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

Enhanced quality and relevance of HTA through patient and citizen involvement

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

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Welcome to our October E-Bulletin

Dear HTAi PCIG Members, welcome to another issue of our PCIG E-Bulletin!

What a month it has been! Everyone was working hard on the HTAi Annual Meeting abstract submissions, and our PCIG team has been tirelessly dedicated to ensuring the success of our upcoming conference. We've been working on PCIG Panel Endorsement, Steering Committee Industry Representative Selection, our PCIG projects and the call for PASS sponsors and volunteers.

A PCIG PASS Team has been formed, and your involvement can make a significant difference. If you're eager to help bring patients to the HTA AM 2024, explore these opportunities:

- If you can offer 1-2 hours per month before the Annual Meeting, here are some of the roles and tasks available: Grant Application Administrator, Application Reviewer, and PASS Recipient Buddies.
- If you prefer to help during the conference, you can be a Patient Lounge Volunteer or a Daily Emailer who emails patients during the Annual Meeting to let them know what is happening that day. These can take only 30 min of your time!
- We are also seeking organisations to contribute a sponsorship amount of USD 8,000.00 for the PCIG PASS program. Supporters of the program will receive many benefits that can be found in this document.

We've also had some fantastic results recently, with Neil and Anke collaborating with great partners, leading to exciting recommendations from a 360°perspective view of current patient involvement practices in Europe. Stay tuned for our regular communications and important updates and messages below. Your engagement and support are crucial to our mission's success!

Aline Silva
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)

PCIG Matters

Call for participation in patient involvement (PI) in LMIC Working Group projects

We, Debjani Müller (Chair of the Developing Countries Interest Group) and Anke-Peggy Holtorf (Project Coordinator of PCIG), are seeking interested HTAi members from HTA agencies, patient organizations, industry, researchers, or other affiliations and backgrounds to continue the work related to patient and citizen involvement in HTA or healthcare decision-making in Low- and Middle-Income countries. We intend to examine the collective experiences of LMICs from around the world and reflect on what works well, what the challenges are and how they can be overcome, and what opportunities may be unique in the LMIC context.
To bring this work forward, we are planning online workshops on these topics in January/February 2023 and an in-person workshop at the upcoming HTAi annual conference. If you would like to participate in this initiative, please send an e-mail to pcig.projects@health-os.com with an expression of interest, a short bio, and your contact details.

Anke-Peggy Holtorf and Jani Mueller

Social Media Research for HTA
Two papers on Social Media Research and HTA are published in the latest issue of IJTAHC, Vol. 39(1), as a result of the work of PCIG. The objective of the PCIG subcommittee was to explore whether and how evidence from Social Media Research can be used in HTA and, if so, which ethical and legal considerations should guide such research. The papers are:

Anke-Peggy Holtorf, Andriy Danyliv, Li-Ying Huang, Yvette Venable, Alissa Hanna, Annekatrin Krause, Miranda Pierre, Donna Walsh, Aline Silveira Silva, Sou-Hyun Lee, T. Joseph Mattingly II. Using social media research in health technology assessment: stakeholder perspectives and scoping review. International Journal of Technology Assessment in Health Care. 2023; 39(1):e63. Available from: https://doi.org/10.1017/S0266462323002593

Holtorf AP, Danyliv A, Krause A, Hanna A, Venable Y, Mattingly TJ, et al. Ethical and legal considerations in social media research for health technology assessment: conclusions from a scoping review. International Journal of Technology Assessment in Health Care. 2023; 39(1):e62. Available from: https://doi.org/10.1017/S0266462323000399

Contributed by Anke-Peggy Holtorf

Better Patient Involvement in HTA - 360° Research leads to comprehensive recommendations
New research shows the way forward for patient involvement in Health Technology Assessment (HTA). The 360 Review of Stakeholder Experiences in HTA in Europe details the recent current experiences of patient involvement practices formed by consensus from the participating stakeholders from HTA bodies, patient communities, and industry. It comes with a range of recommendations to evolve patient involvement practices, based on what we heard works well and what needs improving. The research was conducted by HTAi's Patient & Citizen Involvement in HTA Interest Group (PCIG) along with our fantastic partners at European Patients Forum (EPF) and EUPATI. The research was funded by an unrestricted grant to HTAi from EFPIA and PhRMA. We would like to thank the many people involved in this and the excellent contributions we received throughout from the HTA community, the patient community, and the industry. Contact: PCIG.projects@health-os.com

