HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG) E-Bulletin, December 2016

Enhanced quality and relevance of HTA through patient and citizen involvement

Welcome to this month's E-Bulletin – and greetings to the new year, 2017!

HTAi Annual Meeting 2017: Explore how the global HTA community is evolving towards an integrated ecosystem – from local needs to global opportunities

Join us for HTAi's 14th Annual Meeting June 17-21, 2017 at the Ergife Palace Hotel in Rome, Italy.

Deadlines
Abstract Submissions
Workshops & Panels, Closed
Posters & Oral Presentations, January 16, 2017
Travel Grants: Application, January 16, 2017
Registration: Early Bird, March 3, 2017

Poster and Oral presentation abstract submissions:
http://meeting.htai.org/events/htai-rome-2017/event-summary-1c2301d261504d679c3b63c233b5033a.aspx

Travel grant details are at:
http://meeting.htai.org/events/htai-rome-2017/custom-115-1c2301d261504d679c3b63c233b5033a.aspx

A little about the PCIG

The Patient and Citizen Involvement in HTA Interest Group (PCIG) was established in 2005. Its overarching aim is to enhance the quality and relevance of HTA through patient and citizen involvement.
PCIG objectives are to: either promote or develop robust methodologies to incorporate patient perspectives in HTA, and share good practices in patient and public involvement in HTA processes; strengthen HTA by systematic incorporation of patient perspectives; support countries with limited experience with HTA and incorporating patient and citizen perspectives; and demonstrate the value and impact of patient and public engagement in HTA.

The PCIG operates with a Steering Committee, Patient Panel, and three Working Groups: Methods and Impact Working Group, Patient Involvement and Education Working Group, and Citizen and Community Working Group. Each Working Group has co-leads and a coordinator.
http://www.htai.org/interest-groups/patient-and-citizen-involvement/pcig-home/governance.html

A call for Expressions of Interest to be the next PIE Coordinator!

Ann Single (Australia) has been the coordinator of PIE from the very beginning. She has been instrumental in making sure the Working Group is well organised and productive. PIE has, with her guiding hand, been able to build on the resources available on our website (http://www.htai.org/interest-groups/patient-and-citizen-involvement/resources/for-patients-and-patient-groups.html). We thank Ann for all her hard work and expertise over the years, always positive in her thinking, caring and thoughtful. Our co-leads are: Lizzie Thomas (NICE patient and public involvement), Jen Dickson (SMC patient and public involvement), and Janney Wale (patient advocate). We have four teleconferences a year, contribute to plans for the HTAi Annual Meeting, October face-to-face meeting, and development of resources. Our present undertaking is to map the internet resources available to inform and support patients providing input into HTA processes. This work is done in a voluntary capacity.

If this is something you would be interested in doing, please contact us (through Janney Wale, socrates111@bigpond.com).

Review of SMC, December 2016

An independent Review of Access to New Medicines and specifically of the impact of the new approach introduced by the Scottish Medicines Consortium (SMC) in 2014 with the aim of increasing access to end-of-life, orphan and ultra-orphan medicines. http://www.gov.scot/Resource/0051/00511595.pdf

Proposed changes to improve patient and public involvement at NICE

The National Institute for Health and Care Excellence (NICE) has launched a set of new proposals to improve how it involves patients and the public in its work. The proposals include:

- Standardising how NICE engages with and involves lay people across its guidance and standards programmes.
- Involving people earlier and keeping them involved throughout the development process.
- Being clearer on how NICE finds and takes account of information about people's experiences of care, and their experiences of their condition and its treatment.
- Recruiting a broad pool of people (including people with knowledge and experience of specific conditions or services) who can be drawn on as needed to join decision-making bodies.
- Introducing a formal feedback process so that people who help develop NICE guidance and standards are aware of the impact of their contribution.
- Making better use of social media to communicate with people about NICE's guidance and standards, and to make it easier for them to communicate with NICE.
- Reinforcing the message among NICE staff that involving people is everyone's responsibility.

