

HTAi Methods and Impact Group, FAQ

Question	Answer	Written by
<p>How can patients be involved in research other than simply as respondents or study participants?</p>	<p>In the context of health research data on the experiences of patients are collected using quantitative or qualitative methods of consultation. Following well defined inclusion criteria people that meet these criteria are recruited and approached for their willingness to cooperate as study participant. However, the range of traditional methods for patient participation is rather limited (surveys, interviews or focus groups) and does not allow participants to comment on the applied method and instruments or to contribute in any other manner to the research.</p> <p>For this reason scientific methodologies are exploring more collaborative forms of patient participation on different levels. These levels can be described according to the ladder of citizen participation developed by Arnstein [1] and transferred to the area of health research by Abma & Broerse [2] and to clinical trials by the EU-funded “Patient partner” project [3]. Here patients obtain greater influence on the research process by taking on the role of, for example, reviewers of grant applications, advisors in a project team, co-researchers in a particular phase of the study, or even full partners in the research team taking responsibility for contributing the patient perspective in every phase of the research process [4, 5]. Sometimes patients and their organizations become commissioners of research: raising funds, determining the scope of the research, and identifying the most experienced researchers to carry out the project. What level of participation is appropriate depends on the research questions, the knowledge and competencies of the patients and the skills and attitudes of the researchers.</p> <p>The first results of research exploring the benefits and challenges of higher forms of patient participation show that the level of involvement can be more than consultation or a membership of a committee.[6, 7] The roles and contributions of patients are evolving into a more active, equal and structural involvement where the patient is not the passive object of research but takes co-ownership of the research process and shares decision making with the researchers[8]. The advantages are not only research outcomes that better suit the needs of patients but also increase quality and legitimacy of the research process.</p> <ol style="list-style-type: none"> 1. Arnstein, S.R., <i>A ladder of citizen participation</i>. Journal of the American Planning Association, 1969. 35(4): p. 216-224. 2. Abma, T.A. and J.E. Broerse, <i>Patient participation as dialogue: setting research agendas</i>. Health Expectations, 2010. 13(2): p. 160-73. 3. PatientPartner, <i>Patient involvement in clinical research. A guide for patient organisations and patient representatives</i>2011, Soest: VSOP. 4. Nierse, C.J., et al., <i>Collaboration and co-ownership in research: dynamics and dialogues between patient research partners and professional researchers in a research team</i>. Health Expectations, 2011. 5. Abma, T.A., C.J. Nierse, and G.A. Widdershoven, <i>Patients as partners in responsive research: methodological notions for collaborations in mixed research teams</i>. Qualitative Health Research, 2009. 19(3): p. 401-15. 6. Staley, K., <i>Summary Exploring Impact: Public involvement in NHS</i>, 2009, public health and social care research INVOLVE: Eastleigh. 	<p>Maarten de Wit</p>

	<p>7. Caron-Flinterman, J.F., <i>A new voice in science - Patient participation in decision-making on biomedical research [thesis]</i>, 2005, VU University: Amsterdam.</p> <p>8. Schipper, K., <i>Patient participation & knowledge [thesis]</i>, in <i>EMGO+2011</i>, VU University: Amsterdam. p. 302.</p>	
<p>How can patient issues/perspectives be explored and included in research?</p>	<p>The incorporation of the perspectives and problems of patients in research is important because it can contribute to the research. This is based on knowledge of the everyday reality of the coexistence of the patients with their disease, to ensure that the design of the research is conducted taking into account all aspects that are important to patients themselves. Their inclusion will increase the quality of the research itself. Not an easy task, but you can use two different strategies: 1) searching for evidence from studies that have addressed this perspective, or 2) conducting primary qualitative research on people in the context of applying your research.</p> <p>For the first strategy, a systematic review of the evidence including patient perspective studies, the objective is to search all of the existing evidence, mainly qualitative, regarding patient preferences. In the search strategy, qualitative research terminology and methodological filters can be used to identify the particular publication types and study designs most likely to be associated with high-quality studies.</p> <p>On the other hand, obtaining information on the patient perspective can be achieved either by working with the patients themselves, giving meaning to their experiences of health and disease, or with health professionals by asking for information on patients. Several techniques can be used. The use of a technique or combination of different types of techniques will depend on the research and the researchers. This type of research highlights the use of various qualitative techniques, particularly “participant observation”, “in-depth interviews” and “focus groups”. Methodologies may also be chosen using a combination of several techniques, for example using qualitative and quantitative techniques, such as questionnaires.</p> <p>References of interest:</p> <p>Diaz Del Campo P., Gracia J, Blasco, JA, Andradas E. A strategy for patient involvement in clinical practice guidelines: methodological approaches. <i>BMJ Qual Saf.</i> 2011; 20(9): 779-784.</p> <p>Facey K, Boivin A, Gracia J, et al. Patients’ perspectives in health technology assessment: a route to robust evidence and fair deliberation. <i>Int J Technol Assess Health Care</i> 2010;26:334e40.</p> <p>Nilsen ES, Myrhaug HT, Johansen M, et al. Methods of consumer involvement in developing healthcare policy and research, clinical practice guidelines and patient information material. <i>Cochrane Database Syst Rev</i> 2006;(3):CD004563.</p>	<p>Javier Gracia</p>

