1. Executive Summary

Background

This review synthesises evidence of the impact of patient and public involvement (PPI) on health and social care research. PPI has become an important part of research activity, supported by Government and health policy. At its heart, PPI is about empowering individuals and communities, in order that they can play a greater role in shaping health and social care research. In this way PPI aims to democratise health and social care research, to ensure it has maximum health and social benefit. This systematic review provides a timely synthesis of the evidence base on the conceptualisation, measurement, impact and outcomes of PPI. Key weaknesses in the evidence are identified and recommendations made for strengthening the quality of the future PPI evidence base, in relation to reporting and in terms of future research.

Objectives

The overall objective of the systematic review was to examine the conceptualisation, measurement, impact and outcomes of PPI in health and social care research. In addition, economic evaluations were also sought in order? to understand the financial impact of PPI activity.

Patient and Pubic Involvement

Three users were recruited to the advisory board of this study, and commented on the design, methodology and analysis of the systematic review. An expert seminar was conducted including 24 users and individuals who work in the field of PPI to consider initial findings and to shape the final analysis and synthesis. The impact of users' involvement in this study was in the shaping of the study aims, study methods, and in the synthesis and interpretation of results. Users will also be involved in study dissemination.

Methods

Study design

A systematic review method was adopted for the study, utilising the principles and methods provided by the NHS Centre for Reviews and Dissemination guidelines (2001).

Data Sources

Searches were undertaken from 1995 to current time in the following databases: medical literature (Medline, Embase, PsychINFO, Cochrane library), nursing literature (CINHAL), and healthcare management information consortium (HMIC and HELMIS). Hand searching of reference lists of papers and hand searching of Health Expectations was conducted. Grey literature was searched using the databases: InvoNet and NHS Evidence. Grey literature was also obtained by contact with key experts in the field.

Study Selection

All English language studies which investigated the impact of PPI in health and social care research were assessed for inclusion. All study types, published and unpublished, were included. A set of inclusion and exclusion criteria were utilised to select papers.

Quality assessment

The methodological quality of published studies was assessed using the Critical Assessment Skills Programme (CASP, Oxford). Grey literature was assessed using the Dixon-Woods checklist (2005) as used by Hubbard et al (2007) to review grey literature on involving people affected by cancer.

Data Extraction and synthesis

Data was extracted and categorised according to the reported impact and outcomes of PPI, the definition of PPI, conceptualisation and theorising of PPI, methods of measuring PPI and economic costs of PPI. A qualitative narrative synthesis of the data was performed which involved familiarisation with the papers, and the identification of emergent themes.

Results

The nature of the PPI evidence base

• The evidence base underpinning PPI in health and social care research is complex reflecting the wide diversity of the PPI landscape and activity.

• It is comprised of mainly qualitative or case study reflections of PPI, or cross-sectional studies reporting individual or organisational views of PPI, with relatively little critical evaluation.

• The main ways in which the impact and outcomes of PPI are represented is through narrative description, which is usually too brief to provide a full understanding of impact.

• The evidence base appears to be relatively weak in relation to the quality and detail of impact reporting, and needs significant enhancement. However, this may reflect the timescale of the review which has included studies from the last 15 years and may reflect times when the current interest in evaluating impact was not present in the same way.

Conceptualisation and theorisation of PPI

• Conceptualisation and theorisation of PPI is not common in studies of PPI, apart from the small number who have made it their primary focus. There have been attempts to develop conceptual and theoretical thinking, with more recent examples grasping some of the complexity of PPI, but these are still only partial models. There is a need for a comprehensive theoretical model of PPI that can be empirically tested, and can provide a blueprint for the development of instruments to capture or measure impact.

Capture or measurement of PPI

• Overall, there has been little focus on developing robust instruments capable of capturing or measuring PPI impact and this area is characterised by an absence of formal capture or measurement. There is a need for substantive work to develop instruments that capture or measures impact.

The importance of context and process

• The importance of context and process in the evaluation of impact has emerged from this review and from the user involvement seminar held in October 2009. Context refers to whether the right conditions are in place for PPI and process refers to more specific factors around the way in which PPI is carried out. Taken together, these factors could be described as the 'architecture of PPI' and if they are not appropriately established the chances of beneficial impact seem to diminish.

Impact

• Despite the limitations in the evidence base, it was possible to identify PPI impacts in relation to the following areas: research and the research process, users, researchers, researcher participants, community, journals, policy makers and funders.

