

ReseArch with Patient and Public invOLvement: a RealisT evaluation – the RAPPORT study

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Scientific summary

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Background

This report explores the context, processes, mechanisms and impact of patient and public involvement (PPI) in health research. The ReseArch with Patient and Public invOLvement: a RealisT evaluation (RAPPORT) study was conducted 8 years after PPI became an expectation for research projects that are part of the UK Clinical Research Network (UKCRN) portfolio, and it was therefore timely to assess how embedded PPI is as part of normal research processes.

'Involvement' differs from being a participant in research, indicating input into the research process itself; that is carrying out research *with* members of the public, rather than conducting research on or about the public or patients. There are two main arguments for PPI in health research. The moral argument suggests that involvement is a right, so that the citizen can have a voice in publicly funded research. It also includes an ethical perspective that individuals have the right to be involved with any research intervention potentially being done 'to' them. The methodological argument suggests PPI leads to higher-quality research with greater impact. The policy response to these arguments has been development of infrastructures to support PPI in research. INVOLVE, a national advisory body, is funded by and is part of the National Institute for Health Research (NIHR), and leads on PPI across the NIHR.

Despite this growing emphasis on PPI in health research, there is little evidence of its impact. Previous evaluations have failed to use methodologies that take into account the complexity of PPI. This complexity arises from PPI being a multifaceted social process, making it difficult to pinpoint impact and individual contributions. This is compounded by a lack of robust and routine reporting of PPI outcomes by the research community. The RAPPORT study was designed to address this gap in the evidence.

Objectives

The RAPPORT study sought to evaluate how different approaches to PPI in research with different populations influence the identification of priorities, research conception, design, process, findings and dissemination. Specifically, it aimed to identify what PPI approaches have applicability across all research domains, which ones are context specific and whether or not different types of public involvement achieve different outcomes for the research process, findings, dissemination and implementation of PPI.

The specific research questions were to:

1. determine the variation in types and extent of public involvement in funded research in exemplar areas – diabetes mellitus, arthritis, cystic fibrosis (CF), dementia, public health and intellectual and developmental disabilities (IDDs)
2. describe key processes and mechanisms of public involvement in research
3. critically analyse the contextual and temporal dynamics of public involvement in research
4. explore the experience of public involvement in research for the researchers and members of public involved
5. assess the mechanisms which contribute to public involvement being routinely incorporated in the research process
6. evaluate the impact of public involvement on research processes and outcomes
7. identify barriers and enablers to effective public involvement in research.

Methods

The study was underpinned by realist evaluation utilising mixed methods, conducted in three stages. Six topic areas were focused on arthritis, CF, dementia, diabetes mellitus, IDD and public health. These were purposively selected to ensure a range of study designs, participant populations and histories of PPI. Reflecting mainstream high-quality health research, the sample was confined to non-commercial research eligible for adoption by the UKCRN portfolio. The RAPPORT study design, data collection, analysis, management and dissemination have been conducted in partnership with two lay coapplicants/co-researchers, one co-researcher, two service user reference groups and four lay members of the study advisory group.

Setting

Stage 1 was conducted in England and Wales. Stages 2 and 3 were conducted in four geographical regions in England. These were purposively selected to ensure a range of research centre densities, rural/urban populations and numbers of established PPI groups in research.

Stage 1: national scoping of studies

A national scoping was undertaken of studies currently funded or completed within the previous 2 years. Details of each study were electronically searched via the UKCRN database and relevant documentation was reviewed for any evidence of the nature and extent of PPI. A scoping framework was used to assess the stages of the research at which PPI took place, whether involvement was of lay groups or lay individuals and where it was located on the continuum of PPI from user-led to minimal PPI. As there was very little reference to PPI in the publicly available documents, we contacted research teams via funding organisations or directly to obtain further information. Of the 478 eligible studies identified, we obtained information on 38% ($n = 182$).

