies, Sugandha Dureja, Massimo Falconi, Piero Ferolla, George Fisher, Grace Goldstein, Rodney J. Hicks, Ben Lawrence, Yoshiyuki Majima, David C. Metz, Dermot O'Toole, Philippe Ruzniewski, Bertram Wiedenmann, Ronald Hollander. International Neuroendocrine Cancer Alliance (INCA). Int J Cancer 2019

The ethics and politics of community engagement in global health research. Lindsey Reynolds, Salla Sariola (2018) Critical Public Health, 28:3, 257-268. <https://doi.org/10.1080/09581596.2018.1449598>

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