HTAi Patient and Citizen Involvement in HTA Interest Group (PCIG)
E-Bulletin, October 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 October E-Bulletin – from our Chair

The deadline has now passed for abstracts for workshops and panels for Beijing 2020. This year, the PCIG Steering Committee trialled scoring using agreed criteria to determine which abstracts should receive PCIG endorsement, which gives an abstract one extra point when being considered for inclusion in the Annual Meeting. We received six panel abstracts and two workshop abstracts. One panel abstract, 'Involving Patient in Health Technology Assessment in Low- and Middle-Income Countries (LMICs): Making the Ends Meet', and one workshop abstract, 'Conceptualizing Patient-Involvement in Countries with Expanding Healthcare Coverage: Identifying Opportunities in Low- and Middle-Income Countries', subsequently gained endorsement from the Developing Countries Interest Group so we removed them from our process. The scoring was incredibly tight, but resulted in the following abstracts gaining PCIG endorsement:
Workshop: 'Identify Possible Steps to Improve Patient Involvement in HTA By Applying Patient Involvement Frameworks and High-Level Gap Analysis';
Panels: 'Patient Involvement Impact Stories - Adapting HTA?', and
'Patient Participation at the Organizational Level in HTA'.
We will be hoping that all the abstracts are accepted and that PCIG once again has a strong presence at the HTAi Annual Meeting. I have sent the scoring to all who submitted abstracts, but I'm also happy to share it if it is of interest to you. We will reflect on the process as part of our annual face to face meeting in Brussels this week. Meanwhile, please note the following deadlines:
Thursday 21 November - HTAi 2020 Beijing Travel Grants (patients, carers, LMIC country participants and full time students)
Thursday 21 November - HTAi 2020 Beijing orals, posters and vignettes
Saturday 30 November – Abstracts, Special edition of IJTAHC focusing on patient and public involvement and engagement in HTA (see item below).

Ann Single, Chair – HTAi Patient and Citizen Involvement Interest Group
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HTAi Matters

HTAi 2020 Annual Meeting Beijing
Attaining, maintaining and sustaining healthcare systems in a changing World: the role of HTA HTAi2020.org

Details are available for the main theme https://www.htai2020.org/the-role-of-hta/and plenaries

Abstract submission: https://www.htai2020.org/abstracts/
Workshop and Panel submissions:
Acceptance notification: November 11, 2019
Deadline for Oral, Vignette and Poster Presentation submissions: November 21, 2019
Acceptance notification: February 1, 2020

Travel grants https://www.htai2020.org/travel-grants-2/
Deadline to submit a Travel Grant Application: November 21, 2019
Successful/Unsuccessful Application Notification: February 3, 2020

HTAi offers Travel Grants funded directly by HTAi and, in some cases, sponsored by external parties on an unconditional basis. To be eligible for an HTAi Travel Grant, applicants must qualify to represent one of the following groups:
a. Resides in a low or middle-income country (as defined by the World Bank Link);
[Please note: Individuals temporarily residing in a high-income country but maintaining permanent residence in a low or middle-income country may apply for an HTAi Travel Grant. However, preference may be given to individuals currently residing in low or middle-income countries.]
b. A patient or care-giver who can provide patient insights relevant to health policy and health technology assessment and is associated with a not-for-profit patient engagement network. (necessary to provide a letter of confirmation from organization represented);
c. Full-time student enrolled in a post-secondary education program or course for HTA (necessary to provide a certificate of enrollment).
In addition, the applicant must meet at least one of the following criteria:
a. Be a participant in the submission of an abstract for a panel or workshop or have an abstract submitted for an oral, vignette or poster presentation;
b. Demonstrate a current link (volunteering, employment or academic) to an HTA agency, government body, or academic research center, or to another area of the health system with clear relevance to the field of HTA;
c. Demonstrate clear interest in becoming involved in the field of HTA (e.g. through study or the establishment of HTA activities in the applicant's jurisdiction). Applicants must provide a letter of support in relation to becoming involved in the present or the future.

