

HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG)

E-Bulletin, May 2020

Enhanced quality and relevance of HTA through patient and citizen involvement

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

- Welcome – Values & Standards still valuable!
- PCIG Matters – accessing E-Bulletins
- HTAi Matters – AGM, resources & webinars
- What's Happening – in COVID-19, patient and public involvement
- Publications – much going on

Welcome to our May E-Bulletin!

From our Chair

Six years ago this month, the HTAi Patient and Citizen Interest Group (PCIG) published its [Values and Quality Standards for patient involvement in HTA](#) following a large project led by Karen Facey and supported with an unrestricted grant from Eli Lilly. While pandemics may have been a feature of health system planning, in 2014 we did not consider how it would impact on involvement processes in HTA. However, it's a testimony to the quality of that project that it is no less relevant today. As a result, the PCIG Steering Committee has reiterated its commitment to the Values and Quality Standards, noting their continued importance in guiding decisions about patient involvement in HTA during COVID-19. The Steering Committee notes that capacity building, especially addressing barriers to involvement, is particularly important.

The agility and responsiveness we apply to involvement in these times will be a valuable building block for better patient involvement processes. Citizen involvement has also never been more important. As a result, PCIG is renewing its efforts in this area and I would encourage those of you with expertise in citizen involvement to contact me to discuss this work.

Finally, may I wish Nigel Cook (Co-Lead, Summary of Patient Information Project Sub-Committee) our very best wishes as he retires from Novartis. Nigel has been a dedicated and hard-working member of PCIG who has generously shared his expertise to progress patient and citizen involvement in HTA.

Stay safe

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

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

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



Annual General Meeting (AGM) being held on Monday, June 22, 2020, from 07:30 to 08:30 MDT (UTC-6).

This year has brought great change to the world; global social distancing measures have created the need for virtual solutions for collaboration and participation. With that in mind, HTAi is delighted to announce this year's meeting will be the first virtual AGM in HTAi's history. Members may register for and access the meeting [here](#).

The following items will be for discussion:

Approval of minutes of the [2019 Annual General Meeting](#);

Matters Arising from the Minutes;

President's Report;

Executive Director's Report;

Treasurer's Report

Review of the Audited Financial Statements for the year ending May 31, 2019;

Appointment of Auditor;

Announcement of 2020 Board of Directors Election Results;

Announcement of the 2022 AGM Location.

If you would like to raise any other items of business for discussion please submit your request to the Secretariat in advance via info@htai.org.

Iñaki Gutierrez-Ibarluzea, HTAi President

The HTAi COVID-19 response

<https://htai.org/how-can-we-help-hta-support-for-covid-19/>

HTAi has outlined a three point approach for supporting evidence generation collaborations, and policy decision making consistencies, including: a response team to focus on topic-specific areas of interest and potentially lead and develop projects specifically focused on questions of relevance to the HTA community; webinars to support international collaboration and discussions on common current and horizon issues; and online resources to share publicly available content from members.

The HTAi Board of Directors has created an oversight committee, aptly named the COVID-19 HTA Response Team (C-19 HTA Response Team), to oversee the coordination of society collaborative efforts to support evidence collection, appraisal, dissemination, organizational level collaboration, and foresight deliberations. The C-19 HTA Response Team is Chaired by Iñaki Gutierrez-Ibarluzea, HTAi President. Members include Dan Ollendorf, HTAi Global Policy Forum chair; Leonor Varela-Lema, HTAi Interest Group Steering Committee Chair; Alric Rüther, Scientific Development and Capacity Building Committee Chair; and Chairs from 7 HTAi Interest Groups.

The HTAi COVID-19 Response Webinar series - debuted on May 18, 2020, and attended by over 140 participants! Thank you to all who joined us to discuss the role of Health Technology Assessment during

COVID-19. If you were unable to attend the webinar, but would still like to view the recording, you may access the file [here](#).

This project was initiated by WHO Global Evidence Network.

Email your [Interest Group](#) Chair with projects and topic suggestion ideas.

Webinar Two: Evaluating Rapid Digitization in Hospital Settings. Date: June 5, 2020, 08:00 MDT (-6 UTC). Register for Webinar Two by following this link: [Register Now](#).

