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

Enhanced quality and relevance of HTA through patient and citizen involvement

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

- Welcome – from our Chair
- PCIG Matters – Webinar, other IGs, Annual Meeting planning
- HTAi Matters – HTAi2023 Adelaide
- What's Happening – in and for patient and public involvement
- Publications

Welcome to our April E-Bulletin

From our Chair

Following on from last month's Welcome, I have further news to share about *Expressions of Interest for the PCIG Chair and Vice-Chairs*. The Steering Committee received no nominations from within Steering Committee for the current positions. We recognise that the workload for these positions and a general rise in workloads across our community since Covid arrived, makes it difficult to find people able to volunteer for these posts. As a result, Steering Committee agreed to propose a change in our Terms of Reference to enable us to appoint two Co-Chairs and a Vice Chair. Supported by our Technical Officer and the Outgoing Chair, we believe this can bring a strong and more diverse leadership team with a more manageable workload.

To make this change, we've made some small amendments to our Terms of Reference and submitted them to the HTAi's Executive Committee. If it approves them, they will be considered by the HTAi Board in late May. We will await the outcome of this meeting before calling for Expressions of Interest for the current Vice-Chair vacancy and the vacancy that will arise when I end my term at our AGM in June and take up the role of HTAi Vice-President. The *call for Expressions of Interest will communicate the roles in line with the HTAi Board approval and will be sent out the week of May 29, 2023 with a deadline for EOIs of June 9, 2023*. Please note these dates in your diary now. If you are a member of PCIG and an HTAi member in good standing, please consider if you would be willing to serve as vice-chair, chair (or co-chair if approved by Board). Or encourage someone who you believe will serve our interest Group well. You can look at the current Terms of Reference to gain an understanding of the work. If you wish to start drafting your Expression of Interest now, please note that this should be a 1-page CV accompanied by a letter (of no more than 2 pages) expressing interest in the role and addressing the following 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
- Able to participate in additional HTAi committees.

Preference will be given to those members who have actively participated in the Interest Group.
But please do not submit anything until the final role descriptions are communicated in late May

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

singlehaworth@gmail.com

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

Webinar: A Framework for Characterizing Impact of Patient Involvement in HTA
May 25, 4 pm CET, 10 am EST
https://htai.org/event/webinar-a-framework-for-characterizing-impact-of-patient-involvement-in-hta/
A common framework to characterize the impact of patient involvement may enable greater harmonization of evaluation and reporting across HTAs, facilitating useful comparisons and important variables to inform meaningful improvement.
Presenters: Veronica Lopez Gousset, VLG Consulting, France; Aline Silveira Silva, Patient Voices Network, Canada; Anke Peggy-Holtorf, Health Outcomes Strategies, Switzerland
Please join the team as they propose a framework for reporting on the impact of patient involvement in HTA. This is part two to last year's webinar, which you can rewatch here:
https://www.youtube.com/watch?v=eEA-RaN3StY
Registration link will be circulated in the coming days. Stay tuned!
To learn more, please contact the project co-leads: Aline Silva (alinefarunb@gmail.com) or Veronica Lopez Gousset (veronica@globalhelpgranted.com).

Contributed by Veronica Lopez Gousset

HTAi Ethics Interest Group writing and planning workshop
This was held in Rome at the Catholic University of the Sacred Heart from March 30th to April 1st. It was attended by 19 members of the Ethics IG, as well as members of the Hospital-based HTA IG, the Real World Evidence and Artificial Intelligence IG, and the Patient and Citizen Involvement in HTA IG. Two manuscripts were being planned on topics identified in Utrecht (June 2022): (1) methodology for doing empirical ethics work in HTA, (2) ethical implications of changing evidence requirements (and regulations) in HTA.

The HTA in Developing Countries Interest Group competitive writing project seeking topics pertinent to emerging issues in low- and middle-income countries closed on April 30, 2023. Learn more

PCIG Annual Business Meeting
In line with our Terms of Reference (see 10.1), PCIG will hold its Annual Business Meeting at the HTAi Annual Meeting. Date: Tuesday 27 June 2023. Time: 12:35 – 13:35 pm
Location: Room to be confirmed, Adelaide Convention Centre
Packed lunch available.
An agenda of the business to be transacted will be given to all members at least seven (7) days in advance. The notes of this meeting will be circulated to all members of the Interest Group documenting the actions planned for the forthcoming year.

