
Impact of public involvement on the ethical aspects of research

A joint briefing from the Health Research Authority and INVOLVE on how public involvement can help in the ethical design and conduct of research.

Researchers conducting most types of research in the NHS in England are required to submit their study for ethical review by a Research Ethics Committee (REC) within the UK Health Departments' Research Ethics Service.

A study that looked at RECs' decisions showed the most common concerns they raised were about: informed consent; care, protection and recruitment of research participants; and the quality of information such as information provided to participants and lay summaries of the research (Angell et al. 2008).

Since 2010 a joint Health Research Authority and INVOLVE study has, on a biennial basis, analysed the nature and extent of public involvement in applications for ethical approval assessed by RECs (Tarpey and Bite 2014, Updated analysis to include data from applications in 2014 will be available later in 2016). This work suggests that the information provided by researchers on whether or not they have involved or plan to involve the public in their work can provide assurances to RECs which greatly assist their ethical review. The HRA is reviewing how it can put greater emphasis on assessing public involvement as part of ethical review.

Drawing on literature reviews (Wilson et al 2015; Brett et al 2014; Staley 2009) and other relevant articles and reports this briefing illustrates how public involvement throughout a study can help to make research ethical by:

- **Making research more relevant**
 - so that the research results are more likely to be useful and of benefit patients and the public;
- **Helping to define what is acceptable to participants**
 - particularly in controversial or sensitive research;
- **Improving the process of informed consent**
 - making it easier for prospective participants to understand the research and potential risks;
- **Improving the experience of participating in research**
 - checking that the practical arrangements for participants are appropriate and a respectful use of people's time; and
- **Improving the communication of findings to participants and the wider public**
 - providing information on the progress of the research as well as the final results.

Making research more relevant

Patients and the public frequently prioritise topics for research that are different to those of academics and health professionals (Boers et al 2015; Crowe et al 2015). People living with a health condition are often in a better position to know what questions remain unanswered about their treatment or condition, and what research would most likely improve their quality of life (Evans et al 2011). Patients are also frequently consulted on the most meaningful and relevant outcome measures in clinical trials (COMET Initiative 2016).

Public involvement right at the beginning of a project helps researchers to identify new research topics and to modify their research questions (Whear et al 2012). It can help shift the focus of the research design to become more in line with the public's interests and concerns. Working with members of the public means researchers need to be clearer about why they want to conduct their research and how it is relevant to the public (Staley 2016; Boers et al 2015). It may challenge researchers' aims and assumptions.

Public involvement can also influence what research outcomes are measured as well as how they are measured (Andrews 2015; Ennis and Wykes 2013; Boers et al 2013) helping to make the research findings more relevant and valuable to the people who want to use them (Blackburn et al 2015; Carter et al 2013).

Taking part in research that is more likely to benefit the participants and / or other patients and society more generally is a more respectful and ethically acceptable use of people's time (Staley 2016; Cossar and Neil 2015; Blackburn et al 2010).

Helping to define what is acceptable to participants

Sometimes the risks involved in researching a new treatment make it questionable whether the research should go ahead (Cossar and Neil 2015; Illffe et al 2013; Evans et al 2011). By working with patients and carers and communities who might be asked to take part in high risk projects, researchers can find out:

- whether they would be willing to participate given the risks involved; and
- what potential participants consider to be the most serious risks and how best to explain these.

Involving the public early on during a project also helps researchers to design and conduct their research in a way that potential participants consider to be ethically acceptable (Caldon et al 2010; Carter et al 2013; Littlechild et al 2015). It helps researchers to identify:

- processes for obtaining consent that are acceptable to potential participants, for example when consent may need to be taken at difficult times (Morris 2004) or the process is unusual for example needing people to opt out of a trial (Boote et al 2016);
- the trial design that is most likely to be acceptable to potential participants (Boote et al 2011; Edwards et al 2011; Nuffield Council on Bioethics 2015);

- the most appropriate times to contact patients to invite them to take part in a study or for follow-up interviews / assessments; based on their own experience, patients will know when this is least likely to cause anxiety or distress (Boote et al 2016);
- any ethical concerns that may be specific to a particular community, which is important when carrying out research with people from diverse cultural backgrounds (Blackburn et al 2010; Salway et al 2015); and
- when and how it is appropriate for researchers to collect information which may be sensitive in nature or potentially distressing (Carter et al 2013; Nuffield Council on Bioethics 2015).

Improving the process of informed consent

Public involvement plays an important role in producing good participant information sheets. Many studies do not get a favourable opinion first time around because their participant information sheets are poor. Public involvement is also valuable in shaping the entire consent process because it is as much about the conversation between the researcher and the potential participant as it is about the written information (Jenner et al 2015; Kennedy et al 2011; Langston et al 2005).

Involving the public in designing the consent process ensures that:

- potential participants receive the information they want and need;
- the information is delivered in a way that reflects their interests and concerns; and
- any written or verbal information is clear and accessible.

