

Consumer involvement in health research: a UK scoping and survey

Elsbeth Mathie¹, Patricia Wilson¹, Fiona Poland², Elaine McNeilly¹, Amanda Howe³,

Sophie Staniszewska⁴, Marion Cowe⁵, Diane Munday⁵ and Claire Goodman¹

¹CRIPACC, University of Hertfordshire, Hatfield, UK

²School of Rehabilitation Sciences, University of East Anglia, Norwich, UK

³Norwich Medical School, University of East Anglia, Norwich, UK

⁴RCN Research Institute, Warwick Medical School, University of Warwick, Warwick, UK

⁵Public Involvement in Research group (PIRg), CRIPACC, University of Hertfordshire, Hatfield, UK

Abstract

Consumer involvement or patient and public involvement (PPI) in health research is a UK policy imperative and a prerequisite for many funders. PPI in research is defined as research carried out with or being carried out by the public (or service users), rather than research on patients and public as subjects or participants. Despite the clear policy driver, there is relatively little empirical evidence on the extent, processes and impact of user involvement in research. This paper aims to add to the international evidence base on PPI in research by providing a key overview of current trends and impacts. In order to understand the current extent and variation of PPI in research, a scoping exercise and survey were carried out on selected UK studies. Six research topic areas (cystic fibrosis, diabetes, arthritis, dementia, intellectual and developmental disabilities, and public health) were selected to ensure a range of designs, study populations and histories of PPI in research. A total of 838 studies (non-commercial studies and not older than 2 years) were contacted. The response rate for the scoping was 38% and the survey 28%. In the scoping, 51% of studies had some evidence of PPI and in the survey 79%. The most common PPI activity was steering committee membership and

reviewing patient information leaflets. There appeared to be some blurred roles with patients participating as research subjects as well as carrying out patient involvement roles. A major finding was the limited amount of available information about PPI in publicly accessible research documents. We suggest that the invisibility of this type of involvement and the lack of routinely collected information about PPI results in a lack of shared understanding of what optimal PPI in a study should look like, with important implications for practice. Furthermore, without a framework to review PPI it is difficult to know if different approaches to PPI have a different impact on key outcomes of the research.

Keywords User, patient and public involvement, health research, consumer involvement, research policy.

Correspondence Elspeth Mathie, CRIPACC, University of Hertfordshire, College Lane, Hatfield, Hertfordshire AL10 9AB, UK. E-mail: E.J.Mathie@herts.ac.uk

Introduction

Globally, there has been an increasing recognition of the importance of involving patients as consumers of health services and the public in healthcare governance and research (World Health Organization, 2005; Boivin et al., 2010). In the UK, evidence of consumer involvement in research is a policy imperative and a prerequisite for English National Institute for Health Research (NIHR) and other common sources of medical research funding, and for National Health Service (NHS) Research Ethics approval (Barber et al., 2012; Staley et al., 2012). Consumer involvement in research is defined as research with or being carried out by the public, rather than patients and the public being researched as participants (INVOLVE, 2012). Previous studies have identified a range of impacts of consumer involvement in research (Brett et al., 2010) including improving relevance, appropriateness and conduct of research; refining research questions; ensuring the acceptability of the design to research participants; bringing personal benefits to members of the public involved; contributing to ethical debates; and ensuring research meets policy targets (Entwistle et al., 1998;

Staniszewska et al., 2007; Smith et al., 2008; McKeivitt et al., 2009; Staley, 2009; Howe et al., 2010). However, despite repeated assertions of the benefits of consumer involvement for research, there is limited empirical support for its impact (Brett et al., 2010). What there is, has been criticized as poorly reported (Staniszewska et al., 2011b) or methodologically weak, often failing to fully explore the contextual factors surrounding consumer involvement as a complex intervention (Staniszewska et al., 2011a). There is also a focus on process often to the exclusion of defining or measuring the outcomes of consumer involvement (Kreindler, 2009). This paper reports findings from the first two phases of the RAPPORT study, which evaluated processes, mechanisms, context and outcomes of consumer involvement in UK health research. This first two stages of the study comprised of a scoping and survey to gain an indication of the current level of consumer involvement across six health research topic areas, and provide a sampling frame for the subsequent third in-depth case study phase. Although there is policy support for consumer involvement, there are few studies that have explored the extent and nature of patient and public involvement (PPI) activity in research.

Background

The claims made for consumer involvement as a contributor to improved quality and outcomes of health research are underpinned by one of the three paradigmatic stances on consumer involvement. These are methodological, the moral and ethical, and the political. The methodological argument (Telford et al., 2002; Ward et al., 2010), which Boote et al. (2011) called the consequentialist argument, suggests that consumer involvement has the potential to not only improve quality and impact of research, but also improve accountability of researchers and make the research process more transparent. However, defining consumer involvement outcomes solely in terms of research quality ignores the rights of those being researched or likely to benefit from the research to be involved in how it is defined and executed (McKeivitt et al., 2009). In addition to the methodological stance, there is a moral and ethical perspective that identifies consumer involvement as a right for the tax-paying citizen within a democratic society (Ward et al., 2010).

Involvement as a right is a stance informed by the belief that consumer involvement is empowering for the individual and communities, and gives voice to marginalized people and communities (Barnes et al., 2004). The third perspective is the political value of consumer engagement as a means of enhancing the validity of decision making and policy development (Barnes et al., 2004). The health research community is socially constructed and framed by precepts largely drawn from the medical community (Jordan and Court, 2010). The differing terms used for consumer involvement are derived from the dominant discourse within each context and social group, and within UK health research the term PPI is more commonly used than consumer involvement. There is an inherent tension between the connotations of passivity implied by the word patient and the proactive nature of involvement (Wilson, 2001; Jordan and Court, 2010); however, to reflect common usage, we will use the term of PPI throughout the rest of the paper.

The national infrastructure of health research has increasingly supported PPI (Department of Health, 1999, 2005; National Institute of Health Research, 2013), and there is evidence that PPI is influenced and shaped by local initiatives (Howe et al., 2010) and their histories (Purttell and Gibson, 2012). Hence, it cannot be assumed that there is a shared definition of PPI or a shared approach. The multifaceted world of PPI with its range of context, social groups, assumptions, values and constructions (Staniszewska and Denegri, 2013) requires a methodological approach capable of capturing complexity that can address questions of what kind of PPI works in what kind of settings or structures with what kind of outcomes?

