HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG)
E-Bulletin, January 2023

Enhanced quality and relevance of HTA through patient and citizen involvement

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

- Welcome – from our Chair
- PCIG Matters –updates
- HTAi Matters – HTAi2023
- What's Happening – in and for patient and public involvement
- Publications

Welcome to our January E-Bulletin

From our Chair:
This month, I'm doing something a little different. In November 2022, I asked Steering Committee members to come to our 'planning meeting' ready to speak for five minutes each about where patient involvement and/or citizen involvement in HTA needs to go, or is going. We simply listened to each other rather than responding to what each person said. For me, hearing my colleagues speak like this was gold. It gave me a chance to look over the mountain of PCIG activities and see as a PCIG where we could go. I was encouraged to share 'my 5 minutes' more widely. I admit I wrote it quite quickly the night before the meeting and, if time permitted, I might have edited it to take account of nuances, key literature and practice example, and work on the 'rant' tone. But in the spirit of transparency, I think it is right to share with all members and so it is included here under 'PCIG Matters'.

Stay safe, as we all know too well, the pandemic is not over.

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

NOTE: Present and past issues of the E-Bulletin can also be accessed on the website
https://htai.org/patient-and-citizen-involvement/

PCIG Matters

Expressions of Interest – PCIG Steering Committee
PCIG seeks Expressions of Interest for an industry representative (pharma company preferred) to fill a vacancy on its Steering Committee.
Please submit an Expression of Interest (no more than 200 words) to the PCIG Chair, Ann Single (singlehaworth@gmail.com) addressing the criteria below by Wednesday 15 February 2023. Full details of the role can be found in PCIG's Terms of Reference.
Criteria
- Able to demonstrate active participation in the field of patient or citizen involvement in health technology assessment
- Able to meet the expectations of Steering Committee membership as set out in the Terms of References, e.g. commit to take an active role in driving the work of the Interest Group and providing practical assistance to activities undertaken by the group as appropriate and complete a three-year term

- Able to participate in additional HTAi committees
Preference will be given to those members who have actively participated in the Interest Group.

List serv change
HTAi is now allowing PCIG to manage its membership list, which includes distribution of emails to the interest group membership such as this e-bulletin. We will continue to publish this E-Bulletin on the HTAi website and promote it via our social media accounts on LinkedIn and twitter (@pcisg) as well as circulate directly to the email accounts of HTAi PCIG members. If you are not receiving the direct email, please check that you are (1) up to date with your membership and (2) have ticked the box for PCIG membership. Please note that patient-citizen@mailer.htai.org no longer works and any items for group dissemination should be sent to the Chair until a new Technical Officer is appointed.

Save the date - PCIG workshop
This year's PCIG's pre Annual Meeting workshop will be held in Adelaide on Saturday 24 June, 8.30 am - 4.30 pm. The workshop will begin with an introduction to key concepts, methods and approaches to patient involvement followed by a deeper exploration of key areas for harmonisation activities such as: training and capacity building; integrating patient preferences in HTA; valuing patient and public produced evidence, defining patient-centric HTA and measuring impact.

Registering for Annual Meeting (June 24-28, Adelaide, Australia)
Early bird registration for HTAi 2023 Adelaide opens the first week of February (when we'll also provide information on the PCIG PASS). Don't forget to register for the workshop separately to registering for the Annual Meeting.
Discount flight programs
HTAi is pleased to announce a new partnership with the Lufthansa Group and their global network of flight partners. The partnership provides Delegates to the 2023 Annual Meeting with a global and efficient travel experience at a discounted rate (up to 15%).
Visit the HTAi Annual Meeting website for more information.

HTA Policy and Methods Review Australia
This review began in December 2022. The review's website contains the draft Terms of Reference which were shared for targeted-only (restricted) consultation in early January and communiques from the Reference Panel meetings. The review is due to conclude 31 December 2023.

All contributed by Ann Single

Your thoughts please on the following:

Where is patient and/or citizen involvement in HTA going?
5 minute reflection given to PCIG Steering Committee to provoke reflection, discussion, better and clearer answers. It should be read as an inquiry about these topics, not answers.

It depends. It depends on where you live, how you define HTA, and how you define patient and citizen involvement? I find citizen or public involvement still under-described and challenging. For example, there is often a suggestion of it as a societal view of how budgets should be spent from those without the bias of a patient or carer perspective – like taking mortgage advice from someone still living at home – and at other times I wonder if ethicists would be more appropriate for the role given. I also see potential in the concept for strategies to engage a wider community who may never identify as patients and yet may be those who can most benefit from better healthcare.