Impact on research and research process

• Examples of PPI impacts in relation to research and the research process have been found in the initial stages of research, such as developing research questions,

identifying and prioritising topics, developing commissioning briefs. In undertaking research, there was evidence of impact on developing and commenting on research protocols, adapting and improving the sensitivity of research language in information and invitation letters and identifying poorly worded questions in questionnaires. There is evidence that PPI helps build important links with the community and can help with accessing participants, improving response rates, recruitment from seldom heard groups, development of greater empathy with research subjects and better informed consent based on a more informed participant. There is also evidence that PPI can help in the assessment and development of research instruments, improve the timing of interventions and ensure the instruments are more acceptable to the community. Users can also collect deeper and more insightful data based on their rapport with the participant. There is also evidence of impact on data analysis with users providing a wider perspective, different insights and identifying knowledge gaps for future research. PPI can also impact on dissemination and implementation due to the dedication of users, and in some cases through the development of a cohort of advocates who disseminate key findings.

Impact on users

• There is also evidence of the impact of PPI on users. The beneficial impacts were divided into three main areas: personal benefits, impact on level of knowledge and impact on their level of skill. Personal benefits include feeling empowered, feeling listened to, feeling more positive, feeling more confident, and feeling a sense of fulfilment and satisfaction. Users felt mutual support from being part of a team and appreciated the social interaction with others. Users also felt they had given something back and had done something meaningful for the research community and felt they had made a difference. Users also reported improved levels of knowledge, more open attitudes to research and improved trust in research. Some users reported access to better information about their condition and enhanced capacity to manage their condition and solve related problems. Users also reported positive impacts in relation to gaining skills in research methodology and in gaining other skills such as confidence in speaking, and listening in groups. Some papers reported more negative impacts in terms of personal impacts, skills levels and knowledge levels. For example users reported feeling overburdened, not listened to, frustrated and marginalised.

Other areas of impact

• Most evidence of impact related to research and the research process and to users, with much less impact reported in relation to researchers, researcher participants, community, policy makers, journals and funders. The detail of these impacts is reported in the results section.

Outcomes of PPI

• Studies reported beneficial outcomes (the results of PPI in a study) to the development of research agendas, aims and priorities. These include the following main areas of outcomes: new research, research questions or topic areas identified; new research proposals suggested or developed; new types of medication developed; cultural equivalence of research tools enhanced; context of care and impact on provision of services considered; research gaps identified and development of future research designs.

• Studies reported beneficial outcomes on a range of aspects of study design including applicability of informed consent, improved design of a trial, judging whether the climate was right for a study, deciding on appropriate end points, appropriate time for recruitment, interpretation of information for participants in a study and outcome measure selection.

•The evidence reports that clinical studies that reported outcomes of PPI tended to involve users on a consultation basis, and at just one stage of the study.

•The evidence shows user-led and collaborative studies tended to be more in the areas of mental health, older populations, disabled, and health promotion.

•Consultations with users were more likely to be used at just one stage of the research, the most common one being for setting research agenda.

•User-led or collaborative studies with users were more likely to include users throughout the research project, from proposal, methodology through to writing up and dissemination of results.

Economic analysis

• There was no evidence of economic analysis, reflecting the lack of appraisal of the impact of PPI more generally.

Discussion and conclusions

An emerging evidence base

Overall, the review provides emerging, but important evidence of the impact of PPI on health and social care research, in relation to three key areas: making research more relevant and appropriate for users, improving the quality of the research and in developing better relationships between researchers and communities, which can enhance the research in different ways.

Limited conceptualisation and theoretical development

There has been relatively little conceptualisation and theoretical development in PPI, although more recent theoretical work has attempted to capture some of the complexity of the concept. There is a need to develop a comprehensive theoretical model of PPI that can be tested and refined and underpin future attempts to develop instruments to measure impact.

Poor quality of reporting

While it was possible to identify a range of impacts and outcomes, it is important to recognise the poor quality of reporting, with often brief descriptions, that were like 'nuggets of gold' during data extraction, and did not always provide the depth of information ideally required for a full understanding of impact. In many ways the state of the evidence base is reflective of its developing nature, in an area where little guidance on reporting impact and outcome has existed, no agreed robust ways of capturing or measuring impact have been utilised, beyond short descriptions, and where there has been a lack of a comprehensive theoretical model to inform studies or the development of instruments capable of capturing or measuring impact.