Methodology

The overarching framework of the study was guided by a realist evaluation (Pawson and Tilley, 2001) to explore how PPI might work best, under what circumstances and for whom. The study sought to evaluate how different approaches to public involvement in research with different populations influence the identification of priorities, research conception, design, process, findings and knowledge transfer. This paper reports findings from the first two phases of the study (scoping and

survey), where the aims were to determine the variation in types and extent of public involvement in six selected research topic areas of funded research. The findings from these phases were used to develop a sampling frame for the final case study phase. To ensure a range of research foci and to capture a range of approaches to PPI, we identified six topic areas with different patient populations: cystic fibrosis (CF), diabetes, arthritis, dementia, intellectual and developmental disabilities (also known as learning disabilities), and public health. The topic areas were purposively selected to represent a diverse range of studies and associated PPI. This included studies with participants recruited across the lifespan (e.g. children and young people in CF studies, and older people in dementia studies), research designs (basic science to qualitative), settings (acute care, primary care), and different traditions and history of PPI. For example, diabetes has a strong national patient organization with a record of being involved in research and commissioning of health services. Both diabetes and dementia have a national research infrastructure that has well established PPI mechanisms (Matthews et al., 2007; Iliffe et al., 2011), and the intellectual and developmental disabilities community at both policy and research levels has focused on inclusive practice (Department of Health, 2009). Public health was included to include community interventions and user-led projects and local populations who may not consider themselves as patients. In the UK, clinical research networks have been established in each of the four UK nations funded by the UK health departments. These national networks form the UK Clinical Research Network (UKCRN). The UKCRN portfolio of studies was used as one single database to identify relevant research studies, and information including study title, sample size, end date of recruitment and contact details were downloaded into an Excel spreadsheet. For search terms, see Table 1.

To ensure inclusion of studies most likely to have been designed since the embedding of PPI in the research governance framework (Department of Health, 1999), we excluded studies that were more than 2 years old (end date of recruitment before 1 September 2009). We also excluded studies that were funded by commercial organizations because despite current criticisms of the lack of transparency in drug trials (Thompson and Heneghan, 2012; Chalmers et al., 2013), access to study

documents was likely to be limited. In total, 1464 studies in the six broad topic areas were downloaded from the UKCRN database. One hundred and two were excluded as not in the specific topic areas, more than 2 years old (n = 263) or commercially funded (n = 261). A total of 838 studies were included (Table 2).

Table 1 Search terms for topic areas accessed on UKCRN portfolio

Topic area	Search terms
Cystic fibrosis	Keyword 'cystic fibrosis'
Diabetes	Type 1 and type 2 and other
Arthritis	Musculoskeletal, inflammatory and immune, genetics, primary care
Dementia	Dementia and neurodegenerative diseases, Huntington's disease, motor neurone disease, Parkinson's disease, other
Intellectual and developmental disabilities	Searched on keywords: 'learning', 'attention', 'Downs', 'intellectual', 'autism', 'Asperger'. Mental health: learning difficulties theme. Specific syndromes listed on http://www.rcpsych.ac.uk/pdf/clinical%20syndromes%20associated%20with%20learning%20disability.pdf
Public health	Primary care, infection, keyword 'public health'
All topics	Generic relevance and cross-cutting themes

UKCRN, UK Clinical Research Network.

Table 2 Search of UKCRN portfolio in six topic areas

Topic area	Cystic fibrosis	Diabetes	Arthritis	Dementia	Intellectual and developmental disabilities	Public health	Total
Number of studies identified on UKCRN portfolio	23	512	399	282	90	158	1464
Number of studies for inclusion	8	277	188	192	51	122	838
% of total on UKCRN	35	54	46	68	57	77	57

UKCRN, UK Clinical Research Network.

In order to determine the variation in types and extent of PPI in the six topic areas, our aim was to carry out an initial scoping exercise on PPI information within the documentation available on each study. Variation in PPI was mapped against the type of research, topic area and funding body. A scoping framework (Table 3) based on Brett et al.'s (2010) systematic review and Oliver et al.'s (2008) conceptual framework was used in an attempt to gather information about PPI and assess the stages of the research where PPI occurred, the model of PPI used (e.g. lay panel or individual service user) and where it was located on a continuum from user-led research to minimal PPI.

The scoping phase (October to December 2011) was followed by an online survey (January to February 2012) of chief investigators.

The design of the survey was drawn from Boote et al.'s (2006) indicators of successful PPI including roles, resources, training and support, and recruitment. Four geographical regions in England were purposively selected for the survey to ensure maximum variation: the South West has a relatively large rural population and a long history of PPI (Purtzell and Gibson, 2012), the East of England has established PPI networks (Howe et al., 2006) with rural and urban areas, whereas there is less evidence of a long-established PPI history in the North East, which has one major research hub and the associated impact on socio-economic factors of having a heavily industrialized past. London is the most densely clustered in terms of research centres and has a relatively high population of people from black and minority ethnic groups. The aims of the survey were to explore the key processes, mechanisms and the contextual dynamics of PPI in research, and to identify barriers and enablers to effective PPI in research.

Within the initial scoping exercise, we found that there is minimal direct access to study documentation. Additionally, even when the protocol was available on the funder's or study web site, there was little information about PPI. Therefore we also contacted study teams directly or via collaboration with the Association of Medical Research Charities for PPI information. For studies not covered by the online survey (i.e. running outside of the four geographical regions including Scotland, Wales and Northern Ireland; Fig. 1), direct requests were made. Documents or email replies were then reviewed by two team members independently for background study information and any evidence of the nature, extent and activities of PPI.

Scoping exercise: response and study characteristics

The scoping exercise obtained information about PPI from 182 studies out of a possible total of 478 (38%) (Table 4). Documents received in response to requests for PPI information included 93 protocols, 12 journal articles, 64 email replies, 10 interim/final reports and 3 Integrated Research

Application Service (IRAS) forms. Other documents (such as grant applications, reports to funders, lay summaries) were also provided. Some studies provided more than one source of information.

