

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

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
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- HTAi Matters – Manchester Annual Meeting
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Welcome to our February E-Bulletin!

8 March International Women's Day <https://www.internationalwomensday.com/>

A challenged world is an alert world and from challenge comes change. So let's all choose to challenge. Celebrate women's achievement. Raise awareness against bias. Take action for equality...

From our Chair

Decisions, decisions and more decisions is one of the chapter titles of a book by SMA Australia's founder, Julie Cini, in which she shares her story of the death of her two daughters through Spinal Muscular Atrophy and establishing the charity. Julie's chapter title underlines the necessity for patients and their families to make decisions, often in the face of huge uncertainty and an absence of clear or easy paths.

'Uncertainty' has been the topic of this year's HTAi Global Policy Forum, which brings together senior public and private representatives from the HTA community for strategic discussions. Organisers took advantage of this year's virtual format to extend invitations to more patients. Uncertainty has place(s) and meaning(s) in patients' lives. In HTA, we encounter clinical, economic and other uncertainties, and studies¹ suggest that patient involvement can help resolve some of them. But for that to happen, we need transparency in processes and data. I was pleased to be invited to share with the Forum our recently launched [International Template of Summary of Information for Patients](#) which has already been adapted for trial in Australia and pilots at NICE (which is [currently consulting](#) on its use as part of a wider process review).

Good quality Summaries of manufacturer/sponsor submissions may be useful tools within wider patient involvement processes to support patients to answer some uncertainties HTAs raise and to raise patient uncertainties. This patient input has implications for the evidence we use at input as well as HTAs' output. Following a helpful presentation by Anne-Pierre Pickaert (Patvocates and ALAN), the Forum considered how to improve communicating uncertainty in HTA to stakeholders, including patients. We discussed the need for transparent data, and best practice in health literacy and communication. The need here is meaningful communication that is specific and relevant to peoples' realities. I believe to be meaningful it must foster a connection between the feelings and needs expressed and experienced by those working with the evidence (or lack of) in HTAs to

inform the best possible decisions for populations' lives and the feelings and needs experienced by patients and their families as they grapple to make the best decisions for their own lives.

Thanks to Dan Ollendorf (GPF Chair), Rebecca Trowman (Scientific Secretary), the organising committee and the HTAi Secretariat for a valuable event with a strong patient focus.

Finally, if you've been waiting for the final template designed to support collecting case studies of the impact of patient involvement in HTA, I'm pleased to provide this link where you will find it and more information under [Stakeholders Perspectives of Impact in HTA](#). Members of the project sub-committee are happy to help if you want to provide your input verbally or need assistance.

A long welcome, but shared for information, discussion and respectful debate.

¹ such as Menon D, Stafinski T, Dunn A, et al. 2015. Involving patients in reducing decision uncertainties around orphan and ultra-orphan drugs: a rare opportunity? *Patient 8*, 29–39

Stay safe

Ann Single, Chair – HTAi Patient and Citizen Involvement Interest Group

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GIN toolkit updated

Congratulations to our friends in the Guidelines International Network (G-I-N), especially lead authors Jane Cowl (NICE) and Karen Graham (SIGN), who've been updating their invaluable [toolkit](#) for patient and public involvement in guidelines. There are four updated chapters plus a new chapter on patient involvement in systematic reviews written by Cochrane Consumers.

We were delighted that they also sought an update to Chapter 10 on useful tools which could be adapted for guidelines from HTA, originally authored by Karen Facey and Tania Stafinski in 2015.

Last year, Karen and I updated the chapter to take account of the enormous amount of development over the past 5 years. As always it was a group effort with input and/or review from a variety of HTA bodies. Thanks to Sarah Berglas, Sabine Häfner, Heidi Livingstone, Alessandra Lo Scalzo, Camilla Palmhøj Nielsen, Aline Silva, and Sally Wortley.

Jane and Karen (Graham) have provided more details below.

The Toolkit assembles international experiences and best practice examples of successful patient involvement and aims at supporting guideline developers who consider involving patients in guideline development or dissemination.