Contributed by Anke-Peggy Holtorf

Bertelsen N, Dewulf L, Ferrè S et al. Patient Engagement and Patient Experience Data in Regulatory Review and Health Technology Assessment: A Global Landscape Review. Ther Innov Regul Sci (2023). https://doi.org/10.1007/s43441-023-00573-7

Contributed by Dominique Hamerlijnck

Panel Session Report on Rare Disorders and Patient Reported Outcomes
Held during the HTAi 2023 Annual Meeting in Adelaide, Australia, the panel session titled "Rare Disorders – Is the Lack of Effect in a Patient-Reported Outcome, Reflecting no Benefit?" reviewed the importance of measuring quality of life in rare diseases, and the potential and challenges of using patient-reported outcomes (PROs). The report of the HTAi 2023 Panel on Use of PROs in Rare Diseases is available here.

Patient Involvement in HTA Book Opportunity
Can you write a chapter about social media analysis and AI to elicit patients' perspectives for the revised edition of the book on Patient Involvement in HTA? If so, contact Patients-in-HTA@health-os.com for more details about process. Extended deadline for abstract - 17 November 2023. Deadline for full chapter 5 April 2024.

Contributed by Karen Facey

Canadian Agency for Drugs and Technologies in Health (CADTH)
CADTH released a special report in October entitled 'Equity-Focused Health Technology Assessment at CADTH'. Here's the link: https://canjhealthtechnol.ca/index.php/cjht/article/view/757
There's an important section dedicated to Patient Engagement. This is an evolving trend worth sharing and CADTH could be leading the way.

Contributed by Zal Press

How patient communities may want to interact with pharma
When supporting patient communities to engage in health technology assessment in Australia, the Patient Voice Initiative noticed that there was considerable variation in the way pharmaceutical companies interact with patient organisations. For example, some provided key information on a submission's PICO and adverse events, but some did not. Given the limited public information about submissions to the Pharmaceutical Benefits Advisory Committee and the increase in pharmaceutical company strategies for patient centredness and involvement, the Patient Voice Initiative partnered with Community and Patient Preference Research (CaPPRe) to better understand how patient communities may want to interact with industry. Eleven domains were identified, although patient advocates, patient organisations and online patient communities varied in the interactions they valued. Best Worst Scaling identified levels of satisfaction and importance and a benchmark was created to allow for ongoing monitoring. The following resources are now available:
Interacting with patient communities: Checklist for pharmaceutical industries
One page research summary
Enhancing Patient Engagement in Australia Report 2023
Webinar

Australian HTA Policy and Methods Review
The HTA Policy and Methods Review have released three draft papers which, along with input in consultation 1 and deep dive meetings, will inform the draft options the Reference Committee will release for consultation 2.
Each paper has been prepared by one of three appointed HTA experts (Adelaide Health Technology Assessment; CHERE, UTS; and MI-CRE) and include comparisons of HTA internationally with implications for the Australian system. This includes information about patient (or consumer) involvement internationally.
Paper 2. Horizon scanning and early value assessment
Paper 3. HTA Methods: Determination of Population Intervention Comparator Outcome (PICO)

Paper 4. HTA Methods: Clinical Evaluation

Contributed by Ann Single

HTAi Matters

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
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.
See 2024 Annual Meeting main theme and plenary themes

Abstract Guidelines are currently available on the 2024 Annual Meeting website. The 2024 submission guidelines have changed.
Oral and Poster submissions: close December 7, 2023
Workshop and Panel submissions closed October 25, 2023.

Participation Grants Submissions Are Open
HTAi offers Participation Grants (former Travel Grants) to support HTA stakeholders who would otherwise not be able to attend the HTAi Annual Meeting for the purpose of contributing their expertise, presenting their work or otherwise benefitting from participation in the global HTA community. These grants are funded directly by HTAi and in some cases, are sponsored by external parties on an unconditional basis. Carefully read the 2024 Participation Grant submission guidelines before submitting your application.
Participation Grant submissions: close December 7, 2023 at 23:59 MST (UTC -7).

HTAi Awards
The David Banta Award recognises people who have made outstanding and lasting contributions over their careers (over 25 years) in advancing the development and use of HTA internationally (in over 5 countries). These individuals have also been extensively involved in the work of HTAi.

