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

From our Chair

If you're keeping up with your HTAi news, you will know that it's time to vote for your Board of Directors. We have two PCIG members seeking a second term on the Board (Grace Huang and Franz Waibel) as well as a PCIG member, Dario Sacchini, and former member, Ken Bond, seeking election for the first time. There is a great list of candidates to consider. Check your email (and spam) for voting links and please vote to help shape the leadership of our multi-stakeholder, multi-disciplinary Society. I am really honoured to have been considered for Vice-President on the HTAi Board and elected by acclamation. When I take up the vice-presidency, our Society will have its first President with an LMIC background, Rabia Sucu. Meanwhile, our current President, Wija Oortwijn, will become Past President; the first time all three positions have been filled by women. I believe this reflects HTAi's maturing inclusivity and understanding of partnership with patients and communities globally. I'm grateful to the many giants in this interest group, and the wider HTAi, whose strong shoulders have carried us here. It's always about learning together.
The Steering Committee is working on arrangements for the PCIG chair when I finish in June after four years. We are considering a change to our Terms of Reference to enable us to appoint two co-chairs and a vice chair. Further information will be communicated by email. As always, please contact me if you want to discuss this or any other issues.
Finally, I hope you completed registration for Annual Meeting before the early bird rate deadline on 30 March. Don't forget to make your travel arrangements so you can join our workshop, Patient and Citizen Involvement in HTA, on Saturday 24th June. See the rest of this e-bulletin for further conference information.

Stay safe,

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

Call for input to proposal for new Interest Group on Rare Diseases

A proposal for a new Interest Group (IG) on HTA of Rare Disease Treatments is being developed by a multi-stakeholder group of HTAi members for submission to the HTAi Board on 17 April. If you would like to comment on the draft proposal, or add your name to the list of interested HTAi members, please contact Karen Facey on k.facey@btinternet.com. And do sign up for the HTAi pre-conference workshop that will discuss plans for the new IG!

Contributed by Karen Facey

HTAi Global Policy Forum 2023

On March 26-28 the 2023 HTAi Global Policy Forum was held in The Hague. The theme this year was 'The value and impact of Health Technology Assessments'. Around 70 representatives from both profit organisations (pharma companies, device developers etc.) and not for-profit organisations (HTA organisations, universities etc) from all over the world together with 3 patient representatives met for 3 days of intense exchange on HTA, developments and our vision on the challenges in the future. The diversity of the participants, different presentations and breakout groups led to interesting discussions on the value and impact of HTA and where changes and improvements can be made.
The 2023 background paper can be found here
https://htai.org/wp-content/uploads/2023/03/2023-GPF-Background-paper-_updatd-for-designer_280223-1.pdf

Contributed by Dominique Hamerlijnck, one of the 3 patient representatives

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 2023 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 the annual meeting and perhaps introducing them to others, answering questions or helping them find answers. Please sign up to be one here.

Pre-annual meeting briefing

If you're attending the Annual Meeting for the first time and not sure what to expect, you are welcome to join one of our virtual briefings on 29/30 May 2023. These briefings are especially for patients and their representatives. To register, click on the session you want to attend below.

Event	AEST UTC+10	SGT/CST UTC+8	CEST UTC+2	BST UTC+1	BRT UTC -3	EDT UTC-4	MDT UTC-6
Briefing 1	09:00 30 May	07:00 30 May	01:00 30 May	24:00 29 May	20:00 29 May	19:00 29 May	15:00 29 May
Briefing 2	20:00 30 May	18:00 30 May	12:00 30 May	11:00 30 May	7:00 30 May	6:00 30 May	4:00 30 May
Please send me a link to the recording instead							

Contributed by Ann Single

DCIG Writing Project
The HTA in Developing Countries Interest Group has launched a writing project on a topic pertinent to low- and middle-income countries. The written pieces will be published on the Interest Group website under the title, 'Emerging Issues Relevant to Developing Countries'. Winners of the competition will be awarded a monetary prize. Submissions are accepted until April 30, 2023. Learn more

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) – Early Bird Registration ended on March 30, 2023
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
PCIG's Annual Meeting workshop, Saturday 24 June, 8.30 am - 4.30 pm. The workshop will begin with an introduction to key concepts, methods and approaches to patient involvement followed by a deeper exploration of key areas for harmonisation activities.
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 with a global and efficient travel experience at a discounted rate. The Lufthansa Group network consists of Austrian Airlines, Brussels Airlines, Eurowings, Lufthansa and SWISS. To book your flight, utilizing the Annual Meeting 2023 discount, please follow the instructions on the Annual Meeting website.