	<p>doi:10.1002/14651858. CD004563.pub2.</p> <p>Murphy E, Dingwall R, Greatbatch D, et al. Qualitative research methods in health technology assessment: a review of the literature. Health Technol Assess 1998;2:11e1X, 1e274.</p> <p>Whitstock MT. Seeking evidence from medical research consumers as part of the medical research process could improve the uptake of research evidence. J Eval Clin Pract 2003;9:213e24</p> <p>Sandelowsky M, Barroso J. Handbook for Synthesizing Qualitative Research. New York: Springer, 2007.</p> <p>Dixon-Woods M, Agarwal S, Jones D, et al. Synthesizing qualitative and quantitative evidence: a review of possible methods. J Health Serv Res Policy 2005;10:45e53.</p> <p>Crawford MJ, Rutter D, Manley C, et al. Systematic review of involving patients in the planning and development of health care. BMJ 2002;325:1263e7.</p>	
<p>What kinds of scientific methods are relevant to elicit patient issues, perspectives etc.?</p>	<p>A point of departure for scientific work is a real life situation, which can be translated into a research question. As described e.g. in the Danish handbook on HTA available scientific knowledge about the posed question may be identified as the next step [1]. This may be done by a structured search for published material (e.g. articles and books) in relevant databases and publications. For patient issues it is relevant to extend the search beyond clinical databases in order to identify material published in sociological, psychological and humanistic oriented publications [1 p. 110].</p> <p>If there is a need for further research a primary study may be initiated. The design of the study and the choice of methods for data generation and analysis depend on the nature of the research question. If the question is descriptive or confirmative a quantitative approach might be the best choice. While a question requiring understanding a phenomenon will need a qualitative approach, it might also be relevant to combine the two methods. Quantitative methods include structured observations and enquiries such as surveys, where the distribution of the phenomena is in focus and where the generalization is statistically assessed. Qualitative methods include unstructured or semi-structured observations and enquiries through either informal or formal interviews with individuals or groups of individuals. Here the generalization is theoretical. The research of formal or informal written communication, for instance published literature (e.g. patient narratives) and electronic media (e.g. chat rooms), may be relevant as data.</p> <p>As described in an article by Facey et al, what is of importance when eliciting patient issues is that the research is done in a transparent and robust manner to ensure scientific validity [2].</p> <p>1. Kristensen FB & Sigmund H (ed.). Health Technology Assessment Handbook.</p>	<p>Anne Lee</p>