The Sigrid Droste Ethics Award recognizes Society members in good standing who are making or have made important contributions in ethics in HTA.
Nomination submissions for the Sigrid Droste Award and David Banta Award will open November 1, 2023, and close December 15, 2023.

HTAi Global Policy Forum - Applications to fill a single vacancy reserved for a not-for-profit member
We welcome Expressions of Interest (EOIs) from not-for-profit organizational members of HTAi who hold formal responsibilities within a healthcare system to make HTA-based decisions and/or provide HTA-based advice on coverage or pricing of health care technologies. EOIs from any country are welcome.
The deadline for receipt of EOIs is November 17, 2023. Please send all EOIs via email to policyforum@htai.org.
Full details of the EOI submission and review process and criteria are available in the HTAi Policy Forum Member Selection Process Guidelines.

Please direct all questions to the HTAi Secretariat at policyforum@htai.org.

HTAi currently seeking qualified candidates to fill the role of Executive Director
The HTAi Executive Director Transition Search Committee has contracted executive search and leadership consultants Odgers Berntson to manage the recruitment process for the position.
The full listing and contact details on the position are available here.
We kindly as that all inquiries, referrals, or requests concerning the HTAi Executive Director position are directed to the Odgers Berntson team.

Renew your membership for 2024
HTAi is the only global society championing equitable, responsive, and cutting-edge HTA. Membership opens doors to unparalleled access to top HTA leaders and experts. This exclusive opportunity to connect and collaborate with the best in the field is a unique privilege reserved for HTAi members, providing a platform for growth and influence in the HTA community. HTAi members can actively participate in specialized interest groups, expanding networks among HTA experts. These groups offer opportunities to work on projects that align precisely with individual areas of interest, creating valuable connections and opportunities for professional development.
HTAi membership also brings complimentary access to the International Journal of Technology Assessment in Health Care, a valuable resource for staying informed about the latest research and developments in HTA. Moreover, members enjoy access to a wealth of high-quality resources, engaging webinars, and full access to the HTAi Educational Offers Database to stay at the forefront of this dynamic field.
HTAi memberships are valid January – December each year, which means membership renewal season is almost upon us. Organizational members wishing to use their 2023 budget to renew HTAi memberships for 2024 may do so by contacting info@htai.org. Individual members will begin receiving renewal notices before the end of 2023.

HTAi Interest Group webinars are available online
Visit the HTAi YouTube page to check out our webinar playlist

The HTAi Review
Your biweekly news source for all things HTAi https://htai.org/htai-review-october-20-2023/ 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

EUCAPA - European Capacity Building for Patients, co-funded by the European Union
https://www.eucapa.eu/
EURORDIS-Rare Diseases Europe with European Patients Forum and Tyrolean Private University has launched the European Capacity Building for Patients (EUCAPA) project as part of the EU4HEALTH initiative. It sets out to make Health Technology Assessment (HTA) accessible for patients.
Clifford Goodman's HTA101 – Essential Information for Newcomers is there.

Artificial Intelligence and Digital Health Technologies

FDA has highlighted the revolutionary potential of AI and machine learning (ML), particularly in improving drug development and manufacturing. By advancing two discussion papers (Using Artificial Intelligence and Machine Learning in the Development of Drug and Biological Products and Artificial Intelligence in Drug Manufacturing) as part of its Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) initiative, FDA aims to foster stakeholder dialogue and collaboration regarding best practices for AI and ML integration. These documents cover safety protocols, ethical challenges, and potential risks/rewards of using AI and ML in the biomedical field. FDA's risk-based approach to AI and ML in drug development considers:
Human-led governance, accountability, and transparency;
Data quality, reliability, and representativeness; and
Model development, performance, monitoring, and validation.

Diagnostics
Diagnostics provide a cornerstone for effective medical decision-making, with the Centers for Disease Control and Prevention (CDC) reporting that diagnostics influence 70% of medical decisions. This significant impact makes the need for a contemporary framework for the oversight of laboratory developed tests (LDTs) evident. The VALID (Verifying Accurate Leading-edge IVCT Development) Act emerged to establish a modern regulatory framework for LDTs. FDA is actively collaborating with legislators and the diagnostics industry to reform LDTs, ensuring that regulatory standards align with the evolving healthcare landscape.