Buddies for Annual Meeting wanted
It's not onerous. It is fun. Being a buddy involves agreeing with a PASS or grant recipient how you will interact, greeting them at annual meeting and perhaps introducing them to others, answering questions or helping them find answers. Please sign up to be one here.

PCIG dinner Adelaide
Every year at HTAi Annual Meeting, PCIG members gather for an informal meal on the Monday evening. They welcome patients, carers and their representatives (and partners). Dinner is AUD 50 plus drinks. This

year it will be at Tempus Mezze Bar a 10-minute walk from the Adelaide Convention Centre. As the venue is limited to 50 people, you need to reserve a space by completing the linked form. If you are based in Australia, you will be asked to transfer $50 for your meal into the PCIG Chair's personal account (apologies PCIG is not a legal entity). If you are outside of Australia we will avoid transfer fees by asking you to please bring AUD 50 in cash on the evening. Places are filling quickly so please act today to avoid disappointment.

Patient and Citizen Involvement in HTA workshop, June 24
Don't forget to register for our pre-annual meeting workshop. In the morning, speakers from around the globe will provide an:

- Introduction to HTA and patient involvement
- Introduction to resources to support patient participation in HTA
- Introduction to different forms of patient-based evidence
- In the afternoon, we have three streams to choose from:

Asia Pacific 360: What's currently happening in patient involvement in HTA in the Asia Pacific, what goals do we have, can we work together to document practice and describe good practice?
Training: What's currently being offered to patient communities, where are the synergies, where are the gaps, how should this inform PCIG's review of its tools and resources?
Patient Preferences: How are patient preference studies currently informing HTA, how can we work together to improve their integration.

How do patient communities want to interact with pharma? Webinar
Monday 29 May 12:30 AEST
Patient communities are often asked to complete surveys to measure pharma's corporate reputation, but Patient Voice Initiative and CaPPRe wanted to know how patient communities in Australia want to work with pharma and if patient involvement is improving. So, they undertook focus groups to identify 11 domains of interaction that matter to patient communities, before collecting data using two Best Worst Scaling (BWS) tasks to understand their relative importance and satisfaction and create an engagement index score for future benchmarking.
Register here to join a discussion of the findings of this survey, as well as the implications of the results, including potential approaches to improving domains of low satisfaction and high importance. Speakers: Simon Fifer (CaPPRe), Jessica Bean (PVI), Gabrielle Bietola (AstraZeneca & MA CAWG), Janelle Bowden (AccessCR and Research Gamechangers).

Innovative Health Initiative (IHI) Patient Pool
Applications are now open for people who want to be part of the IHI Patient Pool. IHI is running a webinar for potential applicants on 11 May 2023 at 10:30 CEST (Central European Summer Time).
To be part of the IHI Patient Pool, you must meet the following eligibility criteria:

- be a patient with a chronic and/or lifelong illness/condition, or a family member / informal caregiver of a patient with a chronic and/or lifelong illness/condition;
- be resident of one of the Member States of the European Union or one of the third countries associated to Horizon Europe;
- have a working knowledge of English (at least level B2 in the Common European Framework of References for Languages).

Find further information here.

Contributed by Ann Single

Bellberry Ltd International Scientific Congress 'Toward a Coordinated Approach for Managing Accelerated Patient Access to Promising Medicines. Balancing Patient, Regulator, HTA, Payer, and Other Stakeholder Needs'

https://www.eventbrite.com.au/e/public-meeting-international-scientific-congress-hosted-by-bellberry-registration-620339160127?aff=escb&utm-source=cp&utm-term=listing&utm-campaign=social&utm-medium=discovery&utm-content=attendeeshare
Fri, 23 Jun 2023 8:30 AM - 4:00 PM ACST. Crowne Plaza Adelaide, an IHG Hotel 27 Frome Street Adelaide, SA 5000
Programme governance by a Scientific Advisory Committee, chaired by Professor Emeritus Lloyd Sansom
Registration Cost: Early bird* $495 per person (* Early bird closes Sunday 7 May 2023) Standard $695 per person
Bellberry supports consumer engagement in research conversations. Expressions of Interest for complimentary registration for consumer representatives (incl. patients, trial participants, carers etc) can be sent to events@bellberry.com.au

