

Involving Patients in Research: Considering Good Practice

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Increasingly, patients and members of the public are involved in the design, conduct and dissemination of research. INVOLVE, the UK's national body for patient and public involvement, usefully defines this sort of involvement as: 'research being carried out "with" or "by" members of the public rather than "to", "about" or "for" them' (INVOLVE, 2012). At the Musculoskeletal Research Unit in Bristol, we are often asked about our patient involvement work. In light of the questions that we are asked, this editorial highlights some current practice and guidance. We also reflect on the impact of our patient involvement activity and hope that this serves as a useful introduction and points interested readers to further reading.

Why involve patients in research?

Rationale for involving patients in study design are multiple, and include moral and ethical arguments about citizens' rights, increasing relevance of research, and the view that doing so can improve research quality, although this may be hard to define (Fudge et al., 2008; Gibson et al., 2012; Ward et al., 2010). There are many examples of patient involvement in research, and patients have been involved at different stages in the research process, including:

- Identification of research priorities and agenda setting (Goberman-Hill et al., 2008; Oliver et al., 2009).
- Development of patient information and consent procedures (Boote et al., 2011);
- Design of interventions (Angell et al. 2003) and placebos (Goberman-Hill et al., 2013);
- Identification of outcomes (Boote et al., 2010; Boote et al., 2011; Vale et al., 2012);
- Data collection (Elliott et al., 2002) and analysis (Hewlett et al., 2005);
- Informing policy and practice (Barham, 2011).

What guidance is there?

Available advice about patient involvement in research often focuses on practical elements (Boote et al., 2006;

Buckland et al., 2007; de Wit et al., 2011). Within musculoskeletal research, Hewlett and colleagues emphasize how to 'Facilitate, Identify, Respect, Support and Train' (FIRST) (Hewlett et al., 2006), which provides a useful set of criteria through which to think about elements of design. An assessment of the FIRST model concludes that it has utility for the implementation of 'sustainable relationships between patients and researchers' (de Wit et al., 2013). Relating to clinical trials, a team in Wales have developed a standard operating procedure for involvement, providing some guidance that focuses attention on resources and possible forms of involvement at each stage in the research lifecycle (Evans et al., 2013). Guidance for the reporting of patient involvement also now exists, and aims to encourage transparency. The 'Guidance for Reporting Involvement of Patients and Public' (GRIPP) checklist suggests that reports should include methods, context, process and impact (Staniszewska et al., 2011).

Existing guidance generally mentions the variety of mechanisms that can be employed to deliver involvement activities. Possible options include group-based panels, forum meetings or citizens' juries, and individual membership of advisory groups or co-working with researchers. It is not possible to specify that one type of approach is intrinsically better than another, as choice may be informed by topic area alongside requirements and preferences of patients and researchers (Rowe and Frewer, 2005).

The ethics of involvement

Alongside practical considerations, guidance encourages researchers to consider the ethical dimensions of involvement. If a key rationale for patient involvement is the desire to ensure that patients' views are central to the design and delivery of research, then there is a need to maximize partnership and avoid exploitation. This is a complex issue and it seems best to focus on scrutiny of these issues rather than to make blanket suggestions about how patient involvement 'should' be done.

Consideration of the ethical dimensions of patient involvement may be central to best possible practice. By this, we do not mean that patient involvement activity should be reviewed by an ethics committee through an exercise in 'bureaucratic ethics' (Heimer and Petty, 2010). Instead, that application and reflection about the principles of ethical practice should be part of the design and conduct of patient involvement. This may reduce the potential for inequality and exploitation.

A useful model for thinking about equality and degree of partnership is Arnstein's 'ladder of citizen participation' (Arnstein, 1969). Arnstein argued that degree of involvement could be understood as high or low: citizen control, delegation and partnership are at the upper end of the ladder; informing, therapy and manipulation are at the lower. By considering where an activity sits on the ladder, it becomes possible to highlight any potential power differentials. Although Arnstein's model has been refined and less linear approaches have been suggested (Tritter and McCallum, 2006), we would wholeheartedly suggest a virtual trip up and down Arnstein's ladder in any planning or evaluation of patient involvement activity.

Striving to achieve good practice

In our work at the Musculoskeletal Research Unit in Bristol, we seek to involve patients in research design and conduct through a patient forum: 'The Patient Experience Partnership in Research' (PEP-R). PEP-R comprises patients with experience of musculoskeletal conditions. PEP-R sessions are interactive; training and support is provided; and patients are offered payment and expenses. PEP-R is merely one instance of the many patient involvement activities taking place around the UK. Although PEP-R was developed in collaboration between researchers and patients using guidance from INVOLVE to develop its shape, the PEP-R approach is just one possible way that involvement could be carried out.

Although there is need for evaluation of the impact of involvement in research (Brett et al., 2012; Staley et al., 2012), gains provided by patient involvement may be diffuse and hard to quantify (Fudge et al., 2008). Therefore, we focused attention on evaluation of the impact of patient involvement on stakeholders (Barber et al., 2011). Although we had no funding to support external evaluation, we assessed the impact by asking involved patients ($n=8$) and

researchers ($n=14$) to complete a qualitative questionnaire. The questionnaire was administered 17 months after PEP-R started, over which time PEP-R had met ten times and provided input into 21 studies and project ideas. Patients and researchers were asked to reflect on the impact of PEP-R on them and their work, to identify the elements that they found most useful, and to suggest improvements. We were aware that internal (rather than external) evaluation might limit any open criticism, and so we asked about possible improvements. Key findings were:

- Patients described their interest and learning about the topics and research in general. They particularly valued feedback about how PEP-R's input had shaped studies.
- Researchers identified the benefits of patients' views on the importance, relevance and feasibility of projects. They welcomed the opportunity to speak to an interested and knowledgeable group, stressing the importance of early involvement.

The work of PEP-R is purely one activity based in a single place and we would not wish to generalize from our experience. However, there appeared to be a sense of positive impact and the evaluation highlighted areas that were particularly valued by patients and researchers. Identification of impact and therefore of value indicates where patients and researchers were achieving some gains from the activity. This points towards mutual benefit.

Patient involvement is here to stay

We believe that patient involvement is here to stay, representing an ideological shift within which patients can take a more central, driving role in research that affects their health and healthcare. Many more researchers and patients are becoming actively involved in organizing or facilitating such activity. This takes considerable time and effort for all parties. We would suggest, then, that it is critical to consider best practice in patient involvement. To do so it is useful to reflect on the variety of ways that patient involvement has been conducted to date, to explore current guidance and ethical issues, and to consider evaluating involvement activity. All of these can be done in the context of deliberation about the extent to which an activity enables partnership and mutual gain.

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