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

Enhanced quality and relevance of HTA through patient and citizen involvement

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

Welcome to our November E-Bulletin

Welcome to the latest edition of the HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG) E-Bulletin! With the deadline fast approaching on **7 December**, I know a lot of you have been busy finalising your oral and poster presentation abstracts for the HTAi 2024 Annual Meeting which will be held in Seville, Spain from 15-19 June. There has been a lot of work going on behind the scenes already preparing for this prestigious event and bringing together leading experts and thought leaders in HTA to share their insights and latest research. Just like previous years, the 2024 HTAi meeting is sure to be an unmissable event to hear about innovations, share experiences, and network with people from around the globe.

Speaking of sharing experiences, I was very privileged to be part of the advisory board for the Asia Pacific Oncology Alliance (APOA) this year, which is an initiative of the Pinnacle Program developed by Rare Cancers Australia to support, connect, and empower patient support organisations and improve health outcomes of patients across the Asia Pacific region. Last week was the launch of their report "Pathways for Transforming the Cancer Ecosystem: A Patient Centred Framework" which showcases 36 case studies informed by more than 100 people who contributed to the project. It is an incredibly comprehensive and very important piece of work that discusses how we can all do more to improve cancer survivorship. Although the focus is on the Asia Pacific region, the key findings and recommendations are applicable worldwide, and I encourage everyone to take a look at the report (see link in What's Happening in the E-Bulletin).

I would like to welcome Lucas Miyake Okumura who has recently been appointed as an industry representative on the PCIG Steering Committee. Lucas is based in Brazil and has extensive HTA experience in the pharmaceutical sector which will be a great asset to the Steering Committee. I look forward to collaborating with Lucas and congratulate him on his appointment. If anyone else is interested in joining the Steering Committee, we currently have another industry representative vacancy. Be sure to check out the call for Expressions of Interest for this position. Applications close **on 29 December 2023**.
I hope you enjoy reading this month's issue. It's so inspiring to see all of the patient engagement work that takes place each month by our members!

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)

PCIG Matters

Expressions of Interest – PCIG Steering Committee, Industry Representative
PCIG seeks Expressions of Interest for an **industry representative** (preferably from a medical devices/diagnostics company) to fill a vacancy on its Steering Committee. Please send a CV and cover letter (no more than 200 words) addressing the criteria below to the PCIG Technical Officer, Hadewych Honné, via email: to.patient-citizen@htai.org by **Friday 29 December 2023**.

Criteria

- Able to demonstrate active participation in the field of patient or citizen involvement in health technology assessment
- Able to meet the expectations of Steering Committee membership as set out in the Terms of References, e.g. commit to take an active role in driving the work of the Interest Group and providing practical assistance to activities undertaken by the group as appropriate and complete a three-year term (from January 2024-2027)
- Able to participate in additional HTAi committees
- Preference will be given to those members who have actively participated in the Interest Group. Please note all applicants must be a member of HTAi and PCIG.

Full details of the role of Steering Committee members can be found in PCIG's Terms of Reference (May 2023). The Co-Chairs, Fiona Pearce and Aline Silva are happy to discuss the role with interested members.

Better Patient Involvement in HTA - 360° Research
The 360 Review of Stakeholder Experiences in HTA in Europe (https://htai.org/wp-content/uploads/2023/10/360-HTAi-PCIG-Research-in-Patient-Involvement-Practices-in-HTA-in-Europe-Oct-2023-1.pdf) details the recent 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. The research was conducted by PCIG along with European Patients Forum (EPF) and EUPATI and was funded by an unrestricted grant to HTAi from EFPIA and PhRMA.

PCIG Steering Committee (SC) member Zal elaborates:
At the last SC meeting, Anke-Peggy Holtorf and Neil Bertelson presented their impressive Europe 360° Final Report. In the discussion that followed, Neil disclosed that while doing the research on the case studies they revisited the patient groups who participated. He reported that there was no institutional memory of the group's participation other than recollecting the use of the template for input. These important details have implications regarding the use of the template as well as the capacity of patient organizations to produce submissions.