As global health systems have and continue to respond to the COVID-19 pandemic, there has been a critical need for wide spread and rapid uptake of digital transformation within Hospital and Clinical Practice Settings. Thousands of clinicians around the world have swiftly migrated their clinical practices to provide telehealth consultations, set up and adopt the use of electronic medical records, overhaul record transfer processes, and completely adapt the way that patient outcome data is collected.

The questions we ask now: what worked well, and what didn't? Were technologies adopted properly and how should hospitals go about assessing the adoption of technologies? Are there global consistencies, and opportunities for shared learning and collaboration?

Driven by the HTAi Hospital Based HTA Interest Group, the goal of this webinar is to dig in to this discussion on digital transformation using national examples, with a focus on:

Assessment of the value of digital transformation at hospital level

Indication for quality measurement of digital transformation

Measurement of the economic impact in hospital settings

Evaluation techniques for adapting digital transformation at the hospital level, based on the needs caused by COVID-19: Examples from Danish setting

Evaluate transferability to real practice, multidisciplinary evaluations

Adoption process and impact of digital transformation

MODERATED BY: Laura Sampietro Colom - Deputy Director of Innovation, Head of Health Technology Assessment Unit - Hospital Clinic Barcelona

PANELISTS: Jeanette Kusel - Director, Scientific Advice – NICE; Kristian Kidholm - Head of Research, Center for Innovative Medical technology – CIMT; Americo Cicchetti - Professor, Department of Economic and Business Management Sciences - Università Cattolica del Sacro Cuore

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What's Happening

Inauguration of EATRIS-PLUS Project in Personalised Medicine

<https://eatris.eu/projects/eatris-plus/>

EATRIS-Plus will deliver innovative scientific tools to the research community to accelerate the progress of personalised medicine. The project will aim to improve the understanding, data-sharing and clinical needs of how gene, protein, mRNA and metabolite analysis will directly impact Personalised Medicine Solutions.

This has enormous value for patients, as it can reduce trial-and-error treatments, enable better choices for determining which medications would be most effective, and it can help to manage rising healthcare costs. EPF will lead on Stakeholder Engagement. We will deliver a Patient Advisory Committee to drive patient empowerment at the heart of EATRIS operations and develop a patient involvement toolkit for translational researchers.

From the European Patients Forum May Newsletter

Informed in a world with COVID-19

Call for participation in a Survey on the impact of COVID on citizen's lives

All of you are invited to participate in a survey yourself and to further distribute it to your friends or relatives: <https://www.covid19impactsurvey.org/>

The survey works on a large range of devices and systems and can be easily distributed via social media.

The survey has been created in Spain, and meanwhile has been translated in a range of other languages (Arabic, Turkish, Finnish, Spanish, English German, Catalan Basque, Brazilian Portuguese, Portuguese, Swedish / Persian, French, Italian). In Spain, the results have been and are being used to inform policy making throughout the time of the pandemic, especially in the region of Valencia.

The first results from Spain have been published (Oliver, Nuria, Xavier Barber, Kirsten Roomp, and Kristof Roomp. 2020. "The Covid19Impact Survey: Assessing the Pulse of the COVID-19 Pandemic in Spain via 24 Questions." ArXiv:2004.01014 [Cs], April <http://arxiv.org/abs/2004.01014>, and the authors continue to evaluate the responses weekly to inform the political decisions relating to the regulations in the pandemic. They also strive to collect answers from other countries and to eventually compare the responses across countries. If you are interested check out the current results via the following link:

<https://covid19impactsurvey.org/results>

PCIG and the Developing countries interest group (DCIG) are in contact with the original research group. If you are interested, to use the survey more strategically in your own country please contact Anke Holtorf PCIG.Projects@health-os.com, who will be able to give you more information and make the necessary contacts.

The *Covid19Impact* Survey: Assessing the Pulse of the COVID-19 Pandemic in Spain via 24 questions

Nuria Oliver, Xavier Barber, Kirsten Roomp, Kristof Roomp

We describe the results of analyzing a large-scale survey, called the *Covid19Impact* survey, to assess citizens' feedback on four areas related to the COVID-19 pandemic in Spain: social contact behavior, financial impact, working situation and health status. A total of 24 questions cover the areas of demographics, their home situation, social contact behavior, personal economic impact, their workplace situation and their health. The survey was responded to by 146,728 participants over a period of 44 hours. Such a large response enables us to gain new insights, as well as an unprecedented glimpse at respondents' personal experiences and concerns during the current COVID-19 pandemic. From the analysis, we draw 11 implications for the design of public policies related to the management of the COVID-19 pandemic.

