HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG)
E-Bulletin, December 2020

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 – 2021 Participation Grant applications – HTAi-ISPOR Task Force on deliberative processes for HTA
- HTAi Matters – Manchester Annual meeting – 2021 Policy Forum draft paper – Meet the Secretariat
- What's Happening – in and for patient and public involvement – Covid-19
- Publications

Welcome to our December E-Bulletin!

From our Chair

Happy New Year. I hope this E-Bulletin finds you rested, refreshed and ready for 2021. I've invested in erasable pens for my wall planner and am looking forward to building on the lessons and successes of 2020 with increased and improved opportunities for our community to come together virtually. As mentioned last issue, a lot of thought is going into making the 2021 Annual Meeting (in person or virtual) accessible to patients. We're familiar with initiatives like 'Patients Included', but we're always keen to hear examples of great ways to be more inclusive of patients at conferences and meetings. This year, HTAi is offering participation grants for the Annual Meeting (a variation on the usual Travel Grants). Applications close very shortly, so check out the details below.

PCIG has a new Technical Officer, Veronica Lopez Gousset. Many of you know Veronica from her great work helping out with our Annual Business Meeting and virtual face-to-face meeting in 2020. Congratulations Veronica, great to have you on-board.

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/interest-groups/pcig/e-bulletins/

PCIG Matters

Submit your Participation Grant Application, by 18 January 2021

Participation Grants are now available for in-person and virtual attendance at the Annual Meeting. If you are a patient or with a patient group, PCIG encourages you to apply. Additionally, there are grants for those in low and middle income countries and students.

For more information on Participation Grant eligibility criteria, submission guidelines and to submit an application, please follow the Link.

HTAi-ISPOR Good Practices Task Force (TF) on Deliberative Processes for HTA
Valentina Strammiello (European Patient Forum) and PCIG Vice-Chair recently has joined the HTAi-ISPOR Good Practices Task Force (TF) on Deliberative Processes for HTA. We really are grateful to having her on board! For more information about the TF: https://www.ispor.org/member-groups/task-forces/joint-htai---ispor-deliberative-processes-for-hta

Submitted by Wija Oortwijn

HTAi Matters

HTAi 2021 Innovation through HTA - Manchester UK, June 19-23, 2021
https://htai.eventsair.com/htai-manchester-2021-am/
Co-hosts: NICE, the All Wales Therapeutics and Toxicology Centre (AWTTC) and Healthcare Improvement Scotland (HIS).

Submit your Participation Grant Application until January 18, 2021.
https://htai.eventsair.com/htai-manchester-2021-am/participation-grants
Participation Grants are now available for in-person and virtual attendance at the Annual Meeting.
For more information on Participation Grant eligibility criteria, submission guidelines and to submit an application

2021 Global Policy Forum draft paper 'Considering and Communicating Uncertainty in HTA'
See the draft paper on the HTAi website (member login required): https://htai.org/wp-content/uploads/2020/12/2021-GPF-Background-Paper_Draft.pdf

Are you familiar with the individuals who make up the Secretariat?
We have some new faces and welcome you to find out more about us through the HTAi Secretariat bio page. https://htai.org/about-htai/htai-secretariat/
Rob Abbott, Executive Director rabbott@htai.org
Ali Powers, Manager, Events apowers@htai.org
Marlene Hanke, Manager, Annual Meetings mhanke@htai.org
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What's Happening

PARADIGM project closed
On 30 November 2020, the Patients Active in Research and Dialogues for an Improved Generation of Medicines (PARADIGM) project came to a close. PARADIGM was co-led by European Patients Forum (EPF)

and set out to make patient engagement in medicines development easier for all. Two outputs of the project were presented at a final session of the Patient Engagement Open Forum, organised by EUPATI and PFMD. The outputs are the Patient Engagement Toolbox, which centralises the project recommendations, and the Monitoring and Evaluation Framework with metrics, which connects the dots between metrics to understand how patient engagement translates into impact and why initiatives fail or succeed.

