

HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG) E-Bulletin, August 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 Aline, our Co-Chair
- PCIG Matters – call for Financial Secretary, conversations for change
- HTAi Matters – thinking ahead to Seville 2024
- What's Happening – in and for patient and public involvement
- Publications

Welcome to the August edition of the HTAi Patient and Citizen Involvement Group (PCIG) E-Bulletin!

I start this month's issue by acknowledging and thanking our outgoing chair, Ann Single, for smoothly handing the PCIG activities to the new co-chairs. We also thank our esteemed member Todd Stephenson, who served as our Finance Secretary for the past 5 years. You both played an essential role these last years, mainly ensuring patients are included in the HTAi Annual Meetings.

Please witness this success by watching the thoughtfully crafted video produced by the Patient Voice Initiative. It showcases Patients at HTAi 2023 Adelaide, where we had more than 70 patients enriching the conference discussions: <https://www.youtube.com/watch?v=NIBCrxVIN2M>.

I extend our deepest gratitude to Janney Wale, Editor of the PCIG E-Bulletin, to our contributors and to our readers. Your work and participation fuel the momentum of patient-centred change. As co-chair of the PCIG Steering Committee, I am privileged to witness the dedication and commitment of our community in bridging the gap between patients, evidence, and policies.

Thank you for your ongoing support, and I invite you to dive into the richness of perspectives that await within this month's issue.

Aline Silva, Co-Chair
HTAi PCIG Steering Committee

NOTE: Present and past issues of the E-Bulletin can also be accessed on the website

<https://htai.org/patient-and-citizen-involvement/>

Social media accounts on [LinkedIn](#) and [twitter](#) (@pcisg)

PCIG Matters

The IAPO Board and staff team were deeply saddened to announce that their Chief Executive Officer Kawaldip Sehmi passed away on Tuesday 1st August 2023. "Our hearts are broken by this sad news as he had so much enthusiasm and excitement for life and his work in promoting patient-centred healthcare. He was the pillar and symbol of IAPO this past decade, bringing everyone together and taking care that every patient's voice is heard."

<https://www.linkedin.com/feed/update/urn:li:activity:7093090428651978753/>

Call for PCIG Steering Committee Finance Secretary:

The HTAi PCIG invites Expressions of Interest for a Financial Secretary. The Financial Secretary is responsible for financial issues such as raising funds and managing budgets for meetings.

The role

- Work with the PCIG Steering Committee to:
- Attract sponsorship to support patient attendance at each annual meeting
- Liaise with HTAi Secretariat Finance to manage budgets responsibly
- Raise funds for other meetings and activities as required
- Serve on the Steering Committee as a representative of the biopharma industry

Term

3 years, voluntary

Criteria

- Be a member of HTAi in good standing
- Knowledge or experience in raising funds for a not-for-profit
- 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

How to apply

Submit an Expression of Interest (no more than 200 words) addressing the above criteria and a Curriculum Vitae (no more than 2 pages) by September 8 to the PCIG Technical Office: to.patient-citizen@htai.org

Events:

Putting Patients First 2023: Changing Landscapes and Learning Together for Sustainable Patient-Oriented Research (Free Registration)

24 October 2023. Pinnacle Hotel Harbourfront, Vancouver (Hybrid)

More info: <https://healthresearchbc.ca/bc-support-unit/info-and-resources/putting-patients-first/>

PxPFor Patients, By Patients: Partnering to Make Research Stronger (Free Registration)

12-15 September 2023: Virtual

More info: <https://pxphub.org/>

Ellen Wang, Thalia Otamendi, Linda C Li, Alison M Hoens, Linda Wilhelm, Vikram Bubber, Elliot PausJenssen, Annette McKinnon, Shanon McQuitty, Kelly English, Aline S Silva, Jenny Leese, Wasifa Zarin, Andrea C Tricco, Clayton B Hamilton (2023). Researcher-patient partnership generated actionable recommendations, using quantitative evaluation and deliberative dialogue, to improve meaningful engagement. *Journal of Clinical Epidemiology* 159, 49-57, ISSN 0895-4356.

Available on: <https://www.sciencedirect.com/science/article/abs/pii/S0895435623001105>

Contributed by Aline Silveira Silva

Conversations for change

PCIG member Sally Wortley will be moving from her role as Lead of the Consumer Evidence and Engagement Unit (CEEU) in the Australian Government Department of Health and Aged Care. As the inaugural Lead of the Unit, Sally has imparted four and half years of hard work and expertise. She will be missed - both as a dedicated consumer advocate and a colleague. Sally has taken up another role in the Department. The Unit will continue its work with Liz Marshall as acting Lead, with our current work plan and unit activities being delivered as usual.

