

HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG) E-Bulletin, April 2021

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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- HTAi Matters – Manchester Annual meeting, workshops
– Annual Meeting 2022; Webinars; Board election voting
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Welcome to our April E-Bulletin!

From our Chair

This year, more than 40 patients and their representatives will be able to attend the HTAi Annual Meeting for free. That represents a wealth of expertise and patient perspectives at HTAi 2021. The PCIG PASSes have been given to patient advocates, representatives of patient groups and consumer representatives of HTA committees who applied from the UK, USA, Brazil, Japan, Canada, Australia, Hungary, Belgium, and the Netherlands.

We’re grateful to sponsorship from Edwards Life Sciences, Janssen and Novartis, which enabled PCIG to set up the PASS to provide an additional avenue to patients wanting to attend the Annual Meeting. Thanks to Todd Stephenson (PCIG Finance Secretary and Director of Patient Engagement and Experience, Janssen) for his work to facilitate this opportunity.

Valentina Strammiello (PCIG Vice Chair and Head of Programmes at European Patients Forum) and Hervé Nabarette (PCIG Steering Committee and Deputy Director of Public Affairs, AFM Telethon) will oversee work to welcome patients attending HTAi 2021. Drawing on the recommendations of the Patient and Public Involvement Working Group for 2021, they’ll invite patients and their representatives to a briefing about HTAi 2021 and give participants the option of a virtual buddy from PCIG. Following evaluation with participants, PCIG will form a project sub-committee to ensure the quality of the experience for patients attending all future HTAi Annual Meetings (whether virtual, hybrid or other).

We’re also pleased to be able to offer PCIG PASS and HTAi Participation Grant recipients free access to our PCIG workshop WS19: *Putting Patients At The Heart: Resources And Good Practice For Patient Involvement In Health Technology Assessment* on Sunday, June 20, 2021 – 17.00 to 20.00 (UTC).

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/>

Save the date – PCIG ABM

Once again, we'll be holding a virtual Annual Business Meeting and ensuring PCIG members get an update on all our current projects. Further information to come, but please put the time and date in your diary: Tuesday 29 June, 9-10pm UTC +10 (that's 1-2pm if you're CEST and 7-8 am EDT)

Webinars for patient groups – clinical trials, uncertainty and health economics

Each webinar runs from 10-11am (UTC+10) and includes plenty of time for your questions. By registering for one webinar, your link will work for all three. [Register here](#).

Friday 14 May – Clinical trials and the patient voice

How do clinical trials influence the health treatments we can access and how can the patient voice add value to them? Presenters: Janelle Bowden (AccessCR and Research Gamechangers) and Dr Amanda Ruth (Head of Policy and Public Affairs, Rare Cancers Australia; Executive Director, National Oncology Alliance).

Friday 21 May – Uncertainty and the patient voice

What uncertainties arise from the evidence when valuing medicines (and other health treatments) for reimbursement in Australia and how can the patient voice add value? Presenters: Professor Andrew Wilson (PBAC Chair) and Nicole Millis (Rare Voices Australia CEO)

Friday 28 May – Health economics and the patient voice

How is health economics used to determine the value of medicines and health care for reimbursement and how can the patient voice add value? Presenters: Dr Richard de Abreu Lourenco (Associate Professor, CHERE, UTS) and Dr Sally Wortley (Consumer Evidence and Engagement Unit, Office of HTA, Dept of Health)

Contributed by Ann Single

International Journal of Technology Assessment in Health Care Special Issue: Patient and Public Involvement in HTA, April 2021

Guest Editors: Sophie Söderholm Werkö and Sophie Staniszewska. Twenty-four papers are associated with this special issue.

<https://www.cambridge.org/core/journals/international-journal-of-technology-assessment-in-health-care/special-issue-patient-and-public-involvement-in-hta>

With a letter of support from Professor Gillian Leng CBE, Chief Executive, National Institute for Health and Care Excellence (NICE, England). International Journal of Technology Assessment in Health Care, 37(1), E49. doi:10.1017/S0266462320002287

"It bears repeating that patients and carers are the people most directly affected by HTA recommendations and so it is incumbent on those of us producing these recommendations to ensure their views and experiences are central to our decision making... My congratulations to all the authors, and to Sophie Staniszewska and Sophie Werkö for their sterling efforts in coordinating this work..."