In regards to the input template, there is an interesting report from CADTH. Living With Type 2 Diabetes https://www.cadth.ca/living-type-2-diabetes describes treatment outcomes and considerations important to people living with type 2 diabetes mellitus (T2DM) in Canada, as shared in patient input given for past CADTH Reimbursement Reviews. The patient input was submitted using a template based on the one developed by the PCIG. The report explicitly recognizes "that past input was missing the experiences of Black people, Indigenous people, and other people of colour; people living in poverty or with low income; people living in rural and remote communities; children and adolescents and members of the LGBTQ2S+ community, among others". This is the first report to highlight the absence of any evidence in reimbursement reviews of the lived experience of marginalized populations and equity deserving groups.

The bulk of the input was submitted by the sixth largest patient charity in Canada in terms of revenue and with the second largest public policy budget. This report raises questions about the sufficiency and methodology of patient input to inform Reimbursement Reviews and suggests potential uses of the report to improve the quality of patient input and reduce the burden on patient groups given their limited capacity.

Another report, The State of Patient Associations in Canada, http://patientcommando.com/patient-focused/ provides insights to over 1000 disease specific patient charities in Canada. It analyzed the public information returns these charities submit to the Canadian tax authority and provides a picture of the financial, operational, and human resource capacity of these organizations. It also provides comparison data to the broad charitable sector to understand the gaps and inequities that patient organizations have to contend with in the competition for donor dollars. Patient organizations are key stakeholders in HTA yet have distinct organizational and regulatory issues that affect their ability to participate in an equitable fashion. This report, while specific to Canada, offers data that are relevant to other jurisdictions in the discussions around how to best involve and enable these organizations in HTA.

Contributed by Zal Press

EMA better informs patient advocates
https://clinicaldata.ema.europa.eu/web/cdp/background

The EMA is giving wider access to some of the data in the clinical reports submitted to the agency since 2015. Proprietary data will not be part of the information available. They are not entirely up to date due to COVID. A great step forward.

Contributed by Dominique Hamerlijnck

Keogh A, Mc Ardle R, Diaconu MG, Ammour N, Arnera V, Balzani F, Brittain G, Buckley E...Hamerlijnck D, ... Rochester, L. (2023). Mobilizing Patient and Public Involvement in the Development of Real-World Digital Technology Solutions : Tutorial. Journal of Medical Internet Research, 25, e44206. https://doi.org/10.2196/44206

HTAi Rare Diseases Interest Group
The group is chaired by Karen Facey, and co-chaired by Sheela Upadhyaya and Alicia Granados. They are supported by Technical Officer Lea Wiedmann, and an experienced and committed steering group made up of Dorota Zgodka, Farzana Malik, Heather Logan, Ramiro Gilardino, Veronica Lopez Gousset, and Juan Antonio Blasco. The group is dedicated to sharing good practices in evidence generation for rare disease technologies, fair assessment processes that take account of the feasibility of evidence generation and appraisal processes that take account of the burden of rare diseases on patients and society when determining value.
More information is available here. For inquiries, please send an email to interestgroups@htai.org.

Patient Voice Hub
The Patient Voice Hub has been launched to equip patients, carers, and patient and consumer organisations with the basics of health technology assessment (HTA) processes in 15- 20 minutes. The first four topics on the hub are specific to giving input in the current Australian HTA process, but further topics tackling elements of HTA are being adapted for this short form for people who want to find out more. The Hub brings together the Patient Voice Initiative's resources - designed with patients and in consultation with the Consumer Evidence and Engagement Unit (Department of Health and Aged Care) over the past five years – in one easy to access space developed for people expert in living with a condition but who may be tired, find it hard to focus, or short on time. The resource is free. It just requires a very simple registration. You can find out more by watching this short video or exploring the hub here. It's built on an established training

platform, but the Patient Voice Initiative is working with the platform providers to replace the 'training' jargon with language that better captures its aim of equipping people with the know-how they need to share their expertise with HTA. This work is continuing.

