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

Enhanced quality and relevance of HTA through patient and citizen involvement

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

Welcome to the April E-Bulletin

Funding call to support patient and patient representative attendance at HTAi 2019 Annual Meeting
Thanks to those who have already responded to this call!
As we approach the HTAi 2019 Annual Meeting in Köln, we are looking to be able to support more patients and patient leaders/representatives to attend the congress. To make this happen, we are issuing the following funding call to support travel and accommodation for patients and patient representatives to attend. This is independent of the HTAi Travel Grant process. For those of you who may be able to help, can I ask that you reach out to myself, Valentina and Todd.

Neil Bertelsen (Chair)
Valentina Strammiello (Vice Chair)
Todd Stephenson (Steering Committee Member responsible for funding)

Access to references from previous issues of the E-Bulletin
Thanks to Sam Thomas of PCIG Patient Involvement and Education Working Group, you can readily access these through an additional link under the E-Bulletins header on our Resources page
https://htai.org/interest-groups/pcig/resources/

HTAi Matters

HTAi Meeting to be held 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.

HTA Beyond 2020: Ready For The New Decade?'
Regular: March 23 – June 9, 2019
Onsite: June 15 – 19, 2019
Visit the HTAi 2019 website for currently available information and for registration.
Registration inquiries: registration@htai.org

The HTAi PCIG is excited to have many panels and a pre-conference workshop in Cologne. We are working together with HAS and IQWIG to show a short documentary "Measure of Time" by Benjamin Sylvestre on the experiences of renal dialysis patients immediately after the workshop on the Saturday 15 June.

https://www.htai2019.org/

What's Happening

NICE 2019. 9 May, Manchester: Transforming Care
http://www.niceconference.org.uk/agenda

Around the Globe
Angela Coulter: What we can learn from public involvement at NICE. April 1, 2019
https://blogs.bmj.com/bmj/2019/04/01/angela-coulter-what-we-can-learn-from-public-involvement-at-nice/

NICE celebrates its twentieth birthday today [1 April] and it has much to celebrate. Despite an ever-widening remit and a budget squeeze, it has managed to avoid the turbulence experienced by other UK arms-length bodies, gaining international respect for the robustness of its procedures and recommendations. In the past year alone NICE has produced 288 pieces of evidence-based guidance, including clinical guidelines, technology assessments, quality standards, social care guides, medicines awareness bulletins, technology briefings, and so on. An important factor in its success has been its ability to attract and make good use of contributions from patients and public.
Involvement of people who use services, carers, or members of the public is core business for NICE, embodied in its charter and principles. Each of the plethora of independent committees responsible for developing NICE guidance includes a minimum of two lay members. Since 2010 no less than 1,265 patients, carers and members of the public have contributed to the development of NICE guidance, working alongside professional and topic experts as equal partners. Most find this a fascinating and enjoyable experience and there's no shortage of people wanting to join. Advertisements for lay committee members attract 6 – 7 applicants for each vacancy.
Evidence on people's experience of using services forms part of the discussion in guidance committees, and special steps are taken to obtain the views of particular groups, for example people with learning difficulties, or children and young people. Meanwhile wider public involvement is achieved by inviting voluntary and community organisations to comment on the scope of guidelines or draft recommendations, to help disseminate and implement recommendations, or to use evidence summaries when making decisions about their own care. And any member of the public can choose to attend NICE's public meetings, including board meetings, committees and appeals.
These activities are supported by 16 staff who work in the Public Involvement Programme (PIP) at NICE. They are responsible for organising recruitment to committees, for inducting and training lay members, and providing them with support and financial compensation. PIP staff also support the stakeholder engagement process and organise training in the principles and practice of public involvement for NICE staff and committee chairs, continually reviewing and improving procedures to identify and remove any obstacles.
Much of the work carried out by NICE and its various committees is highly technical and sometimes controversial. Guidance committees represent a broad spectrum of knowledge and interests. It can be challenging to get to grips with the range and nature of the evidence that must be considered before agreeing on recommendations. The chair's role is fundamental to the success or otherwise of the equal partnership between lay and professional members that NICE aspires to. NICE has recently adopted a policy of appointing non-expert chairs, people who do not have specialist knowledge of the topic under consideration. Many chairs have a medical or professional background, but in a recent development some committees now have lay chairs. The chair's job is to ensure that committee members work well together, abide by NICE policies and processes, and see that everyone contributes and respects other points of view. Building agreement on what should be provided by a public service is never easy and there have certainly been times when individual contributors, both lay and professional, have felt their views weren't given

