The PIRICOM Study:

A systematic review of the conceptualisation, measurement, impact and outcomes of patients and public involvement in health and social care research

Jo Brett, Sophie Staniszewska, Carole Mockford, Kate Seers, Sandy Herron-Marx and Helen Bayliss

United Kingdom Clinical Research Collaboration

The UK Clinical Research Collaboration (UKCRC) Partners' goal is to establish the UK as a world leader in clinical research. The UKCRC provides a forum that enables all Partners to work together to transform the clinical research environment in the UK. The forum promotes a strategic approach to the identification of opportunities for and obstacles to clinical research and their resolution. In so doing the UKCRC aims to benefit the public and patients by improving national health and increasing national wealth. The UKCRC recognizes that patient and public involvement is essential to the delivery of its overall mission. The UKCRC is promoting active patient and public involvement (PPI) as part of developing a new environment for clinical research through several activities. Activities over the first four years have included recruitment of patient and public members to UKCRC groups and the development of the People in Research website. In April 2008, the UKCRC Board approved a three-year strategic plan to provide a framework for the UKCRC's future patient and public involvement activities. A UKCRC Board Subgroup for Patient and Public Involvement has been established to oversee its implementation. This systematic review forms part of the UKCRC's commitment to strengthening the PPI evidence base for the future and ensuring PPI can make an important contribution to future clinical research.

Royal College of Nursing Research Institute (RCN RI)

The RCN RI was formerly the research team at the Royal College of Nursing Institute from 1996-2007. In order to enhance its ability to deliver high quality research, the RCN developed a strategic alliance with the University of Warwick and the RCN RI has been a research centre within the School of Health & Social Studies at the University of Warwick since 1st August 2007, led by Professor Kate Seers.

The research of the RCN RI supports the mission of both the RCN "to represent nurses and nursing, promote excellence in practice and to shape health policies", and the University of Warwick's Strategy "to make Warwick an undisputed world leader in research and scholarship."

The RCN RI aims to:

- Produce high quality research that improves knowledge, patient care and impacts on policy
- Increase research capacity relevant to nursing by providing high quality research training
- Contribute towards the RCN and the University of Warwick delivering on their strategic objectives

The RCN RI has a number of research themes which focus on the patient at the centre of care. This systematic review was conducted within the research theme which focuses on patient experiences, evaluation and involvement, led by Dr Sophie Staniszewska.

The User Perspective

Colin Tysall, Advisory Group member, UNTRAP member

Patient and public involvement (PPI) has become an important theme in health and social care research. I have seen great progress made in the last decade and research funders routinely ask researchers to show how they will involve patients and the public in their work. Real involvement can help us to develop research that has real relevance to people's lives. The United Kingdom Clinical Research Council is committed to integrating PPI into research. It commissioned this report to help us understand the current evidence base, the impact PPI has on research, and how the evidence base needs to be improved.

This systematic review has brought together the most recent thinking around PPI and the impact it is making to health and social care research. It has used very robust and thorough methods to gather together and synthesise research in this area. We have identified some key issues in patient and public involvement, particularly the need for better reporting of PPI in research papers to help develop our understanding of the difference it makes to research. It is important to say that the poor reporting may be hiding some of the impacts that PPI is making to research and we have to get better at identifying these. We also need a better idea of how PPI is conceptualised and thought about, which can be hidden. Despite these limitations in the evidence base, it has been possible to identify some of the ways in which PPI is impacting on research. These include: identification of research topics; improving the feasibility of the design for the study; improving recruitment to the study, providing assistance with data collection; identifying patient-important themes in the analysis of the data; and improving the dissemination of the results through close links to the research community.

The study also has some important messages for the future and includes recommendations for how the PPI evidence base could be strengthened. We will be working with others in this area to help strengthen the evidence base and ensure the impact of PPI is clear. This will help ensure future health and social care research is relevant and useful for everyone.

As someone who has seen the change from tokenistic so-called involvement to being fully integrated into the process as a norm, I hope you will agree with the progress we have made and continue to make in the future. Please enjoy reading this report.

Contents

PIRICOM Study:

Patient and Public Involvement in Research: Impact, Conceptualisation, Outcomes and Measurement

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Carole Mockford, University of Warwick

Mark Petticrew, London School of Hygiene and Tropical Medicine

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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.

• **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.

2. Introduction to study

2.1 Background

Patient and public involvement has become a central tenet of health care policy in the UK and internationally in shaping health services and policy (Department of Health 2008). It reflects the goal of encouraging participative democracy, public accountability and transparency in many aspects of life, including health and social care research. The World Health Organisation's declaration of Alma Ata states that "the people have the rights and duty to participate individually and collectively in the planning and implementation of their health care" (WHO 1978).

Policy in the UK has encouraged user involvement in health and social care research. Organisations such as INVOLVE in the UK have been established to promote the involvement of users in all stages of research including the identification of topics, prioritisation, commissioning, designing research, managing research, undertaking research, analysis and interpretation, dissemination and evaluation (INVOLVE 2004). INVOLVE encourages more active forms of involvement, such as collaborative involvement, where users are seen as active partners and may be involved in planning or making decisions about the research process, rather than just being consulted about a study. The distinction between different levels of involvement is important because collaborative forms of user involvement are thought to achieve better quality research, which might lead to better quality services (Smith et al 2005).

Research funders in the UK now often ask researchers to state how users will be involved in a study and will often fund different forms of involvement. In future such funders may monitor the extent to which researchers actually involved patients in studies compared with original plans. Like others, the Health Technology Programme in the UK has developed guidance on user involvement and evaluated the extent of public influence on NHS Health Technology Assessment Programme (Oliver et al 2006). This evaluation has found that while public perspectives are available at all stages of the research process, organisational boundaries of the funding programme restricted involvement. Other health agencies such as the National Institute of Health and Clinical Excellence (NICE) provide national guidance on promoting good health and treating ill health, and have incorporated a strong user involvement element into

their work. The NICE Patient and Public involvement Programme provides advice and support to NICE on patient, carer and public involvement and works with NICE to develop opportunities for involving patients, carers and members of the public across NICE's work programmes. The United Kingdom Clinical Research Collaboration (UKCRC)'s 2008-2011 strategic plan recognizes that patient and public involvement is essential to the delivery of its overall mission. Activities over the first four years have included recruitment of patient and public members to UKCRC groups and the development of the People in Research website. While PPI activity has increased over in the past five years, the underpinning evidence base has been less regularly scrutinised and evaluated, although some reviews in the last decade have helped with the identification of emerging themes (Staniszewska et al 2008, Staley 2009, Mockford 2009). Alongside the increase in PPI activity has been an interest in considering or evaluating the difference that PPI makes to health and social care research. This interest is likely to become magnified in the next few years as fiscal constraints affect all areas of health and social care, including research.

2.2 Focus of the study

This systematic review has provided a timely opportunity to consolidate and synthesise evidence around PPI and its impact from 1995 to the present day. This review utilises very robust and thorough methods for searching for, selecting, analysing and synthesising studies that have focused on PPI and its impact, or the difference it makes to health and social care research. In order to consider impact in this way, it was important to adopt a broader perspective and to consider how PPI has been conceptualised and theorised, and also to consider how impact or the outcomes of PPI have been reliably captured or measured. Because of the nature of the evidence base and the relatively early stage of its development, it was important to adopt a broad approach to the focus of the study. This review is therefore a scoping and mapping of the current state of evidence in PPI, conducted within the rigor of a systematic review methodology. Furthermore, the review is more inclusive of evidence rather than exclusive because of the difficulties in assessing the quality of the PPI activities. For example, the quality assessment tools used to measure quality are developed to measure the quality of the main study, not the quality of the PPI activity within the study, which can be designed in a different way to the main study.

2.3 Study aims

The study aimed to answer the following questions:

a. How has PPI in research been conceptualised and defined? (This refers to how adequately the idea of involvement has been described and understood and whether there is a need to develop a clearer understanding of it.)
b. How has PPI in research been measured?
c. How have the impacts of PPI in research been assessed?
d. How have the outcomes of PPI in research been assessed?

2.4 Terminology

The terminology used in this area varies and it is acknowledged that terminology also changes over time. For the purposes of the report the term, '**patient and public involvement**' (PPI) refers to patients, those who use health and social care services, those who are involved at different levels in research, carers/ guardians, people with a disability and other members of the public. The terms '**user'** or '**users**' are short forms to include those groups. The term '**impact'** is used to refer to the influence or effect of PPI on a range of areas. The term '**outcomes'** refers to the ultimate outcome of the study as a result of PPI, although the relative conceptual blurring and possible overlap between impact and outcomes is recognised by this review.