For me, patient involvement is shared learning and problem solving and, as such, inherently a form of capacity building and empowerment. Because the evidence base remains limited, it is also about robust research into patients' needs, preferences and experiences developed with patients. My views of patient and public involvement come from a background in community engagement and science communication, and so I remain frustrated by the ongoing disconnect or lag behind those fields.

Meanwhile, HTA is a product of goal and setting. The goals are often not sufficiently explicit, but the settings and the challenges are clearer. Global Policy Forum this year will explore the impact of HTA, an area remarkably under-explored and possibly being hindered by a lack of shared agreement about what impact looks like within individual jurisdictions.

I see a continuum where some HTA is working to the idea of good value for money within a belief that a healthy population is key to our society (and other ethical imperatives) and some are very driven by the budget imperative. Some operate in a changing ecosystem of wider patient engagement and some lead the way. Some call regulation HTA. Some only assess evidence from the companies and only do HTA when they receive an application. Others start with clinical or community need. Some operate in big biopharma and medical device markets and some are tiny. Some HTA happens in systems that are highly adversarial between industry and HTA, and some see a flow between workers and have more opportunities for dialogue.

And behind it all sits a culture of science which I believe feels silenced about its concerns regarding patient involvement. This can lead to patient involvement being tokenistic, a belittling of its value, sometimes in an outwardly hostile environment. I see glimpses of partnership working, but still 'patients as input' dominates. On one hand processes can be paternalistic - keeping the real discussion for the adults, making assumptions about patients and their potential role/s, and even wasting their time on work better done by particular professions; and praising patients for contributions unlikely to add value.
Patient involvement must go where HTA goes, but that is in many directions. We try to play by HTA's rules, but often those rules are not transparent and the rules we know may be a barrier to those people most in need of equitable access to healthcare.

In Utrecht in 2022, many in the Society spoke to me as if patient involvement in HTA and the Society was a done deal. It made me nervous because I still see a heavy reliance on process that I once considered stop gap. Process that was a compromise to ensure that patients were a little involved. I see this process light on shared learning and agency. And I sense a push back or backlash in some areas.

This leads me to believe we have created a house with many well designed rooms but we might be wise to check our foundations. For example,
- HTA does not tell its story well, but we tend to be quite good at it – especially outside the Society (which also does not explain HTA well). I wonder if we need to tell that story and the rationale for patient involvement, including evidence to refute misconceptions and principles before process; goals before method. Would this also help to avoid colonising practices when supporting those with emerging HTA systems?
- I wonder if we need to encourage dialogue – perhaps small conversations in a safe space to hear the concerns of those opposed to patient involvement so that we can begin to make some movement within this ongoing tension.

- I wonder what beliefs our materials promote. Does 'patient as a source of input' dominate at the expense of patient as a partner or co-designer? How are we trading:
- Process vs Iterative Learning
- Structures vs Relationships
- Represented vs Underserved

• The context, style and accessibility of our materials needs to be resolved and I think we have ideas to do it quickly and efficiently.
With this reflection and clarity, I wonder if we can better tackle the investment in and integration of patient-based evidence in the variety of typical HTAs and step up our partnership activities to make the meaningful connections across the lifecycle that we need.
Whatever happens to HTA there will be decision making processes used to decide the healthcare we can and can't access. If patient involvement is needed for better outcomes for patients in an equitable system, the foundations and, the knowledge of PCIG should be able to adapt and evolve to whatever comes our way.

Ann Single, November 2022
* Respond to both Ann and Janney for your comments to be included in future E-Bulletins

HTAi Matters

HTAi 2023 Annual Meeting, June 24 to 28, Adelaide: The Road to Policy and Clinical Integration
Australia has some exciting updates, and plenary themes:
- Fast-Tracking Clinical Innovation: The Balance of Speed and Rigour
- Making HTA More Efficient: What Can we Learn about Harmonization, Work Sharing, and Adaptation?
- Feasibility of Aligning Technology Evaluation Processes and Decisions in an Era of Sustainable Development