HTAi Matters

HTAi 2023 Annual Meeting, June 24 to 28, Adelaide: The Road to Policy and Clinical Integration
https://htai.eventsair.com/htai-23-adelaide-am/main-theme
Fast-Tracking Clinical Innovation: The Balance of Speed and Rigour
Making HTA More Efficient: What Can we Learn about Harmonization, Work Sharing, and Adaptation?
Feasibility of Aligning Technology Evaluation Processes and Decisions in an Era of Sustainable Development

Registration for the HTAi 2023 Annual Meeting at https://htai.eventsair.com/htai-23-adelaide-am/annual-meeting-registration
Standard Registration Deadline: Thursday, June 15, 2023 (Midnight MST)
While completing registration for the 2023 Annual Meeting, attendees can also pick up social event tickets and register for Workshops all at the same time!
View the Schedule-at-a-Glance
View the Workshop program

Travel to the Annual Meeting: Learn about the host city, view the hotel and flight deals, and check out the entry requirements. https://htai.org/traveling-to-the-2023-annual-meeting/
HTAi has initiated a partnership with the Lufthansa Group and their global network of flight partners to provide delegates to the 2023 Annual Meeting. To book your flight, utilizing the Annual Meeting 2023 discount, please follow the instructions on the Annual Meeting website.
Exclusive hotel rates for the HTAi Annual Meeting have been secured with hotels surrounding the Adelaide Conference Centre. Please visit the Annual Meeting website and follow the instructions to book your room at the discounted rate. Contact the Annual Meeting team at annualmeeting@htai.org if assistance is needed.

HB-HTA Interest Group Survey
The HB-HTA Interest Group of the HTAi (Health Technology Assessment International) launched a survey to define the current scenario of the Hospital-Based Health Technology Assessment (HB-HTA) at global level. The aim is to collect data on current HB-HTA activities but also on the perception of the role, potentialities, and barriers for HB-HTA at the international level. Therefore, our survey's recipients are both hospitals performing HTA (20-25 min survey), hospitals not performing HTA activities (10 min), and national or regional or local policy makers, HTA agencies included (10 min).
To access to the survey click here. The survey is open to all, members and not members of HTAi. Please, provide your response by Monday May 15, 2023. Results will be discussed during the HTAi Annual Meeting in June 2023 and published. We invite you to contribute to the survey and to share this initiative with your colleagues. If you need further information, please contact: to.hospital-basedhta@htai.org

The HTAi Review your biweekly news source for all things HTAi. Click here 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

May 10th - International Clinical Trials Day

CADTH, ICER, and NICE Release Joint Position Statement on Redacting Clinical Data Awaiting Publication
https://www.nice.org.uk/news/article/nice-collaborates-with-international-partner-agencies-to-streamline-the-confidential-marking-process; https://www.cadth.ca/news/cadth-icer-and-nice-release-joint-position-statement-redacting-clinical-data-awaiting
NICE, the Canadian Agency for Drugs and Technologies in Health (CADTH) and the US's Institute for Clinical and Economic Review (ICER) announced they are changing the way confidential information about health technologies is handled to streamline processes and increase transparency. The International agreement heralds changes in our handling of clinical data. They've agreed a consistent approach to handling clinical data with health technology evaluation partners in America and Canada. See a joint statement setting out the changes. The agreement aims to strike a balance between ensuring transparency of decision-making and protecting confidential information.
This work forms part of NICE's proportionate approach to technology appraisals, to apply light-touch, faster evaluations to simpler, low-risk treatments. The programme recently published its interim methods and process guide.

Use of surrogate outcomes when analysing cost-effectiveness
https://www.nice.org.uk/news/blog/how-surrogate-outcomes-influence-long-term-health-outcomes
NICE's Dr Jacoline Bouvy explains how they are collaborating internationally to develop guidance on using surrogate outcomes when analysing the cost-effectiveness of medicines. Assessing new drugs based on their ability to improve surrogate outcomes will help get new treatments to patients faster.
https://www.nice.org.uk/Contents/Item/Display/134270
You can keep up to date on progress through the NICE website and social media channels.

EU Innovative Health Initiative (IHI) 'Patient Pool' Webinar
https://www.ihi.europa.eu/news-events/events/webinar-ihi-patient-pool
Thursday 11 May at 10:30-11:30 CEST (Central European Summer Time / Brussels time)
The Innovative Health Initiative (IHI) has opened a call for expressions for people who want to be part of the IHI Patient Pool – a group of patients and informal caregivers who can support IHI activities by bringing their unique perspective, experience, and expertise to the table. IHI will hold a webinar on the Patient Pool to help potential applicants prepare their expression of interest.