The studies in the scoping had sample sizes ranging from 12 to 250 000 with a median of 250. The two main funders were NIHR (29%) and charities (29%). The remaining funders were a mix of government departments, European Union, research councils and others. Forty-two percent of the scoping studies were clinical trials, a third were mixed methods (qualitative and quantitative non-clinical trials), a tenth were basic science and 15% tissue bank/database.

Table 3 Framework for data collection and analysis in scoping and survey

Topic
Region
Sample size
Study design
Funder
Chief investigator
Institutional setting (university, NHS)
End date (UKCRN)
Open/closed recruitment (UKCRN)
Type of document (protocol, article, IRAS, report, email, other)
Main source document of PPI information (coverage)
Evidence of PPI
Number of PPI
Reason for no PPI
PPI activities (steering committee, patient information leaflets, data analysis, etc.)
Number of PPI activities
PPI recruitment
Type of PPI (younger people, over 65, general public, etc.)
Capacity of involvement (person with prior experience of disease, established PPI group, charity, etc.)
Training
Costing (travel, expenses, honorarium)
Assessment of public engagement (lay controlled, collaborative, consultation, minimal)
Assessment of researcher engagement (inviting lay groups, inviting lay people, responding to lay action, minor partner or absent)
Impact of PPI
Knowledge, use and scope of regional and local public involvement groups

IRAS, Integrated Research Application System; NHS, National Health Service; PPI, patient and public involvement; UKCRN, UK Clinical Research Network.

Survey: response and study characteristics

Across the four regions 360 studies were identified on the UKCRN portfolio from which the survey was emailed out to all named chief investigators or researchers. From the first email there was a 17% response rate, and after the second reminder a total of 101 responses to the survey (28% response rate) (Table 4). The 101 studies surveyed included sample sizes ranging from 5 to 300 000, and grants awarded ranged from 8% of studies that received less than £50 000 (8%) to 30% of studies that were granted over £1 000 000. Funding was split quite evenly between NIHR (40%) and charities (40%). The survey included two-fifth clinical trials, a third quantitative and qualitative, 12% basic science and 7% tissue/bank database, and a further 7% were coded other (as insufficient information to classify).

Findings

Results from both the scoping exercise and survey suggested some common themes around PPI in research including limited information, lack of a clear definition, differences in approaches, challenges and impact.

Limited information about PPI

Currently, there is no mention of PPI found in UKCRN study information in the six topic areas. Nine funding web sites were searched, and open access to protocols was found to be very limited. The scoping exercise identified open access to study protocols on some funding web sites such as the NIHR Health Technology Assessment programme and some PPI information; otherwise, other funding web sites had very limited information.

Overall, the responses to the scoping requests showed that 51% of studies had some evidence of PPI in the documents supplied, and 79% answered positively that they had PPI in the survey. The protocols obtained confirmed the website findings that there was little space or official requirement

to record PPI, with only one third of protocols including any PPI information. Some respondents explained that other forms such as funding applications and IRAS forms had more detail of PPI.

We are happy to share our information on PPI. As the protocol does not reflect the level of PPI in the design and conduct of the study I have highlighted fields from our original NIHR RfPB application form which reflect our level of PPI – see below. (Scoping: Arthritis: ID:S49)

Researchers acknowledged that PPI is a relatively recent expectation from funders, and older studies may therefore have less. For some studies the external expectation was key to the development of PPI.

We have had no structured PPI for this study. There are a number of reasons for this: The study was developed a while ago and there was less of an expectation for PPI. (Scoping: Diabetes Email Response: ID:S24)

Defining PPI

Various interpretations of PPI were apparent. As a reminder to recipients, the scoping requests for information and survey highlighted the INVOLVE definition (Staley, 2009) of PPI. Although some respondents stated that their study included PPI, this was not corroborated by their other comments and in some instances suggested that they had misunderstood the term PPI. For example: Question: In your opinion at what stage of the research does service user/public involvement have the most impact? 'patient completes the questionnaires. Results help to understand/control disease in specific population'. (Survey: Public Health: ID81) In the scoping there were six studies where it was not clear whether what was being described was actually PPI, and these were excluded from the overall analysis. Similarly, the survey revealed a small number (n = 3) where respondents answered 'yes' to having PPI in the study, but their answers to other questions suggested they meant their study recruited participants. In addition, an 'uncertain' or 'dual role' category was also created to cover four survey responses appearing to describe a role that blurred participants and public

involvement. This emerging model of a dual role included examples of service users being consulted initially to refine study materials (perhaps within a focus group) and then subsequently being asked to join the study; involvement followed by participation. Some studies have participants who give feedback to the study while they are still participating in the trial:

Figure 1 Flow diagram of scoping and survey. PPI, patient and public involvement; UKCRN, UK Clinical Research Network.