NICE is keen to hear what people think of the proposals so they are running a public consultation until **28 February 2017**. You can comment on the proposals via a survey link or you can send a comments form back to NICE, details of how to do both are on the consultation page. NICE has also written a blog explaining more how these proposals were developed. NICE would be very grateful for your views so please comment if you can.

Bringing patient perspectives to NICE: Help us to help you become a key voice, 17 January 2017, Central London

https://medicinesevents.nice.org.uk/npc/frontend/reg/thome.csp?pageID=83938&eventID=263&traceRedir=2&eventID=263

If you are a patient, representative of a patient organisation or a patient lead in the industry or in the public sector, we would like to invite you to a day of talks, networking and interactive sessions to learn about Scientific Advice at NICE and the role of patients. Explore how patient organisations can proactively work with NICE, the industry, and regulatory agencies. Learn how patients help shape product development programmes and what learning and support activities are available.
This event may also be of interest to consultancy companies who are working to accommodate the patient voice.

- Learn how to get the most out of involvement at NICE – we aim to dispel myths and misconceptions about our goals, processes and patient engagement
- Hear from patients and patient organisations about their experiences of being involved in regulatory and health technology assessment
- Take part in an interactive mock NICE appraisal
- Engage with experts from NICE, including patient experts and regulatory experts in a Q&A session
- Help us make healthcare product development processes and evaluation patient-centric – how can we better serve your needs?

Start time: Registration opens at 9:00 with the event starting at 9:30. See the full programme
This event will take place in The Royal College of Gynaecology and Obstetrics, Regent's Park

FREE for patients and patient groups with a nominal charge of £100 per person for private and public sector attendees.
Attendance requires an online registration
Capacity is limited so please book early!
Any questions? Email our team adviceseminars@nice.org.uk

Twitter feed from NICEScientificAdvice @NICESciAdvice

https://twitter.com/NICESciAdvice?t=1&cn=ZmxleGlibGVfcmVjc18y&refsrc=email&iid=1654c972df344f10a3e929e20d7c6fdd&uid=2608720200&nid=244+276959245

Do you want to take part in a mock NICE appraisal & learn how to input as #patients? Register 4 our #patients event!
http://goo.gl/GG2LVf
Find out what makes a good submission to NICE - Meindert Boysen from Tech Appraisals will be speaking at #NICEConf17
http://bit.ly/2gBE3Yq

CADTH symposium April 2017: Measuring value in theory and the real world

https://www.cadth.ca/events/2017-cadth-symposium

April 23, 2017 - April 25, 2017
Location: Shaw Centre, Ottawa, ON
The 2017 CADTH Symposium will feature another outstanding roster of Canadian and international experts, thought-provoking plenary sessions, educational workshops, and insightful panel, oral, and poster presentations. We're coming back to Ottawa so you can also enjoy the history and pageantry of the year-long celebration of Canada's 150th anniversary.

Tributes paid to Eric Low OBE as he announces his departure from Myeloma UK after 20 years of service

https://www.myeloma.org.uk/blog/news/myeloma-uk-announces-chief-executive-eric-low-to-stand-down/?utm_source=Myeloma+UK+Communications&utm_campaign=c73d8c6675-Myeloma_UK_Newsletter_December_2016&utm_medium=email&utm_term=0_3621c1f66f-c73d8c6675-342207009
Eric is a member of the Methods and Impact Working Group and our Patient Panel.