sufficient weight, but NICE committees are remarkable in that they usually do manage to achieve a consensus. The keys to successful public involvement in this work lie in recruitment of enthusiastic and committed individuals who believe in the value of the task they are asked to perform, effective leadership from skilled chairs, strong support from NICE staff, well-developed procedures set out in manuals for all to read, and a commitment to openness, transparency and contestability through the appeals process.
Other lessons we can take from NICE's long experience of supporting public involvement include the need for creative approaches to recruit a diversity of contributors, being aware of the special needs of those with illnesses and disabilities including access arrangements, the importance of securing involvement at all stages of the guidance development process, and the value of good communications and feedback to keep people informed and engaged. NICE has amassed valuable experience on what it takes to do public involvement well. There is much that other public bodies can gain from their experience.
Angela Coulter is a non-executive director of NICE and a member of the BMJ's patient panel.

Submitted by Heidi Livingstone

Patient, carer and public voices to be heard by Health Technology Wales
Patients, carers and members of the public will have their voices heard as we work to improve the quality of care in Wales.
We've now established our Patient and Public Involvement (PPI) Standing Group, which will be influential in supporting a national approach to the identification, appraisal and adoption of non-medicine health technologies.
There are a wide range of health technologies in our remit, which can include; medical devices, surgical procedures, psychological therapies, tele-monitoring and models of care.
The Standing Group is chaired by Claire Davis, Health Services Researcher and PPI Lead. She said:
"Involving patients, carers and members of the public in our work is an important part of producing Guidance for health and social care commissioners.
"It's essential to incorporate the perspectives of both patients and the public, as well as those who have a professional role in health and care systems. We're looking forward to enabling everyone to have a voice in our work to ensure an all-Wales approach to non-medicine health technologies."
Members of the PPI Standing Group were recruited at the start of 2019. The group held its inaugural meeting on 3 April 2019 and will meet four times a year. Its purpose is to provide advice and strengthen relationships with patient and carer organisations, and ultimately to ensure that the views of patients, carers and members of the public are effectively used to inform our decision making process. They will assist us to continuously improve PPI throughout our work, ensuring that patient and public perspectives are fairly represented.
The PPI Standing Group consists of the newly recruited Public Partners who sit on the Assessment Group and Appraisal Panel, as well as PPI representatives and advisors from Wales and beyond, umbrella patient organisation representatives and the Health Technology Wales' PPI Lead.
Members of the PPI Standing Group will help gather and present the views of patients, carers and the public. You may also see them representing us at external events, such as conferences and training events. Members will help raise awareness of opportunities to get involved and will provide support accordingly.
Anyone can suggest a topic for us to consider and topics are welcomed from patients, carers and members of the public. Click here to complete our online form. You can also click here to learn more about Health Technology Wales.

Dr Claire Davis
Health Services Researcher

Australia
In 2019 a designated "Unit" to allow the development of structured projects of engagement with consumer and patient groups was established within the Department of Health. The HTA Consumer Evidence and

Engagement Unit is led by Dr Sally Wortley as the inaugural "Lead" to provide expert coordination and development to this work.
This work, in partnership with the Department of Health, will focus on expanding opportunities for consumers and patients to be central to ensuring that robust decision making can also support better transparency and understanding of HTA decision making processes.
The work commenced of the unit commenced in March 2019, and further updates of the 2019 program will be issued over the next month through this web page.
http://www.health.gov.au/internet/hta/publishing.nsf/Content/hta-1

Submitted by Sally Wortley

European Union
Boosting Cooperation On Health Technology Assessment [EU Legislation In Progress]
This is a good overview on the state of play of the legislative proposal on HTA collaboration at EU level. It was produced by the European Parliamentary Research Service.
https://epthinktank.eu/2018/03/22/boosting-cooperation-on-health-technology-assessment-eu-legislation-in-progress/