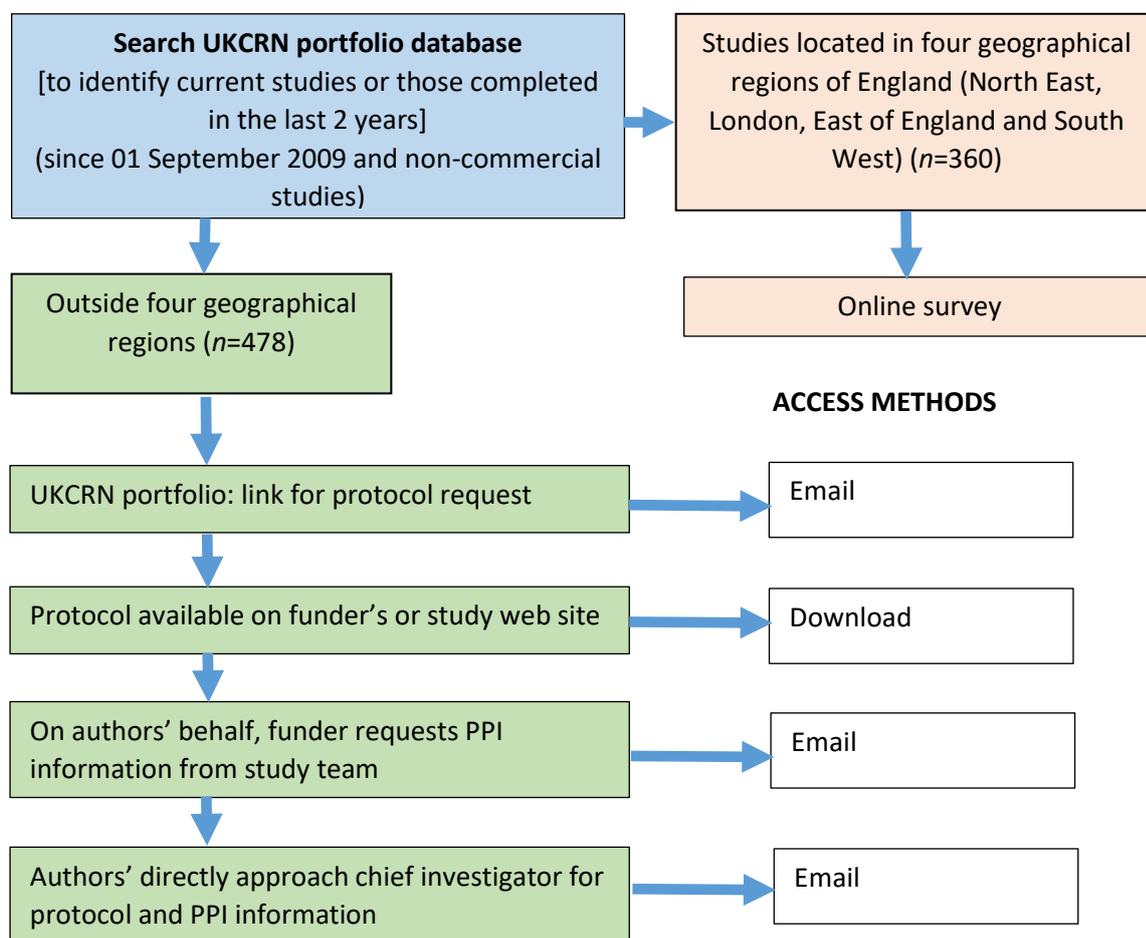


Table 4 Scoping and survey response rate by topic area.

	Scoping response rate	Survey response rate
Cystic fibrosis	40% (n = 2/5)	67% (n = 2/3)
Diabetes	34% (n = 46/137)	20% (n = 28/140)
Arthritis	42% (n = 55/132)	25% (n = 14/56)
Dementia	38% (n = 35/93)	31% (n = 31/99)
Intellectual and developmental disabilities	38% (n = 11/29)	23% (n = 5/22)

Public health	40% (n = 33/82)	53% (n = 21/40)
Total	38% (n = 182/478)	28% (n = 101/360)

We are continually listening to the comments of our participants in relation to study material and where possible modify accordingly. At the end of all the sessions they are asked to complete a feedback form with their comments.

(Survey: Public Health: ID93)

Depending on the research topic, it was suggested that PPI representatives should not be thought solely in terms of patients and the general public:

The position that 'service user' is only defined as patient or carer. Some of my research is focused on different layers of NHS staff, and back-office work, so in this context, we need a much broader definition, that include service users beyond only patients/carers. (Survey: Arthritis: ID37)

Differences in the reported presence of PPI

There were differences in how PPI was approached by research topic and study design. Numbers of studies in some topic areas were very small (i.e. CF). In both the scoping and the survey, intellectual and developmental disabilities studies, compared with the other topic areas, had the highest percentage of PPI (scoping 91%; survey 100%) (Table 5). Second highest was arthritis (60%) in the scoping and dementia in the survey (87%). However, in the survey there was an overall trend for much higher levels of PPI across all topic areas than in the scoping.

Using the IRAS definitions of study design, studies with the highest amounts of PPI had mixed-method design (scoping 61% of studies with this design had PPI; survey 91%), followed by clinical trials (scoping 56%; survey 81%), which both had higher levels of PPI than basic science (scoping 21%; survey 67%), tissue bank (scoping 33%; survey 43%) and other (observational studies and 'cohort'). Basic science or tissue bank design studies appear to have a limited role for PPI. However, the survey findings for the three topic areas of arthritis, dementia and public health showed

examples of all four types of study design, and in these topic areas even basic science and tissue bank studies included some PPI elements. Written answers seemed to link this to the recognized

Table 5 PPI involvement in research studies by topic area

Topic area	Scoping	Survey
Cystic fibrosis	100% (n = 2)	0
Diabetes	41% (n = 19)	79% (n = 22)
Arthritis	60% (n = 33)	79% (n = 11)
Dementia	34% (n = 12)	87% (n = 27)
Intellectual and developmental disabilities	91% (n = 10)	100% (n = 5)
Public health	49% (n = 16)	72% (n = 15)
Total	51% (n = 92)	79% (n = 80)

PPI, patient and public involvement.

need to build and sustain good relationships with patient groups in order to identify priorities and gain the research materials they needed: . . . all our work has been carried out in partnership with the families. . . . often helps to focus what patients with a condition find most urgent to improve.

(Survey: Diabetes: Basic Science Study: ID05) In this project probably all stages, from literature aimed at recruiting potential brain donors to lay people on the committee that gives ethical approval to researchers requesting tissue from the bank. We also invite a potential donor/carer to speak about brain donation from a personal perspective at our Ethics Training Days and this is always very highly rated by people contributing to brain donation, especially those without participant contact, such as mortuary services and neuropath lab staff. (Survey: Dementia: Research Tissue Bank: ID54)

The influence of funders could also be seen in that higher levels of PPI were found in NIHR-funded studies (scoping 75%; survey 89%) and charity-funded studies (scoping 58%; survey 78%). Neither scoping nor survey found any relationship between sample size or geographical area and levels of PPI. There were a similar proportion of studies having PPI in the older studies (as measured by being

‘closed’ on the UKCRN portfolio) as the open studies. These findings suggest that funder requirements and study design appear to be the biggest influence on the extent of PPI within a study.

The extent of PPI activities within studies

The scoping and survey listed nine possible activities that patients or the public could be involved in:

- identify research topic;
- design research methodology;
- develop patient information leaflets;
- data collection;
- data analysis;
- report writing;
- advisory/steering committees;
- review of reports and lay summaries;
- dissemination activities (plus other).