By '**involvement'** we mean:

"An active partnership between the public and researchers in the research process. Active involvement may take the form of consultation, collaboration or user control. Many people define public involvement in research as doing research 'with' or 'by' the public, rather than 'to', 'about' or 'for' the public. This would include, for example, public involvement in prioritising research, advising on a research project, assisting in the design of a project, or in carrying out the research." INVOLVE 2007

2.5 Structure of the report

The study is reported as follows. Following this introductory chapter, which sets the broader context and need for this study, considers terminology and establishes the research questions, the systematic review methods utilised for this systematic review are reported in chapter 2. The results of the review are reported in chapter 3. Section 1 (of chapter 3) focuses on the definition, conceptualisation, theorisation, measurement and economic evaluation of PPI. Section 2 focuses on the impacts of PPI and the outcomes of PPI. Chapter 4 discusses the findings, identifies emerging issues and considers the future evidence base needed for PPI. Chapter 5 addresses the recommendations from the study, in terms of future research required, and the improvements needed in the quality and robustness of reporting. Chapter 6 provides detailed guidelines for reporting impact in peer-reviewed papers. These guidelines could be used for reporting impact in grey literature. Appendices include search strategies, the data extraction and quality assessment tables and details of excluded papers and areas.

3. Methods

3.1 Advisory group

An advisory group was set up consisting of 11 experts in systematic reviews and/or user involvement, and included three lay members who volunteered from the UNTRAP, Warwick University's user involvement network, and the UKCRC PPI Sub-Group. The advisory group was consulted at each major point of the study, that is, at the protocol stage, data retrieval stage and results stage.

3.2 Development of searches and selection of evidence

The strength of a systematic review lies in the ability to develop a robust and effective search strategy which locates studies relevant to the research question. Table 1 illustrates the search terms which were used for this review, from which search strategies for each database were developed.

Table 1 Search Terms:

Pop 1	Pop 2	Pop 3	Intervention	Outcome
Patient*	Health Research*	UK	Involve*	Empower*
User*	Social Care Research	Europe	Participate*	Experience*
Carer*	Health Service	North America	Collaborate*	Reform*
Caregiver*	Social Service	Canada	Engage*	Develop*
Public	Public Health	Australia	Partnership	Economic*
Citizen*	Primary Health Care			Cost*
Client*			Evaluate*	Change*
Consumer*			Consult*	Reconfigure*
Lay (people)			Audit*	Redesign*
Stakeholder*			Consumer panel	Impact*
Representative*			Advisory group	Outcome*
Relative*				Effect*
Family*				Decision making
Survivor				Policy making
MeSH terms: patient participation exp consumer participation				Health planning
				Health priorities

N.B. Pop=Population

From the initial searches conducted, keyword and search terms were used to develop the search strategy alongside an information specialist from Warwick University. Appendix 1 illustrates the search strategy employed for the online electronic databases.

Searches were undertaken by an information specialist from 1995 to April 2009 in the following databases: medical literature (Medline, Embase, PsycINFO, Cochrane library), nursing literature (CINAHL), and healthcare management information consortium (HMIC and HELMIS).

Hand searching of reference lists of papers and hand searching of one journal, Health Expectations, was conducted. Grey literature was searched using the databases: InvoNet and NHS Evidence. Grey literature was also obtained by contact with experts in the field. The INVOLVE collection of resources was also searched.

Title and abstract search was conducted to narrow down the number of papers ordered. The papers obtained were checked against the inclusion and exclusion criteria, and then quality assessed (see section below).

3.3 Inclusion and exclusion criteria

A set of inclusion and exclusion criteria was used to select papers for the review. These included:

Inclusion criteria

Papers were included if they report on the following:

- Definition of user involvement in health (public and primary) and social care research
- Conceptualisation of user involvement for health (public and primary) and social care research
- Methods for capturing user involvement data and measurement of user involvement in health (public and primary) and social care research (reliability and validity reported)
- Impact of involvement at all stages of health (public and primary) and social care research (e.g. protocol, ethic approval, advisory, data collection, analysis, dissemination)
- Impact of the research on individual users or research team members (e.g. personal development/new skills/financial gain or work load/?emotional journey), on groups (e.g. communities, user groups, teams), on organisations

(e.g. communities, NHS, Council, Funders, Ethics committee), and on policy (local and national)

- Outcomes of research (results of the research study)
- Economic evaluation of user involvement in Health (public and primary) and social care research
- Evidence from 1995 to 2009
- English language
- Users involved are adults.

The following additional inclusion criteria for grey literature were used:

- The article/report contained a substantial amount of critical analysis or reflection on the impact of public involvement in research (a 'substantial' amount is defined as a separate or distinct section within the report)

- The article/report discussed public involvement in health and social care research

- The article/report was publicly available as a report form

- The grey literature searches will be from 1995 onwards, in line with the dates searched for the published literature.

Exclusion criteria:

- Foreign language unless deemed a critical study to include in the systematic review
- Children and adolescent services
- Letters, opinions, editorials
- If the study had a fatal flaw, in terms of quality, which compromised its results.

Selection criteria

10% of the abstracts or summaries of material were reviewed independently by two researchers JB and SS.

3.4 Quality assessment

By assessing the quality of studies it is usually possible to define a threshold for including studies in a review. In this review, if papers passed the first two fielding questions, that is, the paper reported a clear statement of aims, stated clear, appropriate methodology, and reported results, then the study was included, but quality assessment was reported as 'partial'. If the papers passed the first two fielding questions and scored 7/10 or more on this quality assessment sheet, they were scored as 'adequate'. These assessments are in the data extraction tables. However, there was very little difference between these two groups of papers, so the utility of describing the evidence in terms of quality was limited and not used to discuss the results. If studies had been fatally flawed in terms of their quality, they would have been excluded.

This decision was made as some important factors describing PPI might be lost to the review if studies were eliminated purely on study design (see quality assessment section in discussion). The methodological quality of published studies was assessed using the Critical Assessment Skills Programme (CASP, Oxford). The quality assessment was conducted by two independent reviewers for each paper. Any disagreement was resolved in consultation with a third reviewer. The evidence base is mainly qualitative, case studies, or cross-sectional studies reporting individual or organisational views of PPI. For this reason, the quality of the evidence was very difficult to assess, and the quality assessments have therefore not been used to weight the papers. Grey literature was assessed using the checklist developed by Dixon-Woods (2005) as used by Hubbard et al (2007) to review grey literature on involving people affected by cancer. Quality assessments are reported in the data extraction tables for each study. If any studies had been judged to be fatally flawed in terms of their quality they would have been excluded from the systematic review.

3.5 Synthesis of data

The data is presented in a descriptive or non-quantitative synthesis where data has been tabulated in a way to allow readers to look at the evidence, the methods used, and the populations studied, the interventions used, and the outcomes of the studies.

A qualitative synthesis of the data was performed which involved familiarisation with the papers, then the identification of emergent themes. The synthesis aimed to draw out key themes that related to our research questions. This has been summarised in a descriptive form to draw conclusions about the evidence.

3.6 Results of searches

The following reports the number of hits from each of the electronic databases:

Electronic database	Number from searches
Medline	7196
Embase	4611
CINAHL (nursing literature)	217
PsycINFO	340
Social Science Citation Index (Web of Knowledge)	17
Healthcare Management Literature (HMIC & HELMIS)	1500
Cochrane	9
Total	13,890

The total number of titles in the first search was 13,890. From the first title and abstract search there were 253 papers. After more detailed viewing of the abstracts, a total of 119 papers were selected. A further 7 papers were obtained by hand-searching the journal Health Expectations. 126 published papers were read and assessed using the inclusion/exclusion criteria.

Of the 126 published papers, 90 were included. 83 published papers were data extracted and are reported on in this review. A further 7 were not data extracted but are included in the results section for conceptualisation and definition of PPI in health and social care research. These papers were not data extracted because, although they were deemed important papers to report, they did not follow the normal report

format (aims, methods, results, discussion), so it was not possible to use the data extraction form.

Of the 83 published papers included, 2 were randomised controlled trials (RCTs), 52 were qualitative studies, 15 were case studies or case series, 4 were cross-sectional studies, and 10 were structured reviews.

The two RCTs (Angell et al 2003, Guarino et al 2006) both assessed the impact of PPI in the provision of information.

36 papers obtained were excluded, 14 because they did not report original data or review data, 8 because they were describing impact on child populations, 5 because they were based on opinion, 4 because they were editorials, and 5 because they were not relevant to PPI in health and social care research.

Grey literature

11 grey literature reports were obtained from the grey literature searches, of which 8 were included. Three of these were qualitative studies, one was a qualitative study and a cross-sectional study, two were reviews, one was a review and a survey, and one was a case series.

Included papers:	
Total published papers reported in data extraction tables	83
Total published papers reported, but not data extracted due to nature of paper	7
Total unpublished papers (grey literature)	8
Total included papers	**98**

3.7 Patient and Public Involvement in study

Three users were recruited to the advisory board of this study, and assisted by commenting on the design, methodology and analysis in the systematic review.

Two months before the end of the project, an expert seminar was conducted including 24 users and individuals who work in the field of PPI. Users were recruited from UNTRAP, the user organisation at Warwick University, and from the Diabetes User Network Research Group, a group attached to the medical school at Warwick University.

The aim of this seminar was to provide an opportunity for users to discuss the emerging findings from the systematic review, and add their interpretations and perspectives. Prior to this seminar, we met with the users from our advisory group to gain their input into our interpretations before we presented them at the expert seminar. The seminar was very helpful in exploring the way in which impact data was grouped and highlighted the need to consider context and process in the interpretation of impact data.

