

HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG)

E-Bulletin, April 2024

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 Co-Chair Fiona Pearce
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Welcome to our E-Bulletin

Dear PCIG Members

I begin this month's issue by acknowledging and thanking Heidi Livingstone who will be stepping down from the Steering Committee in May to coincide with her retirement from NICE. Heidi has made significant contributions to patient involvement in HTA and healthcare decision-making during her career and her valuable insights and advice to PCIG have been greatly appreciated. We will miss her and wish her well during her retirement and future endeavours.

The countdown is on to the HTAi Annual Meeting, which is being held in hybrid format from 15-19 June in Seville, Spain. Early bird registration has closed but there is still time to secure your place! The full program is now available [online](#), and includes an extensive range of topics from distinguished speakers. The extent of the program is testament to how much the HTA landscape has evolved, especially in recent years, and I am sure you are all looking forward to hearing about new innovations and best practices from around the world. For people who will be attending the annual meeting in-person, PCIG will be hosting an afternoon workshop on Sunday 16 June on "Patient and Citizen Involvement in Health Technology Assessment: Networks for Sustainability and Innovation". The PCIG annual business meeting will also be held in hybrid format during the conference for anyone who would like to attend.

Lastly, the Board of Directors election is still open until 2 May 2024 at 23:59 MDT to vote for candidates for Treasurer and Secretary. Two PCIG members, Anke-Peggy Holtorf and Farzana Malik, stand as candidates for Secretary. Your vote is vital to build an engaged society and make your voice heard.

Thank you for your continued engagement and support,

Fiona Pearce
Co-Chair HTAi PCIG

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)

Patient Insight Congress, April 8-10, 2024 in Atlanta, Georgia, USA

Catherine Koola Fischer of ICER presented a poster on the impact of patient engagement on three recent ICER drug reviews. The link to the online publication:

<https://static1.squarespace.com/static/616da4e0a5a5080a7f683e99/t/660d6b43c98bc934ffe6727e/1712155459659/Poster+-+The+Impact+of+Patient-Centered+Engagement+on+ICER+Drug+Reviews+-+Cat+Koola+Fischer.pdf>

Contributed by Catherine Koola Fischer

HTA Learning Modules

Singapore's [Process and Methods Guide for Patient Involvement](#) from the Agency for Care Effectiveness (ACE) has recently been updated to improve existing processes in line with insights gathered from local patient organisations. ACE is also developing a series of short, self-directed HTA learning modules for patients and the public this year. The [first module](#) in the series was published in April and more will be added to the website in coming months.

Contributed by Fiona Pearce

Lessons Learned From Clinical Studies in Centronuclear Myopathies: The Patient Perspective-A Qualitative Study

I would like to bring your attention to the publication of a study to which I contributed by Stinissen L, Böhm J, Bouma S, van Tienen J, Fischer H, Hughes Z, Lennox A, Ward E, Wood M, Foley AR, Oortwijn W, Jungbluth H, Voermans NC. Clin Ther. 2024 Apr 25;S0149-2918(24)00073-0. doi: 10.1016/j.clinthera.2024.03.008

[Lessons Learned From Clinical Studies in Centronuclear Myopathies: The Patient Perspective—A Qualitative Study - ScienceDirect](#)

Contributed by Wija Oortwijn

HTAi Annual Meeting in Seville

Patient and Citizen Involvement in HTA workshop, June 16 (Sunday)

Remember to register for our pre-annual meeting half-day workshop "Patient And Citizen Involvement In Health Technology Assessment: Networks For Sustainability And Innovation" (WS#22). On Sunday from 1:30 pm - 5:00 pm, speakers from around the globe will provide an introduction to key concepts, methods and approaches to patient involvement, including examples of tools adapted internationally for efficient and good practice. This is followed by the choice of three deep dive dialogues: reporting and evaluating; sustainable practice; and the patient community role in innovation.

PCIG dinner, June 17 (Monday)

Every year at the HTAi Annual Meeting, PCIG members gather for an informal meal on Monday evening. They welcome patients, caregivers and their representatives (and partners) for a self-sponsored dinner. Location and more details to be announced soon. Save the date!