Australian HTA Policy and Methods Review
https://www.health.gov.au/resources/publications?search_api_fulltext_listing=HTA+policy+and+methods+review
To ensure that the Reference Committee has sufficient time to consider the extensive and valuable input and material received for the HTA Review so far, as well as conduct further public consultation, the HTA Review has been extended until 15 April 2024.
The Reference Committee has received a vast amount of materials and inputs for the HTA Review. More than 100 stakeholder submissions were received in Consultation 1, and deep-dives on a wide range of topics were conducted, along with research and analysis papers prepared by HTA experts. The Reference Committee is considering these inputs to develop an Options Paper that will detail potential options for reform, which will be workshopped with stakeholders during a second round of public consultation.
For more details about the updated dates for the HTA Review visit the HTA Review web page.

Contributed by Ann Single

HTAi 'Early HTA Terminology Working Group' project on the terminology associated with early HTA
HTA is increasingly used in the earliest phases of development of a health technology. However, multiple terms are currently being used to describe early HTA activities. Terms include early HTA, development-focused HTA and early dialogue or early (scientific) advice and others found in a literature search. The first of three rounds of web-based surveys took place in November.
If you have any questions regarding this Delphi survey, you can contact the two Leaders of the Working Group: Janet Bouttell (Janet.Bouttell@nuh.nhs.uk) or Janneke Grutters (janneke.grutters@radboudumc.nl), at any point in the process.

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

Participation Grant Submissions Closing
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
The new Policy Forum Advisory Committee Chair is Iñaki Gutiérrez-Ibarluzea!
The HTAi 2024 Global Policy Forum is taking place January 27-29, 2024 in San Diego, USA. Discussions will revolve around the main topic 'Designing Collaborations Involving HTA: Finding The Rhythm For Success'.

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-november-17-2023/
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

Asia Pacific Oncology Alliance (APOA) report – Pathways for Transforming the Cancer Ecosystem. A Patient Centred Framework
https://pinnacle-patient.com/sites/default/files/2023-11/APOA%20report%20-%20Pathways%20for%20Transforming%20the%20Cancer%20Ecosystem.pdf
The Pinnacle Program is a peer-to-peer mentoring program developed by Rare Cancers Australia (RCA), which was founded in 2012 by Kate and Richard Vines, for patient support organisations (PSOs) across the globe. The mission of the Pinnacle Program is to support, connect and empower PSOs and improve the health outcomes of patients across the Asia-Pacific region. It is based on the principles of ethnographic teaching and aims to create a community for learning, connecting, collaborating and sharing across PSOs internationally so that we can all learn, grow and better support our patients. Capacity building initiatives need to specifically consider the local context, cultural and linguistic factors relevant for patient organisations in the Asia-Pacific (APAC) region and the Pinnacle program is designed to work in that way. The Asia-Pacific Oncology Alliance (APOA) is an initiative of the Pinnacle Program. The relationship between RCA, the Pinnacle Program and APOA is outlined in Figure 3. APOA is a network of stakeholders (comprising of patients, patient organisations, clinicians, researchers, multiple industries, and healthcare decision-makers) from across the cancer continuum who are committed to improving cancer survivorship in the Asia-Pacific region.

Contributed by Fiona Pearce who is an APOA Advisory Board Member

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, 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.