IMI PARADIGM patient engagement toolbox (PE Toolbox) with a tool for Patient engagement in early dialogue: Tools and resources for HTA bodies.
https://imi-paradigm.eu/petoolbox/pe-in-ed-hta/

WECAN published a position paper on 'European integration of HTA' in 2018.
https://wecanadvocate.eu/wecan-position-further-eu-integration-of-hta/

Contributed by Dominique Hamerlijnck

EMA at 25: learning more from cancer patients, 21 December 2020
https://cancerworld.net/ema-at-25-learning-more-from-cancer-patients/
Marc Beishon wrote:
Responsibility for scientific evaluation, supervision and safety monitoring of medicines was done at the national level until 1995, when EU member states agreed to coordinate that work within the European Medicines Agency (EMA). To mark its anniversary, the EMA invited leading voices from the cancer community with a stake in the development and approval of cancer drugs to share their perspectives in an online meeting entitled 'New approaches in patient-focused cancer drug development'.
Opening the meeting, EMA director Guido Rasi presented the agency's own perspective, focusing on issues of trust and relevance. He highlighted its efforts to be more transparent in publishing clinical data, and to build on the involvement of patients. He talked about a recent initiative to work with the health technology assessment field to ensure the data required from drug developers sheds light on the extent of clinical benefit. And he emphasised the need to gather data after drug approvals to learn about the performance of agents in real-world settings and how to use new treatments to best effect.
"The biggest challenge for us in oncology is defining what is a clinically meaningful medicine," said Solange Peters of ESMO. She highlighted the challenge of rare cancers and emphasised the importance of implementing innovative trial methodologies and focusing on precision medicine. Peters pointed to the ESMO Magnitude of Clinical Benefit Scale (ESMO–MCBS) for solid tumours as a key innovation that is now widely used to improve decision-making regarding the value of anti-cancer therapies, and demonstrating that the benefit derived by patients does not correlate with the cost of drugs.
EMA's strategy up to 2025 includes to strengthen the link between regulatory authorities and health technology assessment….
Responding to the discussion, with particular reference to the issues raised on values, trade-offs and preferences for patients, the EMA's senior medical officer, Hans-Georg Eichler, commented that people generally see the EMA as a body that assesses drugs and makes decisions on approval. There certainly is an assessment stage, he commented, but then there is a second step that is often not spoken about, which is appraisal, and is about values and preferences. Do benefits outweigh risks, and is the uncertainty acceptable? Eichler argued the assessment stage is best left in the hands of experts, but appraisal is where we should ask, whose values count? "I guess we can all agree it should ultimately be patient values," he said.
"Appraisal is where we should ask, whose values count? I guess we can all agree it should ultimately be patient values"…

The PREFER project
https://www.imi-prefer.eu/case-studies/

The PREFER project is running three large clinical patient preference studies in three disease areas: Lung cancer, neuromuscular disorders and rheumatoid arthritis.
'We will test different methods for preference elicitation in clinical case studies; evaluate what patients think is relevant about their disease and its impact; and look at which treatment options they prefer and their willingness to accept trade-offs between benefits and risks of their treatment. These methods will be evaluated at different decision points in the drug development process.'

Eroding Progress On Evidence And Outcomes: CMS's New Proposed Pathway For Medical Device Coverage - Health Affairs blog, 2 December 2020
https://www.healthaffairs.org/do/10.1377/hblog20201130.767638/full/?utm_medium=social&utm_source=twitter&utm_campaign=blog&utm_content=chambers
Peter Neumann, James Chambers
Medicare's coverage rules serve as the gateway for the adoption and use of new medical devices in the US. Thus, the Centers for Medicare and Medicaid Services' (CMS') new proposed regulation to streamline the coverage pathway for medical devices has important implications, not only for patient access to new technology, but for evidentiary standards, Medicare spending and the incentives for product manufacturers as they invest in further advances. However, the proposal raises questions and concerns, and risks eroding decades of progress made to bolster the scientific evidence underlying coverage decisions for medical technology.