Stage 2: survey

An online survey tool was administered to all chief investigators of current studies or studies completed within the previous 2 years. The survey questions were drawn from previous published consensus on the requirements for successful PPI in research. We identified 360 eligible studies, and following one e-mail reminder had a response rate of 28% ($n = 101$). Data were transferred to SPSS (version 20, IBM SPSS Statistics, Armonk, NY, USA) for analysis. This analysis was mapped against the results of the scoping to identify any recurring patterns within and between types of research, stages in research process where PPI occurred and topic areas. The survey was also used as one of the ways to identify research teams who would be interested in taking part in stage 3.

Stage 3: case studies

This final stage provided an in-depth realist evaluation of the context, mechanisms and outcomes in specific research settings to increase understanding of at what points PPI has the most impact and effect on outcomes. Twenty-two case studies were included and, while case study availability varied across the six example areas, there was a broad range of study designs from basic science to qualitative. Initial in-depth telephone interviews were conducted with each research team and PPI representatives; these were followed up by regular tracking telephone interviews to capture any changes in PPI processes and outcomes over time. We also conducted telephone interviews with representatives from the main funding organisations, and with any associated PPI co-ordinator in the host organisations or clinical research networks. Initial interviews were recorded and transcribed, and detailed notes were taken of tracking interviews. A total of 206 interviews were completed. Documents with evidence of PPI impact were collected from each case study; these included notes of meetings and track-changed participant

information sheets. Normalisation Process Theory (NPT) was used as a middle-range programme theory to understand the processes and mechanisms required to embed PPI as normal practice within each case study. Interview guides and coding frameworks were informed by NPT. All data were coded independently, then analysed jointly in team meetings and uploaded into NVivo 9 (QSR International, Warrington, UK). The NPT toolkit was also used to develop radar plots of each case study as a visual representation of how embedded PPI was.

Results

Stages 1 and 2

The scoping and survey provided evidence of the current landscape of PPI in health research. In the scoping, 51% ($n = 92$) of studies had some evidence of PPI, and in the survey 79% ($n = 80$), with funder requirements and study design appearing to be the strongest influence on the extent of PPI within a study. The most common PPI activities undertaken were steering committee membership and reviewing patient information leaflets. There was evidence of some blurring of roles, with research participants also undertaking involvement activities in an advisory capacity on the same study. We found that routinely collected information about PPI was difficult to access or not collected.

Stage 3

Six context–mechanism–outcome configurations based on case studies' salient actions were tested. These were a clear purpose, role and structure for PPI; ensuring diversity; whole research team engagement with PPI; mutual understanding and trust between the researchers and lay representatives; ensuring opportunities for PPI throughout the research process; and reflecting on, appraising and evaluating PPI within a research study.

Key enabling contexts were found that influenced mechanisms for PPI:

- *Research funder.* Funders appeared to prioritise either the methodological (to improve research quality) or the moral (PPI as a right) arguments. Their preferences appeared to influence the operational requirements for PPI in grant applications and their focus in developing PPI processes.
- *Topic and study design.* Established ways of working in PPI influenced how PPI was operationalised in case studies. For example, the commitment to including end-users with IDD showed that PPI was embedded in all these case studies. Some study designs inherently required PPI but basic science and tissue bank designs also had effective PPI.
- *Host organisation.* Organisations hosting research varied considerably in resources available to support PPI, and whether research was core business or sporadic projects. Research conducted within the clinical setting had easier access to the target population and potential PPI representatives.
- *Organisation of PPI.* A dynamic framework for PPI includes ways in which the lay representatives had input; for example, whether they were utilised as individual representatives or organised through a group/panel. It also included different approaches (consultation, collaboration/consensus or co-researching) and forums as the settings in which researchers and lay representatives came together, such as a trial steering committee. The framework was found to be dynamic, because it developed and shifted with time and the research process; PPI frameworks were rarely static in the lifetime of a study. Within this framework we identified three models of PPI:
 - *One-off model.* Lay representatives were brought into the study for a limited researcher-identified task. This was often accomplished through an established external (to research team) PPI panel from which PPI was 'bought in' as a commodity.
 - *Fully intertwined model.* Research question or priorities were often identified by lay representatives and they worked alongside researchers as partners throughout the research process. This model had strongly embedded PPI but was resource-intensive.