FDA Draft Guidance: The Role of RWE in Underrepresented Populations
The US FDA has taken steps to enhance information regarding medical products for populations that are traditionally underrepresented in clinical trials. This is being achieved through the use of real-world data (RWD) and real-world evidence (RWE).
Of the many potential use cases for real-world data (RWD) and real-world evidence (RWE), one of the most important is improving the information available about how medical products work in populations that have been historically underrepresented in clinical trials. Striving for health equity and increasing the visibility of underrepresented populations is a critical topic for the U.S. healthcare system. The safety and effectiveness of treatments cannot be accurately assessed without understanding their effects in all relevant populations. To support this understanding, the U.S. Food and Drug Administration (FDA) released draft guidance on diversity plans in April 2023, Project Equity, and the Diversity in Clinical Trials Initiative.
FDA's most recent guidance in this space, 'Postmarketing Approaches to Obtain Data on Populations Underrepresented in Clinical Trials for Drugs and Biological Products' (released on August 10, 2023), is the latest step in FDA's systematic effort to improve representation in the health data it reviews. In this guidance, FDA confirmed the important role of RWD and RWE in achieving this goal.

ISPOR emphasis on health economics and outcomes research (HEOR)
ISPOR Europe 2023 focused on the theme 'HEOR at the Nexus of Policy and Science' and topics addressed issues surrounding use of real-world evidence, cross-border collaboration, affordability, equity, and more. The ISPOR Patient Representatives Roundtable—Europe was held during the event and focused on 'Joint Clinical Assessment (JCA): Will it improve the patient experience of involvement in HTA?' ISPOR Patient Representatives Roundtables provide a platform for patient representatives to discuss challenges and opportunities of patient involvement in healthcare research and decision-making processes. Learn about

Patient Representative Roundtables here at https://www.ispor.org/member-groups/councils-roundtables/patient-council/patient-representatives-roundtables?utm_medium=email&utm_source=database&utm_campaign=strategic_initiatives&utm_content=engage_november-non-member_comms_2023_nov29&_zs=3hXOX&_zl=Pdcq3
HTA Roundtable–Europe discussed incentivizing high-quality evidence generation, HTA capacity building in Europe, and how to better include payers and clinicians in the decision-making process. The goal of ISPOR HTA Roundtables is to advance the application of research on health technologies and to promote a valuable exchange of information, methods, and knowledge in the development of value assessment, or health technology assessment. Learn more here at https://www.ispor.org/member-groups/councils-roundtables/health-technology-assessment-council/health-technology-assessment-roundtables?utm_medium=email&utm_source=database&utm_campaign=strategic_initiatives&utm_content=engage_november-non-member_comms_2023_nov29&_zs=3hXOX&_zl=Qdcq3

ISPOR 2024 Atlanta, GA, USA, 5-8 May 2024
ISPOR Europe 2024 in Barcelona, Spain, 17-20 November 2024

From the European Patients Forum (EPF)
EPF, as part of collaborative activities on antimicrobial resistance (AMR), has joined the 'AMR Multi-stakeholder Partnership Platform', a new initiative led by the Food and Agriculture Organization of the United Nations (FAO), the UN Environment Programme (UNEP), the World Health Organization (WHO) and the World Organisation for Animal Health (WOAH), to encourage cooperation between stakeholders from different sectors in a 'One Health' approach to tackling AMR.

EPF participated in the European Medicines Agency's (EMA) Patient and Consumer Working Party https://www.ema.europa.eu/en/events/european-medicines-agency-ema-patients-consumers-pcwp-healthcare-professionals-hcpwp-working-parties-12
The Agency updated member organisations on a range of activities, including the development of an EU list of essential medicines and EMA's communication campaign on biosimilars.