These newly updated chapters will be converted to a more accessible digital format very soon and will be available on the new GIN website (PCIG will update the link from the HTAi site).

The next update is due to be completed in 2021 and to deliver this the group surveyed GIN members to seek feedback on its use and areas for development.

Some of the improved features include new key messages within each chapter, top tips and, in some cases, additional resources and examples.

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

<https://htai.org/interest-groups/pcig/e-bulletins/>

PCIG Matters

Patient Insights Research Platform (PIRP) – a new project of the HTAi PCIG

Just imagine, we could just go out into the streets or homes of people, in cities and villages all around the world, and listen to patients in a specific disease area to better understand what their (unmet) needs are or how they experience their current therapies. While as a physical interaction, this may be a complex multi-

year project, patients' communication in social media may contain such information - ready for analysis - because these are subjects patients 'chat' or exchange about among each other.

Social media research has been used to gain consumer or patient insights on many levels, however their use by HTA bodies has been limited. Recently, a new PCIG project has been initiated that will deliver a whitepaper detailing the pre-requisites and stakeholder expectations for a patient insights research platform (PIRP) as a structured, but purely observatory approach for collecting and analysing patient-based communication content from social media to inform HTA bodies on patient needs and experiences.

A multi-stakeholder PCIG subcommittee (composed of HTA practitioners with patient involvement expertise, health technology industry, patient advocates, health policy experts, patient engagement experts) will collaboratively develop a 'roadmap' for creating a platform for social media research for HTA. This roadmap shall serve as a foundation for investigating and piloting a PIRP.

The subcommittee members are planning to engage with key stakeholders from patient organizations, from HTA agencies, and also social media research experts throughout the course of the project. In addition, the plan includes reviews in a few foundation areas such as the legal and ethical aspects to be mindful of, the state-of-the-art methods, and the examples for the use of social media research for informing policies.

Are you interested in contributing to this work? A tight timeline has been set and we can use additional brains and hands, especially from HTA agencies, patient organizations, or social media research expertise. If you are interested and feel that you can and want to contribute to this project, please contact the "PCIG Project Coordinator" at PCIG.Projects@health-os.com

Contributed by Anke-Peggy Holtorf

HTAi Interest Groups have something new and exciting coming their way!

Recently, the HTAi Secretariat has been working on an Interest Group Engagement initiative to help its members collaborate and engage amongst themselves and between groups. The idea behind this project is to create a platform that has greater capacity and enhanced features to offer Interest Group members. The Interest Group Steering Committee recently reviewed the initiative and is offering guidance through the final development stages.

We have many exciting new features in the works such as centralized webinar content, video calls, live chat, and discussion boards! This new platform will provide the Interest Group members greater support and exposure of their work and has been approved by HTAi's Executive Director and the Interest Group Steering Committee. We are excited about this new project and look forward to introducing it to you all in March. There will be updates posted on our social media so keep an eye on our LinkedIn and Twitter page.

If you have any questions or concerns, please feel free to reach out to Bryce Doherty (bdoherty@htai.org) and/or Sydney Ruller (sruller@htai.org).

The NICE process consultation on HTAs [Reviewing our process for health technology evaluation: consultation | NICE guidance | Our programmes | What we do | About | NICE](#) is open until 15 April 2021. It includes: Companies will provide a 'Summary of Information for Patients' with their evidence submission (para 59) which is a PCIG project.

Contributed by Heidi Livingstone

Evaluation of the impact of patient input in health technology assessments at NICE

<https://www.cambridge.org/core/journals/international-journal-of-technology-assessment-in-health-care/article/evaluation-of-the-impact-of-patient-input-in-health-technology-assessments-at-nice/632170C22B9414ED8E87C779707B069C>

Livingstone H, Verdiel V, Crosbie H, Upadhyaya S, Harris K, Thomas L. (2021). *International Journal of Technology Assessment in Health Care*, 37, E33. doi:10.1017/S0266462320002214

The impact of patient input is not necessarily explicit in changing recommendations, but it provides context, reassurance, and new information to the committee for the decision-making process in HTAs.