The HTAi Board of Directors election
HTAi Election activities are managed and performed by a third-party organization called Civica Election Services (CES). Only members in good standing are eligible to vote. If you have not established your 2023 membership, renew your membership today to ensure you can participate. Please contact boardelections@htai.org for assistance. To view each candidate's nomination package, including their

application, bio, and qualifications, click here. Information on nomination criteria can be found here. The 2023 Board Election will close on May 2, 2023 at 23:59 MDT.
Please note: the candidate for Vice President, Ann Single, is running unopposed, and is therefore elected by acclamation.

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

CADTH Symposium 2023
This year's theme is Shaping Future-Ready Health Systems. The CADTH Symposium is a 3-day hybrid event on May 16 to 18, 2023. The in-person program will take place at the Shaw Centre in Ottawa. Read more

New ISPOR CEO
ISPOR's Board of Directors has appointed Rob Abbott as the Society's new CEO and executive director. Mr Abbott assumed the role of ISPOR's CEO on March 13, succeeding Nancy S Berg. More here.

EURORDIS and partners launch major project to empower patient involvement in Health Technology Assessments https://www.eurordis.org/eurordis-launches-eucapa/
The European Capacity Building for Patients (EUCAPA) project offers training and disseminates information about EU HTA, as part of the EU4Health initiative (https://health.ec.europa.eu/funding/eu4health-programme-2021-2027-vision-healthier-european-union_en#:~:text=EU4Health%20is%20implemented%20by%20annual,Health%20systems%20%26%20healthcare%20workforce).
EUCAPA is designed to train patients and their representatives in Health Technology Assessment (HTA). The European Commission selected a consortium composed of EURORDIS, the European Patients Forum (EPF) and UMIT TIROL to build capacity and knowledge for patient advocates to participate in HTAs at the national or European level. EUCAPA will ensure that patients and patient organisations have the necessary knowledge of the HTA process to be meaningfully involved in HTA (both in scientific consultations and assessments), as foreseen by the new Regulation on HTA (EU) 2021/2282, which will start assessing health technologies in January 2025.
It focuses mostly – but not exclusively – on people living with cancer and people who need advanced therapy medicinal products (ATMPs). EUCAPA is set to last two years and will offer three types of training.

Oxford researchers launch GP Evidence – a website designed by GPs, for GPs, to bridge the knowledge gap between scientific evidence and recommended treatments https://gpevidence.org/
GP Evidence is designed to support GPs' decision-making in clinical practice for long term health conditions.
https://www.phc.ox.ac.uk/news/oxford-researchers-launch-gp-evidence-2013-a-website-designed-by-gps-for-gps-to-bridge-the-knowledge-gap-between-scientific-evidence-and-recommended-treatments
Primary Care DPhil student and GP, Dr Julian Treadwell developed the website, with funding from the National Institute for Health and Care Research (NIHR), to make the scientific evidence underpinning guideline-recommended treatments easier to access and understand by practicing GPs.

The majority of evidence provided on the website represents best available expert evidence from NICE guidelines and Cochrane reviews, unless stated otherwise.

From the European Patients Forum newsletter

Formal approval of the extension of the rules on medical devices

We hope that this three-year delay and other changes will be accompanied by measures tackling bottlenecks of access and thus ensuring a high level of readiness for the implementation of the Medical Devices Regulation.

The amendments to the Regulation of medical devices in the EU were published in the Official Journal and introduce new deadlines for compliance with the Medical Devices Regulation (MDR). Originally, devices on the market had to comply with the MDR by 26 May 2024. Under the proposed amendment, the deadline for high-risk devices to comply with the new rules is extended to the end of 2027, while medium and low-risk devices would have to meet the requirements by the end of 2028.