Patient and citizen participation at the organizational level of HTA

Are patients and citizens just a source of input into individual HTAs or should they be involved in shaping HTA bodies at the organizational level? PCIG's project to better understand the use of organizational level in HTA has just published its findings.

The PCIG Project Sub-Committee - Herve Nabarette (Lead) Marie-Helen Chastenay, Jean-Claude Dupont, Isabelle Ganache and Ann Single – describe patient and citizen involvement in governance, defining patient involvement processes, evaluation processes and methods, and capacity building. Their findings, which may be useful to people developing a participation framework, provide:

- rationales for organizational level participation from the perspectives of HTA bodies and patients
- insights into how to involve participants, and
- who may be seen as legitimate participants.

It will also inform PCIG's review of its current resources due to begin later this year.

The work was supported by a Health Technology Assessment international (HTAi) grant to cover the cost of Open Access.

Hervé Nabarette, Marie-Hélène Chastenay, Jean-Claude Dupont, Isabelle Ganache, Ann Single. Patient and citizen participation at the organizational level in health technology assessment: an exploratory study in five jurisdictions. [International Journal of Technology Assessment in Health Care](#)
doi: 10.1017/S0266462323000417

Contributed by Ann Single



2024 HTAi Annual Meeting in Seville. MEETING THEME: "A Turning Point for HTA? Sustainability, Networks and Innovation"

<https://htai.eventsair.com/htai-2024-annual-meeting>

Healthcare has seen significant changes in the past few years due to the emergence of new technologies and innovations. This presents challenges for HTA agencies, which require a variety of expertise (in and outside HTA science) to evaluate and assess these developments. The HTA community through collaboration provides a means to pool resources and expertise for generating reliable evidence for decision-makers. Collaboration on a global scale is essential for data exchange, evidence generation, and building regulatory (EU) and incentive mechanisms.

With the growing emergence of new technologies and innovations, healthcare has seen significant changes. What does this mean for HTA?

The HTAi Review is your biweekly news source for all things HTAi at <https://htai.org/htai-review> to catch up on HTA news and updates from around the world.

Website: <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](#)

ICER Public Webinar on 2023-2026 Value Assessment Framework Updates

The Institute for Clinical and Economic Review (ICER) in the US will be hosting a public webinar at 11:00 am ET on September 28, 2023 where ICER will discuss changes made to ICER's Value Assessment Framework and describe the rationale for the finalized framework updates. The webinar is free to attend and anyone interested can register here:

https://uso2web.zoom.us/webinar/register/WN_qGdkBfPoTLuL65d5JgstAw#/registration

The ICER value framework describes the conceptual framework and set of associated methods that guide the development of ICER evidence reports. ICER typically updates the value assessment framework once every three years. The purpose of the value framework is to form the backbone of rigorous, transparent evidence reports that, as a basis for broader stakeholder and public engagement, will help the United States evolve toward a health care system that provides sustainable access to high-value care for all patients.

Contributed by Catherine Koola

How NICE manages the potential conflicts of interest of patient experts

The National Institute for Health and Care Excellence (NICE) independent technology appraisal and highly specialised technologies committees produce guidance on the use of new medicines in the UK National Health Service (NHS). Their work is greatly enhanced by the voices of people who use services, carers, and the public and help to ensure our work is anchored in real life.

These independent committees make recommendations based on careful analysis of all the evidence in support of the medicine's clinical and cost effectiveness, to determine whether the medicine provides value for money to the NHS.

Patient groups will need to declare payments they have received from manufacturers. We recognise that these payments are made, and our committees are aware that both patient experts and their representative charities give their insights from their own perspective and interests. Having a declared interest does not necessarily mean the person or organisation are conflicted. Our focus is on understanding the interests these patient experts may have, which is important context to the statements they might make in committee meetings.

Although patient experts play a key role in the appraisals process, they are not decision makers. Ultimately, our appraisal committee members will decide whether a medicine provides value for money to the NHS and should be recommended by NICE, informed by the evidence available to them. Our policy therefore outlines the robust risk-based approach for managing committee members' potential conflicts of interests and will usually exclude them from the meeting if they have a direct financial interest. The reality is that many patient organisations have financial ties to the life sciences industry, and initiatives such as Disclosure UK have increased the transparency of financial payments made to patient organisations in recent years, which is a welcome development that supports the ability of our committee members to be aware of the conflicts that experts might have and enables a robust, risk based approach for managing potential conflicts of all those who participate in committee meetings.

