Patient and Public Involvement (PPI) – Briefing Notes for Researchers

These notes have been written in response to requests by researchers who attended a PPI workshop in Oxford in April 2015. They are quick reference guides to resources and sources of help, both internal and external, and will be further developed as feedback on them is received.

Please note that patient and public involvement in research does not need ethical approval. Patients and the public involved in this way are acting as specialist advisers, not as research participants. NIHR INVOLVE and the Health Research Authority (formerly the National Research Ethics Service) have issued a joint statement to confirm that ethical approval is not required, available here:
http://www.invo.org.uk/wp-content/uploads/2011/12/INVOLVENRESfinalStatement310309.pdf.
In addition, the Health Research Authority has a decision tool to help you check – see here:
http://www.hra-decisiontools.org.uk/research/

Please let us have any comments on these resources by contacting Sandra.Regan@ouh.nhs.uk

Table of Contents

1 When can I do PPI in the research cycle?

PPI can be part of the research cycle at any stage. The ***Research Design Service*** (RDS – see note 3) has produced a handbook for researchers entitled "Patient and public involvement in health and social care research" which shows how to incorporate PPI at the following stages:

- Identifying and prioritising research
- Study design
- Development of the grant proposal
- Undertaking/managing research
- Analysing and interpreting data
- Dissemination of findings
- Implementation of findings
- Monitoring and evaluation

The handbook can be downloaded here: http://www.rds.nihr.ac.uk/patient-and-public-involvement/for-researchers/ and there are also links to other resources and information about the services that the RDS can provide. Page 14 of the handbook has a schematic showing the research cycle.

The ***James Lind Alliance*** Priority Setting approach is a well-regarded and robust way to involve patients and carers in identifying and prioritising research (see Briefing Note 2; How do I know what research matters to patients?).

It's easy to think you need to do PPI at every stage of all projects. This may not be so, and it's always worth thinking through what you want your PPI to achieve and hence at what stage(s) it will be most useful. Indeed, you may usefully make these very decisions in partnership with patients and the public.

At whatever stage you want people to take part, you need to find them. You can do this by advertising what you need for your study on the Patients Active in Research in the Thames Valley website at http://patientsactiveinresearch.org.uk/ as well as via INVOLVE's People in Research website at http://www.peopleinresearch.org/ The former covers all health research across the whole of the Thames Valley, while the latter is nationwide. We can help you search for patients who have registered on the Thames Valley site as well as posting your study there and letting them come to you.

There are also condition-specific sites such as:

- www.oxdare.ox.ac.uk/become-a-friend
- www.joindementiaresearch.nihr.ac.uk

These are specific to dementia but there are others, often linked to condition-specific charities. The Association of Medical Research Charities (www.amrc.org.uk) may be able to help you.

If you are looking for young people to get involved, you may find Generation R helpful. It is a National Young Persons' Advisory Group made up of local groups across the country, funded by the NIHR; see http://generationr.org.uk/

You will need to provide clear information explaining what you are looking for and how they can be involved.

2 How do I know what research matters to patients?

Involving patients in identifying and prioritising research will help you to find out what matters most to them. The ***James Lind Alliance*** (JLA) offers a method for setting research priorities involving patients, carers and health and social care professionals in a given condition or health area. These Priority Setting Partnerships (PSPs) are not the only way that research priorities can be set, but they follow a clear process (set out in the JLA guidebook), are co-ordinated by NETSCC (the NIHR Evaluation, Trials and Studies Co-ordinating Centre) and are guided by an independent JLA Adviser.

PSPs take about a year to 18 months to carry out, cost approximately £20-35k (but this is very variable depending on support available) and produce a "Top 10" set of research questions that matter most to patients/carers and clinicians. Research funders are increasingly keen to consider JLA-identified research.

If a PSP has already been conducted in an area of interest to you, you can address the resulting research priorities even if you were not involved in the partnership. If a PSP has not been carried out in your area, why not think about setting one up?

More information about the JLA, previous/current PSPs and "top 10s" is available here: www.**lindalliance**.org

The ***NIHR Oxford Biomedical Research Centre*** (BRC) is unique in that it offers a co-ordinating "hub" to support the setting up and delivery of PSPs that are led from within, or linked with, Oxford. For more information see here: http://oxfordbrc.nihr.ac.uk/working_groups/patients-active-in-research/patients-active-in-research-pair-projects/. If you are interested in initiating a PSP, please contact sandra.regan@ouh.nhs.uk

3 What guidance is available to help me do PPI?

Two key organisations providing help and guidance are the ***Research Design Service*** (RDS) and ***INVOLVE***.