4. Results

This systematic review focused on the conceptualisation, measurement, impacts and outcomes of PPI. Each of these areas received equal emphasis in the searching of literature and in the data extraction of studies. All the evidence identified in relation to each of the four areas is reported in this chapter. However, it is clear that the vast majority of evidence that underpins PPI relates to impact and this is reflected in the balance of the reporting. It is also important to note that the majority of papers concerned with impact and outcomes were reported as research studies, whereas many of the conceptualisation papers were not written in this format, which made data extraction difficult.

The results section is divided into two main sections: the first section reports the evidence on the conceptualisation and measurement of PPI. It was not possible to carry out data extraction on the more conceptual and theoretical papers in the same way as impact and process, so each of the studies that have examined some aspect of conceptualisation are included in significant detail, to demonstrate the nature of the data used to develop study recommendations. The second section reports the evidence of the impact of PPI on health and social care research and the outcomes of studies that have included PPI. The data extraction tables for each study are included in appendices, as a separate report.

Section1 Conceptualisation and measurement

4.1 Introduction

This section reports the evidence around the conceptualisation and measurement of PPI. Conceptualisation refers to the way in which a phenomenon is described, defined and understood. Clear concepts and conceptualisation are helpful when developing a theoretical model. A theoretical model can be built from a set of concepts and can provide a blueprint, once empirically tested, for the development of instruments which aim to capture or measure the concept of interest. This review has focused on identifying papers that have reported conceptual thinking or the development of theoretical models that can be helpful in capturing or measuring impact. These might take the form of models or frameworks that try to grasp some of

the complexity of PPI. However, the influence of 'bigger theory' in relation to PPI is also acknowledged. The growth of PPI has been influenced by a number of factors:

- Consumerism (Almond 2001) – as the NHS has evolved over the past decade, so there has been a growing trend for patients to have more choice over their treatment and care. However, consumerism has created top-down, and managerially led strategies for involving users in health and social care research (Croft 1996, Beresford 03).
- Empowerment of users – progressive levels of power have lead to partnership in decision-making and a freedom to make choices and accept responsibility (Rodwell 1996).
- Patient centred care - The growth of patient centred care has led to patients being more involved in decision-making, and taking more control over their own health through health promotion and prevention of illness (Kuss 1997, Cody 2003).

4.2. Conceptualisation of PPI

It was not possible to data extract the theory-based or reflective conceptualisation literature in the same way as the studies that were focused on frameworks for PPI, so we have included detail about these studies in this chapter. Published papers that developed frameworks around which PPI could be conducted have been data extracted and also summarised in detail in the second part of this section.

Overall, conceptualisation or theoretical thinking about PPI is not common in papers that have reported on impact. Those papers that have focused on conceptualisation are often based on reflection or opinion rather than more formal conceptual development or theoretical development or testing, which has not yet occurred in the field of PPI and the current state is summarised very well by the following quote:

'The literature is replete with enthusiastic reports and reflections but with little or no detail about [conceptualisation of] public involvement, and often little attempt at objectivity. While evidence fits user involvement into various universal theories, few have attempted to test or validate a model of user involvement.' (Oliver 2008).

4.3 Theoretical and reflection-based conceptualisation

There was a range of conceptual papers and each will be reviewed. A common approach has been to regard involvement as a hierarchy or as a continuum. One of the earliest attempts to consider different levels of involvement was Arnstein's work, included in this review because of its significance (outside of search dates). The original concept of citizen participation originated from Arnstein's (1969) ladder of citizen participation, which described the different levels of control and power that the poor had over decision-making processes in the US, although there are limitations to this approach. However, by solely emphasizing power, this limits effective responses to the challenge of involving users in services and undermines the potential of the user involvement process. Such an emphasis on power assumes that it has a common basis for users, providers and policymakers and ignores the existence of different relevant forms of knowledge and expertise. It also fails to recognise that for some users, participation itself may be a goal (Tritter 2006).

Within the remit of this systematic review there are several papers that attempt to conceptualise PPI. Hierarchical levels of consumer involvement are described, from a low level of involvement through a consultation process with users, where the power lies with the researchers, to a more equal partnership through collaboration with users, through to the user-led research where the research is controlled and led by the users (Boote et al 2002). INVOLVE's definition of involvement also distinguishes between different levels including user-led, consultation and collaboration. In reality, the level of involvement can change throughout the research study as users gain skills and confidence to get involved, and as the trust builds between the users and the academic researchers (Hanley 2000), as can the level of contribution of the users at various stages of the research (Dixon 1999). Hence, any conceptualisation of PPI should reflect that involvement might be going on simultaneously at multiple levels of decision-making (for example, users may be in partnership with academic researchers in data collecting, whereas there is also a user advisory group which consults on the study phases) (Smith 2006).

4.4 Development of frameworks and models of PPI

Four published papers reported on the development of a framework or a model in which PPI could be conducted.

Oliver et al (2008) reports a study that developed a multidimensional conceptual framework capable of drawing out the implication for policy and practice of what is known about public involvement in research agenda setting, reported in table 10.

Oliver first reports the evidence from a systematic review, which drew on differing priorities, conceptual frameworks, community equipoise, power, democratic practice and advocacy. The health topics covered in the literature were different: health conditions (asthma, breastfeeding, cancer, cystic fibrosis, dental health, diabetes, disfigurement, HIV, hyperactivity, learning difficulties, mental health, physical complexities and disabilities); populations (older people, younger people); interventions (physiotherapy, organ transplants, wheelchair and other assistive devices); and settings (homelessness, occupational health, school health, urban health).

Table 10 - Oliver et al (2008)

The Framework developed was based on three critical dimensions:

- Whether lay people are involved as individuals or as members of organised groups.
- Whether public involvement was at invitation of the research programme or as a response to action by the lay public ('reactive' or 'pro-active');
- The degree to which public was involved (consultation, collaborative or lay control)

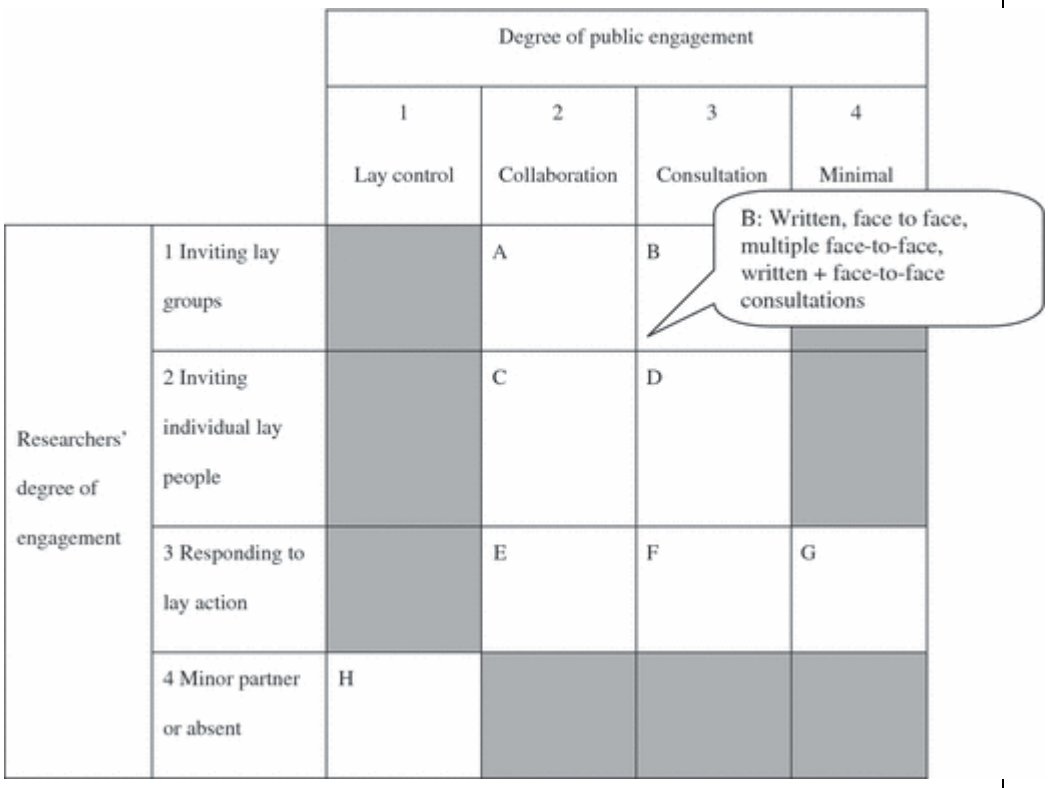
The eight dimensional framework developed (see figure below) reports the following:

Degree of Public engagement (P):

1)Lay control; 2) Collaboration; 3) Consultation 4) Minimal

Researchers' degree of engagement with public (R):

1) Inviting lay groups; 2) Inviting individual lay people; 3) Responding to lay action; 4) Minor partner or absent.



(NB in grid P2, R1= A; P3, R1=B; P2, R2=C; P3, R2=D; P2, R3=E; P3,R3=F; P4, R3=G; P1, R4=H)

The conceptual framework takes into account the people involved; the people initiating the involvement; the degree of public involvement; the forum for exchange; and the methods used for decision-making. It also considers context (in terms of the research focus and historical, geographical, or institutional setting), and theoretical basis.

