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

Enhanced quality and relevance of HTA through patient and citizen involvement

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

All the Very Best Wishes for 2019 and may some of your Dreams Come True!

Welcome to this E-Bulletin - from our new PCIG Vice-Chair Valentina Strammiello, European Patients Forum:

Happy New Year!

A busy year has come to an end and another one starts with new challenges and exciting activities. We are ready to kick off 2019 with some interesting news. Things are moving ahead in the patient involvement sector and it's good to see how patient communities are driving this change. Take for example the case of the haematological cancers people and what they are doing using the AIDS model of Community Advisory Boards. One of our evergreen recommendations to *HTAers* is to provide feedback to patients and patient groups that contribute to HTA. We are glad to see things are improving.

HTAi Matters

Global Policy Forum
Real-World Evidence in the Context of Health Technology Assessment Processes - From Theory to Action
January 27 - 29, Barcelona, Spain
This invite-only three day event will include a range of key note presentations and case studies on real world evidence (RWE) from industry, not-for-profit organisations (HTA agencies and payers) and patient representatives. Through lots of interaction and discussions we aim to bring added value to the topic of RWE and focus on the main challenges identified by members at the scoping meeting at the HTAi 2018 Annual Meeting in Vancouver. Key messages and action items will be developed for attendees to use. More details will be available to the HTAi membership after the meeting.

HTAi Meeting to be held in Cologne, Germany from Saturday 15 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 for currently available information. http://htai2019.org

Scholarships. The Jill Sanders Memorial Scholarship provides funding for individuals residing in African countries to further their knowledge of HTA. The program objective is to have a positive impact on HTA capacity in African countries. Scholarship support is available for individuals attending or planning to attend an educational institution to undertake a defined program of study directly related to HTA or to individuals participating in an internship program through an HTA agency, Ministry of Health, or relevant Non-Governmental Organization (NGO) on a full-time basis. This scholarship is offered in memory of Dr Jill Sanders, former Vice President of HTAi and President and CEO of the Canadian Agency for Drugs and Technologies in Health.
Deadline: 31 January 2019
https://htai.org/membership/scholarships-and-travel-grants/scholarships/

What's Happening

SMC commitment to ensuring patients' voices are heard in HTA is underlined by rise in submissions
A rise in the number of medicines that are accompanied by a patient group submission has underlined SMC's commitment to ensuring the voice of patients are heard in the health technology assessment (HTA) process. In 2018, 93% (61) of the medicines assessed featured a patient group submission, up from 87% (54) in 2017.
The figures feature in an end of year flash report put together by the SMC Public Involvement team, who support patient groups to take part in SMC's work.
https://www.scottishmedicines.org.uk/media/3976/public-involvement-end-of-year-flash-report-2018.pdf

SMC increases public understanding of HTA decisions by producing new 'Decision Explained' public summaries
SMC communicates their advice on new medicines via the Detailed Advice Documents (DADs) on the website and a press release each month. The DAD is a technical document and the reasons behind the final SMC decision may not always be clear from a public or patient perspective. To increase transparency and public understanding of SMC decisions, SMC has started to produce a 'Decision Explained' factsheet for each SMC appraisal. Developed with guidance from SMC's Public Involvement Network (PIN) Advisory Group [https://www.scottishmedicines.org.uk/about-us/public-involvement/public-involvement-network-advisory-group/], each factsheet provides easy to understand information about each medicine, indication, SMC decision and reason for decision, along with signposting for further information and support. The 'Decision Explained' factsheet is published alongside the full guidance for each medicine and circulated to patient groups with an interest in the medicine. You can see an example here.
https://www.scottishmedicines.org.uk/media/3964/decision-explained-pertuzumabneo-final.pdf

Submitted by Jennifer Dickson

NICE Evidence standards framework for digital health technologies (DHTs)
https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies
To ensure new technologies are clinically effective and offer economic value, these standards set out what good levels of evidence for digital healthcare technologies look like, while meeting the needs of the health

and care system, patients, and users. NICE created these standards as part of a working group led by NHS England.
The Standards are:
Credibility with UK health and social care professionals (tier 1)
Relevance to current care pathways in the UK health and social care system (tier 1)
Acceptability with users (tier 1)
Equalities considerations (tier 1)
Reliable information content (tier 2)
Ongoing data collection to show usage and value of the DHT (tier 2)
Quality and safeguarding (tier 2)
Demonstrating effectiveness (tier 3a and tier 3b, minimum evidence and best practice standards)
Use of appropriate behaviour change techniques (tier 3a)