Patients as partners, not just participants www.patient-engagement.eu

Launch of the Patient Engagement Resource Centre (PERC)

On 28 March 2023, EATRIS (European infrastructure for translational medicine) and EPF, together with affiliated partner EATG (European AIDS Treatment Group) launched the platform designed to help researchers better engage patients in their research. The PERC was developed as part of the Horizon 2020 project, EATRIS-Plus. It offers publicly available guidance, training and practical tools to support researchers to begin engaging patients in their research. It is also a practical tool for patients to access and promote to the researchers they work with. The Centre features selected relevant public resources to help researchers understand the basics of patient engagement, and guide them through the different phases of patient engagement: from planning to conducting and evaluating, and will ultimately enable researchers to engage with patients in a meaningful way.

EMA pilots scientific advice for certain high-risk medical devices

https://www.ema.europa.eu/en/news/ema-pilots-scientific-advice-certain-high-risk-medical-devices

EMA has launched a pilot to give scientific advice on the intended clinical development strategy and proposals for clinical investigation for certain high-risk medical devices (all class III devices and class IIb active devices intended to administer and/or remove medicinal product(s)). Manufacturers can submit their letter of interest to be part of the pilot on scientific advice which will be provided by the medical device expert panels.

The expert panels will provide free advice to ten selected applicants on their clinical development strategy and/or proposals for clinical investigation. The pilot will last approximately one year and will help to establish an efficient scientific advice procedure. Scientific advice is a key tool to foster innovation and promotes faster patient access to safer and more effective devices.

The types of medical devices prioritised are:

- devices that benefit a small group of patients in the treatment or diagnosis of a disease or condition, such as devices intended for the treatment of a rare condition, known as 'orphan devices', and devices for paediatric use;
- devices addressing medical conditions that are life threatening or cause permanent impairment of a body function and for which current medical alternatives are insufficient or carry significant risks;
- novel devices with a possible major clinical or health impact.

Launch of PFMD Patient Engagement Training for Medtech

It's a co-created learning program for those who want to start their patient engagement journey or take it to the next level in the medtech sector. In the spirit of PFMD, this training program has been designed and co-created as a multi-stakeholder collaboration and is made available to the community for free. You can also explore other tools to support your patient engagement journey in medtech.

Did you know the pharma version has three courses and is available in seven different languages? You can explore it here. To know more, please visit the PFMD (Patient Focused Medicine Development) website.
https://patientfocusedmedicine.org/?utm_campaign=%5BFEB%202023%5D%20PFMD%20-%20PE%20Training%20MedTech&utm_medium=email&_hsmi=70000295&_hsenc=p2ANqtz-90qAYzAzwTzundgxWynnIo_D-oKkrfVMSfEyK2qLLMZJjcFYYcioXZVQSnkaZoqOy2pXvdFiHpzt5A3t9FHUdBmp4PCA&utm_content=70000295&utm_source=hs_email#

Brian Goodman, Program Director PFMD

The European Patients Academy on Therapeutic Innovation (EUPATI) 3-year training project entitled 'HTA4Patients'
This began in March 2023. HTA4Patients will enhance the education, training and information that EUPATI already provides on HTA via its Open Classroom and Toolbox empowering patients and patient organisations to play a vital role in the implementation of the new framework. Read more

Suite of open-source building blocks to help developers quickly build digital health apps in under-resourced areas
https://www.fiercehealthcare.com/health-tech/google-launches-open-health-stack-app-developers-unveils-new-ai-partnerships?utm_medium=email&utm_source=nl&utm_campaign=HC-NL-FierceHealthTech&oly_enc_id=6899F7383667A2A
Google launched Open Health Stack - digital health solutions built to date have focused on solving for single, disease-focused conditions, leading to data silos and making it difficult for healthcare workers to access the patient information they need. See blog post.