The framework draws together examples of public involvement that share fundamental principles, but that have developed in very different contexts. It distinguishes between variables operating at different levels; at initiation, and subsequent choice of participants, forum, and decision making processes. Using the categories in the framework, (A-H), method A (commonly used in large scale research programmes in committee membership) alone achieved little, while bottom up type C achieved a lot, but only for small scale research. The most effective way of involving the public in setting large-scale research agenda appeared to be a combination of collaboration and consultation, with lay people taking leading roles in consulting their peers.

The study reports that a key barrier to public involvement being effective was not the inability of lay people to identify or

prioritise research topics, but the tendency of professional organisations not to grasp them.

The framework highlighted the abstract concept of empowerment in practical terms: the number of people involved; whether they were individuals or networked group members; within one-off or repeated opportunities for involvement; whether members of the public had leading roles or played a part in decision-making; and whether there was any training or other resources to support their involvement.

Two measures of impact were chosen that related directly to the review question (records of lay priorities, and records of reflection and lesson learnt), and aligned the work with participatory approaches for mutual learning, reflection and change.

In addition to developing a framework, the paper identified some of the complexities in terms of content and process factors which underpin PPI. For example, with consultation, more was learnt by involving patient and public in debate (Delphi study, focus groups, face to face) rather than written consultation. Lack of thought into how to involve the public led to the loss of opportunities for shared learning. Working with community groups gauged local opinion, but could be time consuming, and faced difficulties of lack of attendance, lack of understanding and lack of commitment. Investing time and money into user involvement led to better learning from user involvement. Opinion surveys gave shallow pictures of attitudes, perceptions of benefit and harm of research, and little data on research priorities due to close questions. The study found that collaboration, when it was working well, facilitated democratic processes, openness, appropriate choice of members, and support and training for all involved. But careful management was needed to avoid tensions. PPI was more 'successful' when programmes were required to reflect on their methods for incorporating users' perspectives, and when users were seen as 'partners' in research. If individuals were involved (rather than organised groups), there was a need for more input in training, education and 'knowledge transfer', but it could lead to more meaningful input into research. The study found that lay controlled research was the least formally developed: the study concluded that collaborative strategies with individual consumers achieved more than consultation through committee membership. The most successful method of user involvement appeared to be when using collaboration and consultation, with lay collaborators consulting their peers.

Another study has examined what health consumer organisations in Canada consider meaningful involvement, to examine the current international practices for PPI, and to develop a model for involvement based on identified priorities and needs, reported in

table 11 (Pivik, Rode, Ward, 2003, Canada). However, this study seemed to relate to more functionally related issues such as how to undertake involvement, rather than more conceptual thinking, which aims to develop a better understanding of PPI.

Table 11 Pivik, Rode, Ward, 2003, Canada.

Development of model for PPI

A literature review was conducted, and three main themes were identified:

- Consumer involvement is more meaningful if the focus is on involvement versus consultative strategies
- The most feasible type of involvement based on current practices involved consumer participation on a decision-making committee
- Both health professional and consumer perspectives should be represented

The study then assessed two consumer involvement models already in use:

- National Institute of Clinical Excellence (NICE) model of involvement, UK
- Breast Cancer Consumer Involvement model, Australia

The critique of these two models can be seen in the figures below.

NICE model of involvement – Strengths and Weaknesses

	Strengths	Weaknesses
1	The Commission for Health Improvement is a national governmental initiative to involve patients in clinical governance processes, where patient experiences and social values judgements are defined as one of the key tests of effectiveness of management	Guideline developers (which do not include patient representatives) determine: (1) the scope of the project, (2) whether patient information is to be included as evidence, and, (3) what guidelines are developed
2	The Patient Involvement Unit (PIU) is a semi-independent supporting unit of NICE: based at the College of Health, a national charity that promotes patient interests in the National Health Service	NICE has total control of who the patient representatives will be
3	NHS policy explicitly states that services are to be based around the needs of the patients vs. the organizations: with the aim of developing fair, transparent and defensible methods of patient involvement and that patient issues and perspectives are directly addressed and presented in meaningful ways to patients	Mechanisms need to be put in place that assists in evaluating qualitative or anecdotal evidence from patients. However, the Patient Impact Assessment project is currently being evaluated which may address this issue
4	NICE has developed a formal stakeholder consultation process	Training for professionals not identified
5	PIU coordinates the identification of potential patient representatives through a database	Patient representatives are typically short term, providing feedback but not meaningfully involved in committee decision-making
6	A mechanism is in place where national organizations can register to become part of the consultation process	Developers are given 1 year to develop the guidelines but patient groups are only given 1 month to review them. This time line makes it difficult for patient groups to get feedback from their constituencies. In November 2002, the board is examining a recommendation from the Citizen's Council for extending the tenure for a minimum of 2 years
7	Patient information on guideline development process is created and distributed by PIU	
8	8 PIU expects all guideline groups to have 2 patient representatives	
8	9 Training and resources are provided to patients to facilitate their involvement	
10	PIU has an evaluation component associated with patient involvement	
11	Feedback is provided to patient groups and the public	
12	Patient representatives are paid to assist in clinical guideline appraisals	

Australian Breast Cancer Consumer Involvement model – Strengths and Weaknesses

	Strengths	Weaknesses
1	Extensive consumer consultations to develop the process, resources for the patient involvement model	No policy stating that each committee should have more than one patient representative
2	Selection of patient representatives is conducted by the consumer organization	No policy requiring patient representatives to be paid for their involvement, in fact, they are typically volunteers
3	National database of potential patient representatives that includes Diagnosis Treatment Skills Expertise Interests	Evaluation process discussed but not implemented to date
4	Request for patient representatives broadly disseminated	
5	All patient request submissions reviewed	
6	Selection of patient representative by consumer-based selection committee through consensus	
7	Guidelines regarding role and responsibilities are provided to patient representative prior to their acceptance	
8	Informational kit provided to patient representatives that includes Guidelines for working on committees Research glossary Information about the topic (cancer) A list of additional resource material/sources	
9	Informational kit for organization/professionals	
10	Training is available to all patient representatives and includes Understanding the health system Communication and networking skills Advocacy skills training Scientific aspects (biology, risk, epidemiology, screening) Information about diagnosis, treatment, multidisciplinary care Making sense of scientific research: clinical trials, reading and appraising research articles, issues associated with evidence-based medicine Information on libraries, medical literature, Internet	
11	Replacement process in place if patient representative becomes ill or unable to attend	
12	On-going support provided to patient representatives via consumer organization	
13	Information dissemination strategies using Internet, e-mail, newsletter	
14	Patient representatives involved in committee decision-making	
15	Entire process has external and internal transparency	

Based on the strengths and weaknesses of the two PPI models, the following factors were identified in relation to PPI in Health Technology Assessments (HTAs) in Canada:

- type of involvement
- needed informational resources
- best methods to provide this information
- other resources to facilitate involvement
- accessibility issues
- feedback mechanisms
- level of interest in database that would list members' skills, knowledge, and level of expertise
- importance of consumer involvement in HTA
- timelines required for consumer involvement.

The following PPI model was developed, as illustrated in table 12. As with previous examples, many of the aspects of this model are more functionally orientated, that is, focused on how to carry out PPI, rather than necessarily contributing to an understanding of the concept:

Table 12

• A fair and transparent process involves an independent, national based consumer organisation that works in tandem with, but is not governed by, the centralised review committee. • Federal Government needs to provide funding. • Development of a HTA PPI network. • Development of formal consumer stakeholder involvement process (selection, feedback mechanisms, timelines, accommodation needs, training and educational support, access to expert advice. • The development of consumers' national database providing details of their knowledge, skills and expertise. • Provision of training and education support for consumers (health issues, health policies, treatment or therapy, scientific and research processes, information on practical side of meeting – planning, evaluating, procedures of meeting, communication. • Development of web-page, organisation of educational workshops. • Evaluate programmes and process effectiveness

A study conducted by Telford et al (2005) attempted to obtain consensus on the principles and indicators of a successful PPI model in National Health Service (NHS) research in the UK. Purposeful sampling was used to identify people who had experience/or knowledge of consumer involvement in NHS research. An expert workshop of users who had experience or knowledge of PPI in the NHS research

was recruited. Through the use of a nominal group technique potential principles and indicators were generated (n=13). Furthermore, two rounds of a postal Delphi process were used to obtain consensus on the principles and indicators (n=96/131). Respondents were asked to rate the principles on two nine-point scales (clarity, validity), and each indicator on a 9 point scale (clarity, validity and feasibility). Each principle and indicator had to achieve 85% or more in range 7-9 on each scale to be retained. Table 13 reports the 8 principles identified.

Table 13

Telford R, Boote J, Cooper C (2005)

Principle1:

The roles of the consumers are agreed between the researchers and the consumers involved in the research.

Indicator of Principle 1:

The roles of the consumers in the research were documented.

Principle 2:

Researchers budget appropriately for the costs of the consumer involvement in research.

Indicators of principle 2:

Researchers applied for funding to involve consumers in the research.

Consumers reimbursed for their travel costs.

Consumers were reimbursed for their indirect costs (e.g. carer costs).

Principle 3:

Researchers respect the differing skills, knowledge and experience of consumers.

Indicators of Principle 3:

The contribution of consumers' skills, knowledge and experience were included in research reports and papers.

Principle 4:

Consumers are offered training and personal support, to enable them to be involved in research.