PCIG Annual Business Meeting (Hybrid), June 18 (Tuesday)

In line with our Terms of Reference, PCIG will hold its Annual Business Meeting (ABM) at the HTAi Annual Meeting. Date: Tuesday 18 June 2023. Time: 1:30 - 2:30 pm. Location: Room at Barceló Convention Centre to be confirmed. Packed lunch available. A Zoom link will be provided to virtual attendees. Agenda will be given to all members at least seven (7) days in advance. The notes of this meeting will be circulated to all members of the Interest Group documenting the actions planned for the forthcoming year.

Buddies for Annual Meeting wanted

It is fun to be a PCIG buddy! It involves agreeing with a PASS or grant recipient how you will interact, greeting them at annual meeting and perhaps introducing them to others, answering questions or helping them find answers. Please sign up to be one here: <https://forms.gle/GjVcTnP04vzK5Pcp7>

PCIG Endorsed Panels

There are many works featuring patient and citizen involvement programmed to be presented at the annual meeting. Two of these are the panels endorsed by PCIG, both happening on Monday June 17:

PN#01 - Balancing Impact Versus Burden Of Patient Involvement In Health Technology Assessment

PN#74 - Getting future-ready by learning from the past! Transforming patient involvement practices in HTA

Contributed by Aline Silva



HTAi 2024 Annual Meeting in Seville. MEETING THEME: A Turning Point for HTA? Sustainability, Networks and Innovation <https://htai.eventsair.com/htai-2024-annual-meeting>

With the growing emergence of new technologies and innovations, healthcare has seen significant changes. 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 and incentive mechanisms.



Support PCIG member Chris Munoz in Plenary one, 'Sustainable HTA For Sustainable Health Systems'

What does sustainability mean in a broader context and how can HTA contribute to the sustainability of health systems in an era of increased disruptive innovations and growing networks?

How can HTA ensure sustainability within itself in the face of increasing and challenging demands from health authorities in the race towards reaching a sustainable health system? The discussion will examine common challenges currently faced by health authorities in both developed and in-developing healthcare systems, what these systems need from HTA, and what HTA needs to be able to effectively respond.

Sandra García-Armesto, Health Quality and Assessment Agency of Catalonia; Carole Longson of the UK; Chris Munoz of Philippine Alliance of Patient Organizations; Andrea Rappagliosi, Edward Lifesciences Switzerland; and Adriana Velazquez Berumen, Medical Devices and in-vitro Diagnostics, WHO.

The meeting will be a hybrid format, with engagement and interaction for virtual and in-person attendees. Presentations will take place in-person and simultaneously stream online, ensuring that all participants can actively participate in scientific discussions, network with peers, and take part in this celebrated hybrid event. For all attendees, select presentations will be available on-demand throughout the conference and for several weeks after. More information on the Annual Meeting, including themes, speakers, venue, and accommodation is available online at <https://htai.eventsair.com/htai-2024-annual-meeting/>

View the schedule and Workshop program (<https://htai.eventsair.com/htai-2024-annual-meeting/workshop-program>)

A taster: WS15 – Navigating the Living Health Technology Assessment Journey: From Conceptualization to Implementation

Date & Time: Sunday, June 16 | 9.00AM to 5.00PM. Presenter: María Ximena Rojas-Reyes

The incorporation of the Living Evidence model into HTA development requires guidance, training, and the development of skills among groups accustomed to traditional HTA methods. The LE-IHD project group has developed a comprehensive strategy for building capacity for this purpose among HTA-developers. This workshop provides an opportunity to delve in-depth into the approach with practical examples and hands-on support tools.

Standard registration deadline: Thursday, June 6, 2024 at Midnight MDT (UTC-6)

Last-minute registration: Friday, June 7 to Wednesday, June 19, 2024

Prepare to be enchanted by the vibrant city of Seville, Spain, as the backdrop for our HTAi 2024 Annual Meeting. Nestled along the Guadalquivir River, Seville captivates with its rich history, stunning architecture, and lively culture.