Submitted by Anke-Peggy Holtorf

The European Medicines Agency's human medicines committee (CHMP) starts a 'rolling review' of data on the use of remdesivir for the treatment of COVID-19

<https://www.ema.europa.eu/en/news/ema-starts-rolling-review-remdesivir-covid-19>

The rolling review is to accelerate the assessment of a promising investigational medicine during a public health emergency, such as the current pandemic. Under normal circumstances, all data supporting a marketing authorisation application must be submitted at the start of the evaluation procedure. In the case of a rolling review, CHMP Rapporteurs are appointed whilst development is still ongoing and the Agency reviews data as they become available.

Several rolling review cycles can be carried out during the evaluation of one product as data continue to emerge, with each cycle lasting around two weeks depending on the amount of data to be assessed. Once the data package is complete, the developer submits a formal marketing authorisation application which is then processed under a shortened timetable.

It is expected that the move will allow the EMA to complete its assessment significantly earlier compared with a regular evaluation procedure, while still ensuring a robust scientific opinion is reached. Remdesivir is not yet authorised in the European Union but is available to patients through clinical trials and compassionate use programmes.

EMA prepares for coronavirus vaccine to come to market

https://www.ema.europa.eu/en/news/ema-commissions-independent-research-prepare-real-world-monitoring-covid-19-vaccines?utm_source=POLITICO.EU&utm_campaign=90cd126550-EMAIL_CAMPAIGN_2020_05_27_09_30&utm_medium=email&utm_term=0_10959edeb5-90cd126550-190571555

The EMA has commissioned research to ensure that a potential coronavirus vaccine works in the real world and not just in clinical trials. The EMA announced it has commissioned Utrecht University to carry out research into how best to monitor the safety, effectiveness and coverage of a future coronavirus vaccine once it's in circulation. The first results of the research are expected in August, with the project to be completed by the end of the year.

PharmaTimes and OVID Health Patient Partnership Index 2020 - now open for entries

Entry deadline for the Index is June 23.

The Index is a first-of-its-kind opportunity for pharma companies to showcase, benchmark and measure the quality of their advocacy with patient groups. The aim is to raise the bar across the board.

The COVID-19 pandemic is placing pressure on healthcare systems and patients everywhere. Putting patients at the heart of what pharma does has never been more critical. While patient centricity is now mainstream in R&D, the concept of impactful communications, engagement and advocacy with patient groups is less well defined. This is why PharmaTimes and OVID have co-created the Patient Partnership Index and are inviting life science companies (small, medium and large) to take part, in order to share and profile their partnership working with patient communities, such as (but not exclusively) patient advocacy groups.

The judges will use a metric created by OVID Health in partnership with pharmaceutical companies and patient groups to judge (not rank) entries based on industry best practice. The Index covers six themes: engagement; co-creation; empowerment; transparency; innovative; and impactful.

Take part by visiting: www.patientpartnershipindex.co.uk or email info@patientpartnershipindex.co.uk for more information.

A number of countries are collating their learnings from dealing with COVID-19 so far, identifying what they could have done better and detailing principles. Equity is a key factor.

Many patient support groups have worked hard to identify the concerns of their members, how the pandemic has affected their access to health care, and that of citizens more broadly, and impacted on their health and wellbeing. They have been key in offering support and clear messages.

One example is from IPPOSI in Ireland

Summary of IPPOSI statement on COVID19 pandemic - The need for a patient centered approach and continued patient involvement during a pandemic

IPPOSI are keen to ensure that the patient perspective is understood alongside broader public health considerations. Expediency should not trump the quality and/or representativeness of decisions particularly in the following areas:

Strengthening our mutual commitment to patient-centricity and patient involvement

Patients need to be involved in the preparation of new policy documents, new research proposals, new innovative tools and treatments. We acknowledge that there may be instances where it is not possible to directly involve patients, and on these occasions, decisions must be consistent with agreed, existing national policy or clinical guidance (documents which hopefully benefitted from patient involvement during development).

Investing in our health future by developing patient-driven digital solutions

Patients need to be recognised as key partners in the design, delivery and evaluation of digital health solutions from the earliest possible stage. Decisions around how data is collected, stored, managed, used and shared must be informed by *patient perspectives*

Guaranteeing our medicines supply and approving the use of new (non-COVID) medicines

Patients need to be informed and updated around the supply chain for existing medicines. They must be reassured that the process of assessing and reimbursing new medicines continues. Patients must be able to manage their existing conditions, and new medicines offering potentially life-saving or life-improving outcomes need to be reviewed for their clinical (and cost) effectiveness and made available for use.