Werkö SS, Staniszewska S (2021). Patient and public involvement in Health Technology Assessment: a new dawn? International Journal of Technology Assessment in Health Care 37, e54, 1–2. <https://doi.org/10.1017/S0266462321000234>

"While PPI has become more common, it can still be seen as an optional extra rather than a vital element; therefore, its absence is not considered a fatal flaw in an HTA...Clearer methods of guidance on how to involve patients in more technical or quantitative HTA, in addition to guidance for HTA bodies in incorporating patient evidence into HTA assessments, could drive the field forward, embedding PPI into the bones of HTA..."

Frontiers in Medical Technology, Research Topic. Where to From Here: Advancing Patient and Public Involvement in Health Technology Assessment (HTA) Following the COVID-19 Pandemic

<https://www.frontiersin.org/research-topics/21300/where-to-from-here-advancing-patient-and-public-involvement-in-health-technology-assessment-hta-foll>

This Research Topic naturally follows on from the good work of the IJTAHC Special Issue. It asks people about patient and public involvement in HTA and if and how it has changed as a result of COVID-19; and what patient groups are doing.

The Topic Editors are Janet Wale, Sally Wortley and Marie-Pascale Pomey.

Abstracts are due 25 June 2021, with manuscripts to be submitted by 13 October 2021.

Do look at the website for suggested topics how you could contribute.

HTAi Matters



<https://htai.eventsair.com/htai-manchester-2021-am/>

HTAi 2021 Innovation through HTA - Manchester UK, June 19-23, 2021, Virtual meeting

For updates visit the HTAi 2021 Annual Meeting [website](#) and Twitter at #HTAi2021VirtualAM. Anyone can register for the Annual Meeting, with member and non-member rates available. To take advantage of member registration pricing please become an HTAi member or renew your HTAi membership before registering.

The 2021 Annual Meeting will focus on how adaptive approaches to HTA can continue to provide the cornerstone in leading health systems innovation particularly as technologies advance and novel interventions rapidly emerge. 'Patients at the Heart of Innovation' is one of the three plenary themes.

<https://htai.org/blog/2021/03/31/https-htai-org-p11825previewtrue/>

The HTAi Working Group: Patient Involvement in HTAi 2021 Annual Meeting is developing approaches to attract, welcome and support patients at this year's meeting and to develop processes that can be mainstreamed to support patient attendance at all future HTAi conferences.

The working group is chaired by Karen Facey, HTAi 2021 Local Organising Committee patient representatives, patient involvement experts from the HTA bodies in the UK and the PCIG Chair. To date the group has identified a range of improvements including briefings for patients and moderators, clearly defined patient session streams, buddying, areas for rest, and evaluation of patients' experience at the conference.

"The importance of patient involvement in HTA has never been of more interest," said Karen Facey.

"Patients at the heart of innovation' is a key theme of this year's meeting and we want patient participants to feel valued and able to participate easily. "

Registration: now open and can be [accessed on our website](#).

Early bird registration rates were available only until 30 April 2021.

Workshop registration is now OPEN! Check out the [workshop schedule](#) – see some examples:

<https://htai.eventsair.com/htai-manchester-2021-am/workshops>

Saturday, June 19, 2021 – 09:00 to 12:00 (UTC)

WS06. Values in Doing Assessments of Health Technologies

Saturday, June 19, 2021 - 17:00 to 20:00 (UTC)

WS08: A Hands-on Workshop on the Theory and Practice of Assessing the Impact of Health Technology Assessment. Facilitated by staff at HTA agencies that are members of INAHTA, this session will engage participants in a hands-on activity to apply the INAHTA Impact Framework to case studies.

Sunday, June 20, 2021 - 12:00 to 15:00 (UTC)

WS14: Conceptualizing Patient-Involvement in Countries with Expanding Healthcare Coverage: Identifying Opportunities in Low- and Middle-Income Countries (LMICs)

After exploring examples of emerging Patient and Public Involvement (PPI), the participants will interactively elaborate the determinants for PPI and specific requirements in LMICs.