International Flight Discount Program for the 2023 Annual Meeting
HTAi has initiated a partnership with the Lufthansa Group and their global network of flight partners to provide delegates to the 2023 Annual Meeting with a global and efficient travel experience at a discounted rate. The Lufthansa Group network consists of Austrian Airlines, Brussels Airlines, Eurowings, Lufthansa and SWISS. To book your flight, utilizing the Annual Meeting 2023 discount, please follow the instructions provided on the Annual Meeting website.
Discounts are up to 15% and reduced fares will be automatically displayed. HTAi cannot guarantee that the fares offered through the Lufthansa Group flight program are the cheapest available in the market for any particular route, so check. HTAi does not benefit from any of its delegates booking with the Lufthansa Group, discounts are directly applied to the booking party only.
From the December HTAi Review https://htai.org/htai-review-december-23-2022/

Global Policy Forum
The topic for the 2023 Global Policy Forum, taking place over 3 days from 26 March in The Hague, the Netherlands is: 'The Value and Impact Of Health Technology Assessment'. You can access the document here: https://online.pubhtml5.com/xcuo/urog/

The HTAi Review, your biweekly news source for all things HTAi
The world of HTA is vibrant and active, and staying up-to-date with the latest HTA news is more important than ever. To keep you informed, we have launched a new, biweekly newsletter with the most recent news from the HTAi network. Each Review will include headline news from the organization, upcoming dates and deadlines, HTA news you may have missed, and a look back at events and activities from the past two weeks. The latest issue of the HTAi Review is available now! Click here to catch up on HTA news and updates from around the world.

Website at https://htai.org/

HTAi Social Media
Feel free to follow us or check in on our social media channels and re-post our messaging:
Twitter: @HTAiOrg
Facebook: @HTAiOrg
LinkedIn

What's Happening

ISPOR 2023 Conference, Boston, USA, 7-10 May
Travel grant applications are now open for patient group representatives who have not received such a grant in the past 3 years. The Travel Grant includes complimentary registration to ISPOR 2023 and up to $750 travel reimbursement, per the ISPOR Travel Reimbursement Policy. Deadline to submit an application is Thursday, February 9, 2023.

Invitation to patient experts - TO JOIN RWE4DECISIONS COMMUNITY
RWE4Decisions is a multistakeholder learning network about the use of real world evidence in HTA/Payer decisions for highly innovative medicines in the EU and Canada. Experts from the 'RWE4Decisions Community' are invited to up to 4 closed virtual roundtable meetings per year, to discuss case studies that explore specific issues relating to RWD quality, methods to develop RWE, and underpinning issues such as trust and transparency. If you are a patient expert with expertise in the use of health system or patient generated data, and would like to join the 'Community', please email k.facey@btinternet.com with a few sentences that describes your expertise in the field. Applications by 17 February please.

Both contributed by Karen Facey

Authored by a patient advocate:
Commentary on CADTH's recent (and non-transparent) reduction of QALY values for oncology drugs, by 50%, and implications. https://www.mdpi.com/1718-7729/29/3/127
The quality-adjusted life year is a generic measure of disease burden, including both the quality and the quantity of life lived. It is used in economic evaluation to assess the value of medical interventions. One QALY equates to one year in perfect health. QALY scores range from 1 to 0.

Contributed by Deb Maskens

European Patients Forum (EPF) – from their January Newsletter
Three topics for 2022 stood out: their work on digital health and the European Health Data Space, the pharmaceutical legislation proposals, and the Medical Devices Regulation.
***European Health Data Space** (EHDS)*
Following member consultations, EPF released a position statement on the European Commission's proposal on 28 November, with 19 proposed amendments. EPF's recommendations put patients at the heart of this initiative and focus on trust, transparency, meaningful patient involvement, security, and data

protection.

Pharmaceutical legislation

The Policy team worked extensively on reviewing the Commission's foreseen pharmaceutical legislation proposal, which was originally due to be published in December 2022. In line with the most recent updates, the legislative proposal is now expected to be published towards the end of March 2023. An advocacy strategy, relevant events, and consultation of members took place on how to achieve patient-centred legislation, promoting equitable and fair access to innovative medicines.

MDR (Medical Devices Regulation)

December was marked by a focus on the "new" EU Medical Devices Regulation (2017/745) (MDR). The MDR entered into force on 26 May 2021, setting a new framework of rules for the authorisation process of all medical devices to enter the Single Market. Technically, by 26 May 2024, all medical devices must comply with this new set of rules, but concerns have been raised and reported about disruptions to the availability of many medical devices in the EU. EPF called for action: a lack of capacity of Notified Bodies to certify and re-certify devices and the reported high cost of certification could result in devices being withdrawn from the market, for example, threatening patient safety and continuity of care.