Abstract Submissions are Being Accepted for ISPOR Europe 2023, 12-15 November, Copenhagen, Denmark
Submit your research, case study, issue panel, workshop or other breakout session abstract for consideration at ISPOR Europe 2023, the ideal venue to share and/or present your new research. Interact with attendees during a workshop or other breakout session on your innovative experiences in outcomes research; and/or debate your views on a controversial topic in an issue panel session. Submit and help shape the future of HEOR. Opportunities for sponsorship and to exhibit are available: contact exhibit@ispor.org.

Good Practices Report on Quantitative Benefit-Risk Assessment
A new Good Practices Report from the ISPOR Quantitative Benefit-Risk Assessment in Medical Product Decision Making Task Force was published in the April 2023 issue of *Value in Health*. The report is accompanied by an editorial, Emerging Good Practices for Quantitative Benefit-Risk Assessment: A Step Forward and a case study, Illustrating Emerging Good Practices for Quantitative Benefit-Risk Assessment: A Hypothetical Case Study of Systemic Biologic Treatments for Plaque Psoriasis. See the report here and the press release here.

Webinar on Challenges in Rare Disease Diagnostics: An Overview
From the ISPOR Rare Disease Special Interest Group
Thursday, 1 June 2023, 10:00AM EDT | 2:00PM UTC | 4:00PM CEST open to all ISPOR Members and Non-members
https://www.ispor.org/conferences-education/calendar/event/2023/06/01/default-calendar/challenges-in-rare-disease-diagnostics-an-overview?utm_medium=email&utm_source=database&utm_campaign=educational_webinar&utm_content=non_member_comms_april2023_apr27&_zs=3hXOX&_zl=Ms2a3
This webinar is aimed at all those who undertake research and development as well as value assessment of therapies and diagnostics in the rare disease space. It aims to expose the 'diagnostic odyssey' and explain why a definitive diagnosis is not only important for patients but also for those assessing value. Objectives are to 1) explain what can be done to improve diagnosis in rare diseases and 2) why it matters in the context of value assessment.
Speakers: Sheela Upadhyaya, Life Sciences Consultant Specializing in Rare Diseases, London, England, UK and Eric Low, Eric Low Consulting, Edinburgh, Scotland, UK

Immunotherapies Merit Unique Patient-Reported Outcomes to Inform Treatment Tolerability
https://globalforum.diaglobal.org/issue/april-2023/immunotherapies-merit-unique-patient-reported-outcomes-to-inform-treatment-tolerability/
Matthew Reaney IQVIA, Catherine Coulouvrat Sanofi, Mark Stewart Friends of Cancer Research, Courtney Granville, Maria Paula Bautista Acelas Drug Information Association
Understanding tolerability as part of the development and delivery of **I**mmuno-oncology (I-O) therapies is important as they can lead to symptoms that affect treatment tolerability. New FDA guidance advocates for collecting patient-reported outcomes (PROs) to better assess tolerability and optimize dosage in trials. A comprehensive understanding of patient-reported tolerability helps ensure that clinicians are able to set and manage patient expectations about how they will feel and function while receiving therapy and help patients to make well-informed therapeutic decisions.

DIA is currently establishing a working group to understand, identify, discuss, and potentially develop a patient-reported tolerability PRO instrument(s) for I-O. This working group will consist of pharmaceutical organizations, regulatory representatives, patient advocacy representatives, and healthcare providers, among other subject matter experts. To learn how to contribute, contact science@DIAglobal.org.

From the European Patients Forum (EPF} April newsletter
The proposal of the European Commission for the revision of the pharmaceutical legislation has been published. The revision includes a new directive and a new regulation giving the EU regulatory framework for all medicines (including those for rare diseases and children). In addition to this reform, the Commission proposes a Council Recommendation to step up the fight against antimicrobial resistance. The proposal on the revision of the pharma legislation, as technical and politically sensitive as everyone expected it to be, is now in the hands of the European Parliament and the Council for a first reading.
EPF has issued a statement expressing its support for patient involvement in the Committee for Medicinal Products for Human Use, which assesses applications for marketing authorisation at EU level. A thorough review of the proposal by our policy team and consultation with our members will lead to amendments and a position in the coming months.

In digital health, the focus has been on the European Health Data Space (EHDS) Regulation. In mid-April, the European Parliament published over 2000 amendments to the draft report. The amendments include patient-centred provisions on consent mechanisms, patient involvement in the governance and decision-making structures, digital health literacy and improvement of Electronic Health Records.