Indicators for principle 4:

Consumers' training needs related to their involvement in the research were agreed between consumers and researchers.

Consumers had access to training to facilitate their involvement in the research.

Mentors were available to provide personal and technical support to consumers.

Principle 5:

Researchers ensure that they have the necessary skills to involve consumers in the research process.

Indicator for principle 5:

Researchers ensured that their own training needs were met in relation to involving consumers in research.

Principle 6:

Consumers are involved in decisions about how participants are both recruited and kept informed about the progress of the research.

Indicator for principle 6:

Consumers gave advice to researchers on how to keep participants informed about the progress of the research.

Principle 7:

Consumer involvement is described in research reports.

Indicators for Principle 7:

The involvement of consumers in research reports and publications was acknowledged.

Details were given in research reports and publications of how consumers were involved in the research process.

Principle 8:

Research findings are available to consumers, in formats and in language that they can easily understand.

Indicators for principle 8:

Research findings were disseminated to consumers involved in the research in appropriate formats (e.g. large print, translations, audio, Braille). The distribution of the research findings to relevant consumer groups was in appropriate formats and easily understandable language. Consumers involved in the research gave their advice on choice of methods used to distribute the research findings.

Abelson (2007) carried out a study which aimed to develop a framework of public involvement in technology assessment and health policy in Canada. A review of current evidence and lessons learnt from HTAs in other countries was conducted to develop a framework for involving patient and public in HTA research in Canada. The following framework, reported in table 14, was developed from the evidence and from the lessons learnt:

Table 14

Abelson (2007)
Public representation: ➢ In developing and applying assessment criteria ➢ In formulating assessments Public Involvement: ➢ In setting assessment priorities ➢ In developing and applying criteria ➢ In formulating assessment priorities Accountability (through answerability) ➢ Assessment reports ➢ Assessment methods (replicable) ➢ Recommendations for decisions ➢ Rationales for recommendations Accountability through citizen engagement ➢ Accountability (through sanction or appeals) - although should avoid if possible because creates antagonistic relationships.

Two studies reflected on experience and identified criteria by which to conduct PPI. McCormick (2004) set out to understand the obstacles, processes, and benefits of public involvement in breast cancer research, and to develop criteria of lay involvement in research based on the analysis of three empirical cases. These cases were

- Long Island Breast Cancer Study Project (LIBCSP)
- Silent Spring Institute study (SSI)
- Marin County Breast Cancer Watch study (MCBSW).

Table 15

McCormick (2004) The criteria developed from reflection of these three studies were:

- researchers and lay people need to develop mutual trust
- make a commitment to a time investment for the project
- establish its goals
- define the community being served
- engage a funder who is committed to public involvement
- mutual co-operation, the quality of the leadership, processes of evaluation, and goals of research can be developed only through effort on the part of both partners

Interestingly, by reviewing studies that have attempted to develop our understanding of PPI, it can be noted that many of them identify factors that could be linked to the context and process factors of PPI. These factors could be usefully synthesised by future theoretical modelling of PPI. However such attempts have not yet progressed higher level theoretical modelling which grasps the complexities of PPI sufficiently.

Dewar (2004) reports on the development of criteria by which to support involvement of older people in PPI. The following criteria were reported to improve the success of PPI in older people, in table 16:

Table 16

Dewar (2004)

- Formalise the role of older people who work in partnership
- Education programmes for professionals on how to facilitate involvement
- Further development of theory that guides involvement – existing theories do not address different types of support that are required, nor do they reflect organisational and process issues inherent in involvement (Reed 2004).
- Explore the concept of 'equal but different knowledge and skills' to process of partnership.
- Evaluation of both processes and outcomes of older people in carrying out research is required
- More opportunities need to be created for sharing experiences about the process of involvement in research and development work with other groups (e.g. disabled people, people with mental issues, people with learning disabilities. Also further understanding of barriers to involvement
- Debates with funding bodies to develop systems to enhance user involvement from the outset
- Debates are required with ethics committees to recognise the empowering potential of involvement from older people.

While some of Dewar's (2004) criteria are again related to context and process factors, there is mention of the need for further development of theory to guide involvement.

Summary of conceptualisations of PPI in health and social research:

- **There are some helpful frameworks of PPI that have been developed to provide models by which PPI can be conducted. Models which identify different levels of PPI have also been developed. In addition, criteria for undertaking PPI have been developed.**
- **Studies have tended to focus on identifying factors that could be seen as forming part of the context and process of PPI, as described in this review, rather than higher level theoretical modelling.**
- **As a result, the conceptualisation of PPI remains partial.**
- **There is no evidence of the development of a more complex theoretical model that aims to explain the concept of PPI, identify the factors that influence it and those that it influences, and so could be helpful in the development of an instrument to measure impact.**

4.5 Measurement of PPI in health and social care research:

One of the important aims of this review was to search for and synthesise studies that have attempted to measure the impact of PPI. Other areas that focus on user experiences such as the field of patient satisfaction or patient experiences and patient-reported outcome measures (PROMS) have attempted to measure the impact of interventions, more successfully in the field of PROMS. However, the field of PPI is an area where there has been little, if any, attempt to develop instruments to measure impact. Two studies have attempted to measure the impact of PPI by randomised controlled trial methodology to assess the difference in informed choice, and by assessing the difference in recruitment to a trial using information developed by users versus information developed by academic researchers (Guarino 06, Angell 03). While these two studies may attempt to measure one aspect of PPI, they do not take into account the complexity of PPI or draw on any definition or conceptualisation of PPI. Reflecting the broader literature these studies did not attempt any form of robust measurement. Both studies are also reported in the impact results section.

Across the PPI evidence base, there was no evidence of instruments which had been developed and empirically tested to measure impact which reported data on their reliability and validity, in the same way as occurs in the field of PROMS. This represents an important area for development in the future, but does rely on the need to develop more comprehensive theoretical models of PPI.

4.6 Economic Evaluation of PPI in health and social care research:

One of the important aims of this review was to search for and synthesise studies that have attempted some form of economic evaluation of PPI. The economic impact of PPI activity is of interest to those who undertake it, as well as to funders and policy makers who may wish to appraise costs against benefits. However, as with the measurement of PPI, there is little evidence of studies that have attempted to develop the economic understanding of PPI. As with measurement this offers potential areas for future research in order to develop a comprehensive understanding of PPI impact. Studies would need to consider the cost of implementing PPI, such as staff time and resources.

Section 2

4.7 Impact of PPI on health and social care research

Introduction

This section reports the results of the systematic review in relation to impact of PPI. It is organised according to the key themes, stage of research and the different types of impact that have been identified. These include impact on the research and research process, impact on users, impact on researchers, impact on research participants, impact on the community, impact on funders and impact on policy makers. The categorisation of these areas of impact is supported by the recent INVOLVE review of impact (Staley 2009). The User Involvement seminar supported the grouping of data in these categories. Before reporting the detail of these results, the importance of context and process are considered. One of the key findings from the user involvement seminar conducted in October 2009 and from the review was that the impacts of PPI need to be considered within a broader framework. However, most studies do not report impact in enough detail and fewer still mention impact in relation to context and process in a consistent way. Thus a more general discussion of the importance of context and process for developing the future PPI evidence base is included and some of the context and process factors identified in the review are included.

4.8 The importance of context and process

Context refers to the environment in which PPI is undertaken, that is, the setting for the involvement and the atmosphere/attitude in which it is conducted. The process of involvement can include a number of different things. For example, it could refer to the level of involvement that users have, how they are involved, when they are involved, and what procedures are put in place to improve the likelihood of success. In many ways these contextual and process factors could be described as the 'architecture of involvement' as they reflect the structures and landscape that needs to be in place in order to enable patient and public involvement activity to have an impact (see table 2). If the context and process is not appropriate then the chances of beneficial impact of patient and public involvement activity appear to diminish. Part of this 'architecture' of involvement also includes other factors such as the individual characteristics of researchers and patients. The evidence suggests that the better the

training, planning and procedures that are put in place, the more positive the attitude towards PPI, and the greater the trust and respect that parties (users, researchers, clinicians, funders, policy makers) have with each other, the more potential for beneficial impact. The less involved the users are in the research, for example, if there is a lack of training, poor planning and unclear procedure put in place, a more negative attitude, and a lack of trust and respect between parties, the more challenging the involvement appears to be, and possibly less chance of beneficial impact. There appears to have been a learning curve for most of the studies that reported on the impact of PPI. The evidence shows that some studies had difficulties with integrating PPI into their study in the first instance, but developed their learning over time, sometimes appearing to recognise the importance of process and context as the study developed. Some studies understood the importance of trust and respect between researchers and users, which could lead to more beneficial impacts (Savage 2006, Peterson 2004, McCormick 2004, Meyer 2003, Dockson 2001, Burrus 1998).