Special issue of journal of Community Genetics, Summer 2021
Details at https://springer.com/journal/12687/updates/18702754
Deadlines for submissions: 1 March 2021
Editors: James Buchanan and Ilias Goranitis
Title: Resource allocation in genomic medicine
Topics include: valuing genomic tests – challenges in the HTA process – ethical, legal and social issues associated with resource allocation in genomic medicine – the role of patients in resource allocation decision making in genomic medicine – commissioning genomic services within health systems – policy issues surrounding translation of genomic medicine into clinical practice – resource allocation issues related to genomic testing in primary care and wider community – resource allocation issues related to implementing genomic medicine in low/middle-income countries – incorporating the wider economic impacts of genome sequencing in resource allocation decisions

Updated versions of products developed for CONITEC/Ministry of Health in Brazil
https://aagts.brasilia.fiocruz.br/
The improvement of rapid reviews, social participation, guidelines' implementation and knowledge translation (social appropriation of knowledge for informed decision-making and communication) in HTA. Some such as the report for the systematic review on models and methods of social participation in HTA may be of interest. The introduction, methods and recommendations/guidelines are published in Portuguese, while the tables summarising main findings (and GRADE-CERQual evaluation of confidence in such findings) from the literature are all in English.
https://aagts.brasilia.fiocruz.br/wp-content/uploads/2020/10/Relatorio_POPART_final.pdf

Sharmila Sousa

Interested in innovative research methods?
https://www.youtube.com/channel/UCu1q-2O2HIHLTUEZswtXXbA
Visit Vitalities Lab, University of New South Wales, Australia 'Breaking Methods' short introduction webinars cover TikTok, digital diaries, mapping, zine-making, YouTube, story completion, storyboarding and methods braiding

How to organise high impact virtual events
https://register.gotowebinar.com/register/7863000585851398412
EPF, in collaboration with PFMD and GCO Global, launched a webinar series on how to organise high impact virtual event. The first episode is available and the other two will be broadcasted live on the 15 January and 5 February 2021. https://www.youtube.com/watch?v=qaIY3EGW9b0&t=3s

EPF December newsletter

Covid-19

Information about the COVID-19 vaccine, approved by MHRA in the UK on 2 December 2020
https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19
We explain how this product was assessed and its authorisation recommended, as well as its conditions of use.
Regulatory approval of COVID-19 Vaccine AstraZeneca
https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca

EMA recommends BioNTech/Pfizer coronavirus vaccine approval
https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty
The EU's medicines regulator recommended approval of the BioNTech/Pfizer vaccine against the coronavirus, opening the way for vaccinations to start in the bloc from December 27. The EMA recommended that the European Commission now grant a conditional marketing authorization, which will give the green light to EU capitals to begin administering the jab.

The European Commission approved the BioNTech/Pfizer coronavirus vaccine just hours after a positive recommendation from the European Medicines Agency. The Commission said deliveries would begin on December 26, so countries can begin vaccinating on December 27.

EMA Public stakeholder meeting on the approval and roll-out of COVID-19 vaccines in the EU
8 January 2021 https://www.ema.europa.eu/en/news/ema-organises-second-public-meeting-about-new-covid-19-vaccines

Persistent symptoms after Covid-19:
Qualitative study of 114 "long Covid" patients and draft quality principles for services. Ladds E, Rushforth A, Wieringa S. *et al.* BMC Health Serv Res 20, 1144 (2020). https://doi.org/10.1186/s12913-020-06001-y

Foundational Set of Standards to Measure and Improve COVID-19 Health Globally
https://www.ichom.org/portfolio/covid-19/
The International Consortium for Health Outcomes Measurement (ICHOM) has recently released their COVID-19 Standard Set (C19-SS). In order to help institutions worldwide provide the best care for patients with COVID-19, health professionals, patient advisors, and recognised leaders from across Europe, the Americas, Asia and Australia have joined forces to establish and launch a global set of outcomes and measurement recommendations that reflect what matters most to patients with COVID-19.
Patient and Clinician - Reported Outcome Measures recommended to be collected across primary, secondary and tertiary healthcare settings over a three-month period following their admission, with the opportunity for extension if a patient has not fully recovered.
Now the real work can begin, to track the outcomes that matter most to patients with COVID-19 and use the data from this Standard Set to inform quality improvement across services worldwide.
An open-source Reference Guide has also been created, outlining recommendations for administering the set, time points, and a data dictionary for organisations to begin implementation.

