

HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG) E-Bulletin, July 2018

Enhanced quality and relevance of HTA through patient and citizen involvement

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

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Welcome to the July E-Bulletin

HTAi Matters



HTAi Annual Meeting 2018 in Vancouver

Thanks to you, the first Annual Meeting held on Canadian soil in more than a decade was nothing short of incredible. We were thrilled to welcome more than 900 delegates from around the world to beautiful Vancouver, British Columbia. There were over 500 scientific contributions presented as workshops, panels, orals, posters, and vignettes throughout the five days, with three engaging plenary sessions and a memorable keynote address from Ms. Hannah Kettler. This year's theme centred around the evidence-to-action connection and as always our members and partners presented ideas that spurred enthusiastic discussions.

HTAi has already started planning the 2019 Annual Meeting in Cologne, Germany. Mark June 15 – 19th, 2019 in your calendars and visit www.htai2019.org for more information.

Policy Forum newsletter July 2018

<https://htai.org/blog/category/policy-forum-newsletter/>

What's Keeping Me Up At Night? Reflections from Global Policy Forum members and the report from the Global Policy Forum panel session held at the HTAi 2018 Annual Meeting in Vancouver: "Echoing the key messages from the Global Policy Forum, the session concluded that there is room for improvement in horizon scanning systems (HSS). HSS can only be truly effective when integrated into the healthcare system, taking longer term perspectives, and with policy makers who are receptive to the findings.

What's Happening

European Commission. Proposal for a regulation of the European Parliament and of the Council on Health Technology

https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/com2018_51final_en.pdf

Assessment and amending Directive 2011/24/EU. 31 January

The text of the proposal deals with joint clinical assessment (for drugs and some devices) and scientific consultation. Depending on the final version of the text, European HTA bodies will have to follow or take into consideration an assessment done at the European level. The report of the European Deputy of the

Committee on the Environment, Public Health and Food Safety compares the current version of the proposal and proposed amendments This committee will discuss and vote on the final amendments at the beginning of September. The EU Parliament will vote in October.

<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-622.011+01+DOC+PDF+Vo//EN&language=EN>

Of concern are: how existing HTA agencies and EUnetHTA would work together and the exact roles of patients and patient organisations in a stakeholder network and in joint HTAs to develop a person-centred approach with patient-centred health outcomes.

See the European Patients Forum viewpoint at: <http://www.eu-patient.eu/News/News/epf-calls-on-eu-member-states-to-put-patients-first-and-make-progress-on-hta-negotiations2/>

From members of PCIG Steering Committee

A group of patient organisations in Europe (but some global included) have developed a position paper on harmonization of HTA in Europe

<http://www.wecanadvocate.eu/wecan-position-further-eu-integration-of-hta/>

WECAN believes that patient-centricity is the only way to ensure that healthcare is adequate and relevant. For this reason, WECAN would like to see the role of patients, caregivers and patient advocates clarified in the proposed stakeholder network, the coordination Group and in any clinical assessments. We support the European Patient Forum's (EPF) call for mandatory and meaningful involvement of the patient community in order to ensure HTAs are conducted in the interest of patients.

The International Kidney Cancer Coalition is a member organisation, so I am pleased to submit.
Provided by Deb Maskens

Dutch PROMs advisory group patient perspective

On Monday 10 September 2018, the second meeting of the 'Dutch PROMs advisory group patient perspective' on PROMs for patient organisations will take place in Utrecht. The topic of this meeting will be 'Implementation'. Would you like to join us? Please email us via kwaliteit@patientenfederatie.nl
It will also be possible to attend the meeting online.

Here's an inventory of existing PROMs in the Netherlands:

<https://www.patientenfederatie.nl/algemeen/informatie-over-proms>

Submitted by Marleen Kaatee



An invitation to an August meeting the National Health Council is hosting in Washington DC

Keynote Speaker Dr. Scott Gottlieb: Putting Patients First in Drug Development: A

Dialogue on FDA's Guidance

When: Friday, August 10, 9:00 a.m. - 12:00 p.m. ET

Where: The Capital Hilton, 1001 16th St. NW, Washington, D.C. 20036

Don't miss keynote remarks from FDA Commissioner Scott Gottlieb, MD on patient engagement in drug development on Friday, August 10 hosted by the National Health Council. This is your opportunity to hear perspectives from the FDA, patient organizations, and the pharmaceutical industry on the FDA's recently released draft guidance on patient engagement in drug development and ask questions of key experts and thought leaders. If you have any questions, please contact Katie Soisson at ksoisson@nhcouncil.org

[Register Now!](#)

Submitted by Jason Harris/Elisabeth Oehrlein

[XNocmllcygyZXNIYXJjaC1sdW1iYXltc3BvbmR5bG9saXNoaGVzaXMiLCJidWxsZXRpbGpZCI6JlJwMTgwNzIzLjkzMDIzNTcxIno.VqY3HUz2tExaqS7KgMrudIYllhgKNV6LRP7u7BVoGsk](#)> Available for comment until August 21, 2018

Data Elements Development, Governance, and Harmonization

<<https://lnks.gd//eyJhbGciOiJIUzI1NiJ9.eyJlbWpCbG9zaXNoaGVzaXMiLCJidWxsZXRpbGpZCI6JlJwMTgwNzIzLjkzMDIzNTcxIno.VqY3HUz2tExaqS7KgMrudIYllhgKNV6LRP7u7BVoGsk>> Available for comment until August 21, 2018

Submitted by Catherine Voutier

IMI 10th Anniversary Scientific Symposium 22 and 23 October 2018 in Brussels

<https://www.imi.europa.eu/news-events/events/imi-10th-anniversary-scientific-symposium>

For the last 10 years, our projects – 100 and counting – have been carrying out amazing work to speed up the development of innovative medicines and transform medical research. Interested in what they have achieved? Don't miss our 10th anniversary scientific symposium, where young scientists from IMI projects will present their sterling work.