Table 2: The Architecture of PPI: Context and process factors

To make table consistent with rest of text, I have changed this to Arial 12. Change can be rejected if not required

Architecture of PPI

1.	Budget appropriately for the service users' involvement. This may include contributions to service users for their time, expenses, cost of training etc
2.	Consider additional time needed for PPI activity in time scales for the study
3.	Involve service users as early as possible in the research, preferably at the beginning of the study and maintain involvement throughout
4.	Define roles of service users and researchers in the PPI activity
5.	Provide service users adequate training on research skills required for their involvement in the study
	Provide service users with the additional knowledge of the disease/condition that is necessary in order for them to contribute
6.	Provide researcher with training on how to involve service users in research and encourage a positive attitude to PPI
7.	Establish good relationships between service users and researchers over time, and avoid recruiting service users in a hurry
8	Respect the skills, knowledge and experience that service users bring to a research study
9.	Provide personal support and supervision of service users
10.	Ensure good communication to manage conflict and avoid isolation
10.	Involve service users in developing invitation letters, information sheets, consent forms, questionnaires, interview schedules – as service users will assist in developing this information in a patient-relevant way
11.	Involve service users in decisions as to how participants are recruited
12.	If sufficient training is provided, service users can assist in data collection
13.	Service users can identify patient-important themes in the data
14.	Detail in reports/publications how PPI was conducted
15.	Produce a lay summary of the final report so it can be easily understood

	by the target population
16.	Develop service user advocacies for dissemination and implementation of research to assist in making the results more poignant and more relevant to the target population

Refs: Thompson 2009, Hubbard 2007, Taylor 2006, Telford 2005, Royle & Oliver 2004, McCormick 2004, Dyer 2004, Gilbert 2004, Pivok 2003. NB: the evidence reporting impacts also reports the benefits of following, and the challenges of not following the processes set out in this table.

The poor reporting of impact and the limited consideration of how context and process factors affect impact makes meaningful comparison across studies difficult, and so prohibits firmer conclusions about their influence. In chapter 5, reporting recommendations, there are suggestions for the future reporting of context and process, as part of the review's recommendations for strengthening the PPI evidence base.

4.9 Impact of PPI on the research and research process

In total, 55 papers reported impacts of PPI on health and social care research, of which all 55 reported beneficial impacts, and 37 of these papers also reported negative impacts.

4.9.1 Beneficial impacts of PPI on research and research process

The majority of published papers reported a range of beneficial impacts, with some reporting negative impacts. The impacts on research are divided into the following main categories: Impact on initial stages, data collection, analysis, write-up stage of study, implementation, dissemination of research findings, and impact on the wider relevance of the research. It should be remembered that the assessment of whether an impact is positive or negative is also a matter of interpretation and can vary according to who is assessing it and their role in the research.

Initial stages of research

During the initial stages of setting up a research programme, the evidence reports beneficial impacts of user involvement, with users helping to identify user relevant topics for the research agenda (Lindenmeyer 2002, Shah 2007, Hewlett 2006, Howe 2006, Nilson 2006, Abma 2005, Caron-Flinterman 2005, O'Donnell & Entwistle 2004,

Rhodes 2002, Kelson 1999), prioritising topics for the research agenda,(Hailey 2006, Howe 2006, Abma 2005, Viswanathan 2004, McCormick 2004, O'Donnell & Entwistle 2004), and the development of patient relevant commissioning briefs (Oliver 2006, Ross 2005, O'Donnell & Entwistle 2004 Morgan 2004), in diabetes research, rheumatology research, spinal cord injury research, research for the blind, research for the elderly population, Health Technology research agendas, biomedical research, and Cochrane review agendas. Studies report that the involvement of users in the selection of research topics results in research topics that were grounded in day to day reality of users' experiences. Examples of this include:involving mothers of pre-school or primary school age children to improve health and well-being of families and children before school age; involving stroke patients to identify and direct a research study as co-researchers; consulting members of the general public about their awareness and knowledge of stroke and stroke risk; and involving mental health users in research on adult mental health services (Rowe 2006, Barnard 2005, Morgan 2004, Clark 2004). This made research questions more relevant to patients.

Users were recruited onto steering groups or advisory groups to help advise on studies, such as citizen jury members sitting on a steering group to direct primary health and social care research in one city in the UK, users sitting on a steering group for a randomised control trial of HRT and breast cancer, and the chief executive of the national association for the relief of Paget's disease (NARPD) sitting on the steering group for research into Paget's disease (UKCRC 2009, Gooberman-Hill 2008, Wyatt 2008, Menon 2008, Hewlett 2006, Langston 2005, Marsden & Bradburn 2004, McCormick 2004, Viswanathan 2004, O'Donnell & Entwistle 2003, Dickson 2001). Panels of consumers helped to identify which research proposals should be accepted (Andejeski 2002a).

Undertaking research

During the development of the research proposal, users offered pragmatic criticism of research protocols and commented on the extent to which they perceived the research to be relevant or appropriate to users (Corneli 2007, Staniszewska 2007, Ali 2006, Ali 2005, , Griffiths 2004, Truman 2001, Burrus 1998). Examples include identifying cultural issues to take into account when designing the study (Corneli 2007, Viswanathan 2004, Burrus 1998) , identifying patient important outcome

measures for stroke, solving issues around how to get informed consent (Ali 2005), and advice on appropriateness of design (Burrus 1998).

User knowledge also helped adapt researcher language to suit the lay audience (Smith 2008, Faulkner 2008, Faulkner 2006, Nilson 2006), by improving the wording of patient information and invitation letters (Paterson 2003, Wright 2005), and improving the sensitivity of the wording of the information, such as cultural sensitivities (Smith 2008, Burrus 1998).

There is evidence that by involving users in recruitment, the connections they have with the research community may help identify the most effective ways of accessing participants for the study, potentially improving the response rate to the study (Wyatt 2008, Savage 2006, Barnard 2005, Griffiths 2004, Viswanathan 2004, Angell 2003, Meyer 2003, Minkler 2002, Elliott 2002, Hanley 2001). Users can help recruit from specific (seldom heard) communities such as ethnic minorities (Rhodes 2002).

They can also assist in recruitment through greater access to community (Faulkner 2008, Faulkner 2006, Abma 2005, Coupland 2005, Plumb 2004, Rhodes 2002, Dobbs & Moore 2002) . Many of the user associations, such as the Spinal Cord Injury Association (SCIA), and the National Association for the Relief of Paget's disease (NARPD) have a membership which can be used to identify the study sample.

Research participants become more informed about the investigation and treatment of disease, which may lead to better informed consent (.Coupland 2005, Langston 2005, Wright 2005, Angell 2003, Dobbs 2002, Burrus 1998).

The evidence also reports that user involvement assisted in assessing the appropriateness of research instruments to the community leading to improved design relevance to users (Cashman 2008, Shah 2007, Rowe 2006, Hewlett 2006, Wright 2005, Barnard 2005, Griffiths 2004, Minkler 2002, Hanley 2001, Lloyd 1996), improved timing of intervention, such as the time of day to give therapeutic massage for patients with Parkinson's disease (Patterson 2003), and assisted in the development of questionnaire/interview schedules by identifying lines of enquiry not previously considered, helping with the wording of questions, ensuring questions

being asked are acceptable to the local community (Wyatt 2008, Hewlett 2006, Griffiths 2004, Plumb 2004, Morgan 2004). In one study, users helped researchers gain invaluable cultural perspectives of diabetes, particularly how diabetes was often concealed in the community because of social stigma, which helped in the development of the survey protocol (Burrus 1998).

While interviewing, or collating data in face to face interviews, deeper and more personal insights were gained, due to the rapport and empathy users developed with participants, putting participants at ease and providing a greater understanding of the encounter (Faulkner 2008, Ross 2005, Coupland 2005, Rose 2005, Godfrey 2004, Elliott 2002). This can lead to good quality narrative data, as in one study where ex-injecting drug takers (IDUs) interviewed current IDUs (Coupland 2005).

One study found that users knew the right questions to ask of participants, as the issues were more real to them than for the academic researchers (Abma 2005). Three studies that recruited interviewers from mental health community and from the IDUs community reported there was a more honest flow of information when these users interviewed the participants (Rose 2004, Phillpot 2004, Godfrey 2004, Coupland 2005) , whereas participants have a tendency to report more positively to clinicians and academic researchers because patients do not want to criticise in front of them, or risk having their future care reduced.

Input from users in undertaking research may also help achieve a better balance between scientific integrity and user direction of the research, as reported in a user-led study to assess the public's knowledge of stroke and stroke risk where it is possible that researchers would have targeted a wider population and made the questionnaire more scientific (Morgan 2004).

Analysis and write-up stage of study

During the analysis of the study data, the involvement of users has helped to ensure emerging themes and trends were interpreted appropriately, not just from the academic and clinical perspective, but from a wider perspective, providing a different insight and assisting in identifying findings of most relevance to patients (Wyatt 2008, Cashman 2008, Faulkner 2008, Rowe, 2006, Ross 2005, Clark 2004, Griffiths 2004,

Minkler 2002, Trevedi & Wykes 2002). For example, in one study assessing falls in elderly people, users added another layer of insight to the interpretation of the data. Anonymous extracts from interview transcripts were presented on colour coded index cards to illustrate key themes such as: views on self and ageing, independence, perceived threats to independence, and personal falls prevention strategies. Small groups worked with these cards to construct a story that was discussed with the whole group and refined later by a few members of the panel who volunteered to continue the work outside the panel meeting (Ross 2005).