Insulin prices in the US
Sanofi answers the call, joining Eli Lilly, Novo Nordisk in cutting insulin prices. Kevin Dunleavy, Mar 17, 2023
Eli Lilly is lowering the price of its insulin products. Its brand name Humalog and Humulin by 70% while the company's generic Lispro will be set at $25 a vial. In addition, the company will cap the price of insulin at $35 a month for patients on commercial plans, mirroring the provision found in the Inflation Reduction Act for Medicare beneficiaries. Sanofi has cut the list price of its most popular insulin, Lantus, by 78% and is capping the price at $35 for insured patients. The company also will cut the list price of its short-acting Apidra by 70%.
In a span of less than three weeks, Eli Lilly, Novo Nordisk and Sanofi—in that order—have announced price cuts to some of their insulins in the U.S., answering calls to do so from President Joe Biden and Sen. Bernie Sanders, I-Vermont. The measures will kick in Jan. 1, 2024
https://www.fiercepharma.com/pharma/sanofi-answers-call-joining-eli-lilly-novo-nordisk-cutting-price-insulin
https://www.healtheconomics.com/industry-news/eli-lilly-cuts-us-insulin-price-and-caps-out-of-pocket-monthly-cost?utm_source=HealthEconomics.Com&utm_campaign=e2627c33bf-EMAIL_CAMPAIGN_2023_03_06_07_01&utm_medium=email&utm_term=0_-e2627c33bf-%5BLIST_EMAIL_ID%5D

COVID-19
Routen A, O'Mahoney L, Aiyegbusi OL et al. Patient and public involvement within epidemiological studies of long COVID in the UK. Nat Med (2023). https://doi.org/10.1038/s41591-023-02251-5 – The vital role of patients and the public in guiding Long Covid research and working with diverse groups

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Publications

Research Topic: Where to From Here: Advancing Patient and Public Involvement in Health Technology Assessment (HTA) Following the COVID-19 Pandemic

https://www.frontiersin.org/research-topics/21300/where-to-from-here-advancing-patient-and-public-involvement-in-health-technology-assessment-hta-following-the-covid-19-pandemic
Editorial.
http://journal.frontiersin.org/article/10.3389/fmedt.2023.1168278/full?&utm_source=Email_to_authors_&utm_medium=Email&utm_content=T1_11.5e1_author&utm_campaign=Email_publication&field=&journalName=Frontiers_in_Medical_Technology&id=1168278

The place and importance of patients in deliberative processes. Marjo S Cellier
https://www.frontiersin.org/articles/10.3389/fmedt.2021.794695/full

Patient involvement in health technology assessment process in Taiwan.
Kuei An Chen, Li Ying Huang and Churn Shiouh Gau
https://www.frontiersin.org/articles/10.3389/fmedt.2021.732160/full

Solving the evidence interpretability crisis in health technology assessment: a role for mechanistic models?
Eulalie Courcelles, Jean-Pierre Boissel, Jacques Massol, Ingrid Klingmann, Riad Kahoul, Marc Hommel, Emmanuel Pham, Alexander Kulesza
https://www.frontiersin.org/articles/10.3389/fmedt.2022.810315/full

Patient and citizen participation in the identification of ethical considerations aiming to address uncertainty in the evaluation of promising interventions in a pandemic context.
Catherine Olivier, Isabelle Ganache, Olivier Demers-Payette, Louis Lochhead, Sandra Pelaez, Michèle De Guise, Marie-Pascale Pomey
https://www.frontiersin.org/articles/10.3389/fmedt.2021.794003/full
Innovative Patient Involvement During Covid-19: Keeping Patients At The Heart Of HTA
Mark Rasburn, Helen Crosbie, Amanda Tonkinson, David Chandler, Stella O'Brien, Tasneem Dhanji
https://www.frontiersin.org/articles/10.3389/fmedt.2021.793119/full

Engaging patients and citizens in digital health technology development through the virtual space. Romina H Barony Sanchez, Laurie-Ann Bergeron-Drolet, Maxime Sasseville, Marie-Pierre Gagnon
https://www.frontiersin.org/articles/10.3389/fmedt.2022.958571/full

Where National Medicines Policies have taken us with patient involvement and health technology. assessment in Africa. Kawaldip Sehmi, Janet L Wale
https://www.frontiersin.org/articles/10.3389/fmedt.2022.810456/full