Accounts of patient experiences are increasingly used in health technology assessment (HTA) processes. However, we know little about their impact on the decision-making process. This study aims to assess the level and the type of impact of patient input to highly specialised technologies (HSTs) and interventional procedures (IPs) guidance at the National Institute for Health and Care Excellence (NICE). A questionnaire was developed to capture quantitative and qualitative data on the amount and type of impact of patient input into NICE HTAs. It was completed by committee members of the guidance-producing programs after a discussion of the considered topics. The data were analyzed by topic and overall, for each program, and compared across programs. Patient input was assessed on ten pieces of HST guidance published between January 2015 and November 2019, and on twenty-six pieces of IP guidance scoped between February 2016 and October 2018. A total of 96 responses were collected for HST and 440 for IP. The level of impact of patient input was higher for HST than for IP. For HST, no respondents stated that it had no impact, whereas in IP, 35 percent of respondents did. The most common types of impact found for HST and IP were that it helped interpret the other evidence and that it provided new evidence.

Contributed by Heidi Livingstone

Patient and public involvement in health technology assessment: Update of a systematic review of international experiences

Gagnon M, Tantchou Dipankui M, Poder T, Payne-Gagnon J, Mbemba G, Beretta V (2021). *International Journal of Technology Assessment in Health Care*, 37, E36. doi:10.1017/S0266462321000064

We conducted an update of a systematic review published in 2011. We identified a total of 7872 publications from the main search strategy. Ultimately, thirty-one distinct new studies met the inclusion criteria, whereas seventeen studies were included in the previous systematic review. PPI is realized through two main strategies: (i) patients and public members participate directly in decision-making processes (participation) and (ii) patients or public perspectives are solicited to inform decisions (consultation or indirect participation). This review synthesizes the barriers and facilitators to PPI in HTA, and a framework to assess its impact is proposed.

The number of studies on patients or public involvement in HTA has dramatically increased in recent years. Findings from this updated systematic review show that PPI is done mostly through consultation and that direct involvement is less frequent. Several barriers to PPI in HTA exist, notably the lack of information to patients and public about HTA and the lack of guidance and policies to support PPI in HTA.

An Institutional Ethnographic Analysis of Public and Patient Engagement Activities at a National Health Technology Assessment Agency

Bidonde, Julia, Meredith Vanstone, Lisa Schwartz, Julia Abelson. 2021. *International Journal of Technology Assessment in Health Care* 37: e37. <https://doi.org/10.1017/S0266462321000088>.

We found that despite demonstrated commitment to patient and public engagement (PPE), organizational history, governance structure, and practices were impediments to a unified approach to PPE. Unclear role descriptions for committee members and differences in philosophy and priority given to PPE across the organization presented challenges to effective participation. The high degree of value given to evidence-based principles at times conflicted with meaningful integration of patient input. A lack of clear goals and processes, roles, and differential treatment of evidence in PPE served to minimize the importance of patient experiences and to displace their validity. An acknowledgment of conflicts between multiple epistemic traditions at work within HTA activities may strengthen organizational approaches to PPE.



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

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

#HTAi2021VirtualAM

HTAi announces HTAi VIRTUAL Annual Meeting

This meeting, originally planned as a hybrid event to take place in Manchester/UK, will be held entirely virtual. Detailed announcement [HERE](#). Further details will be released over the coming weeks. For updates visit the HTAi 2021 Annual Meeting [website](#).

The 2021 Annual Meeting will focus on how adaptive approaches to HTA can continue to provide the cornerstone in leading health systems innovation particularly as technologies advance and novel interventions rapidly emerge. As our technological world evolves and new challenges emerge, we will need to adapt HTA to ensure it continues to be a conduit to support technology innovation.