Please do follow us on social media and repost our messages: #HTAi2020Beijing
Twitter: twitter.com/HTAiOrg @HTAiOrg
Facebook: www.facebook.com/HTAiOrg @HTAiOrg
LinkedIn: www.linkedin.com/company/htai

Check out Sam Thomas's interview for the 'Evidence Base' on topics related to 2019 PCIG workshop
https://www.evidencebaseonline.com/users/211204-the-evidence-base/posts/54529-look-behind-the-lecture-patient-engagement-in-health-technology-assessment?utm_source=social%20media&utm_medium=social%20media&utm_campaign=Samuel%20Thomas

Submitted by Samuel Thomas

Call for Papers – IJTAHC Themed Issue: Patient and Public Involvement in HTA
Patient and citizen involvement have become an important part of health technology assessment. Patients and citizens have developed active partnership roles helping to ensure the relevance, acceptability and appropriateness of HTA.

The International Journal of Technology Assessment in Health Care invites the submission of papers (original research, reviews and commentaries) on the role of patients and citizens in HTA for a themed issue of the journal to be published in early 2021, guest edited by Sophie Werkö (SBU, Sweden) & Sophie Staniszewska (University of Warwick Medical School, UK).
We encourage papers that generate new knowledge or thinking about how to engage patients and citizens in HTA. Papers can be methodological or applied. We also encourage submissions from all countries particularly where there has been less written about PPI in HTA.
We are interested in the following topics:

- Capturing and/or measuring impact of patients and/or citizens in HTA
- Development and evaluation of processes or structures that support patient and citizen involvement in HTA
- The roles of patients and/or citizens on HTA committees
- The use of Patient-Based Evidence in HTA
- Any form of co-production between patients & citizens and other actors in HTA
- The role of social media and virtual methods in patient and citizen involvement in HTA
- The ethics of involving or not involving patients and citizens
- Patient and citizen involvement in advancing methods and methodologies in HTA
- The role of patient organisations in HTA
- Cross-country comparisons of patient and citizen involvement in HTA

We are not interested in papers reporting patients participating as subjects in a study as part of a sample or as active collaborators in primary research.
Please submit an abstract describing your proposed paper by 30th November 2019 to both sophie.werko@sbu.se and to sophie.staniszewska@warwick.ac.uk. We will invite full papers following an assessment by 20 December 2019 and manuscripts will be due 30 April 2020.

Sophie Werko and Sophie Staniszewska

What's Happening

Join the Clinical Trials Transformation Initiative (CTTI) public webinar, 'Patient Engagement in Action: Insights from Patients & the FDA' https://www.ctti-clinicaltrials.org
Patient engagement has moved from concept to reality, thanks to the efforts of many patient groups, the FDA, CTTI, and many others. Join us on Thurs., Nov. 21, from 12:00 - 1:00 p.m. ET to hear about ongoing and planned patient engagement initiatives currently underway at the FDA, and the anticipated impact of these efforts on patients and clinical research. This is a public webinar. No registration is required.
Confirmed speakers for 'Patient Engagement in Action: Insights from Patients & the FDA' include:
Michelle Tarver, CDRH, FDA; Robyn Bent, CDER, FDA; Diane Maloney, CBER, FDA; Andrea Furia-Helms, OC, FDA; Theresa Strong, Foundation for Prader-Willi Research
12:00pm | Eastern Time (New York, GMT -04:00 | 1 hour
When it's time, join the meeting.
Meeting number (access code): 732 162 450
Meeting password: ctti

FDA Activities – Public workshop
US FDA CDER (Drug Division) Holding a Public Workshop on Incorporating Clinical Outcome Assessments into Endpoints for Regulatory Decision Making - Workshop in Silver Spring, MD USA on 6 December 2019
https://www.fda.gov/drugs/development-approval-process-drugs/public-workshop-patient-focused-drug-development-guidance-4-incorporating-clinical-outcome
The U.S Food and Drug Administration (FDA) is hosting a public workshop to gather input from the wider community of patients, patient advocates, academic researchers, expert practitioners, drug developers, and other stakeholders. The workshop will address a range of issues and considerations related to the collection

and analysis of clinical outcome assessment (COA) data for drug development and regulatory decision making.
The purpose of this public workshop is to obtain feedback from stakeholders on considerations for: Endpoint development; Estimands and analysis models; Addressing heterogeneity in disease symptoms and functional status between patients and within the same patient over time; Data collection, storage, transmission, and analysis.
Registration for in-person attendance is required and will close on December 3, 2019. This meeting will be available for online viewing, on the day of the meeting via the link. Patient-Focused Drug Development Guidance: Collection and Analysis of Clinical Outcome Assessment Data for Drug Development and Regulatory Decision Making; Public Workshop.