The Heads of Medicines Agencies (HMA), the European Commission and EMA published for the first time electronic product information (ePI) for selected human medicines harmonised across the European Union (EU) to make it more accessible to end users such as healthcare professionals and patients. https://www.ema.europa.eu/en/news/first-electronic-product-information-epis-published-selected-human-medicines
The creation and testing of ePIs in real regulatory procedures is being explored through a one-year pilot initiative by HMA, EMA and the European Commission to enable the transition to the electronic system for medicines evaluated both nationally and at European level. https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information/electronic-product-information-epi#pilot-project-to-test-epi-section

Gravitate Health
https://www.gravitatehealth.eu/
The Gravitate Health is a public – private partnership with 40 members from Europe and the US, co-led by University of Oslo (coordinator) and Pfizer (industry lead), funded by the Innovative Medicines Initiative (IMI) – a joint undertaking of the European Commission, the European Federation of Pharmaceutical Industries and Associations (EFPIA), IMI2 Associated Partners.

Data Saves Lives released its new toolkit on health data
https://datasaveslives.eu/toolkit
The DSL Toolkit 2.0 aims to equip patient groups and health influencers with the information and materials they need to have a positive dialogue with their communities about health data and to potentially launch

their own health data initiatives.

COVID-19

Cash-Goldwasser S, Reingold AL, Luby SP, Jackson LA, Frieden TR. Masks During Pandemics Caused by Respiratory Pathogens—Evidence and Implications for Action. JAMA Netw Open. 2023;6(10):e2339443. doi:10.1001/jamanetworkopen.2023.39443
https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2811136
The totality of all data available strongly supports masks to reduce the spread of SARS-CoV-2, especially those of high quality
Well-designed observational studies demonstrate the association of mask use with reduced transmission of SARS-CoV-2 in community settings, and rigorous evaluations of mask mandates have found substantial protection. Disagreement about whether face masks reduce the spread of SARS-CoV-2 has been exacerbated by a focus on randomized trials, which are limited in number, scope, and statistical power. Many effective public health policies have never been assessed in randomized clinical trials; such trials are not the gold standard of evidence for the efficacy of all interventions. Masking in the community to reduce the spread of SARS-CoV-2 is supported by robust evidence from diverse settings and populations.

Yaneer Bar-Yam, Jon Samet, Alexander Siegenfeld, Nassim Taleb.
https://www.researchsquare.com/article/rs-3486610/v1
Quantitative errors in the Cochrane review on 'Physical interventions to interrupt or reduce the spread of respiratory viruses' https://doi.org/10.21203/rs.3.rs-3486610/v1

Upcoming December 2023 issue on Global Lessons from COVID-19: A Systematic Review Of COVID-19 Misinformation Interventions: Lessons Learned
Rory Smith, Kung Chen, Daisy Winner, Stefanie Friedhoff, Claire Wardle. November 2023. Health Affairs
https://doi.org/10.1377/hlthaff.2023.00717
https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2023.00717?utm_campaign=Health+Affairs+Sunday+Update+2023+November-December&utm_medium=email&_hsmi=283024263&_hsenc=p2ANqtz-grnsvkJb_k_buDE6FitHMaXoTz8gvzXtmsW-jofK9PegwS9P2Wunpo9kdjxUWmVimo34MoHChgNHAirxaDYzVSgRU1lg&utm_content=283024263&utm_source=hs_email
Governments, public health authorities, and social media platforms have employed various measures to counter misinformation that emerged during the COVID-19 pandemic. The effectiveness of those misinformation interventions is poorly understood. We found evidence supporting accuracy prompts, debunks, media literacy tips, warning labels, and overlays in mitigating either the spread of or belief in COVID-19 misinformation. However, by mapping the different characteristics of studies, we found levels of variation that weaken the current evidence base. For example, only 18 percent of studies included public health–related measures, such as intent to vaccinate, and the misinformation that interventions were tested against ranged considerably from conspiracy theories (vaccines include microchips) to unproven claims (gargling with saltwater prevents COVID-19). The field urgently needs to include more public health experts in intervention design and to develop a health misinformation typology; agreed-upon outcome measures; and more global, more longitudinal, more video-based, and more platform-diverse studies.