NICE values the contribution patient groups make to its work and will continue to ensure their voices are heard. You can read the [full blog](#).

Contributed by Heidi Livingstone

Podcast: Retiring Therapeutic Goods Administration (TGA) head and regulation in Australia post-pandemic

https://globalforum.diaglobal.org/issue/august-2023/?utm_source=db&utm_medium=email&utm_campaign=global_forum&utm_content=PUB_GF_August_2023-08-26_nonmembers&mkt_tok=MzQ5LVNWSiowNjgAAAGNzUF85KvyT3y-

[Hgg5G7M7n6t9XsGPaPMbqw7jmYa3OJ2SPGmeJnUZYjxHiTWMSHUtVLezLVNz4l7JszYp74o2M_oyoJFQGKo4wJcoPIEJXeI#tgahead](https://www.linkedin.com/company/hitap-thailand/)

In April 2023, Professor John Skerritt retired as deputy secretary of the Health Products Regulation Group and head of the Therapeutic Goods Administration in Australia. "What's really changed and what will persist after COVID? First, I think regulators have become a bit more comfortable in dealing with uncertainty. Uncertainty is the biggest challenge rather than benefit-risk," he explains. "International regulatory collaboration became the basis of working together on these new products: We exchanged information on policies, on how the clinical data was developing, on the real-world performance of these drugs and vaccines, and on safety and post-approval requirements. These are going to persist."

HTAsiaLink

The 11th HTAsiaLink Conference 2023 is scheduled to take place September 4 – 7 in Putrajaya, Malaysia. The conference theme is "Reshaping and Reshifting Health Technology Assessment in Navigating the future Landscape." [Learn more](#)

The 14th Priorities 2024 Conference

<https://priorities2024.com/about-the-conference/>

This marks the first time the Priorities Conference will take place in Asia, hosted by Health Intervention and Technology Assessment Program (HITAP), Ministry of Public Health, Thailand

Registration: 15 August 2023 – 31 March 2024

Call for proposals: 12 July – 31 October 2023

Call for abstract: 15 August – 31 October 2023

European Patients Forum (EPF) news

European Medicines Agency

On June 27-28, the EPF Head of Policy, participated in the European Medicines Agency (EMA) regular meetings of the [Patients' and Consumers Working Party \(PCWP\)](#) and [joint PCWP and Healthcare Professionals \(HCPWP\) Working Parties](#).

EMA provided updates on a number of initiatives. On [mis/disinformation](#), EMA is using the experience of the COVID-19 pandemic to develop a framework based on three pillars: monitoring, actions (e.g. increased communication and transparency, health media literacy, etc.), and outreach (e.g. joint campaigning). Further discussions will follow with interested organisations on experiences, strategies, and best practices to tackle mis/disinformation.

EMA presented the results of its 2022 communications' [perception survey](#). While most respondents were positive about EMA's communication activities, areas for further improvement include enhancing the user-friendliness of EMA's website and translating content.

Participants were impressed with the progress made with the implementation of [DARWIN EU®](#). This initiative aims to deliver real-world evidence from across Europe on diseases, populations, and the uses and performance of medicines. Stay on the lookout for EMA workshops and opportunities to collaborate in developing patient communication strategies and materials on registries. Related to this, next steps on how to promote inclusion of [patient experience data \(PED\)](#) in all aspects of medicines development and regulation were discussed. A key EMA deliverable is a reflection paper on the best approach to generating and collecting PED, with a planned public consultation by Q1 2024. EMA is contributing to an International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidance on PED. Shortages remain a top priority. EMA is tweaking its [pilot](#) on reporting of shortages by eligible patients and HCP organisations. EMA calls on patient and HCP organisations to continue raising awareness of the [good practice guidance](#) on the prevention of shortages of medicines for human use.

Other presentations related to the [EU Recommendations on Decentralised Elements in Clinical Trials](#), the [EMA 2019-2022 report on pharmacovigilance tasks](#), EMA [activities linked to N-nitrosamines](#), the outcomes of the [kick-off meeting of the ACT-EU stakeholder platform](#), and the [satisfaction survey](#) on the EMA's Human Medicines' Highlights Newsletter.