Table 6 Patient and public activities in research

PPI activities	Scoping %	Survey %
Advisory/steering committee	65	71
Development of participant information materials	35	73
Dissemination of materials	16	49
Review of reports/lay summaries	8	48
Design of research methodology	62	45
Identification of research topic	17	21
Report writing	3	9
Data analysis	12	8
Data collection	3	6
Other	10	10

PPI, patient and public involvement.

The most frequently represented PPI activity was being on an advisory/steering committee (65% in the scoping study) and patient information leaflet development (73% in the survey) with low levels of involvement in data analysis, data collection and report writing in either (see Table 6).

The possible nine activities were then totalled into a score, and the survey revealed that learning disability, followed by arthritis and dementia had the highest median level of activities (4.0 for intellectual and developmental disabilities, and 3.0 for arthritis and dementia). However, Fig. 2 shows that there is little difference in the overall range of activities between each topic area.

Identification and recruitment of PPI members

The survey showed that the half (50%) of PPI representatives involved in research projects were patients or service users known to the researcher/clinician, and that very few were recruited via their local NHS comprehensive local research network or research design service. PPI representatives were also recruited via voluntary organizations (40%) or from an established service user group (35%), and a quarter (25%) had replied to an open invitation (respondents could choose more than one option). Twenty-nine percent of studies had 21 or more individual patient or public representatives involved. However, the PPI information in the scoping documents/emails was very limited, and it was difficult to access who the PPI members were, how many there were and how they had been recruited. It was therefore not possible to make an accurate assessment about PPI models. Just over a third gave any information about PPI recruitment, and only around a quarter of the studies gave any information about the number of PPI representatives. Although the scoping found evidence of the provision of training for PPI representatives in 9% of the studies, over a quarter (28%) of studies with PPI in the survey had provided training for their PPI members, and 43% had been directly costed for in the grant application.

The challenges and limitations of PPI

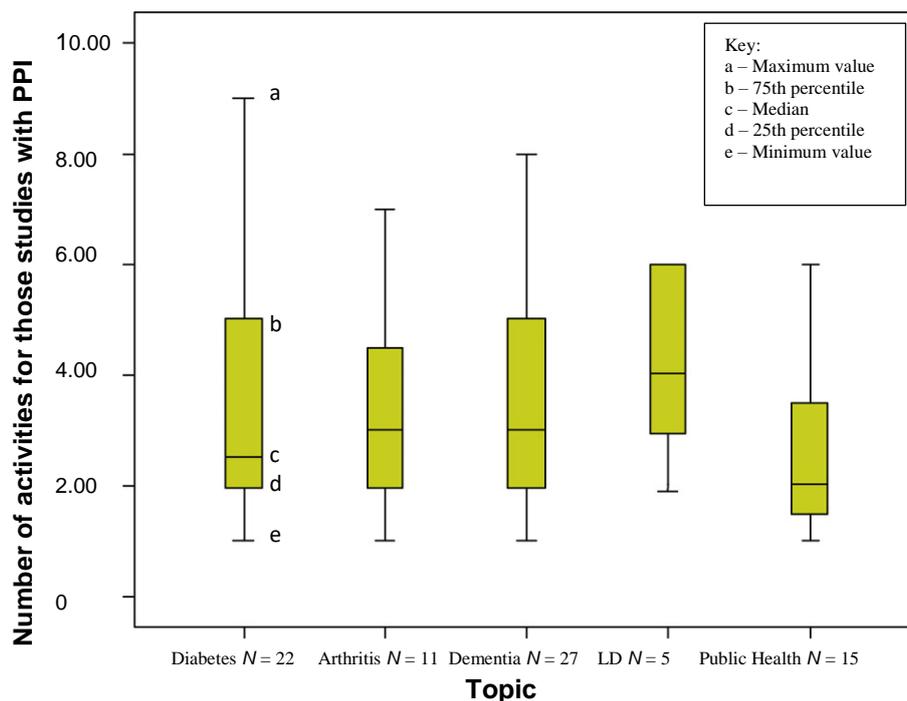
Through the means of an open-ended question survey respondents were asked for their views on the challenges and limitations of PPI in their study. Findings proved to raise similar issues to some of the 'dissenting voices' reported by Boote et al. (2002), such as representativeness. The challenges identified were recruitment, communicating the research to lay people, extra resources needed,

Box 1 Survey: main theme: challenges of recruitment

Trying to get a representative sample and not just the usual suspects. (Dementia: Qualitative Studies: ID50)

The only challenge is in finding appropriate representatives, they need to be able to understand the basics of the type of research that you doing but if they are all former academics and/or health professionals it kind of defeats the purpose, we were fortunate to get a mixture. (Dementia: Mixed Qualitative/Quantitative: ID57)

Figure 2 Survey: boxplot of number of activities for those studies with PPI, by topic, showing the range of the number of activities, 75th percentile, median and 25th percentile.
 Note: the number of activities was calculated only for those studies with PPI.



the potential for tokenism, bureaucracy, confidence of individuals to participate, managing expectations of the PPI individuals and threats to long-term commitment (such as illness). The most common theme that emerged was recruitment and how to gain access to ‘representative’ services users, mentioned by about one third of respondents (Box 1).

These comments may suggest that some researchers feel that the PPI representatives currently volunteering for research studies are not necessarily those they feel should be involved or are not authentically representing the views of others, or do not offer enough diversity, and that recruiting PPI members was challenging.

There was also some evidence of concern about PPI representatives losing the service user perspective through a process of socialization into the research world: In some contexts, we are engaging with a cadre of service users/public that become 'professionalised', that they are being repeatedly asked to speak for others. (Survey: Arthritis: ID37)

In addition to recruitment issues, the next most common challenge highlighted by researchers was being able to communicate their research (i.e. complex design) to lay people and the time (to comment and build relationships) and resources required to make the research accessible and supportive of PPI. Researchers were also aware of the challenge of involving the public in a 'meaningful and real' way. The management of expectations as to what the study could deliver was mentioned by some researchers, and reconciling the sometimes competing priorities of researchers and PPI representatives. This is a particular issue in research that might not bring benefits in the lifetime of the PPI representatives.

