



HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG) E-Bulletin, July 2015

Our vision: *Patient and citizen perspectives improve HTA*

Welcome to this month's E-Bulletin

It is with great pleasure that we welcome Neil Bertelsen as the new Vice-Chair of the Patient and Citizen Involvement in HTA Interest Group. Neil will take over as Chair at the Annual Business Meeting in May 2016.

The Steering Committee has had very helpful discussions about management of potential and perceived conflicts of interest, and received helpful suggestions from the HTA-Regulatory Interactions Interest Group Chair, who is also from industry. We see these as steps to strengthen the PCIG.

The Steering Committee also welcomes Dayane Siviria of Brazil and Ken Bond of Canada to the Steering Committee.

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HTAi was delighted to fund patient representatives to attend HTAi 2015 in Oslo. They added great insight and ideas to all our discussions and they've obviously taken some interesting ideas back home. Eric Low from Myeloma UK used the conference as an opportunity to interview an HTA Agency lead, Jan Jones, Principal Pharmacist at Scottish Medicines Consortium, and reported it in their monthly newsletter:

http://www.myeloma.org.uk/blog/news/principal-pharmacist-at-the-smc-tells-highlights-of-htai-conference/?utm_source=Myeloma+UK+List&utm_campaign=d17f717501-Myeloma_UK_e_newsletter_June_2015&utm_medium=email&utm_term=0_3621c1f66f-d17f717501-342207009

Dr Karen Facey

Evidence Based Health Policy Consultant

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Please note that HTAi 2016 will be in Japan and will be much earlier than usual, 10-14 May 2016, running from Tuesday to Saturday. The deadline for workshops and panels is October 16th.

<http://www.htai.org/meetings/htai-2016-tokyo.html>

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Promoting the development and speeding the approval of new drugs and devices in the US, and a proposed breakthrough pathway for medical devices

PERSPECTIVE: The 21st Century Cures Act — Will It Take Us Back in Time?

Jerry Avorn, M.D., and Aaron S. Kesselheim, M.D., J.D., M.P.H.

N Engl J Med 2015; 372:2473-2475
<http://www.nejm.org/doi/full/10.1056/NEJMp1506964>

And a New York Times opinion piece from 2 US cardiologists on medical device aspects of the Act, which has passed through the House of Representatives
http://www.nytimes.com/2015/07/17/opinion/the-fdas-medical-device-problem.html?smprod=nytcore-ipad&smid=nytcore-ipad-share&_r=1

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Measuring carer/caregiver burden

Karen Facey recently came across this inventory of (informal) caregiver assessment measures – a summary of different PROs for carers. A wide range of measures, with different purposes is presented. The focus is on cognitive diseases, but they could be helpful in other diseases too and this gives a good idea of what's possible.

https://caregiver.org/sites/caregiver.org/files/pdfs/SelCGAssmtMeas_ResInv_FINAL_12.10.12.pdf

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Scottish Medicines Consortium (SMC): – providing feedback on the changes to the SMC process

A video – interviewing patient representatives about their experience after an SMC workshop with them: <https://www.scottishmedicines.org.uk/Home>

The SMC also has the following statement on its website:

“HTAi's vision is that patient and citizen perspectives improve HTA. The HTAi interest sub-group for patient involvement in HTA has developed values and quality standards for patient involvement in HTAs. SMC is committed to achieving the principles laid out by the sub-group.”

https://www.scottishmedicines.org.uk/Public_Involvement/Values_and_quality_standards_for_patient_involvement_in_health_technology_assessment

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Heather Bagley is a patient and public involvement (PPI) co-ordinator working with Professor Paula Williamson at the University of Liverpool UK on the COMET Initiative. Within COMET we have developed an initial PPI strategy which we are taking forward with our COMET People and Patient Participation, Involvement and Engagement (PoPPiE) Working Group. We have also developed a range of resources for researchers who are involving patients in core outcome set studies, including plain language summaries (developed with patients) and videos explaining work in core outcome sets and approaches to involving patients in gaining consensus on core outcome sets. We have been invited to produce a case study for EUPATI.

The PPI strategy can be found here: <http://www.comet-initiative.org/resources/publicinvolvement>. The plain language resources are here: <http://www.comet-initiative.org/resources/PlainLanguageSummary> and the videos are here: <http://www.comet-initiative.org/resources/publicinvolvement>

Via Karen Facey

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The National Institute for Health Research, Evaluations, Trials and Studies Coordinating Centre (NETSCC) has published its new Patient and Public Involvement (PPI) PPI framework for 2015 to 2018.

This is the third version of this comprehensive framework, which seeks to guarantee the involvement of patients, carers and members of the public at all points in NETSCC's research process (from topic identification, selection, prioritisation and through research management and dissemination). It shows the standards required of NETSCC and those required by the research teams that are funded by NETSCC.

Jon Cole (jimec@southampton.ac.uk); Assistant Director, Public Involvement and External Engagement, NETSCC

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EUPATI <http://www.patientsacademy.eu>

The EUPATI project has another 18 months to run, so the tools and resources that will arise out of the expert training course are in full development. In July, the independent selection panel announced the 60 successful applicants to the second cycle of the EUPATI patient expert training course, starting in September. This includes four trainees from Ireland.

The EUPATI National Team in Austria has held its inaugural meeting, marking the start of preparations to launch a National Platform on 2 October. Possibilities for future collaboration with the Austrian Medicines Agency are already on the table. On 16 June, the EUPATI National Team in France launched its National Platform in Paris, and was attended by over 60 patient, academic and industry representatives.

From the IPPOSI Newsletter

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International Society for Quality in Health Care (ISQua) Global Debate: "Health Information Technology is Already Improving Healthcare Safety and Current Regulation Around it is Sufficient"

We have two teams of globally recognised HIT experts with one team supporting the motion and other opposing. All arguments will be published on the ISQua website on the 22nd of July 2015 when the debate will be open for voting.

You are cordially invited to take part in this educational activity by posting your comments and voting for the side of the argument that you support.

The voting will be open until **12th August 2015**.

The outcome of the debate will be announced on the **14th August 2015**.

<http://www.isqua.org/education/activities/debates/live-isqua-debate-2015>

The HTAi President Guy Maddern speaks against the motion.

Provided by Russell McGowan

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AllTrials Campaign: Pharma company investors call for clinical trials transparency

Investors in pharmaceutical companies who together represent over €3.5 trillion in investment assets support AllTrials. This group are now writing to the companies they invest in to ask them to set out plans to ensure their clinical trials, past, present and future, are registered and results reported. AllTrials worked with BNP Paribas Investment Partners to run workshops with investors to develop the steps they are calling on companies to take. Helena Vines Fiestas from BNP

Paribas Investment Partners explains why investors want transparency: "Alongside doctors and their patients, investors also risk being misled ... it is essential that companies publish complete and accurate information on trial results so that investment decisions can be fully informed."

<http://www.alltrials.net/get-involved/>

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Papers of interest

An invitation to contribute a paper for publication in the "**Journal of Rare Disorders: Diagnosis & Therapy**".

You are welcome to submit original research articles, reviews, images, commentaries or case studies which may advance our current knowledge about Medicine. There is no restriction for the length of your manuscript. For manuscript formats and other questions, please visit the journal's website at raredisorders.imedpub.com

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Janet Wale, Chair HTAi PCIG

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I am happy to address any questions you may have as a result of this e-Bulletin, and to forward information