FDA - Seeking public input
Comments due 22 Nov 2019: Guidance for Patient Engagement in the Design and Conduct of Medical Device Clinical Investigations https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-engagement-design-and-conduct-medical-device-clinical-investigations?utm_campaign=2019-09-23%20Patient%20Engagement%20Clinical%20Trials%20Guidance&utm_medium=email&utm_source=Eloqua
The FDA values the experience and perspectives of patients and their family caregivers. FDA believes that these individuals can and should be able to provide their insights about a disease or condition, including living with that disease/condition, and the impact of medical devices in the diagnosis, treatment, and management of the disease/condition, through engagement activities. Such activities can assist the Agency in understanding the patient experience, as well as sponsors as they design and conduct medical device clinical investigations.
On October 11-12, 2017, FDA's Patient Engagement Advisory Committee (PEAC) met to discuss and make recommendations to FDA regarding patient engagement in medical device clinical investigations. In a consensus recommendation, the PEAC stated that some type of framework should be developed by FDA and industry to clarify how patient advisors can engage in the clinical investigation process. Based on this recommendation, FDA is pursuing various efforts to encourage patient engagement in clinical investigations, including issuing this document.
Medical device clinical investigations prospectively designed with input from patient advisors may help to address common challenges faced in these clinical investigations, and could result in: Faster study/research participant recruitment, enrollment, and study completion; Greater study/research participant commitment, resulting in decreased loss to follow-up; Greater study/research participant compliance resulting in fewer protocol deviations/violations; Fewer protocol revisions; Streamlined data collection resulting in better quality data; and More relevant data on outcomes that matter to patients.

Guidance documents that FDA is developing to describe in a stepwise manner how stakeholders (patients, researchers, medical product developers and others) can collect and submit patient experience data and other relevant information from patients and caregivers to be used for medical product development and regulatory decision-making. The topics that each guidance document will address are described below.
Methods to collect patient experience data that are accurate and representative of the intended patient population (Guidance 1)
Approaches to identify what is most important to patients with respect to their experience as it relates to burden of disease and burden of treatment (Guidance 2)
Approaches to identify and develop methods to measure impacts in clinical trials (Guidance 3)
Methods, standards, and technologies to collect and analyze clinical outcome assessment data for regulatory decision-making (Guidance 4)
The most recent version of a guidance https://www.fda.gov/RegulatoryInformation/Guidances/default.htm

Comments due 30 December 2019 - US FDA CDER (Drug Division) Seeking Public Comment on Draft Guidance on Methods to Identify What Is Important to Patients
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-methods-identify-what-important-patients-guidance-industry-food-and
Patient-Focused Drug Development: Methods to Identify What Is Important to Patients. Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders
This guidance (Guidance 2) is in a series of four methodological patient-focused drug development (PFDD) The methods described in this document can be used to elicit what is important to patients, which may in turn help inform the selection or development of clinical outcome assessments and the generation and use of patient preference information. Described are Qualitative research methods (e.g., through interviews or focus groups), quantitative research methods (e.g., through survey instruments), or mixed-methods research (e.g., through open-ended and fixed-response items in a survey instrument) that can be used to identify what is important to patients.