Mainly the wish of families to believe that the genetic, clinical or cell studies will provide rapid answers and treatments. (Survey: Diabetes: Basic Science: ID05)

The research approach did appear to influence what particular aspects of PPI were highlighted by respondents as challenging. Topic-specific issues were mentioned, with dementia studies identifying the extra time needed for PPI, and diabetes studies the need to clearly explain information about the research. These findings point to certain topic areas and study designs having different needs and challenges for researchers when working with PPI representatives.

Impact of PPI

Few studies provided any examples of impact: this is possibly due to the fact that protocols are written at the beginning of the study, and until recently there has been little formal requirement to record potential or actual PPI impact in routine research documents.

More recently, there has been a growing emphasis on making attempts to assess the impact of PPI (Staley, 2009; Brett et al., 2010; Barber et al., 2011; Barber et al., 2012; Staley et al., 2012).

This survey included an open question where respondents could write about which stage they felt PPI had the most impact. The most frequent type of answer given was 'the design stage/at the beginning/as early as possible'. Studies that were clinical trials had the highest proportion of respondents naming PPI as having the most impact at the design stage. The next most frequent was 'at every stage', and mixed methods had a higher proportion of respondents naming PPI as having the most impact at all stages.

To elicit any embedded PPI practices, the respondents with PPI in their study were asked if working with regional/local public involvement groups had altered their practice when writing proposals.

Seventy-nine percent of researcher respondents said they knew of a local or regional and public group that had supported research. Of the 63% who had used such a group, 36% (29) said that this group had altered their practice when writing the proposal.

The main way in which the researchers said they had altered their practice had been by consulting PPI at proposal writing stage to 'define research questions' and making objectives 'more realistic' and 'patient orientated'.

Discussion

Few previous studies have evaluated PPI in research across topic areas and study design. Two surveys conducted 13 (Telford et al., 2002) and 11 years ago (Barber et al., 2007) attempted to quantitatively capture the extent of PPI in English health research.

Telford et al.'s (2002) survey of 66 NHS research and development leads had a 73% response rate, but less than 25% reported any PPI in research activity within their respective NHS organizations.

Barber et al.'s (2007) survey was conducted 2 years later and comprised of a randomly selected sample of 900 researchers from the National Research Register. Their response rate of 58% had an

even lower report of PPI activity in research, with only 17% stating there was PPI in their research studies. Hence, our survey findings with 79% respondents reporting there was PPI in their research study show a significant increase in the extent of PPI activity. This is unsurprising given that there has been a successive flow of national policies aimed at increasing and embedding PPI in research (Department of Health, 1999, 2005, 2006; National Institute of Health Research, 2011). Major research funders now expect to see details of PPI in the grant application and this was reflected in our results where NIHR-funded studies (which require PPI details) were more likely to confirm the presence of PPI.

Despite these encouraging findings indicating that PPI in research is becoming more widespread in England a number of limitations persist. A major finding was the limited amount of publically accessible information about PPI within research documents, despite PPI becoming a requirement by many funding agencies. Although the expectations of the funder was identified as a key influence on PPI within grant applications and study designs, not only was there a lack of transparency within documentation about how PPI would be operationalized, but equally there appeared to be a lack of follow through reflecting some of the problems in the quality of reporting PPI more generally in studies (Staniszewska et al., 2011b). Hence, although PPI processes may be articulated within grant applications, there is no documentation providing evidence of monitoring or how the PPI strategy within a study may have changed as the research develops. This provides a stark comparison to other amendments in study protocols that undergo rigorous and transparent external monitoring and auditing of research governance.

There were some differences in PPI by topic area and study design. The findings support the generally held assumption that certain study designs (qualitative and quantitative) tend to lend themselves to PPI. However, basic science and tissue bank studies can and do include PPI (Nierse et al., 2012); this would suggest that the variation of engagement observed is not related to particular study designs. Certain disciplines such as intellectual and developmental disabilities embedded

within the 'nothing about us without us' approach demonstrated a synergy of the topic area paradigm and engagement with PPI in research. It would be worth investigating further if PPI is a proxy measure of disciplines commitment to public understanding, patient engagement and involvement in decision making.

The survey suggested that PPI representatives were most often involved in steering committees and reviewing participant information leaflets, a similar finding to Barber et al.'s (2007) earlier survey. There were fewer examples of lay people being involved in report writing, data analysis and data collection. Although there appeared to be some basic assumptions around the numbers of lay representatives required to make PPI viable, of more significance than just numbers of PPI representatives within a study was the extent PPI was threaded throughout the study from design to dissemination. Nevertheless, accurate recording of how many PPI representatives have been consulted may provide an indication on the range of views included. Studies with one person on a steering committee may be quite a different type of lay involvement from studies consulting large panels of patients or people representing patients.

A persistent issue is what effective PPI looks like. Pragmatism appeared to shape who was identified and how they were recruited, and as found in another study this may result in seeking retired academics who require little support (Ward et al., 2010) and are deemed as competent (Barnes et al., 2003). Arguably, the unintended consequence of this approach is to reinforce the views and priorities of patient groups who are white, articulate and middle class, and at worse support the inherent inequalities we know are present in healthcare delivery. Representativeness continues to be a vexed issue for the research community (Boote et al., 2011) and includes concerns around familiarity with the research process and discourse leading to loss of the lay perspective (Jordan and Court, 2010), in other words the professionalization of lay representatives (Ives et al., 2013). Depending on the researcher's viewpoint, at one end of a continuum PPI is seen as the source of authentic insider knowledge (McKevitt et al., 2009) with a consequential desire to seek lay people

with close direct experience of the topic area (Beresford, 2005). At the other end, professional knowledge is seen as the only valid epistemology (Ward et al., 2010). Our study demonstrated diverse definitions of PPI shaped by differing values (Kreindler, 2009) and reflecting the range of reasons given for PPI within studies. These reasons included ensuring the research asks the right questions of greatest interest to the population affected, to ensuring that recruitment targets are reached.