For all patient advocates and patient organisations interested in AI: our survey to assess awareness and perceptions of risks and benefits linked to AI in healthcare is open until the 21st of May!

The European Network for Health Technology Assessment (EUnetHTA) has published its guidelines for interaction with patient representatives, health professionals and other experts. The guidelines will inform the European Commission's work on the implementation of the Regulation on Health Technology Assessment (HTA) until 2025.
While we welcome the emphasis on the value of meaningful involvement of patients and patient organisations, we would like to reiterate that patients and patient organisations should not be seen as two mutually exclusive entities. The framework applied to determine conflicts of interest will exclude many patients who are members of patient organisations whose total budget is more than 40% funded by industry. There is a lack of clarity on what constitutes a conflict of interest for patient organisations, leading to a lack of predictability in engagement. Preparing well-informed feedback on joint clinical evaluations and selecting patients as external experts will require a significant investment in human resources and time.

EU-PEARL *all day hybrid event on 25 April in Brussels*
https://eu-pearl.eu/workshops/eu-pearl-closing-event/
Clinical trials must keep pace with scientific development and enable patients to find the right trials for their needs. Conventional clinical trials are lengthy and face significant challenges. This is especially true in therapeutic areas with unmet medical needs, Overcoming these barriers is what drives the mission of EU-PEARL, an Innovative Medicines Initiative (IMI) funded project active since 2019. EU-PEARL announced the fulfilment of 'enhancing clinical development and care by developing sustainable and replicable Integrated Research Platforms (IRPs) that allow collaborative adaptive platform trials to thrive'. Collaborative trials are built around a disease, instead of a pharmaceutical compound. This approach implies that the research does not stop until a treatment is found that brings significant therapeutic benefit to patients. The four disease areas covered are: Major Depressive Disorder, Tuberculosis, Non-Alcoholic Steatohepatitis, and Neurofibromatosis. Valentina Strammiello of the European Patients' Forum is one of the speakers at this event. Decoding Platform Trials: Defining aspects, benefits and challenges, by Tom Parke

The project developed the Platform for Patient and Community Engagement in Platform Trials (PaCEPT) which is a Repository for Patient and Community Engagement.
Head to www.eu-pearl.eu to find out more about EU-PEARL's results, explore the Repository for Patient and Community Engagement, and learn more about the learnings from each of the focus conditions.

The Patient Engagement Resource Centre (PERC)
The PERC offers researchers easy-to-navigate guidance & tools to better engage patients in research, including video stories
Explore it here➞ https://t.co/ZUW5V5jybV

The Patient Engagement Open Forum (PEOF)
A new line-up of exciting sessions went virtual on April 25 & 27, where patients, patient organizations, regulators, academia, pharma and medtech industry representatives addressed key topics in a non-competitive and (co)creative environment. These are co-organized by PFMD (The Synergist), the European Patients' Academy on Therapeutic Innovation (EUPATI) and European Patients' Forum (EPF). Find out more

Global award completely dedicated to those making history in patient engagement
Deadline 20 May.
The 'Made with Patients' Awards are opportunities to celebrate and highlight patient engagement champions and initiatives that go above and beyond in their effort to put the patient at the centre of our health ecosystem. An in-person awards ceremony is happening at this year's in-person Patient Engagement Open Forum on 14 June 2023. Anyone can nominate patient champions or initiatives.
https://patientengagement.synapseconnect.org/campaign/made-with-patients-awards?utm_source=hubspot&utm_medium=email&utm_campaign=mwpawards
Lidewij Vat, The Synergist, PFMD.org

WHO to Consider Adding Obesity Drugs to 'Essential' Medicines List (Reuters)
https://www.reuters.com/business/healthcare-pharmaceuticals/who-consider-adding-obesity-drugs-essential-medicines-list-2023-03-29/
Drugs that combat obesity are under consideration for the first time for the 'essential medicines list', which is used to guide government purchasing decisions in low- and middle-income countries.