Publications

Expertise, experience, and excellence. Twenty years of patient involvement in health technology assessment at NICE: An evolving story
Norburn L, Thomas L. (2020). International Journal of Technology Assessment in Health Care, 1-7. doi:10.1017/S0266462320000860
The National Institute for Health and Care Excellence (NICE) was founded in 1999 with a remit to create consistent clinical guidelines and to end "postcode rationing" by providing guidance on new drugs and technologies for use in the National Health Service (NHS) in England. NICE's first health technology assessment (HTA) provided guidance on the extraction of wisdom teeth — guidance which remains active to this day. Twenty years on "technology appraisals" as they are known remain high profile, using methods and processes that have contributed significantly to the international development of HTAs. Involving people with lived experience of the health condition or treatment under consideration, and their carers and families, has been a core principle in our HTA development. This ensures that our decision making and guidance reflects their needs and recognizes the outcomes they value most. In this commentary, we chart the evolution of patient involvement in HTAs at NICE over the past 20 years. We discuss how the role of patient evidence and lay membership of the committees who develop NICE guidance has evolved, and the value and impact that has had. We have sought to uphold the values and standards for patient involvement in HTA, which is reflected in the progress we have made.

Laura Norburn

Towards a common understanding of competencies for HTA: Enhancing educational and training programs around the globe
Mueller D, Gutierrez-Ibarluzea I, Chiumente M, Oortwijn W. International Journal of Technology Assessment in Health Care, 2020; 1-10. doi:10.1017/S0266462320001919

Core competencies for ethics experts in health technology assessment
Refolo P, Bond K, Bloemen B, Autti-Rämö I, Hofmann B, Mischke C, Mueller D, Nabukenya S, Oortwijn W, Sandman L, Steele D, Stanack M, Van der Wilt G, Sacchini, D. International Journal of Technology Assessment in Health Care, 2020; 1-6. doi:10.1017/S0266462320001968

Submitted by Wija Oortwijn

Developing an agency's position with respect to patient involvement in health technology assessment: The importance of the organizational culture
Cleemput I, Dauvrin M, Kohn L, Mistiaen P, Christiaens W, Léonard C. (2020). *International Journal of Technology Assessment in Health Care, 36*(6), 569-578. doi:10.1017/S0266462320000513
The Belgian Health Care Knowledge Centre (KCE) formally involves stakeholders in HTA since 2012. Patients are treated as one stakeholder amongst others, but it is recognized that patient involvement (PI) requires a different approach. The success of implementing PI depends, however, on the organizational culture toward PI. The objective of this study was to map the PI culture at KCE in the context of the development of organization-wide supported position statements about PI.
A nominal group technique was used to measure the PI culture at KCE. Arguments for and against PI and conditions for PI in different phases of the HTA process were collected. A literature review and interviews fed the draft position statements, for which support was assessed by means of a two-round Delphi process. Arguments in favor of PI in HTA related to the relevance of the scope, expertise with data collection, bringing in fresh ideas for study design, access to survey participants, validation of data analyses, adherence to recommendations. Disadvantages and risks included the lack of scientific knowledge of involved patients, resources requirements, conflicts of interest, and heterogeneity within patient populations.

Conditions for meaningful PI referred to measures mitigating the identified disadvantages. Eighteen position statements supported by KCE could be formulated.
The KCE culture seems predominantly positive toward PI, although attitudes vary between HTA researchers. KCE recognizes the potential value of PI in HTA, but considers the level of involvement to be contingent on the topic and phase in the HTA process.

The rationale and design of public involvement in health-funding decision making: Focus groups with the Canadian public
Lopes E, Street J, Stafinski T, Merlin T, Carter D. (2020). *International Journal of Technology Assessment in Health Care, 36*(6), 592-598. doi:10.1017/S0266462320000537

Use of real-world data and evidence for medical devices: A qualitative study of key informant interviews
Polisena J, Jayaraman G. (2020). *International Journal of Technology Assessment in Health Care, 36*(6), 579-584. doi:10.1017/S0266462320000859

Physician-patient shared decision making, patient satisfaction, and adoption of new health technology in China. Wei Y, Ming J, Shi L, Ke X, Sun H, Chen Y. Int J Technol Assess Health Care. 2020 Oct;36(5):518-524. doi: 10.1017/S0266462320000719. Epub 2020 Oct 2. PMID: 33004085.