Submitted by Karen Facey

Rare Diseases

The Genetic Alliance UK has published a feasibility study of the Hidden Costs of Rare Diseases, for patients suffering from rare diseases in the UK. https://www.geneticalliance.org.uk/media/2502/hidden-costs-full-report_21916-v2-1.pdf

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European Patients Forum (EPF) involvement in the European Medicines Agency

For more than 8 years now, EPF has been an active participant in the Patients and Consumers Working Party (PCWP) of the European Medicines Agency. 2016 was no exception, culminating with the election of EPF as the co-chair of the Working Party.
EPF was represented at two workshops in March The first was on information to patients, where the audience got the opportunity to get acquainted with the results of recent surveys from the EMA and to participate in interactive group sessions exploring the challenges and opportunities for providers of information, be it institutional or peer support groups. The second workshop focused on health literacy, and its impact on risk communication.
Later in 2016, EPF took part in the celebrations of the 10th anniversary of the PCWP, underlining the involvement of the Agency towards patient involvement.
In September, EPF was represented at a workshop on social media, reflecting on the impact of the digital media and communication tools on medicines-related behaviours. Participants got the opportunity to debate the ever growing influence of social media on patients and their behaviour vis-à-vis medicines and treatment.
We were delighted to see Kaisa Immonen, our Director of Policy being elected as the new co-chair of the PCWP in its end-of-year meeting in November! Kaisa will co-chair the PCWP for the next three years, together with Isabelle Moulon, Head of the Public Engagement Department at EMA.

Adapt Smart

Valentina Strammiello of EPF is involved in the IMI project Adapt Smart. This is an enabling platform for the coordination of Medicines Adaptive Pathways to Patients (MAPPs) activities. MAPPs seeks to foster access to beneficial treatments for the right patient groups at the earliest appropriate time in the product life-span in a sustainable fashion.
http://adaptsmart.eu/

EUPATI Interview with Karen Facey, and other key people

A video from EUPATI, and the links down the side feed into all the other EUPATI videos from a range of stakeholders.
https://vimeo.com/195271228

Some 250 delegates attended the EUPATI 2016 Conference to explore the contribution EUPATI has made to patient education, as well as to learn about its plans for the future and the continuation of its work at the European and national level. A live streaming of the event can be found here.

Consultation on HTA in Europe

The European Commission public consultation on how to strengthen EU cooperation on Health Technology Assessment (HTA) closes 13 January 2016. http://ec.europa.eu/health/technology_assessment/consultations/cooperation_hta_en
The survey for citizens is at: https://ec.europa.eu/eusurvey/runner/citizens#

'Patients' Voice' EU Project

Patient Rights in northern part of Cyprus and the story of UPRA, a pioneering organisation
Universal Patient Rights Association (UPRA) was founded in 2002 in northern part of Cyprus in order to raise awareness about patients' rights, advocate for enactment of the EU Charter of Patients' Rights in the country. Our organisation is directly supported by North Cyprus Thalassemia Association, Association for Persons with Orthopaedic Disability and Help Those with Cancer. These CSOs are three of most prominent health organisations within the Turkish Cypriot Community.
When UPRA was founded there was no specific law, legislation or charter for the protection of patients' rights in North Cyprus and unfortunately the situation remains the same, as the draft law prepared by UPRA and which was submitted by the Health Administration in 2008 became obsolete with changing governments. Read more

On 7-10 November 2016, a Cypriot delegation of 10 people was hosted in Italy by Active Citizenship Network for a study visit in the framework of the EU project "Patients' Voice". The trip was meant to give them a practical insight on protection of patients' rights, advocacy techniques and strategies and policy building. The 4-day visit included classes and meetings with several representatives of Italian associations with an expertise in the health field. The tours in local hospitals and exchange of views with health professionals and medical directors were also of great interest and appreciated. To learn more:
Read the programme and download the presentations

Active Citizenship Network (ACN) Newsletter n. 44

Taiwan-based Alliance of Patient Organizations (TAPO) celebrates the end of an active year