- *Outreach model.* This model had regular points of contact between researchers and lay representatives throughout the research. The important features of this model were that, although there tended to be fewer PPI representatives, they acted as a bridge between the research and the wider community. The lay representatives in this model had strong links and networks with populations the research was aiming to recruit. This was an effective model of PPI, was less resource-intensive for researchers and was found in a range of research designs. However, it did require finding lay representatives able to provide this link and is unsustainable without appropriate funding for charities undertaking this role.
- *Positive experience of PPI.* For both lay representatives and researchers a positive experience created a virtuous cycle whereby PPI became increasingly embedded.

Mechanisms to embed patient and public involvement as normal practice (Normalisation Process Theory)

Normalisation Process Theory suggests four main areas of work to embed as normal practice a complex intervention such as PPI.

1. *Coherence: making sense of PPI.* Higher levels of agreement on the purpose of PPI usually led to more embedded PPI. In newly formed groups of researchers and lay representatives, this may take time to achieve. Junior members of the research team tended to have more difficulties in differentiating between participation and involvement. A dual role of participation/involvement was sometimes used to capture the target population perspective.
2. *Participation: relational work to build and sustain a community of practice for PPI.* An assigned, resourced PPI co-ordinator role was important in sustaining PPI. However, it was also important that the research team did not abdicate PPI responsibility to the co-ordinator and was also fully committed to PPI.
3. *Collective action: the operational work to enact PPI practices.* Flexible approaches to enable use of lay representatives' individual skill sets and their personal circumstances were required. Establishing and maintaining good relationships between researchers and lay representatives was crucial. This was done by regular communication, managing meetings in order to address power imbalances and providing opportunities for informal engagement. There was some evidence that this was hard to achieve when PPI was conducted purely through virtual media.
4. *Reflexive monitoring: the appraisal work to evaluate PPI.* There was little systematic appraisal within the case studies. The majority of researchers and PPI representatives felt that PPI is worthwhile but its impact difficult to prove.

Outcomes

All the case studies had evidence of PPI outcomes, including research priority/question setting, study marketing, changes to the design including interventions, ensuring participant safety and recruitment. Observable evidence of impact was more difficult to find, although one case study did report rises in recruitment rates since PPI representatives had made changes to participant information sheets. Range of outcomes per case study was influenced by design and the model of PPI, and case studies with the most embedded PPI were likely to demonstrate the greatest number of PPI-related outcomes. These studies were also likely to demonstrate outcomes from the moral perspective, such as increased self-worth for lay representatives. In the one-off model of PPI, potential outcomes were limited by the researcher.

Conclusions

The research findings indicate what works best in PPI, and in what circumstances:

- Six salient actions were required for positive outcomes and impact of PPI. These were characterised by (1) the researchers and lay representatives having a shared understanding of the moral and methodological purpose of PPI, (2) a key individual co-ordinating PPI, (3) lay representatives having a strong connection with the target study population, (4) the whole research team being positive about PPI input and fully engaged with it, (5) efforts to develop relationships established and maintained over time and (6) PPI is evaluated in a proactive and systematic approach.
- In research studies being conducted in environments with less developed infrastructure resources, or with designs in which PPI was deemed most appropriate at discrete points in the research process, having some PPI representatives who could act as a link to broader constituencies was also an effective model.
- Studies that have little embedded PPI for lack of resources, vision or infrastructure should in future focus on developing and sustaining relationships between researchers and lay representatives, as this appears to be the minimal work required for PPI impact.

The research findings point to areas that merit further research:

- evaluating context, mechanisms and outcomes of PPI conducted through virtual media
- engaging young people in PPI
- exploring the PPI training needs of researchers, using the findings of the study and the NPT process as a curriculum framework
- further evaluation of the impact of PPI on issues of participant safety in clinical trials
- cost analysis of different models of PPI
- exploring implications and outcomes of being a participant/involvee
- longer-term evaluation of PPI-related outcomes on research findings and implementation.

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