HTAi webinars

Visit the HTAi YouTube page to check out our [webinar playlist](#)



Joint Webinar from HTAi-PAHO-RedETS

HTAi partnered with PAHO and RedETS to host a webinar on Patients Involvement in HTA on April 26, 2024.

Panelists were: Ann Single, Vice-President of Health Technology Assessment international (HTAi) and former Chair of PCIG. Ana Toledo Chávarri of Spanish RedETS, Patient Engagement coordinator in the Evaluation Unit in the Canary Islands Health Service and of RedETS, which is a decentralised network that informs policy decision-making regarding medical device reimbursement. PREMS and PROMS are an important part of her work. Andrea Brígida de Souza of CONITEC in Brazil. She is responsible for patient involvement initiatives at CONITEC and Qualitative Evidence Synthesis. Manuel Donato of CONETEC in Argentina is a pharmacist by training. Eva María Ruiz de Castilla of the Latin America Patients Academy (LAPA) is a global leader in patient-based organizational capacity building, patient involvement and alliance development covering several therapeutic areas, including cancer, NCDs and rare diseases. She is expert at organizing forums and building coalitions of patient groups, physicians, public health specialists and government officials to generate dialogue and action plans to address a variety of public health issues. Eva María was previously Director General of the Peruvian Ministry of Health's (MINSA) International Coordination office and has studies in Paris.

The HTAi Review

Your biweekly news source for all things HTAi at <https://htai.org/htai-review-april-26-2024/> 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](#)

What's Happening

Advancing Patient-Centered Research for Quality and Effective Patient Engagement

May 5 | 1:00PM – 6:30PM EDT | Georgia World Congress Center USA

Join us for the [ISPOR Patient-Centered Research Summit 2024](#), on May 5 in Atlanta, GA, USA, and contribute to the advancement of patient-centered research. This year's Summit serves as a forum for the collaboration of researchers and patient communities to exchange new knowledge on advancements in patient-focused research. Attendees can engage in dynamic discussions on strategies, regulatory policies, and methods that enhance the influence of patient involvement in generating evidence and shaping healthcare decisions.

A Growing Convergence: RWE for Regulatory and HTA Decision-Making

GetReal Conference 2024, 14th and 15th of May, 2024 in Utrecht, Netherlands

<https://getreal-institute.org/>

HTAi member Elena Petelos will represent the HTAi RWE&AI Interest Group at the conference. GetReal Institute is an independent, multi-stakeholder, European forum that advances the adoption and implementation of real-world evidence (RWE) in regulatory, HTA and clinical decision-making.

FDA listening session to take place June 13 from 9 am to 4 pm ET

<https://www.fda.gov/news-events/press-announcements/fda-hold-listening-session-part-broader-work-optimize-use-and-processes-advisory-committees>

FDA to Hold Listening Session as Part of Broader Work to Optimize Use of, and Processes for, Advisory Committees. Public Engagement Critical to Further Enhance Input from External Expert Panels
This is part of its broader work to optimise the use of, and processes for, advisory committees. The virtual public meeting will focus on the composition of advisory committees, ways to improve the experience for members serving on committees and ways to ensure public awareness and understanding of the role of FDA advisory committees. Advisory committees are typically made up of technical, scientific, public health and medical experts, as well as representatives of industry, consumer organisations and patients. Advisory committees provide non-binding independent advice to the FDA on key questions related to a drug's potential approval. They are not used for every application, but the FDA can opt to hold the day-long public session to answer key questions related to an application. The agency does not have to agree with the committee's vote but historically approval decisions typically fall in line with what the panel recommends. Final decisions are made by the FDA.

Save the Date for the ISPOR Real-World Evidence Summit 17 November 2024

A co-located event at ISPOR Europe 2024, this Summit will cover the latest developments in the use of real-world evidence across the regulatory-health technology assessment-payer decision-making continuum with a focus on methods, data transportability, and infrastructure.