Interesting approaches have also been gathered among healthcare professionals.

COVID-19: Patient Safety and Quality Improvement Skills to Deploy during the Surge

<https://academic.oup.com/intqhc/advance-article-abstract/doi/10.1093/intqhc/mzaa050/5836316>

Downloaded on 26 May 2020

To respond to the crisis, healthcare systems have had to reorganize instantly, with little time to reflect on the roles to assign to their Patient Safety (PS) and Quality Improvement (QI) experts. Coping with a pandemic primarily requires skills in virology, serology and intensive care, and other infection related disciplines. International authors Anthony Staines, René Amalberti, Donald M Berwick, Jeffrey Braithwaite, Peter Lachman, Charles A Vincent suggest a five-step strategy and actions through which PS and QI staff can meaningfully contribute to support patients, staff, and organizations.

1. Strengthen the system by assessing readiness, gathering evidence, setting up training, promoting staff safety, and bolstering peer support.
2. Engage with citizens, patients, and their families so that the solutions are jointly achieved and owned by both the healthcare providers and the people who receive care, and in particular the citizens who are required to undertake preventive interventions.

3. Work to improve care, through actions such as the separation of flows, flash workshops on teamwork, and the development of clinical decision support.
4. Reduce harm by proactively managing risk to both COVID-19 and non COVID-19 patients.
5. Boost and expand the learning system, to capture improvement opportunities, adjust very rapidly, and develop resilience. This is crucial as little is known about COVID-19 and its impacts on patients, staff, and institutions.

Published by Oxford University Press in association with the International Society for Quality in Health Care.

Publications

Special thanks Nigel!

I would like to say a special thanks to Nigel Cook as a regular contributor particularly to this section. As his last contribution he has let us know about a recent publication of his together with his Novartis colleagues. Read the paper and you can feel the pain – it really captures the people’s experiences with a health condition. His work is innovatively patient-centred, covering patient preferences, use of digital technologies and other topics. His contributions have been varied and informative, extending far beyond his own work. Enjoy your family and doing the things you have been putting off for years Nigel!

Nigel Cook, Kyle Landskroner, Bhavik Shah, Susann Walda, Olivia Weiss, Vikrant Pallapotu. Identification of Patient Needs and Preferences in Pigmented Villonodular Synovitis (PVNS) Using a Qualitative Online Bulletin Board Study. *Advances in Therapy* 2020. <https://doi.org/10.1007/s12325-020-01364-4>

Application of the online bulletin board methodology to a very rare musculoskeletal disease

Submitted by Nigel Cook

Janet Wale, Melissa Sullivan. Exploration of the visibility of patient input in final recommendation documentation for three health technology assessment bodies. *International Journal of Technology Assessment in Health Care*, First View

<https://www.cambridge.org/core/journals/international-journal-of-technology-assessment-in-health-care/article/exploration-of-the-visibility-of-patient-input-in-final-recommendation-documentation-for-three-health-technology-assessment-bodies/883EA3369EFAFCFFC8B08E7375ACDFEE/share/9b72e49b6a66c987d347ba04f7d32010b245c293>

A scoping review of the impact of patient involvement in HTA

<https://www.cambridge.org/core/journals/international-journal-of-technology-assessment-in-health-care/article/evaluation-of-the-impact-of-patient-involvement-in-health-technology-assessments-a-scoping-review/5D0019F993D92E82B6E7F84F43D11992>

Robert Mason, Karlee Searle, Yvonne Bombard, Amanda Rahmadian, et al. Evaluation of the impact of patient involvement in health technology assessments: A scoping review. *International Journal of Technology Assessment in Health Care*, First View

Submitted by Karen Facey

The new definition of health technology assessment: A milestone in international collaboration

Brian O'Rourke, Wija Oortwijn, Tara Schuller and the International Joint Task Group. International Journal of Technology Assessment in Health Care, First View. DOI: <https://doi.org/10.1017/S0266462320000215>

An international joint task group co-led by the International Network of Agencies for Health Technology Assessment (INAHTA) and Health Technology Assessment International (HTAi) has developed a new and internationally accepted definition of HTA. They developed guiding principles for the process and followed an established consultation plan with the broader HTA community to develop the definition.