This makes it more likely that consent will be genuinely ‘informed’ and that people fully understand what taking part in a project will involve (Carter et al 2013; Jenner et al 2015).

When carrying out research with people from diverse backgrounds, public involvement ensures that the process of obtaining consent is culturally appropriate and is sensitive to a community’s concerns. For example, public involvement can check that the language used is not stigmatising to people with mental health difficulties or to people with a disability. Involving the public at this stage helps to make sure that the recruitment process is understood by potential participants (Faulkner 2004; Salway et al 2015).

Improving the experience of participating in research

Public involvement in research design is likely to make sure that the practical arrangements meet the needs of the participants (Ennis and Wykes 2013 ; Jenner et al 2015). This makes it easier for patients and members of the public, including children and young people to take part in research and ensures they are not unduly burdened by their participation. It also demonstrates that researchers respect and value the time given by the participants (Nuffield Council on Bioethics 2015; Staley 2016), for example, by helping to ensure that:

- questionnaires are an appropriate length, relevant and accessible;
- appointments are scheduled at times and places that are convenient for participants to attend;

- participants are not asked to undergo too many assessments or invasive tests; and
- participants are not out of pocket as a result of taking part in research including paying for their travel expenses (unless advised to the contrary before taking part).

Improving the communication of findings to participants and the wider public

It is important that the progress and findings of the research are communicated to participants and the wider public as well as the research community (Evans et al 2011; Fairbrother et al 2013). To inform participants, some research teams produce newsletters to keep people informed of progress, as well as publicising the findings by giving talks to patient groups and publishing lay summaries. This ensures that participants interests are recognised and addressed (Staley 2016).

Public involvement in drafting Plain English and other summaries of the findings helps to ensure that information is presented in a variety of accessible and useful formats, and that the questions that patients and other members of the public may have are properly answered (Supple et al 2015; Littlechild et al 2015; Evans et al 2011: COMET Initiative 2016).

References

- Andrews L., Allen H., Sheppard A. Z., Baylis G., and Wainwright T.W., (2015) **More than just ticking a box...how patient and public involvement improved the research design and funding application for a project to evaluate a cycling intervention for hip osteoarthritis**, Research Involvement and Engagement, 1:13.
- Angell E.L., Jackson C.L., Ashcroft R.E., Bryman A., Windridge K., Dixon-Woods M. (2008) **An analysis of decision letters by research ethics committees: the science/ethics quality boundary examined**. Quality and Safety in Health Care, 17 131-136.
- Blackburn H., Hanley B., and Staley K. (2010) **Turning the pyramid upside down**, INVOLVE, Eastleigh.
- Blackburn S., Higginbottom A., et al (2016) **Patient-reported quality indicators for osteoarthritis: a patient and public generated self-report measure for primary care**, Research Involvement and Engagement 2:5.
- Boers M., Brooks P., Strabd V., Tugwell P., (2015) **The OMERACT Handbook**, OMERACT http://www.omeract.org/pdf/OMERACT_Handbook.pdf.
- Boers M., Kirwan J.R., et al (2013) **Developing Core Outcome Measurement Sets for Clinical Trials: OMERACT Filter 2.0**. Journal of Clinical Epidemiology, 2013.11.013.

Boote J., Julious S., et al (2016) **PPI in the PLEASANT trial: involving children with asthma and their parents in designing an intervention for a randomised controlled trial based within primary care**, Primary Health Care Research & Development, doi:10.1017/S1463423616000025.

Boote, J., Baird, W., Sutton, A. (2011), **Public involvement in the design and conduct of clinical trials: a review**. The International Journal of Interdisciplinary Social Sciences, 5(11), 91-111.

Brett, J., Staniszevska, S., et al (2014) **A systematic review of the impact of patient and public involvement on service users, researchers and communities**. The Patient. DOI 10.1007/s40271-014-0065-0.

Caldon, L., Marshall-Cook, H., Speed, G., Reed, M. and Collins, K. (2010) **Consumers as researchers - innovative experiences in UK National Health Service Research**. International Journal of Consumer Studies, vol. 34, no. 5, pp. 547-550.

Carter P et al (2013) **Mobilising the experiential knowledge of clinicians, patients and carers for applied health-care research**, Contemporary Social Science: Journal of the Academy of Social Sciences, 8(3), 307-320.

COMET (Core Outcome Measures in Effectiveness Trials) Initiative (2016): www.comet-initiative.org/resources/publicinvolvement: Covers public involvement in the development of Core Outcome Sets and End of Study Information.

Cossar, J. and Neil, E. (2015), **Service user involvement in social work research: learning from an adoption research project**, British Journal of Social Work, Vol. 45 No. 1, pp. 225-40.

Crowe, S., Fenton, M., Hall, M., Cowan, K. and Chalmers, I. (2015) **Patients', clinicians' and the research communities' priorities for treatment research: There is an important mismatch**, Research Involvement and Engagement, 1:2.

Edwards, V., Wyatt, K., Logan, S. and Britten, N. (2011) **Consulting parents about the design of a randomized controlled trial of osteopathy for children with cerebral palsy**. Health Expectations, vol. 14, no. 4, pp. 429-438.