	<p>Copenhagen: Danish Centre for Health Technology Assessment, National Board of Health, 2007. Available at http://www.sst.dk/publ/Publ2008/MTV/Metode/HTA_Handbook_net_final.pdf</p> <p>2. Facey K, Boivin A, Gracia J, et al. Patients' perspectives in HTA: A route to robust evidence and fair deliberation. <i>Int J Technol Assess Health Care</i>. 2010;26:334–340.</p>	
Can interviews with patients be seen as patient involvement?	<p>Qualitative interviews and focus group interviews can be seen as patient involvement, and also to some extent questionnaires and telephone interviews.</p> <p>In order to see and utilise an interview with a patient as involvement, it is important that the researcher or interviewer:</p> <ul style="list-style-type: none"> ➤ shares the thinking behind the project, intervention, or evaluation with the patient ➤ explains to the patient how his or her contribution will be used. In qualitative research the patient most often contribute with views, perspectives, ideas, experiences and narratives. Then the researcher analyzes and makes the interpretation. In action research the patient will often be involved in the whole process. ➤ considers if he or she want to discuss the transcript of the interview with the patient for example in order to elaborate on a specific topic ➤ gives the patient the relevant information, perhaps the [draft] outcome (articles, reports etc.) to read and comment on. 	Helle Ploug Hansen
What issues/topics are relevant to include in relation to patient perspectives?	<p>The impact of a disease and the use of a technology on patients and their significant others are issues of relevance. Patients have a unique understanding of living with a medical condition as well as experience with the use of health services and health technologies [1]. Patient's lives are not isolated but are lived in a bodily, social and cultural context. The impact of using a health technology might be physical, psychological, social, ethical and financial [2].</p> <p>Patients are individuals dealing with diseases in their daily life and through applying different actions including the use of technologies and making decisions. Patients, by their using or not using a health technology in a particular way, influence and thereby change the technology. Patients' choices are influenced by, for example, the medical condition, individual circumstances, their understanding and desires as well as family, health professionals and societal expectations at all levels. It might be relevant to include their understanding, experiences, expectations, access and actual actions in relation to a health technology.</p> <ol style="list-style-type: none"> 1. Facey KM, Hansen HP. Editorial. <i>International Journal of Technology Assessment in Health Care</i>, 27:4 (2011), 273–274 2. Kristensen FB & Sigmund H (ed.). <i>Health Technology Assessment Handbook</i>. Copenhagen: Danish Centre for Health Technology Assessment, National Board of Health, 2007. Available at 	Anne Lee

	http://www.sst.dk/publ/Publ2008/MTV/Metode/HTA_Handbook_net_final.pdf	
Can patient input submissions become invalid due to conflicts of interest?	The involvement of the pharmaceutical industry in medical research offers a range of challenges around transparency, accountability and credibility. Guidelines in the medical field for relationships between governmental agencies and industry are therefore important. Everyone participating in technology assessments should complete a declaration of conflicts of interest in which they must disclose any obligation, commitment, relationship or interest that could confound or may be perceived to conflict with his or her duties or interests in the project. Conflicts of interest exist for example when an expert has ties to activities such as a financial relationship with industry (such as through investments, stock ownership, employment, consultancies, honoraria) either directly or through immediate family. It is generally not possible for an external expert or patient representative to take part in a project if there is a conflict of interest regarding the topic of the project. Due to financial reasons, many patient organisations are strongly tied to the pharmaceutical industry and conflicts can be hard to avoid making transparency of declaration even more important. Patient input submissions, like those from other actors, can therefore become invalid if the conflict of interest is deemed to be too strong.	Sophie Werkö

Question	Answer	Written by
What is the impact of patient issues/perspectives being included in research?	Patient issues or perspectives have become an important part of research and complement the clinical and economic data in enabling a holistic assessment of the effectiveness, acceptability, appropriateness and relevance of a particular health technology for a particular patient or group of patients. This reflects the view that in order to assess a health technology appropriately we now need to consider clinical, economic and patient-based evidence. Patient-based evidence can take the form of patient experiences, qualitative or quantitative data, or quality of life data based on patient-reported outcome measures). Such data can provide valuable insights into the appropriateness, relevance and acceptability of an intervention from the patient perspective. Some would argue that this approach produces higher quality research, which ultimately has more relevance and utility for those it is intended to benefit, the patient (Staniszewska et al 2010). One example of this approach is the POPPY study (http://www.poppy-project.org.uk/) which developed a model of care that drew on parent experiences data, a systematic review of effective interventions and a national survey of neonatal units. Parents were also collaboratively involved in the analysis of data and were instrumental in the development of a model of family-centred care, which produced a model that has utility and relevance for parents and their families.	Sophie Staniszewska