Submitted by Nigel Cook and Barry Liden

Protecting and promoting the health of diverse populations central to the mission of the **FDA Office of Minority Health and Health Equity** (OMHHE)
Minority populations in the US may respond differently to certain medical products and so enrolment in clinical trials should reflect the diversity of the population. Yet racial and ethnic minorities have historically been and continue to be underrepresented in clinical trials and are disproportionately burdened by many chronic and debilitating diseases. Barriers to participation include a lack of trust due to historical abuses. Other barriers may be due to language and cultural differences, religion, trial design, time away from jobs and other commitments, or a lack of awareness and knowledge about what a clinical trial is and what it means to participate.
Raising awareness on the importance of racial and ethnic minority participation in clinical trials includes multiple strategies:
Educational materials in English and Spanish that highlight the value of clinical trial participation.
Videos and Public Service Announcements including social media outreach that encourage different groups to participate in clinical trials.
Ongoing outreach to engage different communities and health professionals to raise awareness about the need for diverse participation in clinical trials.
Webinars, lectures, and podcasts.
A dedicated webpage with all resources and materials, including a communications toolkit.
Collaborations across government, professional associations, community-based organizations, academia, industry, and others to educate consumers and communities about the importance of minority participation in clinical trials.
To enhance community engagement efforts, the OMHHE developed a Memorandum of Understanding (MOU) with Yale University. A specific area of focus for the MOU is collaborations to cultivate and advance the Yale Cultural Ambassadors Program and the engagement of community partners to increase participation of diverse and historically underrepresented or underserved populations in clinical research.

Patient-Focused Medicines Development: Book of Good Practices
https://globalforum.diaglobal.org/issue/november-2019/patient-focused-medicines-development-the-book-of-good-practices/?utm_medium=email&utm_source=db&utm_content=PUB_GF_Nov_2019-11-02A&utm_campaign=globalforum&utm_type=aq&mkt_tok=eyJpIjoiTWpJMllqTTBPVGhtT1RoayIsInQiOiJubkp5MUxYVoJUcEpPS05lWlVUbzd5ZlBLTTlRZklOTU1WaTR4SkZ4cGJDakdxbG1iTEtFMUpSTnpmTTlJNXVyNU4zc2lxNld4a1dlMGh1QkJpcjA1S1ZvMFdCQVwvRWxZQzJJNVlvS1JkNjJpMms1UnkzToZvM3ZGUVJCcWlwc1EifQ%3D%3D
Check it out!

Evidence-based advocacy
https://wecanadvocate.eu/academy/evidence-based-advocacy/
Patients and patient advocates may be in the best position to express what patients want and need. However, individual opinions are not always helpful to take discussions forward for a whole population of patients and to convince researchers, healthcare providers or regulatory decision makers. In order to help healthcare to focus on the true needs of patients and their subpopulations, it helps if patient advocates argue with evidence and data. It is difficult for decision-makers to ignore robust evidence. The concept of 'Evidence-Based Patient Advocacy' means advocating in in a targeted, evidence-based, well-educated and professional manner, and measuring the impact and outcomes of the advocacy work. It is based on three core elements: targeted advocacy towards each respective stakeholder, use of robust data about patients needs and preferences, and use of the right packaging of messages to communicate the needs to the respective target group. However, to do so, patient advocates need to acquire the skills and resources to generate evidence in their own community as well as use that evidence in a targeted way.
The site gives links to presentations held at the WECAN Academy 2019.

Plain Language Summaries of Publications Toolkit
https://www.envisionthepatient.com/plstoolkit/
Lobban D, Arnstein L, Wadsworth AC, Woolley KL. Plain language summaries of publications: Addressing the HOW via a stakeholder survey and workshop. Poster presentation at the 15th Annual Meeting of the International Society for Medical Publication Professionals; 15–17 April 2019; National Harbor, MD, USA.

From the European Patients Forum (EPF) Newsletter
EPF 2019 Congress https://epfcongress.eu/
November 12-14, 2019 at the Crowne Plaza, Place Rogier, Brussels, Belgium

International guidance for patient involvement - CIOMS Working Group XI meets in Geneva, 16-17 October 2019 https://cioms.ch/working_groups/working-group-xi-patient-involvement/
Despite progress in the EU and some other regions of the world, where patients' perspectives and preferences are more or less incorporated into medicines research, regulatory evaluation and monitoring, patient involvement in many other regions is patchy and there is little awareness of existing best practices. CIOMS is an international organisation that produces globally applicable guidelines on topics ranging from medical ethics to clinical trials and medicines safety. Until now, the role of patients in CIOMS guidelines was defined primarily by other stakeholders – regulatory authorities and pharmaceutical companies, rather than by direct involvement of patients. In April 2018 CIOMS launched a new Working Group XI on Patient involvement in the development and safe use of medicines. While it has been challenging to find people with the right profiles who also have the time and ability to commit themselves to the work, today the group includes patient representatives from countries including the United States and Uganda.
A new book will give a comprehensive overview of present knowledge and existing initiatives on patient involvement, and will give regulators, industry and other stakeholders guidance and tools to address the remaining challenges and practice gaps. We are still looking for interested patient representatives who could contribute to this work especially from regions outside the European Union and North America. Please do not hesitate to contact EPF at policy@eu-patient.eu

