Patient and Public Involvement in research

BY CARL PHILPOTT AND ANEEKA DEGUN

One step further from involving patients in setting research priorities is to involve them in the planning and recruitment stages of the subsequent trials and studies. Here, **Carl Philpott** and **Aneeka Degun** explain the concept of Patient and Public Involvement throughout the research process.

Aneeka with a patient at a Patient and Public Engagement stand for International Clinical Trials Day 2015, at the Royal National Throat Nose and Ear Hospital.

> “No matter how complicated the research or how brilliant the researcher, patients and the public always offer unique, invaluable insight.”

Traditionally medical research has been driven and dominated by clinicians or by industry, designing and running studies that they think are important to address to improve the health communities that they serve with patients only involved as research participants. However when reviewing medical research and its impact on clinical practice, it was suggested that as much as 85% of investment in medical research has been wasted, with wrong questions being asked by researchers, poor study designs and a lack of impact on clinical practice [1].

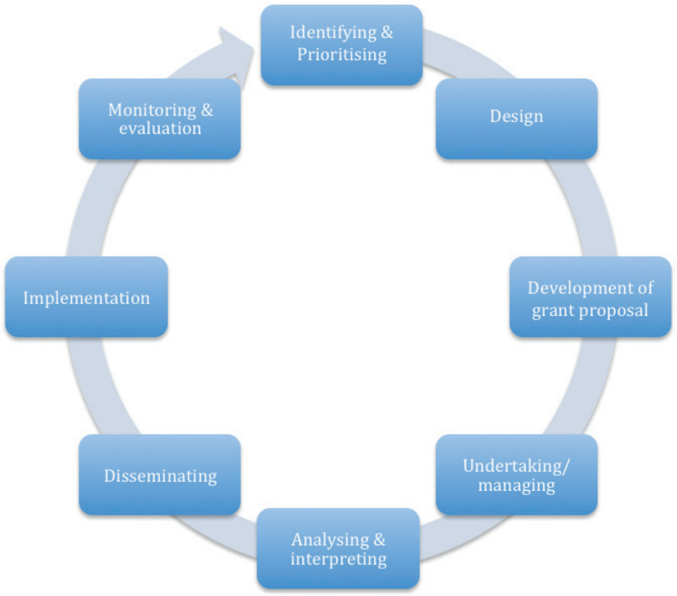
This highlighted that something needed to change, and patients were asked across healthcare disciplines about their care, for example ‘What issues or problems would you like researchers to focus on when designing their studies?’ ‘What results do you want to see from your treatments?’ ‘Which part of your child’s clinical care would you like us to investigate?’

Today it is recognised that to truly deliver people-focused research in the NHS it simply cannot be achieved without the involvement of patients and the public, as captured in this quote by Sally Davis, “No matter how complicated the research or how brilliant the researcher, patients and the public always offer unique, invaluable insight.” Recently there has been a growing recognition of the need for ‘Patient and Public involvement’ (PPI) in the research process right from the generation of ideas through to dissemination and implementation of the results. Currently any applicant seeking to secure funding through funding bodies such as the National Institute of Health Research (NIHR) in the UK will need to demonstrate that they have involved patients and members of the public in their application and have a plan of how this involvement will continue throughout the entire research process.

So what do we mean by PPI and how do we involve patients in our research?

The purpose of PPI is to ensure that the research we do is meaningful and relevant to the patients and families that it is intended for. INVOLVE, who are a national advisory group funded by the NIHR to support public involvement in NHS, public health and social care research. They define PPI as, “an active partnership between patients, members of the public and researchers, clinicians, nurses and allied healthcare professionals”. This involvement can take various forms including; in the choice of the research question, assisting

Figure 1: A typical research cycle from identifying research ideas to monitoring and evaluating any changes made.



in the design of the studies and advising on the conduct of the research, through to getting the message out in the NHS and improving patient care. Essentially, PPI is healthcare professionals and / or researchers working together with patients and the public to improve the health communities that they serve. INVOLVE's definition of the term 'patients and public' includes: patients, potential patients, carers and people who use health and social care services. It also included members from organisations that represent people who use services.

PPI can potentially span the entire course of the research process and the appropriate method of involvement will depend on the research. This article will share some approaches as well as ENT examples from our research teams' experiences, showing the power and impact that PPI brings at each stage of the research process (Figure 1).

Research prioritisation

Initially when you are identifying and prioritising potential research topics, it is an ideal time to involve patients, via surveys or patient panels to help inform the clinical areas that are important to them. Essentially, in your team of researchers, clinicians or surgeons, PPI representatives are providing a missing piece of the puzzle and a different perspective. In the UK, the James Lind Alliance has provided a forum for this process in balance, tinnitus and mild to moderate hearing loss. More recently, ENT UK and evidENT have run a national prioritisation initiative (GENERATE) to identify areas of research importance within ENT, to develop a national research agenda for ENT, hearing and balance care in the UK. This started by asking various stakeholders including patients and lay members to propose topics. After several months of collating the suggested topics the GENERATE team held a consensus workshop in September to decide on the top priorities in key domains of ENT, hearing and balance care. Within each of the domains, patient and lay representatives were present at the workshop to help contribute to the final topics chosen. The results of this were announced at the launch event on 3 December 2015 and available online at http://entuk.org/national-research-agenda-ent-hearing-and-balance/.