Kemper S, Bongers M, Kupper F, De Vries M, Timen A. (2023). Preferences for public engagement in decision-making regarding four COVID-19 non-pharmaceutical interventions in the Netherlands : A survey study. PloS One, 18(10), e0292119. https://doi.org/10.1371/journal.pone.0292119

Publications

Cangelosi Michael et al (2023). Evolving Use of Health Technology Assessment in Medical Device Procurement—Global Systematic Review: An ISPOR Special Interest Group Report. Value in Health, Volume 26, Issue 11, 1581 – 1589. Reports minimal evidence that notes HTA influencing medical device procurement. Procurement bodies and hospitals may not be incentivized to publish their work and transparency could be improved

Auwal FI, Copeland C, Clark EJ, Naraynassamy C, McClelland GR (2023). A systematic review of models of patient engagement in the development and life cycle management of medicines. Drug Discovery Today, 28(9), 103702. https://doi.org/10.1016/j.drudis.2023.103702

John Halamka, Paul Cerrato. 2020. The Digital Reconstruction of Health Care. NEJM Catal Innov Care Deliv 2020;1(6). DOI: 10.1056/CAT.20.0082
Although remote patient monitoring, machine learning, and artificial intelligence hold great promise for care delivery … leaders need to exercise care in their strategy and execution.
The health care delivery landscape is slowly being transformed as hospitals, clinics, and medical offices seek more cost-effective venues and processes. Many patient encounters are transitioning to a virtual setting as telemedicine, hospital-at-home programs, and remote patient monitoring devices play a larger role. That transition, which has seen a sudden increase because of the Covid-19 pandemic, is likely to continue to accelerate. Temporary measures, such as the Centers for Medicare & Medicaid Services restructuring its reimbursement regulations to allow for virtual and home-based hospital visits at the same rate as currently allowed for brick-and-mortar facilities, could be extended or made permanent. This analysis discusses the rationale for moving from brick-and-mortar to online care, the scientific evidence supporting the transition, and trends in third-party fee schedules. Finally, the authors review the essential role of artificial intelligence in making this realignment of services a viable option for health care leaders, clinicians, and patients.

Holly Fernandez Lynch, Lisa Kearns, Kenneth I Moch, Arthur L Caplan. 2023. What's the Worst That Could Happen? A Toothless FDA. Health Affairs Forefront https://www.healthaffairs.org/content/forefront/s-worst-could-happen-toothless-fda
On the face of it, the Food and Drug Administration's (FDA's) regulatory mandate is straightforward: Approve drugs that are safe and effective for their intended use. However, as demonstrated by several recent decisions regarding drugs to treat conditions such as Alzheimer's disease, Duchenne muscular dystrophy, and amyotrophic lateral sclerosis (ALS), the reality is often far more complex, necessitating a balance between speedy patient access and reasonable certainty about drug benefit. When should the FDA demand more evidence, even if it will mean that a promising medicine might take longer to reach patients? And when should it exercise "regulatory flexibility" based on the risk tolerance often exhibited by those facing terrible diseases without good treatment options?

Daniel A Ollendorf, Richard Cookson, Stacey Kowal, Patricia Synnott, Eberechukwu Onukwugha. Nov 2023. We Need Better Data, Not Just New Drugs, To Reduce Disparities In Alzheimer's Care
Health Affairs Forefront 10.1377/forefront.20231116.989833
Making US data fit for equity-informed research in Alzheimer's disease requires some relatively simple ingredients: interested researchers, engaged patients and caregivers, funding, and the political will to make changes in existing data collection vehicles. Many more diseases would also benefit from this kind of information. The time to change the data collection infrastructures was yesterday, but wouldn't it be better to start today than to wait until tomorrow?