CADTH Symposium: Wednesday, September 4 to 6, 2024

Join Canadian and international health care and health technology assessment (HTA) experts from Wednesday, September 4, 2024, to Friday, September 6, 2024, for the 2024 CADTH Symposium, a 3-day hybrid event offering in-person and virtual attendance options. The in-person program will take place at the Shaw Centre in Ottawa, Ontario, Canada.

The theme is 'From Disruption to Opportunity: Embracing Change in Health Care'.

The CADTH Symposium has a well-earned reputation as a must attend event for anyone with an interest in the assessment, adoption, and management of drugs and medical devices. Please watch the [CADTH Symposium website](#) for updates and [subscribe](#) to receive announcements by email.

EUPATI has released online courses on HTA, patient-reported outcomes and quality of life

https://www.linkedin.com/posts/eupati_hta-eupati-openclassroom-ugcPost-7188814869515681792-yrHA?utm_source=share&utm_medium=member_desktop

Contributed by our Technical Officer Pierre Net

ISPOR Responds to European Commission Call for Comments on Joint Clinical Assessment

https://www.ispor.org/docs/default-source/strategic-initiatives/ispor-response-to-ec-jca-procedure---april-2024.pdf?sfvrsn=70bcbfd9_1&utm_medium=social_media&utm_source=twitter&utm_campaign=general_ispor&utm_content=call_comments_jca_apr26

ISPOR recently submitted comments on the European Commission's draft procedural guidance on joint clinical assessment (JCA). ISPOR emphasized the importance of health technology developers having enough time to generate high-quality data for decision makers to make more informed decisions, and suggests engaging with all relevant patient organisations on JCAs for specific disease areas and systematically collecting information from patient groups to ensure consistency.

IPPOSI submission on the implementing act of EU Joint Clinical Assessments (JCAs)

<https://ipposi.ie/ipposi-submission-on-the-implementing-act-of-joint-clinical-assessments-at-eu-level/>

Several key points:

Firstly, we highlight concerns regarding the selection process for patient representatives and stakeholders in JCAs. We advocate for clear, public criteria for selection, ensuring equal involvement of national and pan-European organizations. An open call for expressions of interest would facilitate a more inclusive and transparent process.

Secondly, we stress the importance of transparency in evaluating potential conflicts of interest among patient representatives, with outcomes communicated publicly to maintain trust.

Thirdly, we recommend public notification of upcoming JCAs and standardized templates for Member States to engage their national patient communities in scoping exercises

Furthermore, we propose the creation of lay summaries of JCA assessments. It is essential to involve the patient community in drafting these summaries to ensure they are understandable and relevant.

We emphasize the need for capacity building within the patient community to effectively engage in the JCA process. Compiling annual reports on patient involvement in JCAs will help identify best practices and areas for improvement.

Lastly, a Patient Advisory Panel may be a useful tool to establish to advise on many of the issues raised above, as well as to provide guidance on the general embedding of this new approach to assessment.

The JCA process needs to grow trust and confidence among stakeholders and the public. The key to building support for this new approach to assessment within Member States is through partnership working with the patient community.

From the European Patients Forum

European Patients' Forum (EPF) Awarded Operating Grant under the EU4Health Programme to Advance Patient Advocacy Across Europe

The EPF programme encompasses a large part of our work, including our policy advocacy, awareness, membership support, and core capacity building activities aimed at bringing the patient community voice and reinforcing the democratic participation of patient organisations in EU and national health policy, research and practice. Funding includes for core membership and capacity building activities, notably the Annual General Meeting, Board governance, regular Members' Circles, the support to the EPF Youth Group, and the Advocacy 101 training course. It enables scaling up our communications and dissemination activities to bring the collective voice of patient communities to wider audiences and engage with a wider variety of stakeholders.

