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

Enhanced quality and relevance of HTA through patient and citizen involvement

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

Happy Chinese New Year!

Welcome to this January E-Bulletin

According to Chinese astrology, 2019 is a great year to make money, and a good year to invest. 2019 is going to be full of joy, a year of friendship and love for all the zodiac signs; an auspicious year because the Pig attracts success in all spheres of life. Pay attention to the quality of your relationships with others.

HTAi Matters

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

What's Happening

Rare Diseases Day, 28 February 2019

https://www.rarediseaseday.org/

The theme for Rare Disease Day 2019 is 'Bridging health and social care'. Coordinated by EURORDIS

CADTH new webpages and framework for patient and community engagement

On our new webpages https://www.cadth.ca/patient-and-community-engagement see our Framework for Engagement

https://www.cadth.ca/cadth-framework-patient-engagement-health-technology-assessment

Here, we critically reflect on how we interact with patients and patient groups, and how our current activities align well (and not so well) to the Values and Standards. If you were involved in creating the PCIG's Values and Standards for Patient Involvement in HTA, you will be interested to see them applied at CADTH.

Also see Patient Involvement in Organizational Governance, which uses examples, from across the world, on patient engagement in: process co-design, policy making and governance.
We have resources specific to CADTH, including 'Become Involved' that identifies how patients and other stakeholders can contribute to CADTH's work. And a list of common acronyms that directs readers to the PCIG's HTAi Consumer and Patient Glossary. We'll be promoting the website via CADTH social media and networks in the coming weeks in conjunction with our call for interest in joining our Patient and Community Advisory Committee.

Contact Sarah Berglas (sarahb@cadth.ca) to learn more

US Food and Drug Administration (FDA) framework for evaluating the potential use of real-world evidence
https://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RealWorldEvidence/UCM627769.pdf
Last month, the U.S. Food and Drug Administration (FDA) released its framework for evaluating the potential use of real-world evidence (RWE) to help support the approval of a new indication for a pre-approved medicine and satisfy post-approval study requirements.

The Economist, Intelligence Unit, Healthcare. The Innovation Imperative: The Future of Drug Development 2018
The report is commissioned by PAREXEL
Part I: Research Methods and Findings: a quantitative study around drug development and market access data, quantifying the impact of the most promising innovations on trial efficiency and success in launch and obtaining formulary approval worldwide. It shows that the four innovations evaluated—adaptive trial designs, patient-centric trials, precision medicine trials and real-world data trials—consistently deliver.
Part II: Barriers, Enablers and Calls to Action and investigates the wider landscape through discussions with key opinion leaders to provide an understanding of the barriers to and facilitators of the implementation of innovation.
https://druginnovation.eiu.com/

The global project explored the impact and implementation of the innovations in four key markets: China, the EU, Japan and the US, compared to the rest of the world. The three therapy areas were neurology, oncology and rare diseases.
The data indicate that all four selected innovations—adaptive, patient-centric, precision medicine and real-world data (RWD) trials—improve the chances of drugs being launched.
Looking at specific innovation types, the EU and the US contributed 34% and 38% of patient-centric innovative trials respectively, while China and Japan contributed 5% and 9% of trials respectively. The figures were similar for precision medicine trials: the EU, the US, China and Japan conducted 34%, 38%, 6% and 11% of trials respectively. There were too few RWD and adaptive trials. Drugs developed using the selected innovations were viewed favourably by payers

Patient-centric trials are geared towards involving patients in design and execution, and so designed to improve relevance to patients and to encourage patients to take part in trials.
Precision medicines target known genetic, molecular or cellular markers. They can be tailored to individual characteristics.

Submitted by Nigel Cook

Responding to Stakeholder Input: Finding the Patient Voice in ICER's Value Assessments September 2018
ICER stakeholder engagement process and public comment on draft reports

http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_xcenda_icer_stakeholder_mapping_final_report_2018___003_.pdf

Patient advocates most frequently commented on the adequacy of existing evidence, patient perspective, and transparency
An analysis of ICER reports shows that:

- inputs by patients are less likely to receive a response than inputs from other stakeholders
- only 15.9% of patient inputs find their way into the final report, less than half the rate of the input by other stakeholders

ICER is a private, non-profit organization whose assessments are currently being utilized by both private and public payers in the US.