'Mapping' Health State Utility Values from Non-preference-Based Measures: A Systematic Literature Review in Rare Diseases
Meregaglia M, Whittal A, Nicod E, Drummond M. Pharmacoeconomics. 2020 Jun;38(6):557-574. doi: 10.1007/s40273-020-00897-4. PMID: 32152892.

The estimation of health state utility values in rare diseases: overview of existing techniques
Meregaglia M, Nicod E, Drummond M. Int J Technol Assess Health Care. 2020 Oct;36(5):469-473. doi: 10.1017/S0266462320000665. Epub 2020 Sep 25. PMID: 32981547.

Should We 'Drop Dead' from Health State Valuation?
https://www.ohe.org/news/should-we-%E2%80%98drop-dead%E2%80%99-health-state-valuation
Article by: Chris Sampson, David Parkin and Nancy Devlin – feedback requested
Resource allocation decisions in health care may involve trade-offs between improving people's quality of life and improving their longevity. The quality-adjusted life year (QALY) is used to recognise this trade-off. But is it necessary to use 'dead' as an anchor in health state valuation? The authors argue the case for 'Dropping Dead' as the anchor for health state values.
To 'drop dead' would be a relatively straightforward methodological change, with the 'dead' anchor simply being replaced with an alternative state (such as 'worst health state imaginable'). However, we recognise that such a change raises fundamental questions. Therefore, we would like to hear your views.

Book: Growing up disabled in Australia
'I had become disabled – not just by my disease, but by the way the world treated me. When I found that out, everything changed.'
Although not focused on health technology assessment (HTA), this is a great read for reflecting on how our perspectives of health and everyday ablism create barriers to learning and working with patients in HTA. Compiled and edited by Carly Findlay OAM (appearance activist and author of 'Say Hello'), 'Growing up disabled in Australia' contains the stories of more than forty writers with a disability or chronic illness.

Contributed by Ann Single

Textbook of Patient Safety and Clinical Risk Management

https://link.springer.com/book/10.1007/978-3-030-59403-9
Editors: Liam Donaldson, Walter Ricciardi, Susan Sheridan, Riccardo Tartaglia
Open access

Made to Measure: The Ethics of Routine Measurement for Healthcare Improvement.
Mitchell P, Cribb A, Entwistle V. Health Care Anal. 2020 Dec 20. doi: 10.1007/s10728-020-00421-x. Epub ahead of print. PMID: 33341924.
This paper analyses the ethics of routine measurement for healthcare improvement. Routine measurement is an increasingly central part of healthcare system design and is taken to be necessary for successful healthcare improvement efforts. It is widely recognised that the effectiveness of routine measurement in bringing about improvement is limited—it often produces only modest effects or fails to generate anticipated improvements at all. We seek to show that these concerns do not exhaust the ethics of routine measurement. Even if routine measurement does lead to healthcare improvements, it has associated ethical costs which are not necessarily justified by its benefits. We argue that the practice of routine measurement changes the function of the healthcare system, resulting in an unintended and ethically significant transformation of the sector. It is difficult to determine whether such changes are justified or offset by the benefits of routine measurement because there may be no shared understanding of what is 'good' in healthcare by which to compare the benefits of routine measurement with the goods that are precluded by it. We counsel that the practice of routine measurement should proceed with caution and should be recognised to be an ethically significant choice, rather than an inevitability.

Building on an earlier paper on the distinction between quality as a measurable property and quality as an evaluative judgement. This suggests that a core, but neglected, question for an ethics of healthcare improvement is striking the balance between these two conceptions of quality.
Cribb A, Entwistle V, Mitchell P. What does 'quality' add? Towards an ethics of healthcare improvement. J Med Ethics. 2020 Feb;46(2):118-122. doi: 10.1136/medethics-2019-105635. Epub 2019 Nov 15. PMID: 31732680; PMCID: PMC7035683.