Developing an understanding of all aspects of impact and outcome

The generally poor reporting of impact identified in this review may be acting as 'fog,' obscuring understanding of the real impact PPI can have on research, meaning that at present, it is only possible to identify some aspects of PPI impact and outcome. Absence of evidence does not mean absence of impact and it is important that a better understanding of the dimensions or aspects of PPI impact is developed through fuller and more detailed reporting, alongside better ways of capturing or measuring impact, to enable the 'full picture' of impact to emerge. This needs to be based on robust theoretical models to guide the development of instruments for capturing or measuring impact. There is also a need for further qualitative research to develop a fuller understanding of the nature of impact and outcomes.

PPI as a 'complex intervention'

By working with users in the synthesis of study findings in this review, the importance of context and process were identified as important underpinning factors, or the 'architecture of PPI', that needs to be considered in any evaluation of impact. In many ways PPI could be described as a 'complex intervention' (MRC 2008), where impact needs to be evaluated alongside broader factors, in order to identify what works, for whom and in what circumstances.

Developing measurement of impact

There is a need to develop methods and instruments for capturing and measuring PPI impact and outcomes that ideally would include both qualitative and quantitative components. The development of methods or instruments also needs to consider ways of capturing or measuring context and process in the evaluation of impact, to reflect the idea of capturing a complex intervention. It is important that the development of methods or instruments is robust and includes a focus on developing instruments that are reliable, valid and responsive to change. At present the evidence base does not provide impact data in enough qualitative detail to be the only source in the development of an instrument to measure impact and there is a need for further qualitative exploration. No economic analysis was found in these review studies, which suggests that future collaborations with health economists could advance our understanding of how to develop economic appraisal of PPI impact.

Recommendations

Based on the synthesis of the evidence base, a set of recommendations for reporting PPI are made. These are underpinned by suggestions for how future research can strengthen the evidence base. A summary of the recommendations is provided below, with a longer, more comprehensive, version included in chapter 5. A more specific set of guidelines for papers are also provided to encourage a more consistent approach to reporting impact.

• **Searching for and locating studies:** Studies that address impact should include impact as a key word; health and social care research database managers need to consider developing MeSH (medical subject headings) terms for PPI to enable more sensitive searching. Researchers need to include information about impact in the abstract to ensure these studies are easier to identify.

• **Definitions:** Studies need to provide a definition of PPI and link this with other definitions to enable a more connected body of evidence to emerge.

16

• **Conceptualisation and theoretical underpinnings:** Studies need to clearly report whether they are utilising any conceptual or theoretical influence. Studies need to report how their findings contribute to broader theoretical thinking to enable a more coherent theoretical body to emerge. There is a need to develop theoretical models of PPI that grasp its complexity, can be tested and used to develop instruments for measuring impact.

• **Context:** It is important that studies report, in detail, the contextual factors underpinning their work. This will enable future studies to establish whether certain factors consistently underpin successful involvement. Studies also need to comment on, and justify, the way in which they believe any of the contextual factors identified in their study have enabled or hindered PPI activity, impact and outcomes.

• **Process or method of PPI:** Studies need to routinely report detailed information about the process or method of PPI and whether any? of these factors have enabled or hindered PPI activity, impact and outcomes.

• **Impact and Outcome:** Each impact and outcome needs to be reported, both positive and negative, in adequate detail to enable an understanding of the difference PPI has made. Studies need to consider including PPI as a primary outcome. The impacts and outcomes of PPI need to be reported in a consistent place in the paper (see detailed guidelines in chapters 5 and 6).

• **Capture and measurement of impact and outcomes:** There is a need to develop qualitative and quantitative ways in which PPI impact is captured or measured. Qualitative forms of capture, such as narrative descriptions, can be very helpful but must be reported in adequate detail. There is a need to develop quantitative measurement of impact and outcomes. When methods or instruments have been developed, the results of their testing and application need to be appropriately reported, possibly borrowing on the approaches used to test patient-reported outcomes measures.

• **Developing critical perspectives:** It is important that a critical perspective develops over the next period to ensure that the reporting of more negative impacts and outcomes can be appropriately considered as part of the PPI evidence base and studies build in clearer evaluative components.

• **Economic evaluation:** There is a need to develop economic appraisal of PPI impact.

• **PPI publishing:** Editors and peer-reviewers need to encourage authors to comment on the impact that PPI has had within a study. Journals should include this recommendation in the guidance they provide to authors, and editors should encourage peer-reviewers to comment on impact and assess whether it is present in appropriate detail within a paper.