The gene-therapy revolution risks will stall if we don't talk about drug pricing
- Regulation and new intellectual property laws are needed to reduce the cost of gene-editing treatments and fulfil their promise to improve human health. We need to talk about gene-therapy prices
At US$3.5 million per treatment, the haemophilia gene therapy Hemgenix is the most expensive drug in the world. Other gene therapies are expected to carry similarly eye-watering price tags. This puts them out of the reach of many who need them and diminishes government funders' willingness to pay for related research. Researchers, especially health economists, must work urgently with industry and governments to find a more affordable funding model, argues a *Nature* editorial.
Nature 616, 629-630 (2023) doi: https://doi.org/10.1038/d41586-023-01389-z
https://www.nature.com/articles/d41586-023-01389-z?utm_source=Nature+Briefing&utm_campaign=8b15a3be52-briefing-dy-20230427&utm_medium=email&utm_term=0_c9dfd39373-8b15a3be52-44432605

US Robert Wood Johnson Foundation project on 'A Health System Built on Racial Equity. The Transformational Leadership We Need'
https://racialequityinhealth.org/
CoCreative was engaged to lead a unique eight-month consultative process. They asked more than 230 diverse health system constituents to share their insights about the current system of racial inequities, to

develop a compelling vision of the system we should strive for, and to share their views on the structural shifts needed to realize that vision. This report reflects their collective thinking.
Coming face-to-face with the complexity and scope of structural racism within our nation's health system made it clear that our approach to leadership needs to evolve. RWJF now sees how leadership committed to tackling structural racism is required across the entire health system, not only from clinicians and healthcare leaders. Through this work, we have clearly heard that we all need new ways of working together, particularly the capacity to lead collectively across organizational, sectoral, political, and cultural boundaries.

COVID-19
Marcinow M, Sandercock J, Cadel L, et al (2023). A qualitative study exploring how patient engagement activities were sustained or adapted in Canadian healthcare organizations during the COVID-19 pandemic. PloS One, 18(3), e0282890. https://doi.org/10.1371/journal.pone.0282890

Most published systematic reviews of remdesivir for COVID-19 were redundant and lacked currency
Steve McDonald, Simon Turner, Matthew J. Page, Tari Turner. Journal of Clinical Epidemiology 2022, Volume 146, Pages 22-31.
https://doi.org/10.1016/j.jclinepi.2022.02.006.https://www.sciencedirect.com/science/article/pii/S0895435622000427?via%3Dihub The completeness and currency of published systematic reviews of remdesivir for COVID-19 were investigated and compared with living guidelines.

Jamie Elvidge, Ashley Summerfield, Saskia Knies, Bertalan Németh, Zoltán Kaló, Wim Goettsch, Dalia M. Dawoud. Health technology assessment of tests for SARS-CoV-2 and treatments for COVID-19: A proposed approach and best-practice recommendations. International Journal of Technology Assessment in Health Care. doi: 10.1017/S0266462323000223, 6 pages. Published Online on 24 April 2023.

Routen A, O'Mahoney L, Aiyegbusi OL, et al (2023). Patient and public involvement within epidemiological studies of long COVID in the UK. Nature Medicine. https://doi.org/10.1038/s41591-023-02251-5

Publications

Ferrante di Ruffano L, Harris I, Zhelev Z, Davenport C, et al (2023). Health technology assessment of diagnostic tests: A state of the art review of methods guidance from international organizations. International Journal of Technology Assessment in Health Care, 39(1), E14. doi:10.1017/S0266462323000065
Seven key organizations were identified. The main themes were: elucidation of claims of test benefits; attitude to direct and indirect evidence of clinical effectiveness (including evidence linkage); searching; quality assessment; and health economic evaluation. With the exception of dealing with test accuracy data, approaches were largely based on general approaches to HTA with few test-specific modifications. Elucidation of test claims and attitude to direct and indirect evidence are where we identified the biggest dissimilarities in approach. The focus on test accuracy contrasts with universal acknowledgment that it is not a sufficient evidence base for test evaluation.

Ting Wang, Neil McAuslane, Wim G. Goettsch, Hubert G.M. Leufkens, Marie L. De Bruin. Regulatory, health technology assessment and company interactions: the current landscape and future ecosystem for drug development, review and reimbursement. International Journal of Technology Assessment in Health Care doi: 10.1017/S0266462323000144. Published Online on 11 April 2023

Antal Tamas Zemplenyi, Konstantin Tihomirov Tachkov, Laszlo Balkanyi, Bertalan Nemeth, Zsuzsanna Petyo, Guenka Ivanova Petrova, Marcin Czech, Dalia M Dawoud, Wim Goettsch, Iñaki Gutiérrez-Ibarluzea, Rok Hren, Saskia Knies, László Lorenzovici, Zorana Maravic, Oresta Piniazhko, Alexandra Tzvetanova