Echoing Barber et al.'s (2007) earlier survey, our findings suggest that some researchers continue to have difficulty in distinguishing between research participation and PPI activities. Although some researchers appear not to understand the differences between involvement, engagement and participation in research (INVOLVE, 2012), there is also developmental evidence of some explicit merging of research participant and PPI roles, in which patients undertake a dual role as participant and also as lay representatives. With the current focus on increasing patient participation in research trials (Department of Health, 2011; National Cancer Research Institute, 2012) and given that involvement and participation are listed alongside each other in the NIHR's aims for patient and public awareness of research, this may be an appropriate time to examine the potential advantages and implications of this dual role further. In particular, the ethical implications and the robustness of knowledge gained in this way need to be explored further.

This study found no information routinely available on PPI in open access UKCRN portfolio. Largely due to space limitations and little routine recording of PPI, research study documents again contained limited information regarding PPI in their project. It could be suggested that funding agencies may wish to require the routine collection of more insightful information on PPI: not just whether the project has PPI or not, but its level and extent, the numbers and types of member involved, methods of recruiting them to the study, and the impact of PPI on processes and outcomes of the research by the end of the study. The perspective of PPI representatives involved in the study should be inherent within this reporting mechanism. Such routine recording may enable some

effective systematic oversight and examination of what PPI currently constitutes. In many ways such data are essential in the continual development of the PPI evidence base.

Limitations of the study

The study has concentrated on six topic areas and aimed to compare any differences in approach to PPI. Basing data collection on the UKCRN portfolio will have excluded smaller charity funded projects or user-led projects; however, the portfolio does represent mainstream healthcare research. In addition, some numbers within a topic area are very low, making analysis/significant differences difficult to calculate. Although within normal parameters of an electronic survey, the response rate of 28% was low, and those answering the survey were more likely to be positive to PPI than those who did not. Nonetheless, the scoping and survey provide a useful snapshot of the current trends in PPI in UK.

Conclusion

Although PPI is now an expected component of all UK research studies, it is largely invisible in publicly accessible research study documentation, and many funders do not routinely collect information about PPI. The lack of detail and clarity about PPI has two consequences. There is no shared understanding of what optimal PPI in a study should look like or what a minimum level of engagement and representation should be. Second, the lack of transparency allows PPI to be defined by what the research team says it is. There is no framework for accountability or review, so it is difficult to know if different approaches to PPI have a different impact on key outcomes such as recruitment, generalizability and knowledge translation. The finding that PPI roles blurred with patient participation as research subjects suggests that without greater clarity about the purpose and contribution of PPI and possible ethical conflicts, challenges of tokenism will persist.

Funding source

The RAPPORT study (ReseArch with Patient & Public Involvement: a Realist Evaluation) is funded by the National Institute for Health Research Health Services & Delivery Research Programme (10/2001/36).

Department of Health Disclaimer

The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HS&DR Programme, NIHR, NHS or the Department of Health.

References

Barber, R., Beresford, P., Boote, J., Cooper, C. & Faulkner, A. (2011) Evaluating the impact of service user involvement on research: a prospective case study. *International Journal of Consumer Studies*, 35, 609–615.

Barber, R., Boote, J.D. & Cooper, C.L. (2007) Involving consumers successfully in NHS research: a national survey. *Health Expectations*, 10, 380–391.

Barber, R., Boote, J.D., Parry, G.D., Cooper, C.L., Yeeles, P. & Cook, S. (2012) Can the impact of public involvement on research be evaluated? A mixed methods study. *Health Expectations*, 15, 229–241.

Barnes, M., Newman, J., Knops, A. & Sullivan, H. (2003) Constituting ‘the public’ in public participation. *Public Administration*, 81, 379–399.

Barnes, M., Newman, J. & Sullivan, H. (2004) Power, participation, and political renewal: theoretical perspectives on public participation under new labour in Britain. *Social Politics*, 11, 267–279.

Beresford, P. (2005) Developing the theoretical basis for service user/survivor-led research and equal involvement in research. *Epidemiologia e Psichiatria Sociale*, 14, 4–9.

Boivin, A., Currie, K., Fervers, B., Gracia, J., James, M., Marshall, C., Sakala, C., Sanger, S., Strid, J., Thomas, V., van der Weijden, T., Grol, R. & Burgers, J. (2010) Patient and public involvement in

clinical guidelines: international experiences and future perspectives. *Quality and Safety in Health Care*, 19, e22.

Boote, J., Baird, W. & Sutton, A. (2011) Public involvement in the systematic review process in health and social care: a narrative review of case examples. *Health Policy (Amsterdam, Netherlands)*, 102, 105–116.

Boote, J., Barber, R. & Cooper, C. (2006) Principles and indicators of successful consumer involvement in NHS research: results of a Delphi study and subgroup analysis. *Health Policy*, 75, 280–297.

Boote, J., Telford, R. & Cooper, C. (2002) Consumer involvement in health research: a review and research agenda. *Health Policy*, 61, 213–236.

Brett, J., Staniszewska, S., Mockford, C., Seers, K., Herron-Marx, S. & Bayliss, H. (2010) The PIRICOM Study: a systematic review of the conceptualisation, measurement, impact and outcomes of patients and public involvement in health and social care research. [WWW document]. URL <http://www.ukcrc.org/systematic-review-on-ppi-in-clinical-research/> (accessed on 16 September 2010).

Chalmers, I., Glasziou, P. & Godlee, F. (2013) All trials must be registered and the results published. *British Medical Journal*, 346, f105. doi: 10.1136/bmj.f105.

Department of Health (1999) *Patient and Public Involvement in the New NHS*. Department of Health, London.

Department of Health (2005) *Research Governance Framework for Health and Social Care*, 2nd edn. Department of Health, London.

Department of Health (2006) *Best research for best health*. [WWW document]. URL https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/136578/dh_4127152.pdf (accessed on 29 July 2013).

Department of Health (2009) Valuing people now: a new three year strategy for learning disabilities. [WWW document]. URL

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_093375.pdf (accessed on 5 August 2010).

Department of Health (2011) Innovation health and wealth, accelerating adoption and diffusion in the NHS. [WWW document]. URL

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_131784.pdf (accessed on 12 November 2012).

Entwistle, V.A., Renfrew, M.J., Yearley, S., Forrester, J. & Lamont, T. (1998) Lay perspectives: advantages for health research. *British Medical Journal*, 316, 463–466.

Howe, A., Delaney, S., Romero, J., Tinsley, A. & Vicary, P. (2010) Public involvement in health research: a case study of one NHS project over 5 years. *Primary Health Care Research and Development*, 11, 17–28.