EPF Congress on 'Advancing *meaningful* patient involvement: A path to effective health systems'
November 12 - 13 - 14, 2019, Crowne Plaza, Place Rogier, Brussels, Belgium
Registrations open from April 2019
https://epfcongress.eu/

IPPOSI Conference on 'Patient-Centred Outcome Measures' Report
IPPOSI is pleased to announce the publication of the Outcome Report arising from the October 8th IPPOSI Conference on 'Patient-Centred Outcome Measures'. The Report, along with videos, presentations & other conference outputs, is now available on the IPPOSI website at the link below.
http://www.ipposi.ie/wp-content/uploads/2018/12/PCOMs-outcome-report-final-v3.pdf

Australian Workshops: Influencing Decisions about Medicines and Healthcare Treatments
Does access to new medical treatments matter to you? Do you want to learn how to give effective input into decisions about funding medicines? Patient Voice Initiative is running workshops in Melbourne, Perth, Brisbane and Hobart in February and March 2019 to help consumers and consumer advocacy groups better understand healthcare decision making. This round of workshops will particularly focus on Australia's system for reimbursement of medicines and treatments (that is what gets funded under the Pharmaceutical Benefits Scheme and Medicare).
In the workshops you will:

- Gain an understanding of the pathways and processes by which medicines and treatments become available in Australia
- Hear from Consumer Representative and Deputy Chair of the Pharmaceutical Benefits Advisory Committee, Jo Watson, about how the committee operates and how consumers can be most influential (note in Perth this will be Consumer Representative Jan Donovan)
- Learn from the experiences of other patients who have been involved in advocating for new medicines
- Find out how to use your knowledge to provide the right information at the right time to make sure decisions about funding new medicines in Australia are better informed
- Network with other groups and patients to gain insights into accessing new medicines and how communities can work together for a stronger voice of patients in healthcare decision making.

To register: https://www.eventbrite.com.au/o/patient-voice-initiative-17869800067

Submitted by Ann Single

Top Ten lessons learned from supporting evidence-informed health systems webinar: EVIPNet Europe
23 January 2019, 12:00 – 1:00 pm ET
EVIPNet Europe was established in 2012 to promote the systematic use of health research evidence in policy-making. Working towards a world in which the best available and context-sensitive evidence is used to inform health policy-making, EVIPNet Europe focuses on capacity-building within its member countries.

Mobilizing the best-available data and research evidence to inform health systems strengthening efforts is an important step towards addressing this challenge. Tanja Kuchenmüller will highlight successes and share some of the big lessons that she and her team have learned since launching EVIPNet Europe.
>> Register now <<
https://mcmaster.webex.com/mw3300/mywebex/default.do?nomenu=true&siteurl=mcmaster&service=6&rnd=0.7908301370353606&main_url=https%3A%2F%2Fmcmaster.webex.com%2Fec3300%2Feventcenter%2Fevent%2FeventAction.do%3FtheAction%3Ddetail%26%26%26EMK%3D4832534b000000043bc96809757aece57f35adc4a09581b277d6719caaa4a9d267e74e5c4723ad25%26siteurl%3Dmcmaster%26confViewID%3D112866969951174218%26encryptTicket%3DSDJTSwAAAASBTTgle_ZIIEwzzXIfV3NZOGTyogaFH8HB3aruA00GuA2%26

From McMaster Health Forum newsletter

Sense about Science on clinicaltrials.gov
The FDA has a plan to start identifying and sanctioning rule breakers [https://www.regulations.gov/document?D=FDA-2018-D-0787-0001], which it opened up for public comment. The FDA received 63 comments and it looks like the vast majority of those came from members of the AllTrials campaign! Thank you to those of you who identified yourselves as patients who want information on medicines to be available, and to the doctors and researchers among you who told the FDA you want to know that the information on the ClinicalTrials.gov register is as complete as it can be. The FDA should now understand that public opinion is that it should start to implement the plan as soon as it can.
Read the comments the FDA received here:
https://www.regulations.gov/docketBrowser?rpp=25&po=0&dct=PS&D=FDA-2018-D-0787&refD=FDA-2018-D-0787-0002
The FDA and the NIH (the US federal funder of clinical trials) were asked by the US Congress to set out what they've done to encourage researchers to comply with the rules and laws on reporting results, and were asked to report to Congress by Thursday 13th December.
www.senseaboutscience.org

Patient Focused Medicines Development webinar on co-creation work plans
In the summer 2018 PFMD opened a public consultation on over 150 PE activities we identified to guide us on the priorities for the next steps in co-creating a truly useful and practical Meta-framework for all stakeholders on their patient engagement journey. The hour-long webinar on December 4th, 2018 showed results of that public consultation and discussed the next steps in the strategy for 2019.
The signup form is closed. If you are still interested and have any queries, please contact the PFMD team at pfmd@thesynergist.org
https://patientfocusedmedicine.org/pfmd-webinar-2018/