Self-care and self-management by patients
It is important to develop effective strategies for supporting self-care and self-management by patients. COMPAR-EU is an EU-funded project that is looking to identify technologies to enable self-management and provide insights to help patients and healthcare professionals find the best solutions for managing a chronic condition. Last year EPF identified patients' priorities for the core outcomes of the project. This year, EPF began to summarize and 'translate' key project outcomes to adapt them and make them accessible and understandable for patients EPF has also set up a *patient panel* – a group of patients who will

be involved in the project throughout its full duration. It will ensure that our contribution to this project aligns with patients' needs and priorities.

Publications

A Picture is Worth a Thousand Words: The Role of Survey Training Materials in Stated-Preference Studies

Vass CM, Davison NJ, Vander Stichele G, Payne K. Patient. 2019 Sep 30. doi: 10.1007/s40271-019-00391-w. [Epub ahead of print]

Online survey-based methods are increasingly used to elicit preferences for healthcare. This digitization creates an opportunity for interactive survey elements, potentially improving respondents' understanding and/or engagement.

Our objective was to understand whether, and how, training materials in a survey influenced stated preferences. An online discrete-choice experiment (DCE) was designed to elicit public preferences for a new targeted approach to prescribing biologics ("biologic calculator") for rheumatoid arthritis (RA) compared with conventional prescribing.

300 respondents completed the DCE, receiving either plain text (n = 158) or the animated storyline (n = 142). Using animated training materials did not change the preferences of respondents, but they appeared to improve choice consistency, potentially allowing researchers to include more complex designs with increased numbers of attributes, levels, alternatives or choice sets.

Submitted by Nigel Cook

Unmet Medical Need: An Introduction to Definitions and Stakeholder Perceptions

RA Vreman, I Heikkinen, A Schuurman, et al. Value Health 2019

Despite increasing informal and formal use of unmet medical need (UMN) in drug development, regulation, and assessment, there is no insight into its definitions in use. This study aims to provide insight into the current definitions in use and to provide a starting point for a multi-stakeholder discussion on alignment.

A scoping and a gray literature review were performed to locate definitions of UMN in literature and on stakeholder websites. These definitions were categorized and then discussed among the multi-stakeholder author group via semi-structured group discussions and open session workshops with a broader stakeholder audience. Issues with the formation of a common definition and mechanisms for use were discussed.

The reviews yielded 16 definitions. Differences were evident, but all included 1 or more of the following elements: (adequacy of) available treatments (16 of 16: 100%), disease severity or burden (6 of 16: 38%), and patient population size (1 of 16: 6%). The stakeholder discussions led to a suggestion for a definition including the first 2 items and, depending on context, population size. The discussions also showed that quantification of UMN is highly dependent on the scope and the value framework in which it is used based on different stakeholder preferences and responsibilities.

Kieffer CM, Miller AR, Chacko B, Robertson AS. (2019) FDA reported use of patient experience data in 2018 drug approvals. Therapeutic Innovation and Regulatory Science. doi: 10.1177/2168479019871519

"Patient experience data" (PED) refers to the systematic collection of meaningful data relating to the experiences, perspectives, needs, and priorities of patients. PED can augment traditional clinical trial data in the FDA's review of product applications. Section 3001 of the 2016 21st Century Cures Act requires the FDA to make a public statement about the PED considered in the approval of a drug application. Here, we present one of the first assessments of PED consideration during drug application approval, as reported by the FDA under Sec. 3001 of the Cures Act.

FDA reported use of PED in the Review Documentation of the 59 new molecular entities (NMEs) approved in 2018 were collected, indexed, and cross-referenced against information regarding FDA review and product regulatory designation. The data reported in the PED tables were quantitatively described and visualized.