The role of quantitative bias analysis for nonrandomized comparisons in health technology assessment: recommendations from an expert workshop
Thomas P Leahy, Isabelle Durand-Zaleski, Laura Sampietro-Colom, et al. 2023 .International Journal of Technology Assessment in Health Care, Volume 39, Issue 1
Article

DYNAMIC HTA FOR DIGITAL HEALTH SOLUTIONS: OPPORTUNITIES AND CHALLENGES FOR PATIENT-CENTERED EVALUATION
Jan B Brönneke, Annika Herr, Simon Reif, Ariel D Stern. 2023. International Journal of Technology Assessment in Health Care

CAN KNOWLEDGEABLE EXPERTS ASSESS COSTS AND OUTCOMES AS IF THEY WERE IGNORANT? AN EXPERIMENT WITHIN PRECISION MEDICINE EVALUATION
Thamonwan Dulsamphan, Parntip Juntama, Chotika Suwanpanich, et al Yot Teerawattananon 2023. International Journal of Technology Assessment in Health Care

Mapping horizon scanning systems for medical devices: similarities, differences, and lessons learned
Sari Susanna Ormstad, Claudia Wild, Judit Erdös, Kristen Moulton 2023.
International Journal of Technology Assessment in Health Care, Volume 39, Issue 1

Priority setting for health technology adoption at the national level: Lessons learned over 25 years' experience
Osnat Luxenburg, Tal Morginstin, Vicki Myers, et al. 2023. International Journal of Technology Assessment in Health Care, Volume 39, Issue 1 doi: 10.1017/S0266462323002611

Moving from intervention management to disease management: a qualitative study exploring a systems approach to health technology assessment in Canada
Marina Richardson, Beate Sander, Nick Daneman, et al. 2023. International Journal of Technology Assessment in Health Care, Volume 39, Issue 1

Health technology assessment (HTA) readiness in Uganda: stakeholder's perceptions on the potential application of HTA to support national universal health coverage efforts
Chrispus Mayora, Joseph Kazibwe, Richard Ssempala, et al. 2023. International Journal of Technology Assessment in Health Care, Volume 39, Issue 1

Abell L, Maher F, Begum S, et al. (2023). Incorporation of patient and public involvement in statistical methodology research : A survey assessing current practices and attitudes of researchers. Research Involvement and Engagement, 9(1), 100. https://doi.org/10.1186/s40900-023-00507-5

Blackburn S, Hine R, Fairbanks S, et al. (2023). The INSIGHT project: Reflections on the co-production of a quality recognition programme to showcase excellence in public involvement in health and care research. Research Involvement and Engagement, 9(1), 99. https://doi.org/10.1186/s40900-023-00508-4

Hatch S, Fitzgibbon J, Tonks AJ, Forty L. (2023). Diversity in patient and public involvement in healthcare research and education-Realising the potential. Health Expectations https://doi.org/10.1111/hex.13896

Kim JY, Acelas MPB, Granville CA, Getz K. (2023). Benchmarking Patient Engagement Capabilities and Preparedness of Drug Development Sponsors. Therapeutic Innovation & Regulatory Science, 57(5), 1040-1049. https://doi.org/10.1007/s43441-023-00545-x

Lloyd N, Hyett N, Kenny A. (2023). Barriers and Enablers to Evaluating Outcomes From Public Involvement in Health Service Design: An Interpretive Description. Qualitative Health Research, 33(11), 983-994. https://doi.org/10.1177/10497323231191048

Ankomah SE, Fusheini A, Derrett S. (2023). Implementing patient-public engagement for improved health: Lessons from three Ghanaian community-based programmes. Health Expectations https://doi.org/10.1111/hex.13866

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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.

David W Bates, Jens Deerberg-Wittram, Gregory Katz, Katharina Braeger, Lena S Hirsch, Gary S Kaplan, Lukas Kwietniewski, Christoph A Meier, Camila Plaza de Laifer, Eyal Zimlichman. October 18, 2023. Using Publicly Reported Global Hospital Rankings to Improve Dissemination of Patient-Reported Outcome Measures (PROMs). NEJM Catal Innov Care Deliv 2023;4(11) DOI: 10.1056/CAT.23.0097
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
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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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