DIA: Bridging the Gap in Open Innovation between Academia and Pharmaceutical Companies in Japan

https://globalforum.diaglobal.org/issue/april-2024/bridging-the-gap-in-open-innovation-between-academia-and-pharmaceutical-companies-in-japan/?utm_source=db&utm_medium=email&utm_campaign=global_forum&utm_content=PUB_GF_April_2024-04-27_nonmembers

Fumitaka Noji, Moderna Japan; Takeshi Kono, Nippon Boehringer Ingelheim; Makoto Nagaoka, BeiGene Japan GK on Behalf of DIA Japan's Open Innovation Community

In the US, most drugs approved by the FDA originate from academia or biotech ventures. Over 50% of drugs approved since 2017 originate from US-based biotech ventures or academia, whereas in Japan, the figure is 10%.

Although open innovation in drug research and development has long been recognized as important in Japan, it has not yet become widely adopted practice, and there are significant gaps in understanding and expectations between academia and pharmaceutical companies. For example, when there is an excellent research outcome, academia seeks recognition and research grants for subsequent research through publication of the outcome; whereas pharmaceutical companies generally tend to keep the research results confidential to maintain their competitive edge.

DIA: Patient & Public Involvement – Stranded on the Adoption Curve?

Liz Clark, Amy Rogers. https://globalforum.diaglobal.org/issue/april-2024/patient-public-involvement-stranded-on-the-adoption-curve/?utm_source=db&utm_medium=email&utm_campaign=global_forum&utm_content=PUB_GF_April_2024-04-27_nonmembers

If you're working with patients, consider measuring impact and value: Data is vital in decision-making.

DIA: Signal Management: Pre-Marketing Versus Post-Marketing

May 9 | 11:00AM ET Online

https://go.diaglobal.org/2024-05_Signal_Management_Pre-Marketing_vs_Post-Marketing.html

In this FREE webinar, expert in the field James Buchanan will provide clarification on the application of the EU Pharmacovigilance Module IX to safety signal management



[Nature Awards for Inclusive Health Research: Collection for the Journal of Research Involvement and Engagement](#)

Edited by:

Heidi Surridge, BA (Hons), MA, National Institute for Health and Care Research, UK

Akinlabi Kazeem Jimoh, BSc, MSc, Medical Physiology, MPH Health Promotion and Health Education, Nature Africa, Nigeria

Submission Deadline was: 1 May 2024

Discover research from the Nature Awards for Inclusive Health Research

<https://inclusivehealthresearch.figshare.com/>

Research Involvement and Engagement is a Patients Included accredited journal. Full details on how the Patients Included journal charter clauses are met can be found [here](#)

Publications

Elsman EBM, Smith M, Hofstetter C, Gavin F, Jobson E, Markham S, Ricketts J, Baba A, Butcher NJ, Offringa M (2024). A blueprint for patient and public involvement in the development of a reporting

guideline for systematic reviews of outcome measurement instruments : PRISMA-COSMIN for OMI 2024. *Research Involvement and Engagement*, 10(1), 33. <https://doi.org/10.1186/s40900-024-00563-5>

In recent years, projects to develop reporting guidelines have attempted to integrate the perspectives of patients and public members. Best practices for patient and public involvement (PPI) in such projects have not yet been established. We recently developed an extension of PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses), to be used for systematic reviews of outcome measurement instruments (OMIs): PRISMA-COSMIN (CONsensus-based Standards for the selection of health Measurement INstruments) for OMI 2024.

A patient partner was an integral research team member at the project development and grant application stage. Once the project started, five patient and public contributors (PPCs) were recruited to participate in the Delphi study; three PPCs contributed to subsequent steps. We collected quantitative feedback through surveys; qualitative feedback was garnered through a focus group discussion after the Delphi study and through debrief meetings after subsequent project activities. Feedback was thematically combined with reflections from the research team, and was predominantly positive. The following themes emerged: importance of PPI partnership, number of PPCs involved, onboarding, design of Delphi surveys, flexibility in the process, complexity of PPI in methodological research, and power imbalances. Impacts of PPI on the content and presentation of the reporting guideline were evident, and reciprocal learning between PPCs and the research team occurred throughout the project. Lessons learned were translated into 17 recommendations for future projects.