Of the 59 approved NMEs in 2018, 48 include a table that summarized whether PED was or was not used during the FDA drug review. Thirty-four of those 48 approvals (70.8%) reported using PED in the drug review. Patient-reported outcomes (PROs) represented the most significant source of PED and were used in 60.4% of approved drug reviews. Additional findings, including PED use by FDA review division and by FDA regulatory designation, are described.

Why the Coming Debate Over the QALY and Disability Will be Different
SD Pearson, Institute for Clinical and Economic Review (ICER) in the US. J Law, Medicine & Ethics 2019;47(2):304-7.
https://doi.org/10.1177/1073110519857286
http://icer-review.org/wp-content/uploads/2019/07/Pearson-ASLME-article-on-QALY-and-disability.pdf
The QALY is the gold standard within health economics for the last 30 years plus for measuring the impact of treatments on patients' health – on length of life and quality of life. It is a summary measure used consistently across all types of conditions. The debate in the US about the QALY and disability is gaining new momentum due to the advancing use of cost-effectiveness analysis (CEA) in drug pricing and coverage negotiations. ICER has introduced an additional measure, Equal Value of Life Years Gained (evLYG). This evenly measures any *gains* in length of life, regardless of the treatment's ability to improve patients' quality of life. In other words, if a treatment adds a year of life to a patient population — whether treating individuals with cancer, multiple sclerosis, diabetes, epilepsy, or a severe lifelong disability — that treatment will receive the same evLYG as a different treatment that adds a year of life for healthier members of the community. The evLYG is not as flexible as the QALY in capturing benefits to quality of life.
Norway applies a tiered cost-effectiveness threshold to pay more for treatments that provide health gains for conditions that cause substantial lifetime burden of illness, whereas in England a special weighting of QALYs gained is accorded treatment for conditions that are rapidly fatal. Neither of these approaches have gained broad consensus - many believe that trying to create a quantitative fix within the QALY itself is less desirable than the integration of consideration of social values through robust deliberative processes.

The Role of Integrated Scientific Advice for the Early Determination of RWE Requirements in HTA and Payer Assessments. A Schmetz, S Wise, M Bending, P Hurley of Evidera.
https://www.evidera.com/thank-you-for-downloading-our-white-paper/?doc=eyJyaWQiOiIyNCIsInBpZCI6MTA2Nzl9&dl=1
High-quality practice guidelines lead the way to explaining how to develop robust real-world evidence (RWE), e.g., the Innovative Medicines Initiative's (IMI) GetReal project and the International Society for Pharmacoeconomics and Outcomes Research's (ISPOR) RWE task force. Despite the availability of such guidance, often health technology assessment bodies, payers, and even regulators do not regard submissions of real-world data or evidence as manufacturers hoped they would. The aim of this article is to discuss the current use of real-world data and evidence in HTA and payer appraisals, its potential role in lifecycle management, and how the early dialogue provided by Integrated Scientific Advice (ISA) engagement can be used as a key tool in real-world evidence generation planning. RWE is defined by the ISPOR task force as being obtained from the process of analyzing real-world data (RWD), which in turn is defined as data gathered outside randomized clinical trials (RCTs), e.g., through routine clinical practice. At a minimum, the clinical, regulatory, HEOR, and market access functions of a 'manufacturer' are affected. Markets that do not utilize cost-effectiveness analyses in their HTA appraisal procedures also do not seem to utilize RWE for decision making to a large extent.

Harnessing the patient voice in real-world evidence: the essential role of patient-reported outcomes
Calvert MJ, O'Connor DJ, Basch EM. Nat Rev Drug Discov. 2019 Sep;18(10):731-732. doi: 10.1038/d41573-019-00088-7.
https://www.nature.com/articles/d41573-019-00088-7
Real-world evidence is increasingly valued by regulators and payers. Central to this evidence base is patient-reported outcome data describing the impact of drugs on quality of life, daily activities and symptoms.

Here, we highlight key challenges with current real-world, patient-reported outcome data and describe collaborative next steps for international stakeholders to overcome these issues.