In 2016, after nearly a year of discussion, a number of patient groups formed an alliance with the International Alliance of Patients' Organizations (IAPO) to form a Taiwan-based Alliance of Patient Organizations (TAPO). This is expected to help groups of patients seek equal access to the healthcare system in Taiwan through the power of the group.
TAPO was officially launched in July. Invited scholars and experts from the development of disease explored international trends, as well as in Taiwan, in human rights, medical care, drugs, and the participation of patients. We look forward to working together with medical and patient care through discussion and patient cohesion.
It has been busy with a series of workshops and consultations, including an international round table meeting with other country experts: We want to participate in health policy, decision making, collecting evidence but lack experience. Therefore, we hoped the experts from Hong Kong and Australia could give us some know how
Future expectations :
◎TAPO will stand together with National Health Insurance Administration (NHIA) and Taiwan Health Reform Foundation (THRF). We will guard the next generation national health insurance.
◎TAPO will invite experts and scholars to train a group of patients with experts. We'll cultivate a group of patient experts.
◎We hope patient groups could attend to the Taiwan HTA committee and maintain Taiwanese healthcare.

Kevin Yeh

The U.S. Food and Drug Administration - CDRH Patient Engagement

http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHPatientEngagement/default.htm

The Center for Devices and Radiological Health (CDRH) is committed to including the views of patients during the medical device development process and considering patient perspectives in our regulatory decision-making. To better understand their needs, CDRH engages patients throughout our regulatory process. Patients are interested in contributing their views, data, and resources to increase early access to high quality safe and effective medical devices, reduce adverse events, and improve communication about the risks and benefits that matter most to them.
Part of our public health mission is to help patients be more aware of the health care options available to them. Alongside industry, patient groups, and other government agencies, we are actively engaging individual patients to help them understand how a disease or condition impacts their daily lives and their caregiver's lives, and the types of treatment benefits and risks that matter the most to them.

For the first time in the FDA's history, we are establishing an advisory committee focused on patient engagement. The Patient Engagement Advisory Committee will provide advice on complex issues relating to medical devices, the regulation of devices, and their use by patients to the FDA Commissioner.
CDRH encourages nominations that include patients that represent the full spectrum of demographics (including women and men and members of all racial, age, and ethnic groups), of disease severity and chronicity, and of degree of disability (e.g., patients both with and without disabilities) to serve on the committee. Rather than focusing on a product or specific disease, the PEAC will be asked to weigh in on a variety of important patient-related issues. PEAC will include patients knowledgeable in areas such as clinical research, primary case patient experience, healthcare needs of patients, how to elicit patient preferences, and strategies for communicating benefits, risks, and clinical outcomes to patients. See the *Advisory Committee* to learn more.

Together with other centers and offices across the FDA, we are testing and developing other ways to engage patients and capture their views through public workshops. CDRH hosted a Patient Preference Initiative Workshop and participated in Patient-Focused Drug Development: Disease Area Meetings Planned for Fiscal Years 2013-2017.
CDER's patient-focused drug development meetings can help inform the FDA staff as they conduct benefit-risk assessments for products under review and advise drug sponsors on their drug development programs.
In addition, CDRH is a member of the Medical Device Innovation Consortium (MDIC), a non-profit public-private partnership including National Institutes of Health, Centers for Medicare & Medicaid Services, Patient Centered Outcomes Research Institute (PCORI), medical device companies and trade associations, patient groups and other non-profit organizations. In 2015, MDIC developed a framework for incorporating patient preferences into the device development and assessment process that can be used to develop, design, and market devices that meet the needs of patients. Partner with Patients is one of CDRH's 2016-2017 Strategic Priorities.
For more information about CDRH's commitment to patient engagement, visit CDRH's Patient Engagement webpage.

Input to Help Patients Make Informed Decisions about Healthcare Options

Avalere and *FasterCures* recently released a draft Patient-Perspective Value Framework (PPVF) designed to guide the assessment of the value of different healthcare options (i.e., drugs, devices, diagnostics, and other interventions) from the patient's perspective and in a patient-centered way. The draft PPVF is designed to be a standalone value framework that can be used to develop a number of applications, including a shared decision-making platform for patients and clinicians. The draft PPVF was developed with guidance from a multi-stakeholder Steering Committee, and includes a set of preliminary domains, criteria, measures, and methodology. Input on the draft closed December 30, 2016.