Data Saves Lives. ENGAGING WITH DIGITAL HEALTH TOOLS – CHECK BEFORE YOU CLICK

https://static1.squarespace.com/static/5cc8208b90f904c71c744000/t/616ee2aa8c82f42d83958663/1634656938368/DSL_toolkit_1.0_final_Part3.pdf

There are many ways in which our personal health data can be collected, even when we are not being actively monitored in a medical setting. In the past, our health data was largely confined to medical records stored personally or in a family doctor's practice or hospital. Today, while some European countries still rely on paper records, digital health devices are part of everyday life. Many people wear a smartwatch or fitness tracker. These personal wearable devices can be used to monitor our sleep patterns, track levels of activity or calorie consumption or record pulse rate. Patients with certain health conditions may use sensors to monitor vital signs such as blood sugar or heart rate. Even if we do not own fitness trackers, many of us download apps to help manage our health. We may contribute to online patient groups or take part in online health-based surveys. Often, we make use of digital health tools without giving data protection a second thought. This section of the Data Saves Lives toolkit highlights some of the issues associated with the use of digital health tools, providing advice on how to protect sensitive health data. It will support you in answering questions your members may have in this area

Digital health tools have transformed the way people engage with their own health, allowing them to play a greater role in their own well-being. These tools make it far easier to manage some conditions and can alert healthcare professionals to potential problems at an early stage. Digital health tools increase our 'digital footprint' – the traces of information that record where we've been. And some of these tools routinely share our data with third parties, sometimes without our knowledge or adequately informed consent. Hospital and medical records are legally protected in terms of privacy, but this protection does not currently extend to other forms of digital data.

Attitudes towards sharing health data 73% of EU citizens want to share health data on the precondition that data is secure and only accessible by authorised parties. Some 42 % of the respondents fully agree or agree that a lack trust in services providers prevents them from using digital services. The proportion of the respondents who held this view was the highest in Germany (48 %) and the lowest in the Netherlands (38 %).

Digital tools are accessible, easy to use and most offer benefits in terms of convenience and patient empowerment. To ensure they are used safely, we need to improve patient literacy and equip consumers with the information they need. Some patient-led organisations have reviewed apps for patient communities. MyHealthApps, which was developed in collaboration with patient organisations and launched in 2013, is maintained by PatientView. The website curates hundreds of health apps tried and recommended by patient and health consumer groups worldwide. The General Data Protection Regulation (GDPR) is a 2018 EU law on data protection and privacy, which includes the transfer of personal data in and outside the EU. This means that the personal data of EU citizens is legally protected, and people must be told how their data will be used, for what purposes and how it will be protected.

Master's update! The programme on International Patient Advocacy Management is opening for applications

EPF, together with ALTEMS/Università Cattolica, presents the second edition of the engaging and important master course on International Patient Advocacy Management. Topics and classes range from healthcare management, patient involvement, and health technology assessment to communication, fundraising, and bookkeeping. Find more information [here](#).

'Translational Medicine Explained', a 5-day winter school

The course includes a 12-hour online introduction and a 5-day in-person workshop from 13 to 17 November 2023, hosted at Bayer's facility in Berlin. The program is designed for PhD candidates, master's degree students, and postdocs in biomedical research to learn about the job profiles of scientists in Industry and other sectors. For details and registration, visit [this page](#).

PERISCOPE's final conference takes place on 8 September in Brussels

After more than two years investigating the impact of the COVID-19 pandemic, PERISCOPE will share key results in its final conference - [From Data Science and Socio-Economic Research to Policy and Technology - Learning from COVID-19 to Build Better Health and Care in Europe](#).

The event will delve into the socio-economic and behavioural impacts resulting from the policies implemented in response to the pandemic and examine how policy responses have influenced the path towards better health outcomes in Europe. This full-day conference will present the project's policy recommendations and will gather researchers, policymakers and representatives from medical institutions.