Sunday, June 20, 2021 - 17:00 to 20:00 (UTC)

WS19: Putting Patients At The Heart: Resources And Good Practice For Patient Involvement In Health Technology Assessment

We will share how resources for patient involvement developed by the PCIG are adapted and used around the world, with presentations and discussions about the strengths and limitations of current resources; and small-group work to identify approaches to meet ongoing needs.

The Annual Scientific Meeting of the Society 2022

This will no longer be in Colombia. The HTAi Board made this difficult decision on March 31. Our Society is a global one and we aspire to grow our presence in all regions of the world and in doing so, to bring health technology assessment to a wider audience. The principles of diversity, equity and inclusion matter; these are not just elegant words, they speak to the need to bridge the gap that too often separates the northern and southern hemispheres. Our Society is also one that is emerging from a very difficult financial period, one that has considerably reduced our operational flexibility and capacity to take on risk. For this reason, and the fact that the 2022 Annual Scientific Meeting is just 15 months away, we have chosen The Netherlands as the host country.

HTA and Value-Based Healthcare Webinar series

The Medical Devices and Hospital-Based HTA Interest Groups hosted a two-part webinar series titled "HTA and Value-Based Healthcare: Methods" on March 4 & 25 that discussed the methodological differences between HTA and Value-Based Healthcare (VBHC) and how they can be applied to Medical Devices.

[View the Pt. 1 Recording](#)

[View the Pt. 2 Recording](#)

Over 120 attendees were from all over the world!

"Comparison and contrasting Real World Evidence Guidelines Across Decision-Makers including HTA's / RWE for ICER Sickle Cell Disease (US)" webinar was on 28 April 2021. It was presented by Ashley Jakska from Aetia, USA.

Voting for the 2021 Board of Directors

This is a friendly reminder that voting is open 24 hours a day, seven days a week until May 7.

We hope that you can take a moment to cast your vote. You have received an email from CIVICA (CES), a third-party electoral service that is administrating the election on behalf of the HTAi. For more information about the 2021 Board of Directors Election, please visit our [website](#).

The HTAi Secretariat

HTAi Social Media

Feel free to follow us or check in on our social media channels and repost our messaging:

Twitter: twitter.com/HTAiOrg @HTAiOrg

Facebook: www.facebook.com/HTAiOrg @HTAiOrg

LinkedIn: www.linkedin.com/company/htai

What's Happening

DIA/IMI PREFER Patient Preferences Workshop

https://www.diaglobal.org/en/conference-listing/meetings/2021/06/dia-imi-prefer-patient-preferences-workshop?utm_medium=email&utm_source=db&utm_content=EMEA_21135_First_2021-04-15&utm_campaign=21135&mkt_tok=MzQ5LVNWSiowNjgAAAF8dTw6J-C9mdMF3U9xgKLFt3G5lSig2OsLoM7XHp3B7Q62PKTHoQ_Kb2enpSj1oSDZRbDXCORuiRqIXAcOdUH_uM3FnuD4qRQNLVK2PW6owl

This Workshop has been developed by DIA in collaboration with IMI PREFER, and has been funded by IMI PREFER and IMI PREFER partners.

Jun 15, 2021 2:00 PM – Jun 16, 2021 6:20 PM

Virtual Event

Contributed by Karen Facey

Launch of IMPACT HTA appraisal framework, 12 May 2021

The European Commission funded H2020 project IMPACT HTA is launching its appraisal framework suitable for rare disease treatments. The framework highlights the need for iterative patient involvement during the HTA process. All are welcome to attend via this registration link. [Webinar Registration - Zoom](#)

The framework includes a new patient group submission template for re-appraisal of a rare disease treatment after an "Outcomes-Based Managed Entry Agreement" (mandatory data collection post HTA). Several PCIG members provided helpful comments on drafts of the document and it is now shared for adaptation by HTA bodies. It may also help patient groups and industry consider what issues they need to consider during such data collection processes. <https://tinyurl.com/h5rvjcw>