Research design

Once you have identified an area of importance, you can continue to involve patients in the design process of the specific study, for example when you are specifying your research question. You can run this past a patient panel to ensure that it accurately reflects the needs of the patients with a particular condition. Here are a couple of recent examples of how PPI has impacted the design of ENT studies:

Study One

A randomised controlled trial to determine the most effective treatment for Down's syndrome children who suffer from glue ear was proposed. The trial team needed to ascertain whether parents would agree for their child's treatment to be randomised to the different treatment arms: grommets, hearing aids or no treatment. Upon speaking with parents and healthcare professionals treating these children they did not feel comfortable randomising the treatment and suggested that a study following children after routine treatment would be a better option.

Study Two

A proposal to run two parallel trials in chronic rhinosinusitis offering antibiotics to those without polyps and surgery to those with polyps was put to a PPI panel. Patients in both subgroups questioned why treatments were compartmentalised and suggested combining the two trials with an analysis that would determine any differences between the two subgroups.

Any research team setting out to design clinical research and apply for external funding, especially where patient recruitment is involved, should could include PPI at an early stage in their design / writing process. Most PPI volunteers will not have detailed knowledge of research design, however with training and support from the research team, they will be able to provide their opinions on what the average research participant will find acceptable in terms of the potential burdens of questionnaire completion, additional tests, clinic visits, etc., that may be involved with a particular study. For those who actually suffer with the disease / condition under consideration, they will bring their experience and expertise to the trial design. This can be vital to ensure that patients approached in a research trial will want to participate and are likely to want to stay in a trial. Further to this, they will also be able to help with the writing of the lay summary that is always a key headliner of any funding or ethics application. Having both patients and public members as co-applicants provides ongoing advice on where and how patients and the public could be involved.

Research conduct

Once a research study is funded, there are still some crucial requirements for the ethics application that can benefit from PPI, namely the patient information documents. Again, this input may be pivotal in determining how potential participants respond to the notion of entering the study. In NIHR funding streams, research teams will have been expected to outline how PPI will be utilised during the research itself. This may take a variety of guises but can involve asking a PPI representative to sit on committees such as the Trial Steering Committee or the Trial Management Group. This will offer them the opportunity to provide input if any unforeseen difficulties in recruitment are faced or similarly if there are problems with retention of participants after recruitment. One approach here is to troubleshoot by asking approached patients through structured interviews what stopped them from taking part. Here you may find they report that the trial outcome assessments were not adequately explained. This highlights the opportunity for training staff. After this has been implemented, recruitment numbers may increase to where they were projected to be.

Analysing, interpreting and disseminating

Carrying on the research cycle above, with the results of the study in hand it is then possible to approach your patient and public panel to assist with analysing the research (e.g. as key members of the research team) and to include patients to help produce summaries of the findings, to ensure that summaries are understandable to patients as well as members of the public. Patients are key in advising you on how to best publicise and communicate your results so that they are accessible to your targeted population. For example through snowballing they can communicate these findings to their informal and community networks, they can help co-write reports, assist you in getting results published on charities' or voluntary organisations' websites or give talks at professional conferences. The final stage involves putting the research findings into clinical practice; it takes time to develop the research and sometimes longer to implement into clinical practice. Involving patients early on will have a positive knock-on effect at each stage of the research cycle through to implementation, increasing the likelihood that evidence is implemented into practice sooner.

Summary

The role of PPI throughout the research process from inception to dissemination and implementation is critical and the stages outlined above provide a synopsis of considerations for research teams in how to engage with this process for greatest impact on clinical practice and patient care.

References

1. Chan AW, Song F, Vickers A, et al. Increasing value and reducing waste: addressing inaccessible research. *Lancet* 2014;**383(9913)**:257-66.

PPI resources

1. INVOLVE
www.invo.org.uk/resource-centre/resource-for-researchers
www.invo.org.uk/find-out-more/invodirect
www.invo.org.uk/resource-centre/evidence-library
www.invo.org.uk/resource-centre/involvement-cost-calculator
2. Heathtalkonline http://www.healthtalk.org/
3. People in Research www.peopleinresearch.org
4. Regional Research Design Services http://www.rds.nihr.ac.uk/public-involvement/
5. James Lind Alliance (JLA) Guidebook http://www.jla.nihr.ac.uk/about-the-james-lind-alliance
6. Fifth Sense www.fifthsense.org.uk
7. PPI case studies http://www.nihr.ac.uk/funding/pgfar-patient-and-public-involvement.htm
8. Cartwright J, Crowe S, Perera R, et al. (Eds.) Patient and Public Involvement Toolkit. 2011; Hoboken, NJ, Wiley-Blackwell.

Carl Philpott,

PPI Champion for the NIHR ENT Specialty Group;
Clinical Senior Lecturer,
Norwich Medical School,
University of East Anglia, Norwich;
Honorary Consultant ENT Surgeon and Rhinologist, James Paget University Hospital, Norfolk, UK.

E: C.Philpott@uea.ac.uk

Aneeka Degun,

PPI Lead for evidENT, UCL Ear Institute,
Audiologist, Royal National Throat, Nose and Ear Hospital, 330 Gray's Inn Road, London, UK.

E: aneeka.degun.10@ucl.ac.uk

Declaration of competing interests
None declared.

For more information on the GENERATE reasearch agenda, see our interview with Professor Schilder on page 62, and a report from the launch night on page 170.