RDS South Central covers Oxford - see http://www.rds-sc.nihr.ac.uk - and offers "a number of resources to help researchers achieve meaningful PPI in their projects". Your point of contact for PPI support when writing a grant application for NIHR or other national peer reviewed funding streams is the Patient and Public Involvement Officer based in Southampton: Megan Barlow-Pay, Tel : 023 8120 4772, e-mail M.S.Barlow-Pay@soton.ac.uk

One of the issues often raised by researchers wanting to do PPI at an early stage is the cost of working with patients (both expenses and payment for time where this is made – see note 5). RDS South Central is able to help with reimbursement for PPI expenses and time. To request support you will need to use this link http://www.rds-sc.nihr.ac.uk/request-support/

INVOLVE offers resources on a range of PPI topics - see http://www.invo.org.uk/; these include a cost calculator for those who want to work out how much to budget for PPI, a document on Senior Researchers doing PPI, briefing notes for researchers, case studies of involvement, a database on training and support, and templates of documents such as job descriptions and terms of reference for committees and steering groups.

One frequently asked question is how to handle difficult situations in meetings where patients and the public are involved. Some of the INVOLVE guidance may help, but there are skills to chairing or facilitating all meetings. It may be a good investment to get an external facilitator if there are likely to be especially challenging issues raised or if you don't yet feel confident in your facilitation skills. We can connect you with freelance facilitators working in the field of patient involvement if you ask us.

We are building a library of local case studies, and these will be published on the Patients Active in Research website, where you can also advertise opportunities for involvement in the Thames Valley. Opportunities can also be advertised nationally via INVOLVE's People in Research database.

The strategy for involving patients in research at the ***NIHR Oxford Biomedical Research Centre*** BRC), Musculoskeletal ***Biomedical Research Unit*** (BRU) and ***Oxford University Hospitals*** (OUH) NHS Trust covers issues such as paying for involvement, embedding PPI within governance structures and preparing suitable lay summaries. It is available at http://oxfordbrc.nihr.ac.uk/public/ppi-strategy/ and more information on PPI at the BRC/U can be found here: http://oxfordbrc.nihr.ac.uk/working_groups/patients-active-in-research

Sophie Petit-Zeman, Director of Patient Involvement at the *NIHR Oxford Biomedical Research Centre* (BRC), Musculoskeletal *Biomedical Research Unit* (BRU) and *Oxford University Hospitals* (OUH) NHS Trust writes a regular patient involvement blog which you may find offers you helpful insights – see http://oxfordbrc.nihr.ac.uk/blog/

4 How do I record what PPI I have done?

This is an area of growing interest and activity in PPI and is necessary both to enable others to follow your methods, and to identify what sort of PPI practices are most effective - you cannot measure the impact of a given process unless you know what it has been.

INVOLVE provides some information on this - http://www.invo.org.uk/document-and-record-public-involvement-in-your-research/ - and we are also awaiting publication of the final version of the Guidance for Reporting Involvement of Patients and Public (GRIPP). You can see the first steps towards the production of this checklist here: (http://www.ncbi.nlm.nih.gov/pubmed/22004782).

5 How and what do I pay patients who get involved?

The ***NIHR Oxford Biomedical Research Centre*** (BRC) and Musculoskeletal ***Biomedical Research Unit*** (BRU) have a policy on paying for patient involvement. There are three documents: one that sets out guidance on rates of pay for activities such as taking part in meetings and reviewing documents. It is based on similar national guidelines and provides details on how to manage payments through the OUH, and what to do about tax/national insurance etc. A second document is available that can be given to involved patients explaining what payment is on offer. Both can be obtained from Sandra.regan@ouh.nhs.uk.

These were launched in June 2015 in the knowledge that many themes and working groups of the BRC/U will not yet have budgets to enable them to make such payments, but that all should work towards this. The third document sets out how members of Patients Active in Research (PAIR), our PPI strategy group, are paid, as this is budgeted for, and this policy has thus been implemented.