EPF Congress 2019: the first ever European Congress on patient involvement
The European Patients' Forum is pleased to announce that registration for the first patient community-driven Congress is officially open. This unique event will take place from 12 to 14 November 2019 at the Crowne Plaza Hotel – Le Palace, set in a prime location in the heart of Brussels, Belgium. You may now register via this link.
What is the EPF Congress? This event will provide an exceptional opportunity for dialogue and engagement with a wide range of health players who work hard to make patient involvement happen. We will exchange best practices and knowledge to help create a framework for more structured and effective patient involvement across health systems and services.
More details, preliminary programme and some speakers' information is available on our dedicated website www.epfcongress.eu .

Submitted by Valentina Strammiello

A second Workshop of the EUnetHTA Task Force on HTA and Medical Devices
Organised by the Ludwig Boltzmann Institute for Health Technology Assessment, this is to be held on 28 May 2019 in Vienna, Austria. Valentina Strammiello will be attending.
https://www.eunethta.eu/events/

European Patients Forum (EPF) News
The long-standing Secretary General of European Patients Forum Nicola Bedlington has stood down from this role after 13 years of leadership. She has been a truly inspirational and dedicated leader and has made EPF the successful organisation it is today. The incoming Executive Director Usman Khan officially joined the EPF Secretariat on 29 April. We in the PCIG welcome her and wish her well.

On 10 April, EPF participated in the first meeting of the Stakeholder Dialogue Platform of the EURIPID collaboration. The EURIPID collaboration is a "voluntary and strictly non-profit cooperation between mostly European countries on building up and maintaining a database with information on national prices of medicinal products in a standardized format." It is funded by the European Commission.

Canada – McMaster Health Forum
In February, Carolyn Canfield an active citizen-patient) and François-Pierre Gauvin (Senior Scientific Lead, Citizen Engagement and Evidence Curation of the McMaster Health Forum) shared a pan-Canadian

perspective on what has been done to engage citizens in health-system policymaking, key lessons learned, and insights on emerging approaches.
https://www.mcmasterforum.org/learn-how/public-events/event-item/top-ten-insights-into-citizen-engagement-a-canadian-perspective

FDA Webinar on Tissue Agnostic Therapy Drug Development
The drugs are targeted towards specific sets of genetic mutations that can lead to different cancer types.
FDA-ASCO-Friends Workshop on Development of Tissue-Agnostic, Biomarker-Based Indications - https://www.fda.gov/Drugs/NewsEvents/ucm634050.htm
The FDA, American Society of Clinical Oncology (ASCO) and Friends convened this public workshop on 26 April to identify clinical trial designs and strategies to accelerate drug development based on biomarkers that are agnostic to tissue types. The workshop is intended to explore concepts in research and development that would assist the research community and regulators in understanding how to optimize product development and patient access to safe and effective biomarker-driven therapies that have clinical use across a variety of cancer types.
Input is sought from multiple stakeholders on approaches the FDA uses to review applications for drug products that are intended to treat cancers based on the presence of a biomarker, rather than specification of the tissue type.

The evaluation of potential tissue agnostic treatments in oncology raises a number of issues for consideration of orphan drug designation. Tumors represent heterogeneous disease states and that histologic context may be of importance in evaluating potential targeted treatments. These complexities raise a number of issues for consideration of orphan drug designation and orphan drug exclusivity. The discussion and input from this workshop will inform the Agency as it seeks to integrate evolving science in the orphan drug designation of drugs to treat, prevent, or diagnose diseases or conditions in oncology.

Submitted by Simone Leydon

Publications

Cook NS, Cave J, Holtorf A-P. Patient Preference Studies During Early Drug Development: Aligning Stakeholders to Ensure Development Plans Meet Patient Needs. Front Med [Internet]. 2019;6. Available from: https://www.frontiersin.org/articles/10.3389/fmed.2019.00082/full
In this paper, we formulate three hypotheses supporting the use of patient preference studies in early product development: (1) integration of the patient perspective into the development process from phase 1 onwards will result in healthcare solutions with outcomes that best address patients' needs; (2) a structured process to build patient-based evidence involving partnerships between patients and other key stakeholders will improve alignment of development activities with the needs of patients; (3) quantitative patient preference research built on robust qualitative insights is necessary to strengthen development decisions in the interests of patients. These hypotheses are demonstrated and discussed at the example of qualitative insights research, quantitative patient preference studies, and in the context of how different stakeholder groups and organizations are working to embrace fully the patient perspective in product development and healthcare decision-making.