Resell M, Stranden M, Qvigstad G, Chen D, Zhao C-M (2024). Gaps between needs of patient and public involvement and interests of researchers on pancreatic cancer. *Patient Education and Counseling*, 120, 108125. <https://doi.org/10.1016/j.pec.2023.108125>

There were gaps between the needs of end-users and interests of researchers on basic research and treatment. The value chain of "return on investment" is more relevant regarding early detection, quality of life and risk factors. PPI constituted an insignificant part of the overall pancreatic cancer research literature and had negligible impact in terms of citations. PPI also hold potential in applications in other patients groups.

Our study indicates that end-users value their role [in PPI](#) efforts. To better understand potential gaps between end-users' needs and researchers' interests in pancreatic cancer research, a larger sample size in future studies is recommended. This will enhance insights for more informed PPI implementation and research decisions. To fill up the gaps, PPI should be incorporated throughout the research process. The impact of PPI can be enhanced by prestigious journals in consideration of journal policies and encouragements by dissemination at academic conferences.

Bart Bloemen, Wija Oortwijn April 2024. [ASSESSING MEDICAL DEVICES: A QUALITATIVE STUDY FROM THE VALIDATE PERSPECTIVE](#). *International Journal of Technology Assessment in Health Care* doi: 10.1017/S0266462324000254

Diana Beatriz Bayani, Hwee Lin Wee April 2024. [Value-based payment for high-cost treatments in Singapore: a qualitative study of stakeholders' perspectives](#). *International Journal of Technology Assessment in Health Care*. doi: 10.1017/S0266462324000217

Fernando-Ignacio Sánchez-Martínez, José-María Abellán-Perpiñán, Jorge-Eduardo Martínez-Pérez, Jorge-Luis Gómez-Torres April 2024. [Design of a Multiple Criteria Decision Analysis Framework for Prioritizing High-Impact Health Technologies in a Regional Health Service](#). *International Journal of Technology Assessment in Health Care*. doi: 10.1017/S0266462324000205

Dan-Dan Ai, Bin-Yan Sui, Cheng-A-Xin Duan, Qian Xu, Kun Zhao April 2024. [Health Technology Assessment in Traditional and Complementary Medicine: a Scoping Review of International Activity and Examples of](#)

[Acupuncture](#). International Journal of Technology Assessment in Health Care. doi: 10.1017/S0266462324000151

Colombo C, Caldara D, Banzi R. Citizens' views on prices of medicines reimbursed by the National Health Service: Findings from Italian online focus groups. *Health Expect*. 2024 Apr;27(2):e14005. doi: 10.1111/hex.14005

Eleven women and six men participated. The mean age was 53 years (range: 28-73). Most (n = 15) had a university degree or attended secondary schools. Eight had a job, five were not employed, and four were retired. In general, participants supported the role of the public health service. Almost all had limited knowledge of medicines' R&D and price setting. Most asked for transparency on medicine prices and negotiation criteria. Participants considered revenues of pharmaceutical companies disproportionate and most called for containment measures of profits. Most were in favour of a stronger public intervention in R&D and prices' negotiations. Few were sceptical of the public sector's ability to play this role. Medicines' prices were discussed as a health matter. Increasing citizens' awareness of these topics is needed by providing spaces and conditions to participate in the discussion, including different perspectives and interests.

Kidanemariam M, Neve OM, van den Heuvel I, Douz S, Hensen EF, Stiggelbout AM, Pieterse AH. Patient-reported outcome measures in value-based healthcare: A multiple methods study to assess patient-centredness. *Patient Educ Couns*. 2024 Mar 7;125:108243. doi: 10.1016/j.pec.2024.108243

The implementation of standardised PROMs in a VBHC care pathway was associated with more discussion on patient-reported outcomes in clinical consultations. Overall, the implementation of PROMs was not observed or perceived as leading to more patient-centred consultations.

Keij SM, Stiggelbout AM, Pieterse AH. Patient readiness for shared decision making about treatment: Conceptualisation and development of the Ready^{SDM}. *Health Expect*. 2024; 27:e13995. [doi:10.1111/hex.13995](https://doi.org/10.1111/hex.13995)

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