Howe, A., MacDonald, H., Barrett, B. & Little, B. (2006) Ensuring public and patient participation in research: a case study in infrastructure development in one UK Research and Development consortium. *Primary Health Care Research and Development*, 7, 60–67.

Iliffe, S., McGrath, T. & Mitchell, D. (2011) The impact of patient and public involvement in the work of the Dementias & Neurodegenerative Diseases Research Network (DeNDRoN): case studies. *Health Expectations*, 16, 351–361. doi: 10.1111/j.1369-7625.2011.00728.x.

INVOLVE (2012) What is public involvement in research? [WWW document]. URL

<http://www.invo.org.uk/find-out-more/what-is-publicinvolvement-in-research-2> (accessed on 12 November 2012).

Ives, J., Damery, S. & Redwod, S. (2013) PPI, paradoxes and Plato: who's sailing the ship? *Journal of Medical Ethics*, 39, 181–185.

Jordan, Z. & Court, A. (2010) Reconstructing consumer participation in evidence-based health care: a polemic. *International Journal of Consumer Studies*, 34, 558–561.

Kreindler, S.A. (2009) Patient involvement and the politics of methodology. *Canadian Public Administration*, 52, 113–124.

Matthews, D.R., Kennedy, E.D., Darbyshire, J.H. & Johnston, D.G. (2007) The UK Diabetes Research Network – an opportunity and a challenge. *Diabetic Medicine*, 24, 7–9.

McKevitt, C., Fudge, N. & Wolfe, C. (2009) What is involvement in research and what does it achieve? Reflections on a pilot study of the personal costs of stroke. *Health Expectations*, 13, 86–94.

National Cancer Research Institute (2012) ACTION ON ACCESS: widening patient participation in clinical trials. [WWW document]. URL

http://www.ncri.org.uk/includes/Publications/reports/action_on_access_report_final.pdf (accessed on 12 November 2012).

National Institute of Health Research (2011) Making the difference. [WWW document]. URL

<http://www.crncc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/PPI/Documents/Making%20the%20difference%20May%202011.pdf> (accessed on 29 July 2013).

National Institute of Health Research (2013) Central Commissioning Facility National Institute for Health Research and Policy Research Programme Patient and Public Involvement Plan: purpose, objectives and work (April 2013 to March 2015). [WWW document]. URL

<http://www.ccf.nihr.ac.uk/PPI/Documents/CCF%20PPI%20Plan%202013-15.pdf> (accessed on 26 July 2013).

Nierse, C.J., Schipper, K., van Zadelhoff, E., van de Griendt, J. & Abma, T.A. (2012) Collaboration and co-ownership in research: dynamics and dialogues between patient research partners and professional researchers in a research team. *Health Expectations*, 15, 242–254.

Oliver, S.R., Rees, R.W., Clarke-Jones, L., Milne, R., Oakley, A.R., Gabbay, J., Stein, K., Buchanan, P. & Gyte, G. (2008) A multidimensional conceptual framework for analysing public involvement in health services research. *Health Expectations*, 11, 72–84.

Pawson, R. & Tilley, N. (2001) *Realistic Evaluation*, 2nd edn. Sage Publications, London.

Purtzell, R. & Gibson, A. (2012) How to make health and social care research radical and really, really useful. In *Long-Term Conditions, Challenges in Health and Social Care* (ed. by C.E. Lloyd & T. Heller), pp. 69–79. Sage, London.

Smith, E., Ross, F., Donovan, S., Manthorpe, J., Brearley, S., Sitzia, J. & Beresford, P. (2008) Service user involvement in nursing, midwifery and health visiting research: a review of evidence and practice. *International Journal of Nursing Studies*, 45, 298–315.

Staley, K. (2009) Exploring impact: public involvement in NHS, public health and social care research. INVOLVE and National Institute of Health Research. [WWW document]. URL http://www.invo.org.uk/pdfs/Involve_Exploring_Impactfinal28.10.09.pdf (accessed on 10 February 2010).

Staley, K., Buckland, S.A., Hayes, H. & Tarpey, M. (2012) 'The missing links': understanding how context and mechanism influence the impact of public involvement in research. *Health Expectations*. Epub ahead of print, doi: 10.1111/hex.12017.

Staniszewska, S., Adebajo, A., Barber, R., Beresford, P., Brady, L.-M., Brett, J., Elliott, J., Evans, D., Haywood, K.L., Jones, D., Mockford, C., Nettle, M., Rose, D. & Williamson, T. (2011a) Developing the evidence base of patient and public involvement in health and social care research: the case for measuring impact. *International Journal of Consumer Studies*, 35, 628–632.

Staniszewska, S., Brett, J., Mockford, C. & Barber, R. (2011b) The GRIPP checklist: strengthening the quality of patient and public involvement reporting in research. *International Journal of Technology Assessment in Health Care*, 27, 391–399.

Staniszewska, S. & Denegri, S. (2013) Patient and public involvement in research: future challenges. *Evidence Based Nursing*, 16, 69.

Staniszewska, S.H., Jones, N., Newburn, M. & Marshall, S. (2007) User involvement in the development of a research bid: barriers, enablers and impacts. *Health Expectations*, 10, 173–183.

Telford, R., Beverley, C.A., Cooper, C.L. & Boote, J.D. (2002) Consumer involvement in health research: fact or fiction? *British Journal of Clinical Governance*, 7, 92–103.

Thompson, M. & Heneghan, C. (2012) We need to move the debate on open clinical trial data forward. *British Medical Journal*, 345, e8351. doi: 10.1136/bmj.e8351.

Ward, P.R., Thompson, J., Barber, R., Armitage, C.J., Boote, J.D., Cooper, C.L. & Jones, G.L. (2010) Critical perspectives on 'consumer involvement' in health research: epistemological dissonance and the know-do gap. *Journal of Sociology*, 46, 63–82.

Wilson, P.M. (2001) A policy analysis of the Expert Patient in the United Kingdom: self-care as an expression of pastoral power? *Health and Social Care in the Community*, 9, 134–142.

World Health Organization (2005) Ninth Futures Forum on Health Systems Governance and Public Participation. WHO Regional Office for Europe, Copenhagen.