

HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG) E-Bulletin, May 2019

Enhanced quality and relevance of HTA through patient and citizen involvement

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

- Welcome
- HTAi Matters
- What's Happening – in patient and public involvement
- Publications

Welcome to the May E-Bulletin!

In PCIG, we have worked with many of you over the years on particular projects that have delivered real value to the promotion and implementation of patient involvement in HTA. Those of you that have been involved with these projects will know that we have split our work across three working groups – Patient Involvement and Education (PIE), Methods & Impact (M&I) and Citizen & Community (CC). However, to accelerate our project work and make it easier for you to get involved in particular activities without having to be a member of a particular working group, we are planning to move to a project based structure. This will involve us publishing project synopses and calling for involvement on a project by project basis, allowing those of you are interested in a particular project to easily get involved. It will also give the membership an ability to propose project ideas without having to be within any working group.

Under this plan, the working group structure will be dissolved, allowing us to devote maximum time on delivering the projects. We are in the process of adapting our Terms of Reference to reflect this approach and this will be brought to the PCIG Annual Business Meeting at HTAi 2019 for discussion and approval before any changes are made. This move came out of the face to face meeting we held in Stockholm last autumn. At this meeting, the working groups met and decided jointly that a project based structure would be a simpler way to both lead projects and gain involvement in each activity, and I thank all the attendees of that meeting for being so clear in their recommendations to the steering committee.

We will keep you updated as we progress our plans!

Neil Bertelsen – Chair

Valentina Strammiello – Vice Chair

In addition

🎉 We would like to congratulate our Technical Officer Rebecca Addo for receiving her PhD from University of Technology in Sydney (UTS). Rebecca graduated this month.

🎉 A suggestion from Eva Reviriego of OSTBA, San Sebastian, Spain: It could be interesting to add a FAQ section and a methodological help or assistance about patient involvement in the E-Bulletin. We are happy to open up discussion on this, using the e-mail pcig.htai@gmail.com

HTAi Matters

HTA Beyond 2020: Ready For The New Decade?'



HTAi Meeting in Cologne, Germany from Saturday June 15 to Wednesday 19 June, 2019

Supported by the Institute of Quality and Efficiency in Health Care (IQWiG) and the German Institute of Medical Documentation and Information (DIMDI) as host organisations.

Visit the [HTAi 2019 website](https://www.htai2019.org/) for currently available information and for registration.

Registration inquiries: registration@htai.org

The full programme is on the website. Have a look to see which sessions interest you most. We have some exciting panel sessions as well as oral presentations and vignettes <https://www.htai2019.org/>

PCIG Workshop

The HTAi PCIG is running a workshop entitled WS 04 PCIG Cologne Workshop: Listen, Exactly What Do We Each Want from Social Engagement in Health Technology Assessments. 8:30 am – 4:30 pm, 15 June 2019

Restaurant for our PCIG dinner

The PCIG informal dinner is scheduled for the Monday (17th June) at 19:30. As usual, people will be expected to pay for their own meals. The restaurant is Brauhaus Sunner im Walfisch, Salzgasse 13, 50667 Cologne. It is in the old part of the city but not too far from the annual meeting.

Annual General Meeting (AGM) at the Museum Ludwig (Heinrich-Böll-Platz, 50667 Cologne)

The meeting will take place 6:30 PM to 7:30 PM CET on Monday, June 17, 2019 and is open to all active members of the Society.

Items are: [minutes of the 2018 Annual General Meeting](#); the President's report; the Audited Financial Statements for 2018; the 2019 Board of Directors election results; the 2021 Annual Meeting location; and any other business as needed.

If you would like to raise any other items of business for discussion, please do so in person during the AGM, or by submitting your request to the Secretariat in advance via info@htai.org.

Following the AGM, we invite you relax and enjoy the beautiful art of the Museum Ludwig. The museum is one of the finest collections of modern art in the world, containing the third largest collection of Picasso, the largest collection of Popart in Europe and much, much more. All registered attendees of the 2019 Annual Meeting will have free entrance to the museum from 6:00 PM to 10:00 PM. We would like to thank Digital Health Germany and the City of Cologne for providing this valuable space for us to gather.

Documentary film "Measure of Time/ Le Temps Retranché" by Benjamin Sylvestre, Writer & Director

- on the experiences of himself and other renal dialysis patients is now to be shown between 6 and 7 pm on Tuesday 18 June.