The main theme is supplemented by three plenary themes:

Evidence for HTA: Innovative Methods for Challenging Times

Patients at the Heart of Innovation

Innovating HTA to support Novel Interventions

HTAi gives special thanks to Global Policy Forum Chair, Dan Ollendorf and Scientific Secretary, Rebecca Trowman for their hard work and commitment to the 2021 Virtual Global Policy Forum

February 22, 24, 26 2021 <https://htai.org/policy-forum/global-policy-forum/>

Background Paper (draft) – [“Considering and Communicating Uncertainty in HTA”](#) R. Trowman, on behalf of the HTAi Global Policy Forum

Anne-Pierre Pickaert of Myeloma Patients Europe provided a patient perspective on communicating uncertainty in HTAs. Key message: Making data available to patients in a transparent and easy to understand format is key to reduce uncertainty and inform shared decision making.

HTAi Social Media

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

Twitter: twitter.com/HTAiOrg @HTAiOrg

Facebook: www.facebook.com/HTAiOrg @HTAiOrg

LinkedIn: www.linkedin.com/company/htai

What's Happening

Inaugural Precision Medicine Forum - Patients Virtual Week - 8-11 March, 2021

<https://precisionmedicineforum.com/our-conferences/patient-week/>

We convene a group of experts from a range of disciplines within precision medicine, and via a moderated discussion, allow unique insights in a relaxed, interactive environment. Our platform allows for audience Q&A, polls, and open discussion amongst the panellists to create a fully immersive experience.

Online Sessions: Four, two-hour sessions over 8-11 March 2021. Free to attend for healthcare and patients/advocates and research. Richard is speaking on the 11th March.

Contributed by Richard M Ballerand www.Ballerand.net

WHO 's informal consultation for people living with diabetes on March 9-11: Expression of Interest

<https://www.surveymonkey.com/r/WHOPLWDS>

If you could use your experiences of diabetes to reshape the world for better, what would you do?

This collaborative meeting seeks to connect people living with diabetes from around the world with the

community of people living with non-communicable diseases convened in December and apply insights gained to date to their involvement in the Global Diabetes Compact. The consultation will include a mixture of presentations, discussions and breakout sessions that will be co-led and facilitated by those with lived experience.

Invitation to be a co-author: Standardised Data on Initiatives (STARDIT)

What is it? STARDIT (Standardised Data on Initiatives) exists to help everyone in the world find and understand information about collective human actions, which are referred to as 'initiatives'. STARDIT is being co-designed to create a standard way to share information about research, projects and initiatives, including health technology assessment processes and information about medical devices.

Why did we build STARDIT? There is currently no standardised way to share information within and across disciplines about initiatives in fields such as health, environment, basic science, manufacturing, media, and international development. Too often, information about initiatives and their impacts is not consistently reported across disciplines, or even across departments.

Who is involved so far? Jack Nunn, Director of the charity Science for All, has been hosting and leading the co-design process for 'Standardised Data on Initiatives' (STARDIT) since 2019, with over 40 people involved from different organisations, including the Wikimedia Foundation, Cochrane, Johns Hopkins University (USA), the Health Research Authority (UK), the Poche Centre for Indigenous Health (Australia) and multiple universities.

The Beta version of STARDIT is now ready for feedback, with anyone in the world invited to become a co-author. Find more information and get involved here: <http://scienceforall.world/STARDIT/Beta/>

Contributed by Jack Nunn

H2O: new IMI project website <https://health-outcomes-observatory.eu/#:~:text=The%20Health%20Outcomes%20Observatory%20project,and%20those%20of%20the%20entire>

On 19 February 2021, the Health Outcomes Observatory (H2O) project launched its official website for the public. H2O, a project of the Innovative Medicines Initiative (IMI). This aims to equip patients with the tools to measure their outcomes in a standardised way, while giving them full control of their data. This is the first-ever attempt at scale to collect and incorporate patient outcomes into healthcare decision making at an individual and population level.

From the European Patients Forum February newsletter

EUPATI Open Classroom : <https://learning.eupati.eu/>

EUPATI Open Classroom is a brand new e-learning platform featuring a flexible and on-demand learning catalogue and allows patients, patient representatives and other stakeholders from anywhere in the world to take courses in medicines research and development.