Early 2023, the Commission published proposed amendments introducing new deadlines of 3 to 4 years for compliance with the MDR, depending on the risk class of the medical devices. EPF supported a one-year postponement, but raised the concern that the three-year postponement and other deadline changes should not lead to a lower level of ambition and preparedness for the implementation of MDR, as patient safety remains the core element.

Project Spotlight on H2O: Strengthening the Patient Voice In Healthcare

The European Patients' Podcast has a Project Spotlight on the Health Outcomes Observatory (H2O) project. H2O is a project of the Innovative Medicines Initiative; it's a public-private partnership drawing together patients, providers, researchers, industry, and policy makers who share an interest in putting patients at the heart of healthcare. H2O is set to transform the use of patient-reported information in healthcare, enrich the interaction between patients and healthcare providers and, as a result, drive better outcomes for patients. In this episode, EPF speaks with Linetta Koppert of the Erasmus Medical Centre and Jolanda Koenders of Takeda, H2O country leads for the Netherlands, to learn more about how H2O is strengthening the patient voice in healthcare. Listen to the episode here

Patient and Carer Survey on systemic sclerosis or scleroderma across 20 European countries

The European Federation of European Scleroderma Associations (FESCA) is launching a survey, translated into 16 languages to gather the perspective of patients and their carers on the socio-economic burden of the disease as well as the obstacles along the care pathway. The surveys have been developed in collaboration with medical experts and patient representatives. The results of the surveys will inform FESCA's Report identifying gaps where further attention and interventions from policymakers and health authorities are needed. Stay tuned for the launch of the Report on World Scleroderma Day, taking place on 29 June 2023! Access the Patient and Carer surveys here!

For EU citizens: Public consultation on the past, present and future of the European Research & Innovation Framework programmes 2014-2027

https://ec.europa.eu/eusurvey/runner/Horizon2020HorizonEuropeStrategicPlan2025-2027 -

The PREFER Recommendations - Why, when and how to assess and use patient preferences in medical product decision-making https://zenodo.org/record/6592304#.Y9iZznZBzIU

Two key uses of patient preference information are to inform the choice of patient-relevant endpoints by providing information on the relative importance of what matters to patients, and to provide information on patients' views about the acceptability of trade-offs between treatment characteristics, or other attributes of treatments or health interventions.

The PREFER Recommendations provide expert and evidence-based guidance from six years of research on when and how to design and conduct a patient preference study.
The PREFER project was a joint undertaking by 33 public and private partners with more than 130 people representing academic institutions, pharmaceutical companies, health technology agencies, and patient organisations in European countries and in the US.

Hilda Bastian's 'My Mastodon guide' on her PLoS 'Absolutely Maybe Blog'
https://absolutelymaybe.plos.org/2022/12/12/some-shortcuts-to-giving-mastodon-a-try/

African Development Bank unveils the African Pharmaceutical Technology Foundation
- At the 2nd International Conference on Public Health in Africa, Kigali, Rwanda, on 14 December
The African Development Bank Group has formally introduced its new initiative that will join hands with the African Union to boost Africa's capacity to produce drugs, vaccines, diagnostics, and therapeutics all along the value chain, to help build its pharmaceutical sector. The WHO, the Coalition on Epidemic Preparedness, the South Centre, Geneva, and the Federal Ministry for Economic Cooperation and Development of Germany have expressed keen interest in working with the Foundation in the coming year.

It's time to gamify behavioural science
How games can make behavioural science better. By Bria Long, Jan Simson, Andrés Buxó-Lugo, Duane G. Watson, Samuel A. Mehr. Nature Comment, 17 January
https://www.nature.com/articles/d41586-023-00065-6?utm_source=Nature+Briefing&utm_campaign=0e9793851a-briefing-dy-20230119&utm_medium=email&utm_term=0_c9dfd39373-0e9793851a-44432605
Wordle, Minecraft and Scrabble are played online by millions. Gamifying experiments can make behavioural research more inclusive, rigorous and reproducible — if it's done right.
Gamifying experiments can help researchers to reach thousands or millions of people from diverse groups, argue five behavioural researchers. For example, a game that guessed where in the world English-speaking players learnt the language went viral on social media, giving scientists access to data from almost 670,000 people. Researchers will have to sacrifice carefully controlled laboratory environments, but they often gain more engaged, naturally behaving participants, including many who wouldn't have taken part in lab-based studies.