HTA is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.

Note 1: A health technology is an intervention developed to prevent, diagnose or treat medical conditions; promote health; provide rehabilitation; or organize healthcare delivery. The intervention can be a test, device, medicine, vaccine, procedure, program, or system (definition from the HTA Glossary; <http://htaglossary.net/health+technology>).

Note 2: The process is formal, systematic, and transparent, and uses state-of-the-art methods to consider the best available evidence.

Note 3: The dimensions of value for a health technology may be assessed by examining the intended and unintended consequences of using a health technology compared to existing alternatives. These dimensions often include clinical effectiveness, safety, costs and economic implications, ethical, social, cultural and legal issues, organizational and environmental aspects, as well as wider implications for the patient, relatives, caregivers, and the population. The overall value may vary depending on the perspective taken, the stakeholders involved, and the decision context.

Note 4: HTA can be applied at different points in the lifecycle of a health technology, that is, pre-market, during market approval, post-market, through to the disinvestment of a health technology.

Linda Mundy, Rebecca Trowman, Brendon Kearney. Sustainability of healthcare systems in Asia: exploring the roles of horizon scanning and reassessment in the health technology assessment landscape. . International Journal of Technology Assessment in Health Care, First View

<https://www.cambridge.org/core/journals/international-journal-of-technology-assessment-in-health-care/article/sustainability-of-healthcare-systems-in-asia-exploring-the-roles-of-horizon-scanning-and-reassessment-in-the-health-technology-assessment-landscape/2218A49184B06676D1A4F9419F90B22B>
<https://www.cambridge.org/core/journals/international-journal-of-technology-assessment-in-health-care>

Jacqueline Barker, Pam Moule, David Evans, Wendy Phillips, Nick Leggett. Developing a typology of the roles public contributors undertake to establish legitimacy: a longitudinal case study of patient & public involvement in a health network. BMJ Open <https://t.co/EGg9K548bb>

<https://bmjopen.bmj.com/content/10/5/e033370>

Public contributors established their legitimacy by using nine distinct roles: (1) lived experience, as a patient or carer; (2) occupational knowledge, offering job-related expertise; (3) occupational skills, offering aptitude developed through employment; (4) patient advocate, promoting the interests of patients; (5) keeper of the

public purse, encouraging wise spending; (6) intuitive public, piloting materials suitable for the general public; (7) fresh-eyed reviewer, critiquing materials; (8) critical friend, critiquing progress and proposing new initiatives and (9) boundary spanner, urging professionals to work across organisations. Individual public contributors occupied many, but not all, of the roles.

G Sharf, C Marin, JA Bradley, Z Pemberton-Whitely, F Bombaci et al. Treatment-free remission in chronic myeloid leukemia: the patient perspective and areas of unmet needs. *Leukemia* 2020
<https://www.nature.com/articles/s41375-020-0867-0>

Involving 1016 CML patients from 68 countries. Healthcare professionals should further consider how they monitor the psychological well-being of patients who are discontinuing or re-initiating treatment, and review what support is offered in response to identified concerns. Surveillance of withdrawal symptoms should be a priority during treatment discontinuation, along with how healthcare professionals assist in the management of these.

Oortwijn W, Jansen M, Baltussen R. Use of evidence-informed deliberative processes by health technology assessment agencies around the globe. *Int J Health Policy Manag.* 2020; In Press. doi:10.15171/ijhpm.2019.72

Culyer, A. Use of Evidence-Informed Deliberative Processes – Learning by Doing; Comment on “Use of Evidence-informed Deliberative Processes by Health Technology Assessment Agencies Around the Globe”. *International Journal of Health Policy and Management*, 2020; 9(6): 263-265. doi: 10.15171/ijhpm.2019.116

Goetghebeur M, Cellier M. Deliberative processes by health technology assessment agencies: a reflection on legitimacy, values and patient and public involvement: Comment on “Use of evidence-informed deliberative processes by health technology assessment agencies around the globe.” *Int J Health Policy Manag.* 2020;x(x):x–x. doi:10.34172/ijhpm.2020.46

Schlander M. HTA agencies need evidence-informed deliberative processes: Comment on “Use of evidence-informed deliberative processes by health technology assessment agencies around the globe.” *Int J Health Policy Manag.* 2020;x(x):x–x. doi:10.34172/ijhpm.2020.22

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