Users were also able to assist in identifying research gaps (Wright 2005, Oliver 2001). Final research reports have benefited from being grounded in user experiences, by providing a wider, more relevant perspective (Hewlett 2006), by providing cultural relevance (Savage 2006), and by giving the results better credibility with stakeholders (Dobbs 2002).

Dissemination and implementation

The evidence reports that involvement of users may achieve better dissemination and implementation of research findings due to dedication and influence of users to the community (Shah 2006, Ross 2005, Langston 2005, Griffiths 2004, Viswanathan 2004, Rhodes 2002, Minkler 2002, Andejeski 2002b). Users created a cohort of advocates for implementation and dissemination of results (Wyatt 2008, Rowe 2006, Langston 2005, Barnard 2005, Hanley 2001). For example, members of the National Association for the Relief of Paget's disease (NARPD) updated its members on the study through their quarterly newsletter, and by displaying posters about the trial at workshops and the annual patient day (Langston 2005). At conferences and meetings, users related the findings to their own experiences which made the message more poignant (Smith 2006). Users may also conduct the dissemination in a more lay user-friendly way (Morgan 2004).

Other impacts of PPI on research

Studies reported that PPI raised awareness of research in the community (Guarino 2006, Smith 2006, Dobbs 2002, O'Donnell & Entwistle 2003, Oliver 2001, Dickson 2001). It made research more relevant to the patient population (Clark 2004) and

gave research better local community credibility (Rowe 2006, Dobbs 2002, Rhodes 2002), and greater credibility among research stakeholders (Burrus 1998).

Dickson reports that PPI improved the feasibility and value of research in a study of older Aboriginal women's health needs (Dickson 20010. It also assisted in more valued changes to mental health services (Minogue 2005) and encouraged diversity in workforce by recruiting elderly users in a study reflecting on the learning from the recent 'joint review' of the National Service Framework for Older People (Cornes 2008)

4.9.2 Negative impacts of PPI on research

Compared to the more beneficial impacts, there was a much smaller body of evidence around more negative impacts. The more negative impacts are divided into the following main categories: impact on initial stages of research, impact on data collection stage of research, impact on implementation and dissemination of research findings, and impact on the time and cost of the study. A consideration of more negative impacts raises the issues that interpretation of impact is in the eyes of the beholder as one person's positive impact might be someone else's negative impact. For example, a user may develop skills throughout a research project and view that as a positive benefit, while this may have a significant impact on the budget held by the researcher. Some of the impacts presented in this section could be viewed from different perspectives. We have tried to reflect the way in which they have been presented in the literature, but acknowledge the potential for different interpretations.

Initial stages of research

During the initial stages of setting up a research programme, studies report several more negative impacts of PPI. For example, one study reported that incorporating user views into agenda setting for a research programme led to scientific and ethical conflict in protocol design (Ali 2006). Another study reported conflicting goals of research rigour versus community concerns, when the review of ethical and scientific need for a trial of HRT lead to a no placebo arm as patients wanted to know if they were taking HRT (Marsden & Bradburn 2004). While this may have raised issues for researchers, it provided a more appropriate study design for users, although there may have been an impact on the integrity of the study design that could have

impacted on the useful of results. A similar issue was reported in a trial protocol for a study of Oxygen supplementation in acute stroke (Ali 2005).

Users should routinely be offered training in research methodology (Shah 2006, Telford 2005, Oliver 2001). Poor provision of such training could lead to negative impacts for users who are asked to comment but experience the frustration of not having the knowledge to contribute. In one study users did not know how to question the appropriateness of the research design and methods during the development of the research proposals, with the research becoming more about process (talking about experiences) than outcomes (formulating questions) (Ong & Hooper 2003).

There is also evidence of some researchers' tokenistic attitude towards PPI, for example researchers involving users for political correctness (Wyatt 2008, Smith 2006, Minogue 2005), or because they do not really understand the contribution PPI could bring to the research (Telford 2002). This type of involvement can result in users' input being devalued by the research team and a poor experience for users. Furthermore, power struggles between researchers and users at the beginning of studies led to conflict between parties (Sainsbury 2008, Coupland 2005, McCormick 2004, Reed 2004, Minkler 2002). For example in a research study that assessed the needs of elderly people, difficulties emerged in the partnership between researchers and users and led to the 'turning upside down of existing power relationships'. Academic researchers and health professionals have traditionally had control over what is researched in health, and user involvement involves sharing out this power. This can provide an important challenge for researchers and potentially a negative impact on their research, from their perspective. As a result, the study reported tensions between academic criteria of good quality research compared with the user perspective on this issue.

Data collection stage of research

Studies report the difficulty in involving a diverse range of users during the research study. For example studies reported difficulties in involving seldom heard groups (i.e. ethnic minorities, the frail, the elderly, people with disabilities), involving users who have low self esteem and felt they have nothing to contribute, and involving users who suffer anxiety concerning group situations (Sainsbury 2008, Abma 2005, Dobbs,

2002, Truman 2001, Lloyd 1996). Even after service users have agreed to be involved in the study, low attendance rates in research meetings caused further problems (Cornes 2008, Dobbs 2002, Dickson 2001). Again, users may view the potential for involvement to be a positive impact, whereas researchers focused more on the difficulties that involvement caused.

Where users are asked to comment on pre-developed materials during a consultation, they may not feel able to comment, and their involvement may still result in materials that do not reflect the user's perspective. This can have a very different impact compared to a study that involves users in the initial development of the information or materials. In a study that compared an informed consent document adjusted by a user group with the original informed consent document developed by the study investigators (when assessing exercise and cognitive behavioural therapy (CBT) for treatment of gulf war veterans), there was no significant difference in participant's understanding of the study reported between the two consent documents, although users may have been involved at too late a stage in the formation of the materials (Guarino 2006).

During meetings, issues of patient confidentially were sometimes difficult to maintain, for example, in a study exploring the views of people affected by cancer, users discussed their treatment and care during steering group meetings which could raise a range of ethical issues (Sainsbury 2008, Hewlett 2006, Abma 2005, Wright 2005). Such discussions could, if they formed part of the research study, require ethical approval.

In one study older users challenged traditional research methods. During the interviewing phase, users felt restricted by the interview schedule, and departed from it when they felt it was appropriate, leading to rich, in-depth data which may not have been collected from using the interview schedule. However, this challenged the traditional academic criteria about reliability of data and raised issues of academic integrity for researchers (Reed 2004).

Studies report that when involving users in focus groups, to identify topics for research or issues in conducting research, researchers were concerned that users

may influence each other, easily resulting in what the researchers viewed as potential (unintentional) over-emphasizing of particular problems which could affect the analysis and interpretation of data (Caron-Flinterman 2005, Elliott 2002).

Furthermore, researchers were concerned that meetings or focus groups may be dominated by personal experience stories, and so it may be difficult to get users to identify research topics, the primary focus of the research study (Ong & Hooper 2003). The same study reported that focus groups were seen as a forum to get other people to accept their (users) understanding of the disease (Ong & Hooper 2003). While these impacts may not necessarily be seen as negative impacts by users, and in many ways may reflect the essence of involvement, from the more traditional research perspective this could be viewed as changing the range of experiences data collected, as well as reflecting researchers' concerns about the focus of their work and perhaps identifying reasons why resistance to involvement may exist in some research areas. In addition some researchers have raised concerns about users losing their objectivity, becoming 'professionalised' as the boundaries between lay researchers and academic researchers becomes more blurred over the lifetime of the project (Cornes 2008, Wright 2005). The complexity of such issues requires further discussion to identify impacts and to consider how different individuals interpret them.

Dissemination and implementation

The evidence mainly reports beneficial impacts of PPI in the dissemination and implementation phase of studies. One study investigated whether researchers publishing in international general medical journals had actively involved consumers in their research. They used the definition of involvement as: 'Consumers involved at any or all stages of the research process (setting research agenda, commissioning research, undertaking research, interpreting research, and disseminating the results of research)'. However, involvement was reported as being integral to the research undertaken in just 6/200 original published papers. The researchers reported the following challenges which prevented them from involving users: word limits of journal paper; information was not perceived as important; and concern that the users involved may disseminate the results before they have been written up and published in academic journals (Chambers 2004).

Time and Cost

Practical aspects of planning, gaining access to, and managing the user involvement in the research can be timely and costly, increasing the workload of the academic researchers (Faulkner 2008, Shah 2006, Wright 2005, Abma 2005, Coupland 2005, Dobbs 2002, Elliott 2002, Trevedi & Wykes 2002, Oliver 2001, Lloyd 1996). The evidence reports the importance of developing good relationships with communities and good links to user organisations, and reports the importance of education and training of users (Shea 2005), but this may be difficult within the time limitations of the study (Ross 2005, Shea 2005). One study reported that the short time scale given to researchers to set up a user group led to a lack of diversity within the group (Goobeman-Hill 2008) . Further time delays may occur due to the conflicting time frames of researchers and users (Abma 2005), and due to additional time needed for users to read documentation because subject and terminology may be unfamiliar to them (Sutton 2008).

Running and maintaining the user membership, existing work commitments, the need to account for health status of those involved and the conflicting time-frames of users and researchers can all increase the time scale of the study (Shea 2005, Abma 2005, Rhodes 2002). While the extra time required may be beneficial for users, for researchers on short time scales this may cause difficulties unless projects have been developed from the outset that incorporate these additional timescales and funders agree to fund this activity and additional timescales.