The US Food and Drug Administration approves more drugs that have genetic evidence to support their use than drugs that lack genetic evidence
Genetic support for FDA-approved drugs over the past decade. Polina V Rusina, Maria J Falaguera, Juan Maria R Romero, Ellen M McDonagh, Ian Dunham, David Ochoa
doi: https://doi.org/10.1038/d41573-023-00158-x
— the value of growing insight into genes for the design of effective treatments. (Nature Reviews Drug Discovery)
https://www.nature.com/articles/d41573-023-00158-x?utm_source=Live+Audience&utm_campaign=f2d96e87f9-briefing-tr-20231011&utm_medium=email&utm_term=0_b27a691814-f2d96e87f9-49176559&mc_cid=f2d96e87f9&mc_eid=e4b88ab2ce

WHO outlines considerations for regulation of artificial intelligence for health 19 October 2023
https://www.who.int/news/item/19-10-2023-who-outlines-considerations-for-regulation-of-artificial-intelligence-for-health
The publication emphasizes the importance of establishing AI systems' safety and effectiveness, rapidly making appropriate systems available to those who need them, and fostering dialogue among stakeholders, including developers, regulators, manufacturers, health workers, and patients.

Launch of WHO Tool for Benchmarking Ethics Oversight of Health-Related Research Involving Human Participants
https://www.who.int/news/item/25-09-2023-launch-of-who-tool-for-benchmarking-ethics-oversight-of-health-related-research-involving-human-participants
The World Health Organization has launched its tool for benchmarking ethics oversight of health-related research involving human participants, which is intended to assist countries in evaluating their capacity to provide appropriate ethical oversight of health-related research, promote policy convergence and best practices in research ethics oversight, enhance public trust in health research, and ensure that the rights and safety of humans involved in health-related research are adequately protected.

From the European Patients Forum (EPF)

October also saw the finalisation of two position papers on key notions of the EU pharmaceutical legislation - paediatrics and unmet medical needs. With regard to paediatrics, EPF is concerned about the disappearance of the EMA's Paediatric Committee (PDCO). Regarding the notion of unmet medical need, EPF advocates extending the definition of unmet medical need to criteria of the utmost importance for patients with chronic conditions, such as the appropriateness of existing treatments and impacts on quality of life.

Patient centricity in Early Feasibility Studies (EFS) for Medical Devices is key
The four-year Innovative Health Initiative (IHI) project 'Harmonised Approach to Early Feasibility Studies for Medical Devices in the EU (HEU-EFS)' was recently launched and we consider this a perfect opportunity to put patient engagement at the centre of EFS. EPF joins this initiative led by Bocconi University and Edwards Lifesciences and is teaming up with patient organisation Global Heart Hub (GHH).
Valentina Strammiello, Yasemin Zeisl are EPF's projects Team

Improving Pain Management and Mental Health in the Hemophilia Community: Let's Take Action
At a recent Hemophilia Changemakers event, in partnership with Sanofi, advocates for people living with bleeding disorders gathered to discuss the profound impact mental health issues and pain have on their daily lives.
Advocates highlighted that to truly improve the quality of life of those living with bleeding disorders, holistic well-being must be prioritized and a revised care strategy for pain and mental health management developed. To bridge the gap in care, a particular focus of all stakeholders must be placed on research, data collection, standardisation of methods for identifying and treating pain, normalising open and honest conversations about pain and mental health, and giving patients agency.
Read the article in full here

New Patient Engagement Country Guidelines for Switzerland, Singapore, the US, Brazil now available on Synapse
https://patientengagement.synapseconnect.org/badge/patient-engagement-guidelines?utm_source=synapse&utm_medium=blog&utm_campaign=countryguidelines&utm_term=publiclaunch
Navigating Country Codes of Conduct and other regulation that impact interactions between pharmaceutical companies and the patient community can be an overwhelming task. The Patient Engagement (PE) Guidelines provide a quick reference to point you in the right direction

Nicholas Brooke, The Synergist
https://patientengagement.synapseconnect.org/resources/the-maturing-patient-engagement-landscape-shaping-the-next-chapter-together
https://patientengagement.synapseconnect.org/badge/patient-engagement-guidelines

Zoom Conversations vs In-Person: Brain Activity Tells a Different Tale
https://neurosciencenews.com/zoom-conversations-social-neuroscience-24996/
A new study reveals a significant disparity in neural activity during face-to-face conversations compared to Zoom interactions. Using advanced neuroimaging, researchers observed suppressed neural signals during online exchanges.