AllTrials – review of 2016 plus 2017 plans

This year we published our roadmap to transparency showing how and where to bring pressure for change across the globe – something many of our supporters have been asking for. The absence of trial information on many drugs we use and prescribe today is a shocking story that many have yet to hear. I went to Madrid to give a TEDx talk about AllTrials and was mobbed for three hours by European press and organisations who want to take it up.
We have just completed a major benchmark of pharmaceutical companies on their trial registration and reporting policies which is now awaiting publication. It took longer than we'd have liked but it has been worth it. It took a massive collaboration with companies to do it right and make sure it's watertight. Many of the companies worked openly and constructively with us. We have finished the benchmark and have submitted it to a peer-reviewed journal for publication; we hope to be able to share it with you all very soon.
The goal has to be to build the social pressure to get past trials published - the hardest goal of this campaign because it is less susceptible to regulation. New tools like OpenTrials and TrialsTracker which are being tested now make it easier to identify specific trials which have never published results, so that's what we're going to do in 2017.
This year the UN added its voice saying that all governments should bring in laws mandating that trials in their country are registered and results reported and organisations continue to join, especially in the US. The future of clinical trial reporting is going to be different.

Síle Lane & Ben Goldacre
AllTrials Campaign alltrials@senseaboutscience.org

Should Money Come into It? A Tool for Deciding Whether to Pay Patient- Engagement Participants

The Change Foundation, Ontario Canada's independent health policy think tank that engages the voices of patients, caregivers and providers to explore health care issues and evolve our system

Should patient and family-caregiver participants be paid? It's a growing question as patient engagement activities become more common. The Foundation has designed an easy-to-use tool, to help us decide on a case-by-case basis. We now offer this tool to other organizations. You are free to adopt it as is, adapt it for your needs, or use it as a springboard to discussion. In this brief, straightforward paper, you will also find pros, cons and expert opinions on the philosophical and practical issues involved. A note about process: We developed the decision tool with input from our own key patient engagement group, the PANORAMA panel.
http://www.changefoundation.ca/patient-compensation-report/

Relevant literature

Metasynthetic Madness: What Kind of Monster Have We Created? By Sally Thorne

From its origins in the 1990s, the qualitative health research metasynthesis project represented a methodological maneuver to capitalize on a growing investment in qualitatively derived study reports to create an interactive dialogue among them that would surface expanded insights about complex human phenomena. However, newer forms positioning themselves as

qualitative metasynthesis but representing a much more technical and theoretically superficial form of scholarly enterprise have begun to appear in the health research literature. It seems imperative that we think through the implications of this trend and determine whether it is to be afforded the credibility of being a form of qualitative scholarship and, if so, what kind of scholarship it represents. As the standardization trend in synthesis research marches forward, we will need clarity and a strong sense of purpose if we are to preserve the essence of what the qualitative metasynthesis project was intended to be all about.

Qualitative Health Research 2017, Vol. 27(1) 3–12. A Commentary
http://journals.sagepub.com/doi/pdf/10.1177/1049732316679370

Ontario's Health System: Key Insights

Ever wondered how the Ontario health system works? You can find answers in a book recently published by the McMaster Health Forum, entitled 'Ontario's Health System: Key Insights for Engaged Citizens, Professionals and Policymakers.'
The goal of this book is to help make the system more understandable to the citizens who pay for it and are served by it, the professionals who work in it (and future professionals who will one day work in it), and the policymakers who govern it. Each chapter begins with key messages for each of these groups.
The full book will soon be available for purchase on Amazon.ca (and is now available for individuals outside of Canada on Amazon.com). If you are interested in particular topics (e.g., how money flows or how the primary care sector functions), McMaster University is making individual book chapters freely available on the McMaster Health Forum website.
Here are some additional details about the book:

- Part 1 describes the 'building blocks' of the system, including who gets to make what decisions (governance arrangements), how money flows through the system (financial arrangements), and what and who make up the system's infrastructure and workforce (delivery arrangements).
- Part 2 explains how the building blocks are used to provide: 1) care in each of six sectors – home and community care, primary care, specialty care, rehabilitation care, long-term care, and public health; 2) care for four conditions or groupings of conditions – mental health and addictions, work-related injuries and diseases, cancer, and end-of-life; 3) care using select treatments – prescription and over-the-counter drugs, complementary and alternative therapies, and dental services; and 4) care for Indigenous peoples.
- Part 3 describes recent and planned reforms to the system and assesses how the health system is performing.

From McMaster Health Forum: Update

Bulletin du Labo du partenariat / Partnership Lab Bulletin

L'équipe du **Labo du partenariat** du **Centre d'excellence sur le partenariat avec les patients et le public** (CEPPP) vous souhaite un joyeux Temps des Fêtes! Voici quelques lectures pour agrémenter vos vacances.
The team from the **Partnership Lab** of the **Centre of Excellence on Partnership with Patients and the Public** (CEPPP) wants to wish you Happy Holidays! Here are some readings for this Holiday Season!

Engagement en recherche / Engagement in research

Using a co-production prioritization exercise involving South Asian children, young people and their families to identify health priorities requiring further research and public awareness (Accès libre/Open access)
Manikam et al (2016) Health Expectations

Involvement of persons with lived experience of a prenatal diagnosis of congenital heart defect: an explorative study to gain insights into perspectives on future research (Accès libre/Open access)
Carlsson et al. (2016) Research Involvement and Engagement

Patients' motivations and interest in research: characteristics of volunteers for patient-led projects on PatientsLikeMe (Accès libre/Open access)
Bradley et al. (2016) Research Involvement and Engagement

Patient and public involvement in Paediatric Intensive Care research: Considerations, challenges and facilitating factors (Accès libre/Open access)
Menzies et al. (2016) Research Involvement and Engagement

Engaging patient representatives in the identification and prioritization of Health Technology Assessment topics (Accès libre/Open access)
Gagnon et al. (2016) International Journal of Hospital-Based Health Technology Assessment

Evaluating community engagement in research: Quantitative measure development
Goodman et al. (2017) Journal of Community Psychology

Is knowledge translation without patient or community engagement flawed?

Ramsden et al. (2016) Family Practice

Recommendations for the Involvement of Patient Research Partners (PRP) in OMERACT Working Groups. A Report from the OMERACT 2014 Working Group on PRP
Cheung et al. (2016) Journal of Rheumatology

Engagement dans la transformation des systèmes de santé / Engagement in health-system transformation
The power of symbolic capital in patient and public involvement in health research (Accès libre/Open access)
Locock et al. (2016) Health Expectations

Envisioning mechanisms for success: Evaluation of EBCD at CHEO (Accès libre/Open access)
Rhode et al. (2016) Patient Experience Journal

Engaging active citizen participation in the co-creation of an educational and information campaign to support older people to be empowered against abuse: Key learnings for integrative care (Accès libre/Open access)
O'Donnell et al. (2016) International Journal of Integrated Care

Promoting citizen participation in health in the Basque Country (Accès libre/Open access)
Viñegra et al. (2016) International Journal of Integrated Care

Engagement en santé des communauté / Engagement in community health
Community engagement: Behavioral strategies to enhance the quality of participatory partnerships
Matthew (2016) Journal of Community Psychology

Engagement en enseignement / Engagement in teaching
Accredited training for user involvement in higher education teaching – Exploring an innovative training programme in public involvement and partnership working (Accès libre/Open access)
Jørgensen et al. (2016) Journal of Practice-based Learning in Health and Social Care

Rural clinical education through the lens of community engagement
Berry et al. (2016) Collaborating in Healthcare

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