Patient and Public Partnership Conference

<https://www.hse.ie/eng/about/who/national-services/partnering-with-patients/patient-partnership-conference/>

On 12 October 2023 the Health Service Executive (HSE) Operational Performance and Integration Directorate and the HSE National Patients' Forum will host Ireland's first Patient Partnership Conference from 10am-4pm in the Convention Centre, Dublin. This conference marks a commitment to change how we invite people to participate in health and social care. It confirms the HSE's intention to place people at the heart of our practices, our processes, our programmes, our policies and our systems. Conference participants will explore how co-design, co-decision-making, co-implementation, and co-evaluation can take place. There will be discussions on how this can start at the national level and filter down to the regional and local levels. "The essence of genuine partnership lies in collaborative equal relationships and thrives in a culture of cooperation. The early idea for this conference, coming from the members of the HSE patient forum, needed it to be met by people in the HSE with a 'partnership' mind-set. It is this spirit of cooperation that has brought us to the point of seeing the idea become a reality. This is an event that I am truly pleased to see happen and one that I hope is just the first of many" – Anne Lawlor, Chair HSE Patient Forum

Publications

Caroline Farmer, Maxwell S Barnish, Laura A Trigg, Samuel Hayward, Naomi Shaw, Louise Crathorne, Thomas Strong, Brad Groves, John Spoons, GJ Melendez Torres (2023). An evaluation of managed access agreements in England based on stakeholder experience. *International Journal of Technology Assessment in Health Care* doi: 10.1017/S0266462323000478

Harvard S, Winsberg E (2023). Patient and Public Involvement in Health Economics Modelling Raises the Need for Normative Guidance. *Pharmacoeconomics*, 41(7), 733-740. <https://doi.org/10.1007/s40273-023-01274-7>

Staniszewska S, Jakab I, Low E, Mossman J, Posner P, Husereau D, Stephens R, Drummond M (2023). Commentary: Advocating for patient and public involvement and engagement in health economic evaluation. *Research Involvement and Engagement*, 9(1), 45. <https://doi.org/10.1186/s40900-023-00444-3>

Hogervorst M, Vreman R, Heikkinen I, Bagchi I, Gutierrez-Ibarluzea I, Ryll B . . . Oortwijn W (2023). Uncertainty management in regulatory and health technology assessment decision-making on drugs: Guidance of the HTAi-DIA Working Group. *International Journal of Technology Assessment in Health Care*, 39(1), E40. doi:10.1017/S0266462323000375

The systematic approach taken in this guidance has the potential to facilitate understanding of uncertainty and its management across different stakeholders involved in drug development and evaluation. This can improve consistency and transparency throughout decision processes. To further support uncertainty management, linkage to suitable mitigation strategies is necessary.

Linda Mundy, Guy Maddern. HTA capacity building in Asia: Towards one goal. International Journal of Technology Assessment in Health Care doi: 10.1017/S0266462323000405

Giorgio Casilli, Dario Lidonnici, Claudio Jommi, Marika De Nigris, Armando A. Genazzani (2023). Do France, Germany, and Italy agree on the added therapeutic value of medicines? International Journal of Technology Assessment in Health Care doi: 10.1017/S026646232300048X

de Jel DVC, Young-Afat DA, Ooms-Renckens MM, Smeele LE, Rakhorst HA; DHNA study group. Patients' and Healthcare Professionals' Perspectives on Better Use of Patient-Reported Outcome Measures in Head and Neck Cancer. Value Health. 2023 Aug;26(8):1210-1216. doi: 10.1016/j.jval.2023.04.009. For patients, the most important element of patient-reported outcome collection systems was including a call to action for those with worse-than-average scores (28%), whereas clinicians found discussing scores during clinical visits the most important (39%). Although 16% of clinicians found short completion time the most important element, none of the patients selected completion time as most important. Additionally, 17% of patients stated completion time was not an issue, provided clinicians would use the outcomes for clinical purposes.

Hudgens Stacie et al (2023). Best Practice Recommendations for Electronic Patient-Reported Outcome Dataset Structure and Standardization to Support Drug Development. Value in Health 26(8), 1242–1248. Currently, ePRO data are not required to follow a standard model, and the data models used often vary by electronic clinical outcome assessment (eCOA) provider and sponsor. The project was formed to collate and examine the issues arising from the lack of adoption of standardized approaches and this paper details recommendations to address those issues.

Hinton EC, Fenwick C, Hall M, Bell M, Hamilton-Shield JP, Gibson A (2023). Evaluating the benefit of early patient and public involvement for product development and testing with small companies. Health Expectations : An International Journal of Public Participation in Health Care and Health Policy, 26(3), 1159-1169. <https://doi.org/10.1111/hex.13731>

Jennifer Horton, Deirdre DeJean, Kelly Farrah, Amanda Hodgson, David Kaunelis, Melissa Walter. Ethics information retrieval in HTA: state of current practice. International Journal of Technology Assessment in Health Care 2023 doi: 10.1017/S0266462323000247

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