chapter 9

Patient and public involvement

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The involvement of patients and the public in the development of clinical research initiatives in the UK has been central and is increasing. Whilst initially developed in relation to cancer research and cancer care, this activity has now generalized to all of healthcare research particularly through organizations such as INVOLVE (www.invo.org.uk). Patients and Public Involvement (PPI) has been evaluated and shown to be established across the NHS in the UK. The National Institute for Health Research in England has made PPI central in its development. More recently evidence is accumulating that PPI has significant impact on the quality and delivery of clinical research in healthcare but more work on the evaluation of its impact is required.

introduction

Patients and members of the public, in the UK), have been taking an increasingly active role in the development, conduct and governance of clinical research, becoming involved and working with healthcare professionals. This approach, often described as Patient and Public Involvement or PPI, has evolved significantly. The involvement of parents and other groups of carers such as in stroke, dementia and mental health and of service users in mental health has extended the definition of PPI considerably to include all groups who represent patients. Initially, in primary care where everyone is at some time a patient, the definition is even broader. Initially, in the UK PPI consisted of shared discussions in committees with patient representatives having seats on planning and oversight committees for research projects or programmes and operational, protocol-based groups responsible for conducting trials. More recently, it has developed a shared agenda of making a difference to patient care including through decisions about which research is undertaken and the delivery of research. This involvement has been at its strongest and perhaps most effective with clinical research where organizations such as INVOLVE (www.invo.org.uk) have led and produced helpful advice and support to researchers and patients, and many charities have actively supported the activities. Although the most active areas were initially HIV and cancer, many other chronic diseases such as diabetes and stroke have developed active patient and carer involvement. PPI for generic areas such as primary care, acute medicine or accident and emergency have been more challenging but valuable initiatives have been developed. During the last decade healthcare professionals and patients have worked with government, industry and charity to strengthen support for clinical research and make it central to the delivery of healthcare in the UK. The involvement of patients and the public has become key to this process. The initial arguments focused on ethical, social and political aspects of patient and public involvement and the belief held by many patients and many healthcare professionals that it was appropriate, especially for clinical research, for there to be an active programme to involve patients and the public. This view was not universal. There were healthcare professionals who were concerned that patients would bring very personal issues to the table when discussing research development at a strategic, operational or individual protocol level. There were many patients who were anxious about interacting with healthcare professionals in this way and concerned that their lack of relevant knowledge would hinder the dialogue. Generally these concerns have not been borne out and patients and professionals have become advocates and supporters of each other’s activities.

The view that PPI should be central in clinical research has been summarized by Dame Sally Davies, the Chief Medical Officer in England:

No matter how complicated the research, or how brilliant the researcher, patients and the public always offer unique, invaluable insights. Their advice when designing, implementing and evaluating research invariably makes studies more effective, more credible and often more cost efficient as well. I have always taken the view that public involvement in research should be the rule not the exception. It is fundamental to ensure high quality research that brings real benefits for patients, the public and the NHS. ‘Involvement’ means an active partnership between the public and researchers in the research process, rather than using people as the ‘subjects’ of research. Active involvement can take the form of consultation, collaboration or user control. This would include, for example, public involvement in advising on a research project, assisting in project design, or carrying out the research.

As the experience with patient and public involvement has developed over time the central issues have changed. PPI has become a recognized part of strategic and operational development of research and of the development of research...
with a regular stakeholder Forum and interfaces for PPI in the CRN with organizations such as INVOLVE, the UKCRC and the James Lind Alliance. The early experience in the National Cancer Research Network (NCRN), the first to be set up and building on a pre-existing Consumer Liaison Group (CLG) highlighted the benefits of patient and carer involvement. Members contributed to the activities and meetings of the Clinical Study Groups that oversee the development of clinical studies, including activities such as study design and study prioritisation. PPI evolved in the NCRN to become an integral part of its activity, and a facilitator was employed to support the work of the CLG. Similarly, in the Mental Health Research Network (MHRN) the need to engage patients, users and carers was recognized from the outset and resource was committed to supporting a Service User Reference Group (SUR), and associated support staff, and subsequently to the development of FACTOR (a Family and Carers Group) to ensure that both users and carers are represented.

The key objectives for CRN PPI in the years 2006–2010 are listed below:

• Explore and agree ways to actively involve patients and members of the public in the work of the Coordinating Centre, and to implement these. The first priority was to develop effective PPI training for Network staff and clinical researchers. A PPI Development Group, a mixture of patients, carers and Coordinating Centre staff, advised on the optimal approach to involving patients and the public.