Contributed by Karen Facey

EUnetHTA Forum held 15 April 2021 <https://eunetha.eu/2021-eunetha-forum-agenda/>

Challenges to a lifecycle approach to EUnetHTA's work: Lessons learned from the current Joint Action: Moderator Ansgar Hebborn, EFPIA ; panellists Alex Correia, INFARMED; Ansgar Hebborn, EFPIA; Chantal Guilhaume, HAS; Michael Berntgen, EMA; Valentina Strammiello, EPF; Zoe Garrett, NICE

Research needs in HTA: What is needed today and what we will need tomorrow. Moderator Wim Goettsch, ZIN/Utrecht University/HTx; panellists Carmen Laplaza Santos, DG Research & Innovation, European Commission; Claudia Wild, AIHTA/EUnetHTA; Inaki Gutierrez-Ibarluzea, PARADIGM; Irina Cleemput, PREFER; Páll Jónsson, NICE/GetReal; Panos Kanavos, IMPACT; Rosanna Tarricone, COMED

EUnetHTA: The past, the present and the future - Lessons learnt and recommendations. Moderator Marcus Guardian, ZIN; a) A EUnetHTA perspective; b) A patient perspective; c) The upcoming EC regulation on HTA: Anna Eva Ampelas, European Commission (DG SANTE); Niklas Hedberg, TLV/EUnetHTA; Rui Santos Ivo, EU Council Presidency; Tiemo Wölken, MEP/EP Rapporteur; Yann Le Cam, EURODIS

Patient Engagement Open Forum (PEOF) April 14 and 15, 2021

[Synapse – the global patient engagement map and network.](#)

PEOF 2021 - A Time to Reflect & Move Forward – slides and recording

PEOF 2021 - Patient Engagement to design, generate, analyze and decide on Patient Experience Data – slides and recording

<https://synapse.pfmd.org/resources?filters%5BresourceCategory%5D%5Bvalue%5D=video>

The GetReal Institute

<https://www.getreal-institute.org/join/#1526043758798-a7563ef4-6444d70a-627e>

An independent membership-led organisation of key stakeholders involved in the generation and use of RWE, including decision makers, public and private researchers, patients and clinicians, data custodians, and technology developers. It is positioned to address critical challenges requiring multi-stakeholder input and collaboration in a pre-competitive environment. It is a trusted 'brand', building on a record of influential thought leadership and highly regarded tools and resources. Although focused on Europe it has linkages to other initiatives and stakeholders around the globe.

Stakeholder-members pay a fee, including patient organizations.

Congressional Budget Office (CBO) US – Report on 'Research and Development in the Pharmaceutical Industry' April 8, 2021 <https://www.cbo.gov/publication/57126>

CBO assesses trends in spending for prescription drug research and development (R&D) and the introduction of new prescription drugs. CBO also examines factors that determine how much drug companies spend on R&D.

Shaping the future of digital technology in health and social care

<https://www.kingsfund.org.uk/publications/future-digital-technology-health-social-care>

7 April 2021

This report, commissioned by the Health Foundation in the UK, provides a summary of evidence for how emerging technologies such as artificial intelligence, smartphones, wearable devices and the internet of things are being used within care settings around the world.

Strengthening the Accelerated Approval Pathway: An analysis of potential policy reforms and their impact on uncertainty, access, innovation, and costs

Institute for Clinical and Economic Review (ICER), 26 April 2021.

<https://34eyj51jef417itp82ufdoe-wpengine.netdna-ssl.com/wp-content/uploads/2021/04/Strengthening-the-Accelerated-Approval-Pathway--ICER-White-Paper--April-2021.pdf>

US Accelerated Approval Pathway. Insightful analysis of pros and cons, dilemmas of balancing uncertainty, risks and costs for patients with few options.

Publications

The Role of Patient Experience in the Value Assessment of Complex Technologies - Do HTA Bodies Need to Reconsider How Value is Assessed? <https://europepmc.org/article/med/33814201>

Sarri G, Freitag A, Szegvari B, Mountian I, Brixner D, Bertelsen N, Kaló Z, Upadhyaya S.