Trailer: <https://vimeo.com/301827984>

Facebook: <https://www.facebook.com/letempsretranche/>

The idea to make this film came to me when I returned to dialysis 18 months ago. Shifting from the world of people to transplants to that of people on dialysis, I felt the need to make an account of the chronic illness that is kidney failure and the daily treatments that it involves. For the past twenty years, I have been working, trying to put the illness to one side, to think like everyone else. Today, I feel the desire and the need to link this personal experience to a cinematographic adventure and to share every moment of this human and medical adventure.

This immersive documentary shares the day to day life stories and tribulations about those whose very survival depends on a pump, a blood filtration device. Time is restructured between two worlds...

Becoming familiar with dialysis and with those who fight illness is the best way to break down certain preconceived notions, to change the way we look at people with illness and to encourage their integration into our society...

Daily life with a chronic illness is difficult to capture and to summarise, because an entire life, an entire being is built around it. Through this project, I want to open our eyes to the situations, lives, developments, trials

and errors with which anyone may one day be confronted, because this film tells us about accepting to build our lives around the life that we are given and what we choose to do with it.

HTAi Interest Group webinar series, 3 and 5 June

Representatives from 4 of the HTAi Interest Groups will present an overview of their group. The overview will include a review of recent achievements and planned activities.

By participating in these webinars, you will be able to:

- Gain an understanding of how HTAi Interest Groups interact
- Understand how you can become involved with Interest Group activities
- Find out how you can become a member of an Interest Group
- Learn what to expect from Interest Group business meetings at HTAi Annual Meetings including Cologne

MONDAY 3 JUNE – [REGISTER HERE FOR FREE](#)

07.00-08.00am Mountain Daylight Time (MDT) / 15.00-16.00pm Central European Summer Time (CEST)

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

HTAi Interest Group on Ethical Issues in HTA (Ethics IG), Ken Bond

WEDNESDAY 5 JUNE – [REGISTER HERE FOR FREE](#)

07.00-08.00am Mountain Daylight Time (MDT) / 15.00-16.00pm Central European Summer Time (CEST)

HTA in Developing Countries Interest Group (DCIG), Jani Mueller

Disinvestment and Early Awareness Interest Group (DEA-IG), Rosmin Esmail and Roberta Joppi

Pre-conference webinars for registered attendees for the 2019 Annual Meeting

These events provide a unique opportunity to connect and engage with other delegates before the meeting.

The next is on Thursday, June 6, from 7:00 – 7:45 am MDT (3:00 – 3:45 pm CEST) as MSD discusses early treatment in cancer. Please register in advance here:

<https://attendee.gotowebinar.com/register/7505452587786927883?source=XCD+email>

What value do we place in sparing patients the experience of living through metastatic disease? This webinar will introduce the concepts in advance of the MSD Idea Factory at HTAi Cologne and allow attendees to interact with the speakers by sending in questions to be answered.

The first webinar was on Tuesday, May 28th when Pharmerit International discussed the potential for joint HTA in Europe.

Webinar Information

Europe is striving towards greater cooperation in Health Technology Assessment (HTA). Opportunities exist to create synergies through mutual information sharing among member states to support national HTAs. Although there is increasing focus on the uptake of EUnetHTA joint clinical assessments, challenges need to be identified and addressed, before current efforts can translate into seamless and efficient HTA harmonization in Europe. During this webinar, we will present an overview of current trends, and our findings based on a qualitative comparison of the methodologies used in the JCA (within the JA3 framework) and the appraisals performed by the national HTA bodies (NICE, G-BA and HAS) in oncology.

What's Happening

IMI plans to create a pool of patient experts

<https://www.imi.europa.eu/get-involved/patients/imi-pool-patient-experts>

The pool of patient experts is to strengthen the role and voice of patients in IMI activities at both strategic and operational levels. Patients who are part of the pool would be invited on an ad hoc basis to: provide input on IMI's scientific strategy (annual priorities, topic development etc.), for example by taking part in early consultations / workshops, SGG meetings, etc.; participate in panels to review project proposals;

participate in reviews of ongoing and closed projects; review the content of documents prepared for patients and the general public; participate in IMI events.

The basic criteria for inclusion in the pool are: being a patient (or a family member or carer of a patient) with a chronic / lifelong illness or condition; being a resident of an EU Member State, a country that is associated with the EU's research programme Horizon 2020, or the WHO European Region having a specific interest in one of the disease areas featured in IMI's Strategic Research Agenda; a working knowledge of English.