	<p>Ref: Brett J, Staniszewska S, Newburn M, Jones N, Taylor L (2011). A systematic mapping review of effective interventions for communicating with, supporting and providing information to parents of preterm infants. British Medical Journal Open. doi:10.1136/bmjopen-2010-000023</p> <p>Ref: Staniszewska S, Crow S, Badenoch D, Edwards C, Savage J, Norman W (2010). The PRIME Project: Developing a Patient Evidence-Base. Health Expectations, 13 (3): 312-322.</p>	
<p>What is the impact of patient involvement in research?</p>	<p>The evidence base underpinning the assessment of patient and public involvement impact is relatively weak, primarily because of poor reporting (Staniszewska et al 2011). The GRIPP 2 study is addressing this by developing consensus on reporting guidance, in collaboration with the EQUATOR network. http://www.equator-network.org/resource-centre/library-of-health-research-reporting/reporting-guidelines-under-development/</p> <p>Some important evidence has emerged showing a wide range of impacts that contribute to enhancing the quality of research. We have included some examples from the PIRICOM study (Brett et al 2009), a systematic review that examined the impact of patient and public involvement in health and social care research. Impacts were identified in relation to the following areas: Research and the research process, users, researchers, researcher participants, community, journals, policy makers and funders. Full details of the findings are included in the review document. http://www.ukcrc.org/publications/reports/</p> <p>Impact on research and research process</p> <p>Examples of beneficial impacts of patient and public involvement (PPI) in relation to research and the research process have been found in the initial stages of research, such as developing research questions, identifying and prioritising topics, developing commissioning briefs. In undertaking research, there is evidence of impact on developing and commenting on research protocols, adapting and improving the sensitivity of research language in information and invitation letters and identifying poorly worded questions. There is evidence that PPI helps build important links with the community and can help with accessing participants for the research, improving response rates, recruitment from seldom heard groups, development of greater empathy with research participants and better informed consent based on a more informed participant. There is also evidence that PPI can help in the assessment and development of research instruments, improve the timing of interventions and ensure that the instruments are more acceptable to the community. Users of PPI can collect deeper and more insightful data based on their rapport with the participant. There is also evidence of impact on data analysis with users providing a wider perspective, different insights and identifying knowledge gaps for future research. PPI can impact on dissemination and implementation due to the dedication of users, and in some cases through the development of a cohort of advocates who disseminate key findings. In many ways PPI can help researchers achieve many of their research goals and improve the</p>	<p>Sophie Staniszewska</p>

	<p>quality of their work.</p> <p>Impact on users of health care</p> <p>There is also evidence of the impact of PPI on users of healthcare services. The beneficial impacts are divided into three main areas: personal benefits, impact on level of knowledge and impact on their level of skill. Personal benefits include feeling empowered, feeling listened to and feeling more positive, feeling more confident and a sense of fulfilment and satisfaction. Users feel mutual support from being part of a team and appreciate the social interaction with others. Services user also feel they have given something back and have done something meaningful for the research community, feeling they made a difference. Users have also reported improved levels of knowledge, more open attitudes to research and improved trust in research. Some service users report access to better information about their condition and enhanced capacity to manage their condition and solve related problems. Users also report positive impacts in relation to improved skills in research methodology and with other skills such as confidence in speaking and listening in groups. Some papers have reported more negative impacts in terms of personal impacts, skills levels and knowledge levels. For example, users reported feeling overburdened, not listened to, frustrated and marginalised.</p> <p>Other areas of impact</p> <p>Most evidence of impact is related to research and the research process and to users, with much less impact reported in relation to researchers, researcher participants, community, policy makers, journals and funders.</p>	
<p>How can better research evidence be generated by involving patients?</p>	<p>As a start, in the US there has been a lot of focus in the past few on 'patient centeredness'. This focus has come about for several reasons, but is mostly related to improving quality of care and generation of better evidence for individual patient decisions through comparative (relative) effectiveness. Don Berwick has been one of the leaders in quality of care. He wrote an interesting article in 2009 about patient centeredness from the quality of care perspective.</p> <p>The new Patient-Centered Outcomes Research Institute (PCORI) has posted a draft definition of patient-centered outcomes research (PCOR), which they sought public input on.</p> <p>The draft PCOR definition ...</p> <p>This research answers patient-focused questions:</p> <ol style="list-style-type: none"> 1. "Given my personal characteristics, conditions and preferences, what should I expect will happen to me?" 2. "What are my options and what are the benefits and harms of those options?" 3. "What can I do to improve the outcomes that are most important to me?" 4. "How can the health care system improve my chances of achieving the outcomes I prefer?" 	<p>Newell McElwee</p>