Submitted by Nigel Cook

https://www.iqvia.com/institute/reports/2018-and-beyond-outlook-and-turning-points

IQVIA Institute for Human Data Science Study: 10 Predictions for Innovation, Spending Drivers and Societal Value of Medicines that Will Transform Global Healthcare in 2018 and Beyond
This new report with latest predictions for the global pharmaceutical market has found that global spending on medicines is set to exceed $1.5 trillion by 2023 – marking a 50% increase within seven years. Global spending on medicines reached $1.2 trillion in 2018, up from $1.1 trillion in 2017 and $1.0 trillion in 2016. Biosimilar competition is also expected to be nearly three times larger than it is today, with the adoption and introduction of biosimilars in Europe expected to continue at a faster pace than in the US until later in the decade. By 2023, eighteen of the current top twenty branded drugs will be facing competition from generics or biosimilars.
Further to these findings, the report data shows that over the next five years, life sciences companies intend to continue to develop and invest in artificial intelligence, machine learning and deep learning programmes leading to breakthroughs impacting the discovery and development of medicines. Mobile apps to provide prescription digital therapeutics (DTx) are a new emerging treatment modality with indications and disease-specific treatment effectiveness claims in their prescribing labels.
http://www.pharmatimes.com/news/report_says_global_medicine_spend_set_toexceed_$1.5_trillion_by_2023_1276470?utm_source=Virdis+Newsletter&utm_medium=email&utm_campaign=virdis+news+alert

Clinical Trial reporting in the UK
https://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/news-parliament-2017/clinical-trials-letters-chairs-comments-17-19/

The UK Parliament has announced it is going to be monitoring UK universities' clinical trial reporting. The House of Commons Science and Technology Committee asked AllTrials to produce a list of all the UK universities that run clinical trials and has put these institutions on notice that if it doesn't see an improvement in their reporting rates, the head of the university will be called before the Committee to explain why not. In six months' time AllTrials will advise the Committee on which universities have made progress in reporting trials and which have not, using its trial tracking tools.
www.alltrials.net

23andMe Granted FDA Authorization for Direct-to-Consumer Pharmacogenetic Reports
https://mediacenter.23andme.com/press-releases/23andme-granted-the-first-and-only-fda-authorization-for-direct-to-consumer-pharmacogenetic-reports/

This is the first authorization of a direct-to-consumer report on pharmacogenetics, and came through the FDA's de novo classification process. The FDA has classified these direct-to-consumer pharmacogenetic reports as moderate risk with special controls to ensure safety, effectiveness and accuracy. The authorization enables 23andMe to report on numerous variants associated with pharmacogenetic response.
"We've continued to innovate through the FDA and pioneer safe, effective pathways for consumers to directly access genetic health information," said 23andMe co-founder and CEO Anne Wojcicki.
Studies showed that more than 97 percent of users understood that they should not use the report to make any changes to treatment without consulting their doctor.
This latest FDA authorization follows several years of work by 23andMe that has led to four separate FDA de novo authorizations for direct-to-consumer genetic tests for carrier status, genetic health risk reports, select BRCA1 and BRCA2 variants and now pharmacogenetic reports.

Free course on partnering with patients in medical research
https://lagunita.stanford.edu/courses/course-v1:Medicine+MedxPPStrategy+Winter2019/about
This is our first free course aimed at those interested in partnering with patients in medical research or patients interested in partnering with clinicians etc. WE have patients, clinicians, researchers all sharing so we can learn from each other! New year new goals: earn a Statement of Accomplishment in Partnering with the Public and Patients in Medical Research from Stanford Medicine X. Our no-cost online course starts Feb 15, 2019. This course has been partially funded through a Patient Centered Outcomes Research Institute (PCORI) Engagement Award Initiative.

Submitted by Catherine Voutier

Publications

Mandeville KL, Barker R, Packham A, Sowerby C, Yarrow K, Patrick H. Financial interests of patient organisations contributing to Technology assessment at England's National Institute for Health and Care Excellence: policy review. BMJ 2019; 364 doi: https://doi.org/10.1136/bmj.k5300
https://www.bmj.com/content/364/bmj.k5300

Finn Børlum Kristensen, Don Husereau, Mirjana Huić, Michael Drummond, Marc L. Berger, Kenneth Bond, Federico Augustovski, Andrew Booth, John F.P. Bridges, Jeremy Grimshaw, Maarten J. IJzerman, Egon Jonsson, Daniel A. Ollendorf, Alric Rüther, Uwe Siebert, Jitendar Sharma, Allan Wailoo
Identifying the Need for Good Practices in Health Technology Assessment: Summary of the ISPOR HTA Council Working Group Report on Good Practices in HTA. Value in Health January 2019;22(1):13-20.
https://www.valueinhealthjournal.com/article/S1098-3015(18)36144-8/fulltext

Roy M, Ganache I, Dagenais P. Advocating for a better engagement of patients, users, caregivers, and citizens in healthcare and social services technology assessment (HSTA)
Commentary on "Assess, triangulate, converge, and recommend (ATCR): A process for developing recommendations for practice in the social sector using scientific, contextual and experiential data".
International Journal of Hospital Based Health Technology Assessment 2018, 15-18.
https://doi.org/10.21965/IJHBHTA.2018.002

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