Submit an Expression of Interest <https://cloud.imi.europa.eu/web/pool-of-patient-platform/pool-of-patients>. Information is available <https://www.imi.europa.eu/sites/default/files/uploads/documents/get-involved/patients/CallIMIPatientPoolMay2019.pdf>

The closing date is 16 July 2019 at 17:00 CEST (Central European Summer Time / Brussels time). All applicants who meet these basic requirements will be added to the pool.

If you have any questions about the pool of patient experts, or IMI's patient engagement work in general, don't hesitate to contact us via patients@imi.europa.eu

From the European Patients Forum (EPF) May Newsletter

EUPATI activities going ahead

<http://www.eu-patient.eu/News/News/eupati--activities-for-2020-2025/>

The European Patients' Academy (EUPATI) is about to embark on a new journey. This upcoming phase in 2020 marks exciting new developments for EUPATI run under the auspices of EPF. This Public Private Partnership (PPP) has transformed the knowledge and impact achieved over the past 8 years in order to offer more meaningful patient education and engagement in the future.

A little about Patiëntenfederatie Nederland

<http://www.eu-patient.eu/News/News/introducing-the-netherlands-patient-federation-patientenfederatie-nederland/>

Patiëntenfederatie Nederland represents more than 200 patient organisations across diseases and has recently joined EPF. EPF asked them a few questions that give us an understanding of the priority areas for the organisation:

"shared decision-making is on the agenda of very many healthcare providers; in general patient participation is on the agenda of many stakeholders in the sector. We are proud of our 'tripadvisor' for the healthcare sector (www.zorgkaartnederland.nl) with 700.000 patients' reviews on doctors and healthcare providers.

Patients are well informed and can make validated decisions about which health care provider and which treatment; Shared decision making; Quality of life, quality of care, value-based healthcare; eHealth; and Availability, affordability and accessibility of medicine and medical devices."

IPPOSI News

IPPOSI continues to organise the AGM of the EUPATI National Platform (ENP) Network which this year will take place in Copenhagen on May 20th. This year's meeting of the 20 platforms around Europe, focuses on creating a common message that can be applied to a diverse range of stakeholders; and future sustainability.

FDA Priority List of Patient Preference-Sensitive Areas

<https://www.fda.gov/about-fda/cdrh-patient-engagement/priority-list-patient-preference-sensitive-areas#broad%20...>

Patient preference-sensitive areas may be cross-cutting topics related to approaches of delivering treatment (such as minimally invasive approaches) or related to specific diseases and conditions. This proposed priority list is not an exhaustive list of all patient preference-sensitive areas for medical devices but is intended to provide examples of these areas. These areas may shift over time as more patient preference studies are done and as technology evolves. Feedback is welcome.

Submitted by Anke Peggy Holtorf

FDA to stop hiding millions of adverse event reports on devices

– by ending 'alternative summary reporting'. Written by Christina Jewett for Kaiser Health News May, 2019 https://www.medpagetoday.com/publichealthpolicy/fdageneral/79692?xid=nl_mpt_investigative2019-05-08&eun=g957426dor&utm_source=Sailthru&utm_medium=email&utm_campaign=InvestigateMD_050819&utm_term=NL_Gen_Int_InvestigateMD_Active

A *Kaiser Health News* investigation in March [revealed](#) that the obscure program was vast, collecting 1.1 million reports since 2016. The program, which began about 20 years ago, was so little-known that forensic medical device experts and even a recent FDA commissioner were unaware of its existence.

Former FDA official S. Lori Brown, PhD, MPH, said ending the program now is a "victory for patients and consumers." "The No. 1 job of the FDA -- it shouldn't be 'buyer beware' -- is to have the information available to people so they can have information about the devices they are going to put in their body," Brown said.

...The FDA for years reached agreements with makers of about 100 devices, allowing them to cease public reports of certain types of problems. The agency previously said the agreements and resulting records were available only by filing a Freedom of Information Act request, a process that can take months or even years. Going forward, device makers will be required to file individual reports describing each case of patient harm related to a medical device.

The FDA has not said it will stop allowing device makers to file other types of device-harm exemption reports that are withheld from the public, such as when there is mass litigation over a device or when a company is submitting reports from an independent device-tracking registry. Nor has a plan been announced to open those records, which contain reports of harm related to pelvic mesh and surgical robots and reports of deaths related to several cardiac devices.