COVID-19
Davis, H.E., McCorkell, L., Vogel, J.M. *et al.* Long COVID: major findings, mechanisms and recommendations. Nat Rev Microbiol (2023). https://doi.org/10.1038/s41579-022-00846-2
Long COVID is an often debilitating illness that occurs in at least 10% of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections. More than 200 symptoms have been identified with impacts on multiple organ systems. At least 65 million individuals worldwide are estimated to have long COVID, with cases increasing daily.

Publications

Themed Section: The Patient Journey
Value in Health January 2023 26(1):1-150 https://www.valueinhealthjournal.com/current
Delivering what patients want requires a deep understanding of the diversity of patient preferences. The collection of studies reported in this themed section illustrates the wide range of activities that contribute to patient-centered care and optimize the patient experience.

Mühlbacher A, Stolk E. Patient-Reported Satisfaction, Experiences, and Preferences: Same but Different? Value Health. 2023 Jan;26(1):1-3. doi: 10.1016/j.jval.2022.10.005. The authors summarize key issues in the

development and use of patient-reported experience measures that capture patient satisfaction and perception of products and services.

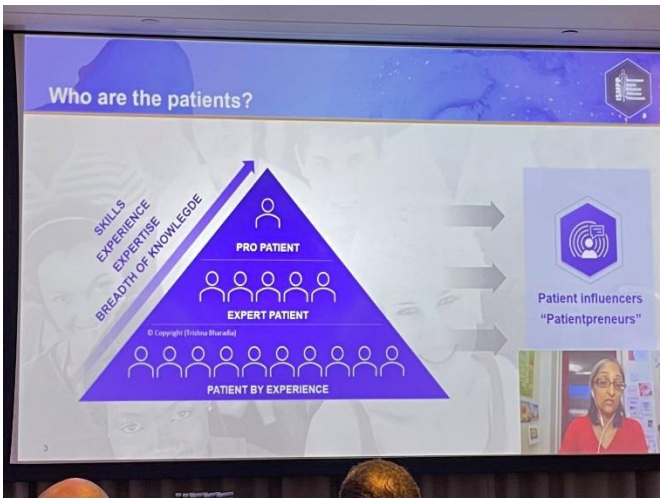
Oehrlein EM, Burcu M, Schoch S, Gressler LE. Enhancing Patient Centricity of Real-World Data Research: An Exploratory Analysis Using the Patient Experience Mapping Toolbox. Value Health. 2023 Jan;26(1):10-17. doi: 10.1016/j.jval.2022.10.002. This paper examines how researchers could leverage qualitative patient experience data captured through the Patient Experience Mapping Toolbox to guide real-world data research designs.

Rismanchian F, Kassani SH, Shavarani SM, Lee YH. A Data-Driven Approach to Support the Understanding and Improvement of Patients' Journeys: A Case Study Using Electronic Health Records of an Emergency Department. Value Health. 2023 Jan;26(1):18-27. doi: 10.1016/j.jval.2022.04.002. A process mining–based patient journey modeling approach supports an understanding of patient experiences and performance improvement of healthcare delivery processes.

Oehrlein EM, Schoch S, Burcu M, McBeth JF, Bright J, Pashos CL, Willke R, Love TR, Mattingly TJ 2nd, Perfetto EM; Patient-Centered Real-World Evidence Working Group. Developing Patient-Centered Real-World Evidence: Emerging Methods Recommendations From a Consensus Process. Value Health. 2023 Jan;26(1):28-38. doi: 10.1016/j.jval.2022.04.1738.
This article describes how patient experiences/insights data can be incorporated into the design, conduct, and translation of real-world research that reflects patients' lived experiences.

Subbiah, V. The next generation of evidence-based medicine. Nat Med 29, 49–58 (2023). https://doi.org/10.1038/s41591-022-02160-z
Before the COVID-19 pandemic, the conduct of clinical research had remained almost unchanged for 30 years and some of the trial conduct norms and rules, although archaic, were unquestioned. The success of future clinical trials requires a fundamental transformation in how trials are designed, conducted, monitored, adapted, reported and regulated to generate the best evidence. The status quo model is unsustainable. Instead, preventive, personalized, pragmatic and patient-participatory medicine is needed, and paradigm shifts are required to get there via sustainable growth. Silos need to be broken. Methodological advances and future AI-based analyses of all data will provide deep evidence to realize the goal of personalized medicine— that is, to offer the right treatment to the right patient at the right time.

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



Trishna Bharadia's patient pyramid, International Society for Medical Publication Professionals https://connect.ismpp.org/events/event-description?CalendarEventKey=7120b2f0-9034-402c-ab48-e7031d838905&Home=%2Fhome