Publications

Amelia Katirai, Beverley Anne Yamamoto, Atsushi Kogetsu, Kazuto Kato (2023). Perspectives on artificial intelligence in healthcare from a Patient and Public Involvement Panel in Japan: An exploratory study. Front. Digit. Health 5:1229308. doi: 10.3389/fdgth.2023.1229308

http://journal.frontiersin.org/article/10.3389/fdgth.2023.1229308/full?&utm_source=Email_to_rerev_&utm_medium=Email&utm_content=T1_11.5e4_reviewer&utm_campaign=Email_publication&journalName=Frontiers_in_Digital_Health&id=1229308

Thistlethwaite JE, Towle A, Canfield C, Lauscher D. When I say … the patient voice. Med Educ. 2023;57(10):898-899. doi:10.1111/medu.15121
https://asmepublications.onlinelibrary.wiley.com/doi/10.1111/medu.15121
Patients and educators discuss the meaning and importance of 'patient voice' in health professional education. They consider the questions and perspectives that medical educators need to hear.

Using Publicly Reported Global Hospital Rankings to Improve Dissemination of Patient-Reported Outcome Measures (PROMs). David W Bates and an international group of expert co-authors study how PROMs can be incorporated into a hospital rating system — one of the many such rankings that are widely circulated and influential. https://catalyst.nejm.org/doi/full/10.1056/CAT.23.0097
Patient-reported outcome measures (PROMs) represent an essential element of value-based care in health care sectors worldwide by transferring the quality definition from process- to outcome-based indicators that focus on the patients' needs. The adoption rate of PROMs in hospitals is still low. To address this challenge, Newsweek and Statista developed a PROMs implementation survey along with a global board of medical experts to determine the current state of PROMs implementation in hospitals. The results of this survey were incorporated into the 2023 editions of Newsweek's World's Best Specialized Hospitals and World's Best Hospitals rankings.

Caryn Mathy, Christophe Pascal, Isabelle Bongiovanni-Delarozière, Lauriane Favez. 2023. Proposing a health-specific organizational impact framework to evaluate organizational impacts in health technology assessments. Int J Technol Assess Health Care Volume 39(1), e60
DOI: https://doi.org/10.1017/S0266462323000508

Challenges in the Evaluation of Emerging Highly Specialised Technologies: Is There a Role for Living HTA? Tracy Merlin, Jackie Street, Drew Carter, Hossein Haji Ali Afzali 2023 © Applied Health Economics and Health Policy https://doi.org/10.1007/s40258-023-00835-3
There is currently deep uncertainty about the clinical benefits and cost effectiveness of highly specialised technologies (HSTs), like gene and cell therapies. These treatments are novel, typically have high upfront costs, the patient populations are small and heterogenous, there is minimal information on their long-term safety and effectiveness, and data are limited and often of poor quality. With their high cost burden on governments and health care providers, policy makers are currently walking a decision tightrope. On the one hand, an unfavourable funding decision could potentially limit patient access to life-saving treatments, while on the other, a favourable decision could result in unsustainable budget impacts and perhaps poorer patient health outcomes. Health technology assessment (HTA) is meant to determine the value of a health technology in order to promote an equitable, efficient, and high-quality health system. However, standard HTA processes have failed to mitigate the deep uncertainties associated with these technologies. In this paper, we propose a Living HTA framework to address these challenges.

Willgoss T, Escontrias OA, Scrafton C, Oehrlein E, Livingstone V, Chaplin FC, Benivento M, Chapman H, Brooke N. Co-creation of the Global Patient Experience Data Navigator: a multi-stakeholder initiative to ensure the patient voice is represented in health decision-making. Res Involv Engagem. 2023 Oct 12;9(1):92. doi: 10.1186/s40900-023-00503-9. PMID: 37828617; PMCID: PMC10571339.

The Global Patient Experience Data Navigator
A co-created dynamic tool for clarity and understanding of the generation and use of Patient Experience Data (PED)

https://pemsuite.org/ped-navigator/?utm_medium=email&_hsmi=78068642&_hsenc=p2ANqtz--lzMfSZb3YdF8Iu45rC3WVkZSYj4HRTBqgM7cE_eyBAkFRM9UCsPex1tcSI-ZxLhCT-kevdUWgepk7MwOEUJYiozKVdw&utm_content=78068642&utm_source=hs_email

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