Savova, Manoela Manova, Tomas Tesar, Spela Zerovnik, Zoltán Kaló. Recommendations to overcome barriers to the use of artificial intelligence-driven evidence in health technology assessment. Front. Public Health 2023;11:1088121. doi: 10.3389/fpubh.2023.1088121
http://journal.frontiersin.org/article/10.3389/fpubh.2023.1088121/full?&utm_source=Email_to_rerev_&utm_medium=Email&utm_content=T1_11.5e5_reviewer&utm_campaign=Email_publication&journalName=Frontiers_in_Public_Health&id=1088121

Sarah Stothers Rosenberg, Brittany B Carson, Amiee Kang, Ting-Hsuan Lee, Rajshree Pandey, Evelyn J Rizzo. The Impact of Digital Health Technologies on Health Equity: Designing Research to Capture Patient-Reported Outcomes. Value & Outcomes Spotlight (Jan/Feb 2023):9(1)
https://www.ispor.org/publications/journals/value-outcomes-spotlight/vos-archives/issue/view/addressing-assessment-and-access-issues-for-rare-diseases/the-impact-of-digital-health-technologies-on-health-equity-designing-research-to-capture-patient-reported-outcomes?utm_medium=social_media&utm_source=facebook&utm_campaign=value_and_outcomes_spospotli&utm_content=her_sig_vos_march2

Sharon Hems, Louise Taylor, Jan Jones, Eileen Holmes. Patient-based evidence: its role in decision making on end-of-life, orphan, and ultra-orphan medicines. International Journal of Technology Assessment in Health Care. doi: 10.1017/S026646232300003X. Published Online on 11 April 2023

Germeni E, Szabo S (2023). Beyond clinical and cost-effectiveness: The contribution of qualitative research to health technology assessment. International Journal of Technology Assessment in Health Care, 39(1), E23. doi:10.1017/S0266462323000211. Multidisciplinary efforts to generate patient-focused evidence relevant to HTA, using both quantitative and qualitative approaches, are needed. Although it has been more than 20 years since opportunities for qualitative methods to inform HTA were first discussed, their use remains infrequent. The goal of this article is to resurrect the debate about the value of qualitative research in HTA. Drawing on examples from published literature, we propose five key areas where qualitative methods can contribute to HTA, complementary to studies of clinical and cost-effectiveness: (i) assessing acceptability and subjective value; (ii) understanding perspectives and providing context; (iii) reaching the groups other methods cannot reach; (iv) laying the groundwork for subsequent quantitative exercises; and (v) contributing to economic model development.

Riganti P, Kopitowski KS, McCaffery K, et al. The paradox of using SDM for de-implementation of low-value care in the clinical encounter. BMJ Evidence-Based Medicine 2023. doi: 10.1136/bmjebm-2022-112201

Tommi Tervonen, Jorien Veldwijk, Katherine Payne, et al. Quantitative Benefit-Risk Assessment in Medical Product Decision Making: A Good Practices Report of an ISPOR Task Force. Value in Health 2023, Volume 26, Issue 4, 449-460.
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Leila G Lackey, Xinyi Ng, Jorien Veldwijk, Praveen Thokala, Bennett Levitan, Katherine Payne, Martin Ho, Tommi Tervonen. Illustrating Emerging Good Practices for Quantitative Benefit-Risk Assessment: A Hypothetical Case Study of Systemic Biologic Treatments for Plaque Psoriasis. Value in Health 2023, Volume 26, Issue 4, 519-527
-risk assessment is increasingly used to inform medical product decision making. This case study in psoriasis illustrates how to implement recommendations from an ISPOR Task Force.