A step forward on patient group and industry interactions
The patient advocates will see you now Cancer groups trial the AIDS model for interacting with industry
http://cancerworld.net/wp-content/uploads/2018/11/CW84_patient-voice.pdf

Changing the way they interact with industry in favour of a model developed by the HIV/AIDS community, 11 patient groups invited nine pharmaceutical companies to join in a frank discussion. Termed community advisory boards, advocates chose the topics on the agenda and invited companies to send representatives with the expertise and authority to discuss how both sides can work better together to help achieve shared goals. The first ever haematology community advisory board (Hem-CAB) took place in June 2018, immediately after the European Hematology Association congress and was formally convened by Myeloma Patients Europe. The companies contributed equally to cover the costs of the meeting.
On the agenda were: Increasing patient engagement at all stages of industry research and development; Strengthening the quality of evidence generated by patient organisations, and using it to improve industry

decision-making; and Legal compliance issues that hinder effective collaboration between patient organisations and industry. Hem-CAB was able to successfully create a neutral space, where people can meet and talk about things that matter – about science and policy.

Submitted by Nigel Cook

Publications

Evaluating patient and public involvement in research.
Antoine Boivin, Tessa Richards, Laura Forsythe, Alexandre Grégoire, Audrey L'Espérance, Julia Abelson, Kristin L Carman. BMJ 2018; 363: k5147

If we are serious about involvement, we need to be equally serious about evaluation. Research funders increasingly recommend and require patient and public involvement (PPI) in the design, conduct, and dissemination of health and social care research. In the literature and policy discourse, PPI is justified by two lines of argument: one on the basis of ethical principles, the other on the assumption that it may improve the quality, relevance, and uptake of research. The scientific community holds polarised views on involvement, but all are calling for stronger evidence. Those critical of PPI want more evidence on the costs, benefits, and risks before they undertake anything more than a tick box approach to obtaining grants. For advocates already engaging with patients and the public, evaluation is necessary to understand how best to do PPI and fully reap the benefits of working together. Over the past 10 years, the international literature evaluating PPI has more than tripled. https://www.bmj.com/content/bmj/363/bmj.k5147.full.pdf

Submitted by Sally Wortley - with the spin off discussions around evaluation: "These are exciting times in terms of moving from discussing value, to beginning to assess what value has been achieved":

NASH Online Bulletin Board (OBB) study now published in Advances in Therapy
Available online at https://rdcu.be/bdoVj
OBB is an asynchronous online qualitative market research tool that provides an open forum for interactive discussion among participants. Patients with non-alcoholic steatohepatitis (NASH) were recruited via physician referral and completed a screener questionnaire to ensure their eligibility and willingness to participate. A trained moderator managed the discussion that allowed open answers and responses to other participants' posts over 4 days (16 patients). The patient insights gained can inform early drug development strategies and stakeholder discussions on NASH.
https://rdcu.be/bdoVj

Submitted by Nigel Cook

PPI in clinical trials likely to improve enrolment of participants, especially if it includes people with lived experience of the health condition under study
Joanna C Crocker, Ignacio Ricci-Cabello, Miguel Servet, et al. Impact of patient and public involvement on enrolment and retention in clinical trials: systematic review and meta-analysis. BMJ 2018;363:k4738 . Open access. https://www.bmj.com/content/363/bmj.k4738

Deficiencies in health-related quality-of-life assessment and reporting: a systematic review of oncology randomized phase III trials published between 2012 and 2016
http://bit.ly/2UUPPyD (free full article)
QoL is not included among end points in a relevant proportion of recently published phase III trials in oncology. In addition, QoL results are subject to significant under-reporting and delay in publication.

In total, 446 publications were eligible. In 210 (47.1%), QoL was not included among end points. QoL was not an end point in 40.1% of trials in the advanced/metastatic setting, 39.7% of profit trials and 53.6% of non-profit trials. Out of 231 primary publications of trials with QoL as secondary or exploratory end point, QoL results were available in 143 (61.9%). QoL results were absent in 37.6% of publications in the advanced/metastatic setting, in 37.1% of profit trials and 39.3% of non-profit trials. Proportion of trials not including QoL as end point or with missing QoL results was relevant in all tumor types and for all treatment types. Overall, 70 secondary QoL publications were found: for trials without QoL results in the primary publication, probability of secondary publication was 12.5%, 30.9% and 40.3% at 1, 2 and 3 years, respectively.

Boivin, A. 2018. From craft to reflective art and science; 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.

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