A Content Analysis of Patient Advocacy Organization Policies Addressing Institutional Conflicts of Interest https://www.tandfonline.com/doi/abs/10.1080/23294515.2019.1670278?journalCode=uabr21
JH Brems, MS McCoy. AJOB Empirical Bioethics, Volume 10, 2019 - Issue 4 Published Online: 08 Oct 2019. https://doi.org/10.1080/23294515.2019.1670278
Patient advocacy organizations (PAOs) provide patient education, raise public awareness, and influence health policy for a wide range of diseases. These organizations frequently receive financial support form from drug, device, and biotechnology companies. Though PAOs often develop policies to address institutional conflicts of interest arising from industry relations, little is known about the substance of these policies. We sampled all PAOs that are members of the National Health Council. Using a standardized search strategy, all policies were obtained from each organization if publicly available. We reviewed policies for content related to restrictions on corporate partnerships, disclosure of corporate funding, and governance and monitoring of corporate partnerships. We found that 24 of 47 (51%) organizations had policies that addressed institutional conflict of interest. A total of 9 of those 24 (38%) policies placed any restriction on the types of corporations that the PAO would or would not partner with. While 16 of the 24 (67%) outlined some process for disclosure of the organization's corporate donors, only 5 of 24 (21%) specified a manner for disclosing the financial value of those donations. Further, 15 of the 24 (63%) policies identified the person or persons responsible for approving corporate partnerships. However, 17 (71%) failed to address or specify the person(s) responsible for ongoing review of those partnerships.

Engaging patients and the public in Health Research: experiences, perceptions and training needs among Manitoba health researchers
https://researchinvolvement.biomedcentral.com/articles/10.1186/s40900-019-0162-2
LK Crockett, C Shimmin, KDM Wittmeier, KM Sibley. Research Involvement and Engagement 2019;5:art28
The significance of patient and public engagement is increasingly recognized in health research, demonstrated by explicit requirements for patient and public engagement by funding agencies and journals. Such requirements have charged health researchers with leading patient and public engagement efforts. This study aimed to establish a baseline understanding of the experiences, perceptions and training needs of health researchers in engaging patients and the public in health research in the context of Manitoba.
A cross-sectional 50-item questionnaire was distributed using a multi-phase purposive sampling strategy targeting health researchers in Manitoba, Canada. Data was summarized using frequencies, percentages and analyzed using chi-square testing. A local patient engagement advisory group was consulted at the interpretation stage of the study to obtain feedback and input on the findings and their implications. Responses from 53 health researchers were included. Most participants had engaged patients and the public in their own research (n = 43, 81.1%). Those who had engaged reported having some (n = 19, 44.2%), extensive (n = 14, 32.6%) or a little (n = 10, 23.3%) experience with this process. Most engaged at the levels of inform, consult or involve (81.3, 64.6 and 54.2% respectively), while fewer engaged at the collaborate (37.5%) or patient-directed levels (12.5%). Recruitment occurred using a number of approaches and engagement occurred at various phases of the research process, while main groups engaged were patients (n = 38, 82.6%) and families/caregivers (n = 25, 54.4%). Barriers to engaging patients and the public in health research included funding, time, compensation, logistics, recruitment, motivation at both the patient and researcher level, and skills of researchers to engage. Researchers reported an overwhelming need and interest for supports, funding and training to effectively engage patients and the public in health research. Findings highlight the barriers to effective, authentic and meaningful patient and public engagement and support the need for targeted training, supports, funding and time for health researchers.

Identifying approaches for synthesizing and summarizing information to support informed citizen deliberations in health policy: a scoping review MG Wilson, A Nidumolu, I Berditchevskaia et al. J Health Serv Res Policy First Published September 14, 2019 https://doi.org/10.1177/1355819619872221
The choice and framing of information to inform citizen deliberations about health policy can strongly influence their understanding of a policy issue, and has the potential to impact the discussions and recommendations that emerge from deliberations. Our review confirmed that there remains a dearth of literature describing methods of the preparation of information to inform citizen deliberations about health policy issues. This highlights the need for further exploration of optimal strategies for citizen-friendly approaches to synthesizing and summarizing information for deliberations.

PCORI's Health Literature Explorer database – have a look https://www.pcori.org/literature/engagement-literature).

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