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Yangfan Shi, Lingli Zhang, Jianan Fu, Rong Shao, Jianzhou Yan. An Analysis of Accessibility of Representative Psychotropic Medicine From the World Health Organization Model List of Essential Medicines in Developing Countries With Different Income Levels. Value in Health 2023, Volume 26, Issue 4, 528-535. The low availability, inflated costs, and low affordability are major barriers to the long-term use of psychotropic medicine by patients worldwide.
This study included 5 types of psychotropic medicines listed in the 22nd edition of the World Health Organization Model List of Essential Medicines published by the World Health Organization in 2021. Derived from 84 surveys in 59 countries, this study summarizes the availability, price, and affordability of originator branded drugs (OBs) and lowest-price generic drugs (LPGs) in the public and private sectors and compares them based on income levels in different countries.
The average availability of psychotropic medicine was 45% in low- and lower-middle-income countries (LLMICs) compared with 49% in high- and upper-middle-income countries (HUMICs) whereas the availability of LPGs was higher than that of OBs in all country groups. The average patient price for OBs and LPGs was 94.0 and 23.2, respectively, and the overall patient price of psychotropic medicine in LLMICs was higher than that in HUMICs. The affordability of psychotropic medicine in LLMICs was lower than that in HUMICs.
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Thi Hao Pham, Jurjen van der Schans. A Conceptual Framework for Life-Cycle Health Technology Assessment. Value in Health 2023, Volume 26, Issue 4, 612-613
- The framework emphasizes the need for de novo models conducted by HTA agencies and proposes using the risk-based price in decision making when a high level of uncertainty exists. This approach can bring many advantages as mentioned in the article; nevertheless, it also presents some methodological limitations and challenges when applied as a routine activity in the HTA processes. We reflect on these aspects and how they can be compromised given the diversity in organization and functionality of HTA agencies worldwide.
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These cancer specialists want to offer patients less treatment, and more care. Carly Weeks. Health Reporter, April 23, 2023 https://www.theglobeandmail.com/canada/article-specialists-patient-advocates-meeting-to-discuss-how-to-provide-better/
A small group of cancer specialists and patient advocates from around the world are gathering in Kingston this week to launch a global movement aimed at providing less treatment to patients.
While it may sound counterintuitive, the inaugural Common Sense Oncology Symposium is designed to recalibrate the delivery of cancer care around patient needs and desires so that they can make the best choices about how they want to approach their disease and spend their time.
Things such as improving quality of life and, in the case of terminal illness, making the time that remains meaningful.

In Medicare Drug Price Negotiations, Avoid Metrics Steeped In Stigma. Health Affairs Forefront, April 24, 2023. DOI: 10.1377/forefront.20230421.234917. Tony Coelho
In a January 4 Health Affairs Forefront article, "Options for CMS Drug Price Negotiations," Daniel Ollendorf and Dominic Voehler discuss pricing methodologies based on how much a drug improves health. However, the authors overemphasize reliance on frameworks that, especially for people with disabilities, are red flags due to their reliance on valuing people's lives in dollars.
Instead, the Centers for Medicare and Medicaid Services (CMS) has an opportunity to achieve a level of patient-centeredness that other programs lack.
The law requires CMS to consider a drug's impact on specific populations, such as people with disabilities, and bars consideration of evidence that devalues extending the life of "an elderly, disabled, or terminally ill

individual." This is consistent with the Affordable Care Act explicitly barring CMS from using quality-adjusted life-years (QALYs) and similar metrics in Medicare, instead of therapeutic benefit to patients and people with disabilities.
These metrics disproportionately impact care access for subpopulations already experiencing substandard health care; such groups often experience discrimination doubly by virtue of being Black, Indigenous, or people of color and having a disability or chronic condition.
CMS should further state that it will not rely on assessments from organizations such as the Institute for Clinical and Economic Review that reference QALYs as the "gold standard" and are entrenched in old, one-size-fits-all methods.
When the Patient-Centered Outcomes Research Institute (PCORI) was created in 2010, its authorizing statute not only prohibited cost-per-QALY research by the Institute but called for robust patient engagement and consideration of subpopulations to protect against a one-size-fits-all (p. S1796) standard for value and effectiveness. In 2019, the National Council on Disability, an independent federal agency advising Congress and the administration on disability policy, wrote a report finding QALYs to be discriminatory; in 2022, the Council again recommended a consistent bar on the use of QALYs across federal programs as part of its Health Equity Framework.
Congress created PCORI to ensure that the comparative effectiveness or "added benefit" of a treatment or service is defined by achieving outcomes that matter to patients, and that evaluations provide an explicit understanding about the different impacts among subpopulations.
We agree factors such as clinical benefit, burden on society, and impact on caregivers are essential considerations. Evidence should identify the range of treatment impacts among subpopulations and acknowledge limitations on making conclusions about subpopulations not studied.

Smoking is linked to cancer, heart disease, chronic health conditions, and early death. With May 31 marking World No Tobacco Day, it's important to remember that it's never too late to quit smoking. Read (and share) these evidence-based tips to help you, or others, quit smoking.
https://www.mcmasteroptimalaging.org/blog/-in-category/categories/healthy-aging-practice/smoking

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