Shared by Anke Holtorf and Nigel Cook – also:

Patient preference study in Non-Alcoholic Steatohepatitis in Frontiers in Medicine
The Patient Perspectives on Future Therapeutic Options in NASH and Patient Needs
Nigel Cook, Andreas Geier, Andreas Schmid et al. Front. Med. 6:61. doi: 10.3389/fmed.2019.00061

https://www.frontiersin.org/articles/10.3389/fmed.2019.00061/full?&utm_source=Email_to_authors_&utm_medium=Email&utm_content=T1_11.5e1_author&utm_campaign=Email_publication&field=&journalName=Frontiers_in_Medicine&id=443221
Adaptive choice-based conjoint exercise (ACBC) results showed that efficacy, defined as "impact on liver status" was the single most important attribute of a potential future NASH therapy. Other attributes considered to have secondary importance included impact on weight, symptom control and the presence of side effects.
Patients demonstrate a general lack of understanding of their disease and appeared to be unfamiliar with longer-term consequences of NASH.

Frameworks for supporting patient and public involvement in research: Systematic review and co-design pilot
Greenhalgh T, Hinton L, Finlay T, Macfarlane A, Fahy N, Clyde B, Chant A. Health Expect. 2019 Apr 22. doi: 10.1111/hex.12888. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/31012259
The plethora of frameworks combined with evidence of limited transferability suggests that a single, off-the-shelf framework may be less useful than a menu of evidence-based resources which stakeholders can use to co-design their own frameworks. The authors used the Canadian Centre for Excellence on Partnerships with Patients and Public (CEPPP) evaluation tool and hermeneutic methodology to grade and synthesize the frameworks.

Submitted by Liesl Strachan

'Patient-Centeredness of Advanced Payment Models' - making the case for Core Outcome Sets in helping to ensure patient-centeredness in defining high value care.
exCERpts April 2019: Updates from Center for Medical Technology Policy (CMTP)
http://www.cmtpnet.org/docs/resources/COS_APM_Infographic_FINAL.pdf?utm_source=CMTP+Newsletter&utm_campaign=2ffc91f0e4-April+exCERpts+2019&utm_medium=email&utm_term=0_6fa1e92b62-2ffc91f0e4-255619597
Rachael Moloney**,** Donna Messner, Sean Tunis and Diana Brixner. Academy of Managed Care & Specialty Pharmacy Annual Meeting, held March 25-28, 2019, San Diego, CA. A framework for vetting 'good' outcomes-based measures in alternative payment models, based on a multi-stakeholder exploratory project of the Green Park Collaborative. The framework suggests looking for existing core outcome sets as a starting point when selecting or assessing outcomes-based quality measures that may ultimately be incorporated into working definitions of high value care. Patients and clinicians are meaningfully engaged throughout the consensus process for developing the measures.
In addition to being clinically relevant and meaningful to patients, other criteria in the proposed framework include: actionable, inclusive of important patient populations, feasible to observe from available data, associated with cost savings, minimizes reporting burden on patients and providers, and associated with long-term health outcomes.

Submitted by Nigel Cook

Miles Sibley: Evidence-based practice—a double standard? April 24, 2019
https://blogs.bmj.com/bmj/2019/04/24/miles-sibley-evidence-based-practice-a-double-standard/
The NHS has "a strong scientific tradition of evidence-based decisions about care". So says the NHS Long Term Plan in its opening chapter. That claim could easily be skimmed over by casual readers. But is it true? In terms of clinical practice, it probably is: procedures and treatments emerge from years of careful research and rigorous observation. But for "care" in terms of patient experience, the claim is on somewhat shaky ground.

Clinical effectiveness and patient experience are, according to the Darzi review, equal partners in a high quality healthcare system. Neither is more important than the other. So let's look at how each of these are treated when it comes to "evidence-based decisions about care."