There are currently 4 Topics ('Modules') available; Getting started, Introductions to Medicines R&D, Pre-Clinical Development and Clinical Development. Two more Topics will be added by May 2021: Regulatory affairs and HTA. Each Topic contains several 'Courses' (Training Units) which a learner can complete online and receive a certificate for (for 8 EUR/Course).

You can become a EUPATI Fellow by completing all online courses in the programme. The total cost is estimated to be EUR 232 (incl. VAT) to complete 29 courses which make up the EUPATI Patient Expert Programme.

European Federation of Neurological Associations (EFNA): Training initiatives for neurology advocates <https://www.efna.net/elearning/>

EFNA has developed a series of elearning modules for patient advocates. These open-access courses aim to upskill participants on how they can effectively advocate in a virtual world by identifying and engaging key

stakeholders, hosting successful online events and developing and disseminating key advocacy messages. The courses are video-based and divided into sections that can be watched independently at times that suit you. Each module includes supporting notes and the option to receive a personalised certificate of completion.

International Conference for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

https://admin.ich.org/sites/default/files/2020-12/ICH_ReflectionPaper_PFDD_Endorsed-ForConsultation_2020_1118.pdf

ICH was established in 1990 to achieve greater harmonization worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner. In 2015, its name was changed to the International "Council" for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

ICH Reflection Papers are intended to articulate ideas for potential future harmonisation work, lay out an area where harmonisation work is needed, or make proposals for a series of future topics for harmonisation. The ICH Reflection Paper on *Patient-Focused Drug Development* (PFDD) identifies key areas where incorporation of the patient's perspective could improve the quality, relevance, safety and efficiency of drug development and inform regulatory decision making. It also presents opportunities for development of new ICH guidelines to provide a globally harmonized approach to inclusion of the patient's perspective in a way that is methodologically sound and sustainable for both regulated industry and regulatory authorities. As part of ICH public consultation on this Reflection Paper, stakeholders are invited to provide their comments to their respective Regulatory Authorities or directly to the ICH Secretariat by 7 March 2021 at pfdd@ich.org.

Global Alliance for Patient Access (GAfPA)



Dec 2020 Report: Patient engagement in HTA. Practices and principles in Europe and the United States
http://gafpa.org/wp-content/uploads/GAfPA_Patient-Engagement-in-Health-Technology-Assessment_Dec-2020.pdf

Pfizer sponsored.

ROADMAP: Real world Outcomes across the AD spectrum for better care

<https://kb.imi-neuronet.org/>

ROADMAP and the members of the Neuronet (Efficiently Networking European Neurodegeneration Research) programme launched a pan-European Knowledge Base which brings together key information about the 18 projects of the Innovative Medicines Initiative (IMI) neurodegeneration (ND) portfolio.

COVID-19

How You Make an Adenovirus Vaccine

An informative read by Derek Lowe 8 February, 2021

<https://blogs.sciencemag.org/pipeline/archives/2021/02/08/how-you-make-an-adenovirus-vaccine>

Patient Engagement in the COVID-19 Pandemic: Evaluating Remote & Online Methods

CHI KT Platform

By Leanne Dunne & Ashley Struthers

<https://medium.com/knowledgenudge/engaging-during-covid-19-evaluating-remote-online-methods-bd60ab8d1b5a>

Publications

Parker L, Grundy Q, Fabbri A, Mintzes B, Bero L. (2021) 'Lines in the sand': an Australian qualitative study of patient group practices to promote independence from pharmaceutical industry funders. *BMJ Open*;11:e045140. doi: 10.1136/bmjopen-2020-045140 <http://bmjopen.bmj.com/cgi/content/full/bmjopen-2020-045140?ijkey=vJJREH8hMhS1rp4&keytype=ref>

Following on from:

Parker L, Fabbri A, Grundy Q, Mintzes B, Bero L. (2019) "Asset exchange": a qualitative study of interactions between Australian patient groups and the pharmaceutical industry. *BMJ* 367:l6694 <https://www.bmj.com/content/367/bmj.l6694>

Parker L, Brown A, Wells L. (2020) Building Trust and Transparency - health consumer organisation-pharmaceutical industry relationships. *Australian Health Review*. 3 December, <https://doi.org/10.1071/AH20206> <https://www.publish.csiro.au/ah/Fulltext/ah20206?subscribe=false>

Parker L, Brown A, Wells L, Joyner S, Mintzes B, Fabbri A, Chiu K, Wang Z, Bero L. (2020) Consumer-pharmaceutical industry relationships: Building trust and transparency. Health Consumers NSW, Sydney. Available at <https://www.hcnsw.org.au/trust-and-transparency/>

Contributed by Sally Wortley

Sievers H, Joos A, Hilgsmann M. Real-world evidence: perspectives on challenges, value, and alignment of regulatory and national health technology assessment data collection requirements. *International Journal of Technology Assessment in Health Care*. doi: 10.1017/S0266462321000131

Assess stakeholder perceptions on the challenges and value of real-world evidence (RWE) post approval, the differences in regulatory and health technology assessment (HTA) real-world data (RWD) collection requirements under the German regulation for more safety in drug supply (GSAV), and future alignment opportunities to create a complementary framework for postapproval RWE requirements. Pharmaceutical industry experts, regulatory authorities, health technology assessment bodies and academia agree that RWE could close evidence gaps by showing the actual value of medicines in patients under real-world conditions. However, experts acknowledged certain challenges such as: (i) heterogeneous perspectives and differences in outcome measures for RWE generation and (ii) missing practical experience with RWD collected through mandatory registries within the German benefit assessment due to an unclear implementation of the GSAV.

Biddle MSY, Gibson A, Evans D (2021). Attitudes and approaches to patient and public involvement across Europe : A systematic review. *Health & Social Care in the Community*, 29(1), 18-27. <https://doi.org/10.1111/hsc.13111>

The Innovative Medicines Initiative (IMI) is making great strides in promoting patient and public involvement (PPI) in health research across Europe, supporting patient organisations to be involved in the projects that it funds. Despite this, the literature around PPI in health services and research originating from European countries appears less than from the United Kingdom (UK), where PPI is well established. We included all studies reporting PPI activity in both public and private health services and research institutions in the World Health Organization European region, excluding the UK, published in the English language from 1996 to 2018. The studies imply a growing interest and support for the idea of PPI in health services and, to a lesser extent, in health research. There seems to be a convergence of conceptualisations of PPI across Europe, with internationally significant areas of innovative work taking place in countries such as the Netherlands and the Scandinavian countries.

Vat, Lidewij Eva, Teresa Finlay, Paul Robinson, Giorgio Barbareschi, Mathieu Boudes, Ana Maria Diaz Ponce, Michaela Dinboeck, et al. 2021. « Evaluation of Patient Engagement in Medicine Development: A Multi-Stakeholder Framework with Metrics. Health Expectations. <https://doi.org/10.1111/hex.13191>

Faulkner Stuart D, Suzanne Sayuri Ii, Chi Pakarinen, Fabian Somers, Maria Jose Vicente Edo, Lucia Prieto Remon, Ana Diaz Ponce, et al. 2021. Understanding Multi-Stakeholder Needs, Preferences and Expectations to Define Effective Practices and Processes of Patient Engagement in Medicine Development: A Mixed-Methods Study. Health Expectations. <https://doi.org/10.1111/hex.13207>.

Muscat Danielle M, Heather L Shepherd, Don Nutbeam, Lyndal Trevena, Kirsten J. McCaffery 2021. Health Literacy and Shared Decision-Making: Exploring the Relationship to Enable Meaningful Patient Engagement in Healthcare. Journal of General Internal Medicine 36 (2): 521-24. <https://doi.org/10.1007/s11606-020-05912-0>.

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