The symposium will feature more than 80 poster displays, over 25 oral presentations and several interesting panels on topics ranging from personalised medicine to patient-centric approaches in drug development.

The oral presentations and the scientific posters have been selected by a panel of top experts. Taking an open innovation approach, our young scientists will offer a glimpse into some of the stellar science that IMI projects have been doing in various disease areas, such as severe asthma, Alzheimer's disease, diabetes and cancer, to name but a few. Please find the draft agenda [here](#)

Registration for the Scientific Symposium is free but obligatory. If you would like to attend, please register [here](#).

Latest IMI Calls for proposals

<https://www.imi.europa.eu/news-events/press-releases/new-antimicrobial-resistance-accelerator-programme-part-latest-imi-calls>

Research platforms for patient-centric drug development – Currently, clinical trials are generally carried out in silos and all too often, they are not patient friendly, making it hard to enroll enough patients. This topic aims to develop and disseminate reusable best practices, tools and guidelines for establishing multi-company platform trials capable of running patient-friendly clinical trials that test multiple treatments in parallel. The topic focuses on developing platform trial designs and protocols in four disease areas: major depressive disorder, tuberculosis, the liver disease non-alcoholic steatohepatitis (NASH), and neurofibromatosis. In the short term, the research platforms will speed up the enrolment of patients in clinical trials and increase the likelihood that participating patients are allocated a promising treatment instead of the placebo. In the longer term, this will help to accelerate medicines development.

Clinical trials go digital – Current clinical trial assessments are often based on subjective clinical scoring systems, which do not provide an accurate, detailed picture of a patient's condition. This topic aims to tackle this problem by identifying, assessing and validating digital technologies (e.g. wearable and home-based devices) that could reliably and sensitively measure patients' clinical conditions in their homes or as they go about their daily lives. The project will focus its efforts on technologies capable of monitoring patients with neurodegenerative disorders (namely Parkinson's disease and Huntington's disease) and inflammatory diseases (rheumatoid arthritis or lupus, and inflammatory bowel disease). The project will ultimately result in better clinical trials that provide more detailed data on patients' condition and also allow more patients to take part in clinical trials.

Submitted by Nigel Cook

Publications

Current Opinion: Putting Patients at the Centre of Healthcare: Progress and Challenges for Health Technology Assessments

Karen M. Facey, Nicola Bedlington, Sarah Berglas, Neil Bertelsen, Ann N.V. Single, Victoria Thomas. *Patient* (2018). <https://doi.org/10.1007/s40271-018-0325-5>. Online First

<http://link.springer.com/article/10.1007/s40271-018-0325-5>

Karen Facey (k.facey@btinternet.com) was invited by *The Patient* to contribute a paper to their series on Patient-Centred Healthcare. She has worked with others over the past 18 months to develop this latest paper that gives a critical exploration of issues relating to patient involvement – picking up on the benefits to HTA and burdens on patients groups and how we should be helping to alleviate those. If you or your institution doesn't have a link to this Springer journal, please email any of the authors and they can send you a copy of the paper directly.

HTAi Annual Meeting 2017 Supplement

HTAi is excited to share that the 2017 Annual Meeting Supplement has been published in the International Journal of Technology Assessment in Health Care (IJTAHC). As part of the benefits of being an HTAi member, you are able to access and review the Supplement for free. [Conference Theme: Towards an HTA Ecosystem: From Local Needs to Global Opportunities \(Volume 33 – Issue S1 – 2017\)](#). Many thanks to Associate Professor Wendy Babidge, IJTAHC Editor in Chief, and Marlene Hanke and Laura Varga from the HTAi Annual Meeting team who all supported the process.

Articles for a Value in Health “Back to the Future” theme

To view the full Call for Papers, see https://www.ispor.org/docs/default-source/publications/vih_back_to_the_future_071618_v8.pdf?sfvrsn=e5e00eab_0

This special issue will feature topics that have been widely discussed in the journal over the past 20 years, but for which there is an exciting future agenda. The Editors are soliciting proposals for papers and welcome suggestions on any topic, no matter how unconventional. This is the time to be creative. The themed section is tentatively scheduled to appear in the January 2019 issue of Value in Health. The deadline for submissions has been extended to September 1, 2018.

Submitted by Marleen Kaatee

Stakeholder participation in healthcare priority setting

Our paper on stakeholder participation in healthcare priority setting was published online at the International Journal of Health Policy and Management, titled: *Stakeholder participation for legitimate priority setting: a checklist'* ([link](#)). I believe it would be of interest to the readers.

In this paper, Maarten Jansen (Radboud University, the Netherlands), Rob Baltussen (Radboud University, the Netherlands), and Kristine Bærøe (University of Bergen, Norway) discuss how decision makers who are required to legitimize their priority setting decisions in health to members of society can be held accountable. The focus is on the special moral concern for being accountable to those who end up being adversely affected by decisions in terms of not being provided the treatment or care they would hope for. The authors translate this requirement into a checklist for real world action. This list consists of 29 reflective questions to assist decision-makers in organizing legitimate priority setting in healthcare.

Submitted by Maarten Jansen

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