Aline Silveira Silva, Ana Cláudia Wekmuller França, Matheus Padilla, Luana Schroeder Macedo, Carlos Alberto Magliano, Marisa Santos (2022). Brazilian Breast Cancer Patient-Reported Outcomes: What Really Matters for These Women. Front. Med. Technol. 4:809222. doi: 10.3389/fmedt.2022.809222
https://www.frontiersin.org/articles/10.3389/fmedt.2022.809222/full

Can we afford to exclude patients throughout health technology assessment?
Janet L Wale, David Chandler, Deborah Collyar, Dominique Hamerlijinck, Roberto Saldana, Zack Pemberton-Whitely
https://www.frontiersin.org/articles/10.3389/fmedt.2021.796344/full

Civil society and medical product access in Africa; lessons from COVID-19.

Janet L Wale, Kawaldip Sehmi, Regina Kamoga, Robert Ssekubugu
https://www.frontiersin.org/articles/10.3389/fmedt.2023.1091425/full

The Impact of Digital Health Technologies on Health Equity: Designing Research to Capture Patient-Reported Outcomes. Sarah Stothers Rosenberg, Brittany B Carson, Amiee Kang, Ting-Hsuan Lee, Rajshree Pandey, Evelyn J Rizzo. 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

Adopting recommendations for implementing patient involvement in cancer research: a funder's approach. Costa Alencar AB, Selig WKD, Geissler J. et al. Res Involv Engagem 9, 6 (2023).
https://doi.org/10.1186/s40900-023-00410-z

The added value of applying a disinvestment approach to the process of health technology assessment in Italy. Chiara Cadeddu, Luca Regazzi, Eugenio Di Brino, Michele Basile, Fidelia Cascini, Andrea Paladini, Filippo Rumi, Americo Cicchetti, Walter Ricciardi. International Journal of Technology Assessment in Health Care doi: 10.1017/S0266462323000107

Transvaginal mesh in Australia: An analysis of news media reporting from 1996 to 2021. Mina Motamedi, Stacy M Carter, Chris Degeling. Health Expectations 2023. https://doi.org/10.1111/hex.13734
https://onlinelibrary.wiley.com/doi/full/10.1111/hex.13734
Transvaginal mesh (mesh) surgeries have been used to treat stress urinary incontinence (incontinence) and/or pelvic organ prolapse (prolapse). In Australia, as in many other countries, the harms caused by mesh eventually prompted individual and collective attempts to achieve redress. The rise of mesh surgery as a procedure, the experience of mesh-affected women and the formal inquiries and legal actions that followed all occurred in social, cultural and discursive contexts. We conducted a media analysis of the most highly read Australian newspapers and online news media platforms, focusing on how mesh and the interaction of stakeholders in mesh stories were presented to the Australian public. After early scant media reporting focusing on the benefits of mesh procedures, major Australian medicolegal processes created a hook to shift reporting about mesh. The news media then played a significant role in redressing women's experienced epistemic injustice, including by amplifying previously ignored evidence of harm. This created an opportunity for previously unreported suffering to be revealed to powerful actors, in settings beyond the immediate control and epistemic authority of healthcare stakeholders, validating women's testimony and creating new hermeneutic resources for understanding mesh. Over time, media reports show healthcare stakeholders responding sympathetically to these new understandings in public discourse, contrasting with their statements in earlier media coverage.
In this case, media reporting appears to have contributed to shaping medical knowledge in significant ways.

Thinking Differently About Multicancer Early Detection Screening Tests. Karen E Knudsen, Phillip G Febbo 2023 Health Affairs FOREFRONT 10.1377/FOREFRONT.20230329.965384
https://www.healthaffairs.org/content/forefront/thinking-differently-multicancer-early-detection-screening-tests?utm_medium=email&utm_source=hasu&utm_campaign=HASU+4+2+2023&utm_content=forefront&vgo_ee=5icSXgfbm70t7Jpq5JopvdkQ%2FWwV9buthshoDDDX%2FrlLRw%3D%3D%3AEoD%2FdIrAQjy1D%2BRinf%2Bf%2FG%2BXXwrx8dzA

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