Health Policy (Amsterdam, Netherlands), 25 Mar 2021. DOI: 10.1016/j.healthpol.2021.03.006.

Contributed by Sally Wortley

Hispa-NICE: A Pipe Dream or a Realistic and Necessary Initiative? Fernando Antoñanzas.

PharmacoEconomics. Accepted: 26 March 2021 <https://doi.org/10.1007/s40273-021-01025-6>.

https://link.springer.com/epdf/10.1007/s40273-021-01025-6?sharing_token=zBRLY9smWYNn1tey_zYYmve4RwlQNchNByi7wbcMAY6qE1udzWs_tg-KgcytrViBo-C8doYw7Fb72_mgYlgryjJSXYgu_wjStYiepDlafeFCEqzSJVjVn64-vs8FHK6edN3cH5ys1KVUecCt73p4ir7mjiV5Nr-V8nhig_WheqQ%3D

[vs8FHK6edN3cH5ys1KVUecCt73p4ir7mjiV5Nr-V8nhig_WheqQ%3D](https://link.springer.com/epdf/10.1007/s40273-021-01025-6?sharing_token=zBRLY9smWYNn1tey_zYYmve4RwlQNchNByi7wbcMAY6qE1udzWs_tg-KgcytrViBo-C8doYw7Fb72_mgYlgryjJSXYgu_wjStYiepDlafeFCEqzSJVjVn64-vs8FHK6edN3cH5ys1KVUecCt73p4ir7mjiV5Nr-V8nhig_WheqQ%3D)

In December 2020, a group of 300 professionals and experts on the Spanish health care system signed a manifesto [1] advocating for the creation of an independent authority for the evaluation of health practices

and policies, a kind of Hispa-NICE, to promote that price and reimbursement (P&R) decisions are systematically based on efficiency criteria.

How does HTA address current social expectations? An international survey. Gagnon H, Legault G, Bellemare C, et al (2021). *International Journal of Technology Assessment in Health Care*, 37(1), E9. doi:10.1017/S0266462320000793

As to how HTA reports should fulfill their social role, over 84 percent of survey respondents agreed upon the necessity to address this role for decision makers, patients, and citizens. And to make value-judgments explicit in different report sections, including ethical analysis...

Lessons from the vaginal mesh scandal: Enhancing the patient-centric approach to informed consent for medical device implantation. O'Neill J. (2021). *International Journal of Technology Assessment in Health Care*, 37(1), E53. doi:10.1017/S0266462321000258

Vaginal mesh manufacturers were found to have had financial links to research, royal colleges, and influential clinicians, which then influenced the basis of the evidence-based practice that often guides such bodies of medical opinion. Information disclosure for informed consent for patients should relate to the risks, benefits, and alternatives to the surgical procedure and medical device.

The thorny issue of value alignment: How development-focused health technology assessment can help find win-win situations for patients and healthcare systems and commercial investors. Bouttell J, Briggs A, Hawkins N (2021). *International Journal of Technology Assessment in Health Care*, 37(1), E57. doi:10.1017/S026646232100026X

A different animal but the same beast? Using development-focused health technology assessment to define the value proposition of medical technologies. Chalkidou A (2021). *International Journal of Technology Assessment in Health Care*, 37(1), E58. doi:10.1017/S0266462321000209

A different animal? Identifying the features of health technology assessment for developers of medical technologies. Bouttell J, Briggs A, Hawkins N. *Int J Technol Assess Health Care*. 2020;36:285–91.

Adaptive health technology assessment to facilitate priority setting in low- and middle-income countries. Nemzoff C, Ruiz F, Chalkidou K, et al. *BMJ Global Health* 2021;6:e004549. doi:10.1136/bmjgh-2020-004549

With a growing appetite for HTA in low-and middle-income countries (LMICs) to better inform healthcare priority setting.

LMICs may benefit from adaptive HTA (aHTA), which is defined as a broad term for HTA methods and processes which are fit-for-purpose and focus on context-specific practicality constraints.

More work is needed to design, support and test bespoke aHTA for LMICs to better understand its strengths and limitations.

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