Community Attitudes Towards Sharing Government Health Data with Private Companies: A Scoping Review
Street J, Fabrianesi B, Bosward R, Carter S. Braunack-Mayer A. (2020) *International Journal of Population Data Science*, 5(5). doi: 10.23889/ijpds.v5i5.1531.
We have identified a research gap. The international experience suggests that public scepticism about data sharing with private industry will need to be addressed by good communication about public benefit of data sharing, a strong program of public engagement and information sharing conducted through trusted entities. Large volumes of health data are generated through the interaction of individuals with hospitals, government agencies and health care providers. There is potential in the linkage and sharing of administrative data with private industry to support improved drug and device provision but data sharing is highly contentious.
We conducted a scoping review of quantitative and qualitative studies examining public attitudes towards the sharing of health data, held by government, with private industry for research and development. We screened 6788 articles. Thirty-six studies were included primarily from UK and North America. No Australian studies were identified. Across studies, willingness to share non-identified data was generally high with the participant's own health provider (84-91%) and academic researchers (64-93%) but fell if the data was to be shared with private industry (14-53%). There was widespread misunderstanding of the benefits of sharing data for health research. Publics expressed concern about a range of issues including data security, misuse of data and use of data to generate profit. Conditions which would increase public confidence in sharing of data included: strict safeguards on data collection and use including secure storage, opt-in or opt-out consent mechanisms, and good communication through trusted agents.

Digital technology and health inequalities: a scoping review (2020)

Honeyman M, Maguire D, Evans H and Davies A. (2020). Cardiff: Public Health Wales NHS Trust https://phw.nhs.wales/publications/publications1/digital-technology-and-health-inequalities-a-scoping-review/
There is good evidence to believe that many groups who are already subject to disadvantage and worse health outcomes are also subject to digital exclusion, but the relationship is complex. Important differences in access and use persist: ■ People living in rural areas have less access to, and slower, internet infrastructure. Recent data is lacking but deprived areas also seemed to be more likely to lack access. ■ Older people are less likely to own smartphones or connect to the internet. ■ Where differences between ethnic groups persist in internet access this is explained by the age and income profile of these groups. There are concepts of digital literacy and health literacy, as well as trust and privacy concerns, that are likely to be important in the success of digital health initiatives. Simple measures of use and access cannot account for these.

Can Oncologists Predict the Efficacy of Treatments in Randomized Trials?
Daniel M Benjamin, David R Mandel, Tristan Barnes, Monika K Krzyzanowska, Natasha Leighl, Ian F Tannock, Jonathan Kimmelman. First published: 27 July 2020. The Oncologist. https://doi.org/10.1634/theoncologist.2020-0054
Decisions about trial funding, ethical approval, or clinical practice guideline recommendations require expert judgments about the potential efficacy of new treatments. We tested whether individual and aggregated expert opinion of oncologists could predict reliably the efficacy of cancer treatments tested in randomized controlled trials. An international sample of 137 oncologists specializing in genitourinary, lung, and colorectal cancer provided forecasts on primary outcome attainment for five active randomized cancer trials within their subspecialty; skill was assessed using Brier scores (BS), which measure the average squared deviation between forecasts and outcomes. A total of 40% of trials in our sample reported positive primary outcomes. Experts generally anticipated this overall frequency (mean forecast, 34%). Individual experts on average outperformed random predictions (mean BS = 0.29 [95% confidence interval (CI), 0.28–0.33] vs. 0.33) but underperformed prediction algorithms that always guessed 50% (BS = 0.25) or that were trained on base rates (BS = 0.19). Aggregating forecasts improved accuracy (BS = 0.25; 95% CI, 0.16–0.36]). Neither individual experts nor aggregated predictions showed appreciable discrimination between positive and nonpositive trials (area under the curve of a receiver operating characteristic curve, 0.52 and 0.43, respectively).
These findings are based on a limited sample of trials. However, they reinforce the importance of basing research and policy decisions on the results of randomized trials rather than expert opinion or low-level evidence.

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