• Explore and agree opportunities for involvement of patients/members of the public in CRN industry activities. The involvement of patients and carers in industry-sponsored studies was identified as a key area of activity and led to guidance on involving patients and carers in the process for the adoption of Industry studies. Issues around the provision of confidential data pose a particular challenge and the ‘Industry Letter of Agreement’ that a patient representative will sign to agree confidentiality and cover them for insurance has now been finalized.

• Explore the inclusion of a lay summary for each study on the CRN Portfolio. Each study on the CRN Portfolio is being populated with a lay summary and links with Patient Information Leaflets.

• Develop a plan to support PPI at local level. Local staff and patients explored the added value of PPI and this led to increased activity to involve local research communities in development work.

• Continue to meet and work with key strategic partners to identify and develop joint initiatives. A stakeholder forum of patients, investigators and funders to identify common issues across organisations involved in PPI.

In December 2009, following the 5-year external peer review of CRN, a formal new plan resulted for PPI. The CRN was congratulated on its programme of PPI activity overall but greater coherence was needed for patients and carers. The implementation of the review recommendations and strategy across CRN beyond 2011 will promote:
An individual perspective on research in healthcare systems

As a former cancer patient I have always been concerned at the lack of integration between the healthcare researcher, the commissioners and those who deliver the care. I have always found it strange that the word ‘research trial’ seemed to follow the diagnosis of my illness rather than being a normal part of being a patient. I have been particularly keen to see more research that would directly lead to improved patient care.

One of the early stories I heard when I became involved was that patients who went on a clinical trial had better outcomes. In my own mind I could reconcile this with factors such as extra visits to the hospital, more people looking at you and additional tests that might make things better. But, surely it might make little difference whatever if you were in the group that received the standard treatment or a placebo. Perhaps some patients might choose to go a trial in the sole belief of a better outcome. The other and more worryingly aspect was the notion that this argument of clinical trial equals better outcomes was being talked about as a reason for doubling the number of trials. It was even suggested that patient groups should advocate on behalf of trials on this basis.

I did not actually take part in a clinical trial as part of my treatment yet I had a good outcome. Did I make a mistake by not asking about research opportunities? Would I have had even better outcomes although as I am still alive I consider that to be the best result? I did, however, later discover that the clinicians who treated me were research active and working in an establishment with an excellent record of clinical research and strong academic links. These were the main reasons I choose to accept the offer to participate in the discussions around this topic.

As a participant to the email discussions and the dialogue in Lyon it was fascinating to see the levels of collaboration that are taking place across continents in the interest of patients. It was interesting to meet and hear about the differences in healthcare systems, which make comparison extremely challenging. It was valuable to understand the complexity of data collection within the nature of such enquirys.

We need to gain a broader understanding of all the issues rather than rely on the outcomes of individual patients taking part in a trial. It is important to know if the other patients attending the same clinics receive better outcomes in general. I think that I would still rather be treated by professionals who were applying recent research findings, using the most modern technologies and working in an environment of professional challenge. I will however insist on asking about whether the people are research active. I will enquire about trial opportunities and become informed about their purpose, risk and burden. I will also ask how it might affect patient care in the future. Additionally, there does need to be more research into what we each mean by health outcomes as the patients’ view may be significantly different.

1. Coherence
   - Promote the involvement of patients in research studies
   - Encourage and sustain such involvement – for reasons that are ethical, pragmatic, social and cultural
   - Target involvement where it creates the maximum benefit and impact

2. Collaboration
   - Recognize, acknowledge and share good practice
   - Gather patient experiences, and use these as a stimulus for change
   - Create a series of dialogues on issues that matter to patients

3. Coordination
   - Co-ordinate activities, where possible, across the networks
   - Ensure equity whilst recognizing diversity across the networks’ activities

The involvement of patients, carers and the public in research needs to continue to be embedded in a culture that places the patient at the centre of clinical research. This includes activities to assist investigators to develop patient sensitive study design, membership of groups which develop new studies, and active involvement with study delivery teams to maximize recruitment to studies and sustain follow up (including contribution to problem solving). It will be important that the clinical research communities develop, learn, support and benefit from experience of ongoing PPI practice, and the increasing expertise of PPI lead staff.

**Conclusion**

There is good evidence of engagement and impact of PPI on clinical research in the UK. It has become a central part of clinical research in the NHS. The success of the early topic specific networks can be extended to the primary care and comprehensive network. Our belief that PPI enhances the quality and delivery of clinical research will be tested systematically in the new approaches to be put in place for the next 5 years and be recognized by patients, the public and politicians.

First that patients must be at the heart of everything we do, not just as beneficiaries of care but as participants in shared decision making. As patients, there should be no decision about us without us.

Andrew Lansley, CBE, MP – Secretary of State for Health

**Disclosures**

The authors have not declared any conflicts of interest.