The FDA had granted Covidien, now a division of Medtronic, a long-standing "alternative summary reporting" exemption for its surgical staplers, a device used to cut tissues and vessels and quickly seal them during a variety of surgeries. In 2016, when just 84 reports of stapler-related harm were disclosed in the FDA's MAUDE database, almost 10,000 more malfunction reports were sent directly to the FDA's in-house database, the agency acknowledged. The device has been subject to numerous lawsuits over patient deaths and grave harm...

In late March, after *KHN's* investigation landed, the FDA convened another panel to review breast implant-related injuries and a rare form of lymphoma. For that meeting, the agency did provide a full tally of previously unreported injury and malfunction reports related to breast implants...

Kaiser Health News is a national health policy news service. It is an editorially independent program of the [Henry J. Kaiser Family Foundation](#), which is not affiliated with Kaiser Permanente.

Publications

Karen Facey was invited to write a Commentary for the *Journal of Comparative Effectiveness Research*, which will be published shortly. In it she reflects on the value of patient involvement and its enactment as HTA has evolved. Please email Karen if you'd like a full copy of the article.

<https://www.futuremedicine.com/doi/10.2217/cer-2019-0039>

Canfield, C. 2018. The capacity for patient engagement: What patient experiences tell us about what's ahead. *Healthcare Quarterly* 21, 68-72. <http://doi.org/10.12927/hcq.2018.25635>

Marseille E, Kahn JG. Utilitarianism and the ethical foundations of cost-effectiveness analysis in resource allocation for global health. *Philosophy, Ethics, and Humanities in Medicine* 2019 14:5
Efficiency as quantified and promoted by cost-effectiveness analysis sometimes conflicts with equity and other ethical values, such as the "rule of rescue" or rights-based ethical values. We describe the utilitarian foundations of cost-effectiveness analysis and compare it with alternative ethical principles. We find that

while fallible, utilitarianism is usually superior to the alternatives. This is primarily because efficiency – the maximization of health benefits under a budget constraint – is itself an important ethical value. Other ethical frames may be irrelevant, incompatible with each other, or have unacceptable implications. When alternatives to efficiency are considered for precedence, we propose that it is critical to quantify the trade-offs, in particular, the lost health benefits associated with divergence from strict efficiency criteria. Using an example from HIV prevention in a high-prevalence African country, we show that favoring a rights-based decision could result in 92–118 added HIV infections per \$100,000 of spending, compared to one based on cost-effectiveness.

<https://peh-med.biomedcentral.com/articles/10.1186/s13010-019-0074-7>

Submitted by Sharmila Sousa

Sofaer, S. 2018. Using the taxonomy and the metrics: What to study when and why comment on "metrics and evaluation tools for patient engagement in healthcare organization- and system-level decision-making: A systematic review". *International journal of health policy and management*, 8, 51-54.

<http://doi.org/10.15171/ijhpm.2018.99>

Staley, K. & Barron, D. 2019. Learning as an outcome of involvement in research: What are the implications for practice, reporting and evaluation? *Research involvement and engagement*, 5, 14-14.

<http://doi.org/10.1186/s40900-019-0147-1>

Lindskov, M., Colding-Jørgensen, S., Helboe, P., et al. 2019. Danish physicians' views on the appropriateness of the involvement of patients with type 2 diabetes in regulatory decision making: A qualitative study. *Pharmaceutical Medicine*, 33, 99-107. <https://doi.org/10.1007/s40290-019-00275-2>

De Wit, M., Cooper, C., Tugwell, P., et al. 2019. Practical guidance for engaging patients in health research, treatment guidelines and regulatory processes: Results of an expert group meeting organized by the world health organization (who) and the european society for clinical and economic aspects of osteoporosis, osteoarthritis and musculoskeletal diseases (esceo). *Aging Clinical and Experimental Research*,

<http://doi.org/10.1007/s40520-019-01193-8>

Young, K., Kaminstein, D., Olivos, A., et al. 2019. Patient involvement in medical research: What patients and physicians learn from each other. *Orphanet Journal of Rare Diseases*, 14, 21.

<http://doi.org/10.1186/s13023-018-0969-1>

Crocker, J. C., Ricci-Cabello, I., Parker, A., et al. 2018. Impact of patient and public involvement on enrolment and retention in clinical trials: Systematic review and meta-analysis. *BMJ*, 363.

<http://doi.org/10.1136/bmj.k4738>

Janet Wale, HTAi PCIG

E-mail: pcig.htai@gmail.com