Ennis, L. & Wykes, T. (2013) **Impact of patient and public involvement in mental health research: longitudinal study**, The British Journal of Psychiatry, 203(5) 381-6.

Evans, I., Thornton, H., Chalmers, I. and Glasziou, P. (2011) **Testing Treatments: better research for better healthcare**, Pinter & Martin, 2nd Edition.

Fairbrother P et al (2013) **Involving patients in clinical research: the Telescot Patient Panel**, Health Expectations doi: 10.1111/hex.12132.

Faulkner A., (2004) **The ethics of survivor research: Guidelines for the ethical conduct of research carried out by mental health service users and survivors**, Joseph Rowntree Foundation.

Iliffe S., McGrath T., and Mitchell D. (2013) **The impact of patient and public involvement in the work of the Dementias & Neurodegenerative Diseases Research Network (DeNDRoN): case studies**, Health expectations, 16(4), 351-61.

Jenner M. K. (2015) **Practical considerations in improving research through public involvement**, Research Involvement and Engagement, 1.3.

Kennedy S in association with involved carers (2011) **Older cares involvement in research: Why what and when?** Nottingham: University of Nottingham and London: Macmillan Cancer Support.

Langston A., McCallum M., Campbell M., Robertson C. and Ralston S. (2005) **An integrated approach to consumer representation and involvement in a multicentre randomised controlled trial**, Clinical Trials, vol. 2, no. 1, pp. 80-87.

Littlechild R., Tanner, D. & Hall, K. (2015) **Co-research with older people: Perspectives on impact**, Qualitative Social Work, 14(1), 18-35.

Morris M., Nadkarni V., Ward F. and Nelson R. (2004) **Exception from informed consent for paediatric resuscitation research: Community consultation for a trial of brain cooling after in-hospital cardiac arrest**. Paediatrics, vol. 114, no. 3, pp. 776-781.

Nuffield Council on Bioethics (2015) **Children and clinical research: ethical issues**, Nuffield Council.

Salway, S., Chowbey, P., Such, E. and Ferguson, B. (2015) **Researching health inequalities with Community Researchers: practical, methodological and ethical challenges of an 'inclusive' research approach**, Research Involvement and Engagement 2015, 1:9.

Staley K et al (2016) **Making it clear and relevant: patients and carers add value to studies through research document reviews**, Mental Health and Social Inclusion, Vol. 20 Issue 1 pp. 36-43.

Staley, K. (2009) **Exploring impact: Public involvement in NHS, public health and social care research**, INVOLVE, Eastleigh.

Supple, D., et al and on behalf of the U-BIOPRED PIP group (2015) **From tokenism to meaningful engagement: best practices in patient involvement in an EU project**, Research Involvement and Engagement, 1.5.

Tarpey, M. & Bite, S. (2014) **Public involvement in research applications to the National Research Ethics Service: Comparative analysis of 2010 and 2012 data**, INVOLVE, Eastleigh.

Whear, R. et al (2012) **Establishing local priorities for a health research agenda**, Health Expectations, 18, pp.8–21.

Wilson P., Mathie E., et al (2015) **ReseArch with Patient and Public invOLvement: a RealisT evaluation – the RAPPORT study**, Health Services & Delivery Research, No 3.38, Ch 2.

Implications for practice

This briefing provides an overview of how the information on public involvement provided by researchers can facilitate ethical review of research studies by RECs. The earlier researchers start to involve the public in designing their studies the more likely they are to address the range of issues covered in this briefing prior to submitting their application for ethical review. This should reduce the likelihood of researchers being asked to change and resubmit aspects of their documentation and enhance the likelihood of recruiting participants to their studies to time and target.

The section below provides more information on public involvement in research to help researchers successfully find and involve patients and the public in their work.

Useful reading

HRA / INVOLVE joint statement (2016) **Patient and public involvement in research and research ethics committee review**. INVOLVE, Southampton.

www.invo.org.uk/posttypepublication/patient-and-public-involvement-in-research-and-research-ethics-committee-review

INVOLVE (2014) **Guidance on the use of social media to actively involve people in research**, INVOLVE, Eastleigh

www.invo.org.uk/posttypepublication/guidance-on-the-use-of-social-media

The **Evidence library** on the INVOLVE website contains reports and articles that cover:

- the nature and extent of public involvement in research
- the impact of public involvement in research
- reflections on public involvement in research

www.invo.org.uk/resource-centre/evidence-library

See also INVOLVE resources and references on **involvement of children and young people in research**:

www.invo.org.uk/find-out-more/how-to-involve-people/involving-children-and-young-people

The HRA website has a section for the research community providing advice and guidance on making applications for HRA Approval in England and on ethical review. It included includes guidance on the provision of information for participants at the end of a study for clinical trials and other interventional studies:

www.hra.nhs.uk/research-community/end-of-study-and-beyond/participants-at-the-end-of-study

About this briefing

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