Firstly, medicine respects evidence. So clinicians have access to huge databases of medical research. Their training and professional development are informed by that research, and their clinical guidelines and practice protocols are evidence-based.

Medical research is progressing all the time, but even when older evidence becomes outdated, it is not abandoned. There is recognition of the importance of organisational memory, and the need to understand where current knowledge comes from. So historical evidence is cherished and preserved in well-maintained archives.

Patient experience evidence, by contrast, has been treated as disposable. Government has invested heavily in "patient voice" initiatives, starting with the establishment of Community Health Councils in the 1970's. Those were succeeded by Patient and Public Involvement Forums, then by Local Involvement Networks and latterly by Healthwatch. All gathered large volumes of evidence on patient experience, but none was ever archived. So as each initiative shut down, its entire body of knowledge went with it. Evidence collected over decades has been lost forever.

Fast forward to today's digital era, and we might reasonably expect that patient experience evidence is now better organised. Unfortunately, this is not the case.

Evidence gathering on patient experience is carried out via the Friends and Family Test, the CQC national patient surveys, and the NHS England national patient surveys. Alongside these are thousands of reports emanating from 150 local Healthwatch organisations, as well as from health charities and other patient voice organisations. Academic studies add to the mountain of literature, while NHS Trusts and Clinical Commissioning Groups carry out their own surveys and focus group work.

The output from this welter of activity is published across hundreds of different websites. Some are poorly maintained, so links get broken, pages go out of date, and more evidence gets lost. Even dedicated patient experience staff can find it hard to know where all the evidence is held. One is reported as saying "*…you're flying blind with your service and you're just picking out bits of data from everywhere*". Another said, "*We are data rich, but we don't bring it all together… It's a nightmare to see what's going on*".

The NHS Long Term Plan claims "a strong scientific tradition of evidence-based decisions about care". But the facts show a disparity between how clinical evidence and patient experience evidence are treated…

We are on a journey to get patient experience evidence taken as seriously as medical evidence. Collating and cataloguing the literature is just the start—our next move is to help people understand and make use of it. That means breaking the mountain of reports down into themed collections to increase access and availability. It means scoping the evidence base to identify gaps, and aid research prioritisation. And it means interpreting the literature—turning complex studies into simple summaries that hard-pressed NHS staff can easily get to grips with…

www.patientlibrary.net

The risks of equating 'lived experience' with patient expertise

https://healthydebate.ca/opinions/patients-as-experts

This article. Dated February 13, 2019, is provocative and perhaps of interest. The author, Frank Gavin, was a long-time Public Representative on the Common Drug Review with CADTH for non-cancer drugs. It is interesting now that he has retired from that role to read about his thinking about patient input.

Does being a patient make you an expert? The Canadian Institutes of Health Research (CIHR), the country's largest funder of health research, certainly seems to think so. Eight times in the patient engagement framework for its Strategy for Patient-Oriented Research (in which patients are partners in all phases of the research process), the CIHR attaches the word "expert" or "expertise" to patients.

There appears to be a hedge, however. In one statement, patients are said to "bring the perspective as 'experts' from their unique experience and knowledge." Why the quotation marks around "experts," which

to me seem to qualify or even question the view that patients are actual experts? If it were simply a statement of fact, the quotation marks would not be needed…
Health care and health research are full of experts whose status is signalled by white coats, titles, lots of letters after their names, and much deference directed their way. There are specialists and sub-specialists as well as fellows and post-docs—and not just among physicians. It is a very hierarchical world in which expertise is the coin of the realm.
Enter the era of patient preferences, shared decision-making, and patient-oriented research—each founded, at least in part, on an altogether welcome and necessary recognition that patients possess essential knowledge and important skills and that long-standing power imbalances need to be eliminated. ..

A Commentary in response to the article concludes:
By arguing the question of whether patients and caregivers are expert or not, are we missing the point that the idea of expertise is just a substitute for having power, credibility and a voice at the table? I am not sure power can be afforded to us until the value of our area of expertise—the patient experience—is truly recognized and understood. There are many barriers to patients and caregivers gaining expertise. Being told we are not capable of achieving it because of who we are and our circumstances should not be one of them.

Written by Francine Buchanan

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