Payment for time is separate from payment for expenses such as travel or for carers to support the person getting involved. Expenses should always be reimbursed as no-one should be out of pocket from PPI activities or prevented from getting involved because they cannot afford the associated costs. Payment for time should, as set out above, be offered; however, many people choose not to accept as they see their PPI role as something they wish to do on a voluntary basis or do not want to complicate e.g. tax affairs with additional income. Again, the basic principle is that financial constraints should not prevent people from getting involved.

There are special considerations that apply to people who receive benefits accepting payment for their time. A free national helpline has been set up offering individual advice to people on benefits who are involved with NIHR projects – see here: http://www.invo.org.uk/resource-centre/benefits-advice-service/benefits-advice-service-for-involvement-for-members-of-the-public/.

The service also advises researchers who want more details about benefits and PPI payments.

6 How do I write information for patients?

Much is said about writing for lay audiences, and many guidelines have been written, but there is little evidence about what actually works best. We are therefore trying to improve the evidence base for this, and hope to have some robust guidelines available in about a year.

Meanwhile, the main thing to remember is to write as simply as you can – and get a non-expert (or a few) to read your work before making it public. The language that you use on a daily basis may well not be understandable to non-experts so you need to think carefully about how to phrase complex terms, and avoid jargon and acronyms unless you spell them out and/or explain them.

Clear information is needed in a number of different places e.g. lay summaries in grant applications and for ethical approvals, clinical trial summaries (at the start and the end of a trial) and patient information sheets.

In respect of clinical trials, it is now mandated that lay summaries for all new BRC and BRU-sponsored trials must be checked by the Oxford BRC &U Patients Active in Research (PAIR) Group. Turnaround time is about 2 weeks. Please contact sophie.petit-zeman@ouh.nhs.uk or sandra.regan@ouh.nhs.uk

Lay summaries of clinical trials are our current priority because once your trial is registered (now a requirement), this summary will automatically be taken from the registry and put onto the UK Clinical Trials Gateway (UKCTG). However, this is currently a very poor system as the Gateway contains a lot of information that not suitably "lay" - see http://oxfordbrc.nihr.ac.uk/blog/making-it-even-clearer/. This is why we mandate patient review of trial lay summaries and Sophie is on the UKCTG project and editorial boards currently overseeing its re-launch as a truly patient friendly site.

Sandra, Sophie and PAIR members will help wherever possible with other lay summaries and are always happy to be asked.

INVOLVE has a section on its website about plain English summaries, see http://www.invo.org.uk/resource-centre/plain-english-summaries/

Overall, involving patients and the public in your research gives you the chance to get their help in ensuring that your written material is in plain English.

7 How do I know what patients and researchers think about PPI?

www.healthtalk.org provides free, reliable information about health issues, by sharing people's real-life experiences. You can read about or listen to people sharing their stories about cancer, autism, motor neurone disease, pregnancy, drugs, depression and much more. Created in 2001, healthtalk.org comes from a unique partnership between a charity called DIPEx and The Health Experiences Research Group or 'HERG' at The University of Oxford's Nuffield Department of Primary Care. The website is managed by the charity and the research that appears on the site is produced by the HERG team.

There is a section of healthtalk.org on patient and public involvement in research; interviews have also been conducted with researchers and these are currently being analysed and will then be published on the site.

8 What is "good" PPI?

NIHR and other funders increasingly ask to see evidence of PPI, either in the lead up to making a grant application, in the planned studies themselves, or in both. There is a growing PPI "industry" to support this: many groups in Oxford that do health research have PPI leads, strategies and plans, and much is said about the need to ensure "best practice" is followed.

However, while there have been numerous studies that in some way evaluate the impact of PPI, we know very little about what "works" to make research better for patients. There are many reasons why it's hard to pin this down – in part because of the length of time between research and outcomes, and the very variable ways in which PPI activity is reported in published papers (see briefing note 4). You can read more here: http://www.nature.com/news/health-care-bring-on-the-evidence-1.13697. As we say there: "One of the knottiest problems in PPI is how to best weigh up anecdotes and evidence."

All that said, the resources highlighted in this pack should help you to make a good start with PPI based on sound principles and much experience. For some, the moral arguments for doing PPI are enough to ensure that it happens; meanwhile, we are part of the growing efforts to assess the impact of PPI on research for patient benefit, including through the work of our OxBRC PPI Impact Assessment Fellow Dr Joanna Crocker, and are always happy to discuss this with you.