4.9.3 Summary of impacts on research

The evidence reports beneficial and challenging impacts on health and social care research in the following research areas:

Benefits:

Initial stages of research: PPI helped identify relevant topics for the research agenda, assisted in prioritising topics for the research agenda; and provided pragmatic criticism of research protocol in perceiving whether research is relevant or appropriate to users.

Undertaking research: PPI helped assess the appropriateness, wording, and timing of research instruments (e.g. questionnaires, interview schedules) to the community, and helped adapt the language

of the instruments and information to suit the lay audience. PPI also assisted with recruitment to the study, and improved response rates. Furthermore, PPI helped gain deeper and more personal insights due to the rapport users had with participants.

Analysis and write-up: PPI ensured emerging themes and trends were interpreted from the user perspective as well as the academic researcher perspective, assisted in identifying relevant knowledge gaps, and the final research report benefited from being grounded in user experiences**.**

Dissemination and implementation: PPI helped with the dissemination and implementation of research findings due to dedication to and influence of users to the community. Dissemination is more poignant and user-friendly way.

Other impact on research: PPI gave local research community credibility, raised awareness of research in the community, and provided more valued changes to services.

Challenges

Initial stages of research: PPI may lead to scientific and ethical conflict in protocol design, highlights the need for training, may lead to tokenistic nature of users' involvement, and can cause power struggles between researchers and users.

Data collection stage of research: PPI studies have reported the difficulty in recruiting a diverse range and representative sample of users to a project, the difficulty in getting the balance between traditional academic criteria for reliability and user perspectives in a protocol for research, and the difficulty in maintaining user confidentiality within meetings, where users may discuss personal experiences.

Challenges in running PPI focus groups from researchers perspective included: users influencing each other, which may result in an over-emphasising of particular problems; focus groups being dominated by strong characters, and so data may also be dominated by certain perspectives, focus groups being focused on personal experience stories, when the aim is to identify research topics; and focus groups being seen by researchers as a forum to get other people to accept their (users') understanding of their disease.

Dissemination and implementation: PPI has led to research findings being disseminated before the academic papers published, therefore jeopardising academic publication.

Time and Cost: PPI leads to increased time and cost due to the practical aspects of planning and managing the users involvement in the research, and the time and cost of building up relationships within the community and setting up user groups, of training and education for both users and researchers, and additional time needed for users to read and comment on documentation.

4.10 Impact of PPI on users

In total, 52 papers reported impacts of PPI on health and social care users, of which 52 reported beneficial impacts, and 37 reported negative impacts.

4.10.1 Beneficial impacts on users

This section reports the impacts on users. The majority of papers reporting on impact of PPI users involved in health and social research reported beneficial impacts. The beneficial impacts reported in these studies are divided into three main categories: impact on personal issues for the independent user; impact on their level of knowledge; and impact on their level of skill. Each of these areas will be presented in this section.

Impacts of PPI on personal issues

In studies where the PPI was conducted in a positive environment with good processes in place to support it, users reported feeling empowered (Hewlett 2006, Coupland 2005, Minogue 2005, Barnard 2005, McCormick 2004, Clark 2004, Dickson 2001, Burrus 1998), and felt more valued (UKCRC 2009, Wyatt 2008, Cornes 2008, Cotterell 2007, McLaughlin 2006, Hewlett 2006, Collins 2005, Minogue 2005, Clark 2004, Dickson 2001). Users reported feeling listened to, which made them feel more positive (Sainsbury 2008, Rees 2004, Ong & Hooper 2003). Almost half of the papers reporting beneficial personal impacts for users reported their increased confidence. Users also felt a sense of fulfilment (Shea 2005) and satisfaction (Cotterell 2008, Hewlett 2006, Shea 2005, Meyer 2003, Patterson 2003). Users achieved a sense of fulfilment and satisfaction gained from positive feedback (Shea 2005).

There was a feeling a mutual support reported between users (Bryant 2006, Minogue 2005, Barnard 2005, Schneider 2004, Rhodes 2002, Dickson 2001 as users reported feeling part of a team (Cornes 2008, Faulkner 2006, Hewlett 2006, Bryant 2006, Collins 2005, Minogue 2005, Shea 2005, Royle & Oliver 2004, Dobbs 2002)..Users felt re-assured when listening to other users experience (Ong & Hooper 2003), and

appreciated the social interaction with people in the same position as them (Hewlett 2006, Rowe 2005, Clark 2004, Rhodes 2002, Dickson 2001.

Users talked of being able to give something back (Gooberman 2008, McLaughlin 2006, Hewlett 2006, Minogue 2005), and doing something meaningful for the research community (Cotterell 2008), with some users reporting feeling that they could make a difference(?) (Cornes 2008, Shea 2005, Collins 2005, Dobbs 2002) or could do something worthwhile for those suffering the same illness as them (Gooberman 2008, Minogue 2005).

Some studies report that it may have helped the users with recovery from illness, for example improvements in mental illness, supported drug users, and improved the health of aboriginal women (Minogue 2005, Dickson 2001, Truman 2001, Ramon 2000). PPI may also have improved communication between these users and their clinicians (Marsden & Bradburn 2004, Koops & Lindley 2002). Users in one study report that PPI was something positive that came from having the illness (Hewlett 2006).

Financial reward and employment were also reported as beneficial impacts for users, for example those who have not been able to work due to mental illness, recovering drug users, mothers with young children, and older people (Cornes 2008, Wyatt 2008, Rowe 2006, Howe 2006, Abma 2005, Clark 2004, Godfrey 2004, Stevens 2003, Maslin-Prothero 2003, Elliott 2002, Rhodes 2002, Oliver 2001).

Impact of level of knowledge

Where training in research had been conducted with users, they reported improved knowledge of research (Faulkner 2008, Minogue 2005, Beer 2005, Plumb 2004, Faulkner 2004, O'Donnell & Entwistle 2004, Stevens 2003) and improved knowledge of the study (UKCRC 2009, Minogue 2005, Ross 2005). Collaborative involvement in the research demystified research and gave users a more open attitude to research, leading to a better understanding of research and improved trust in research (Meyer 2003, Oliver 2001, Dickson 2001). This was especially in communities who traditionally were suspicious of research, for example the Aboriginal communities and the Hispanic communities.

Furthermore, users reported the benefit of having improved direct access to knowledge of current treatment or management of their illness (Langston 2005, Minogue 2005), and appreciated the exchange of information about their illness with other users and the academic researchers (Langston 2005, Rhodes 2002). This improved their knowledge of the condition and improved their ability to identify problems and come up with solutions (Sutton 2008, Hubbard 2007, Meyer 2002).

Some studies reported the benefits of reflection, where users learnt about their illness, learnt about issues in their community, which helped them re-evaluate their own assumptions (Cotterell 2008, Nilson 2006, Beer 2005, Rees 2004, Meyer 2003). Users reported the benefit of receiving regular updates of the research (e.g. through reports, newsletters, and seminars) to keep their knowledge up-to-date (Maslin-Prothero 2003).

Impact of improved skills

Users not only benefited from gaining skills in research methodology, and in the treatment or management of their condition, but they also reported gaining skills such as confidence in speaking, listening in groups, where group work was conducted (Rowe 2006, Sainsbury 2008, Faulkner 2008, Minogue 2005, Godfrey 2004, Schneider 2004, Rees 2004, Stevens 2003, Minkler 2002, Rhodes 2002) and improved skills in public speaking where users were involved in disseminating the results of the research at conferences (Minogue 2005), computer skills, and working as a team. These new skills may improve the users' chances of future employment (Faulkner 2006, Coupland 2005, Beer 2005, Faulkner 2004, Johns 2004, Clark 2004, Krieger 2002). One study reported that user involvement may have had the benefit of resurrecting skills which appeared to be lost from many years of concentrating on recovery from mental breakdown (Clark 2004).

4.10.2 Negative impacts of PPI on users

All the studies that report negative impacts on users also reported beneficial impacts. The more negative impacts are divided into three main categories: impact on personal issues for the independent user; impact of their level of knowledge; impact

of their level of skill, impact of communication methods, financial impacts on the users, and practical impacts on the users.

Negative impact of PPI on personal issues

One study reported that users involved in PPI consultation felt they were not being listened to (Ong & Hooper 2003), and reported feeling frustration at what they saw as rigid and rather limited beliefs of some 'experts' (Ong & Hooper 2003), Another study reported that users felt marginalised, for example, with just one person from an ethnic minority background sitting on advisory groups, leading to isolation of their views (Patterson 2003, Oliver 2001). Furthermore, users reported frustrations at assumptions that they lack knowledge, and therefore their views are not taken seriously (Hewlett 2006, Sainsbury 2008, Rees 2004, Ong & Hooper 2003, Andejeski 2002b) In one study, users reported the perceived insensitivity of health professionals and researchers (Cotterell 2008) while another reported that researchers 'speak another language' Oliver 2001).

Low self-esteem led to users feeling they had little to contribute (Hewlett 2006, Collins 2005, Truman 2001) and they felt unease at being asked about their problems (Dickson 2001) or at expressing their opinions (Dickson 2001). Furthermore, one study reported a low level of perceived benefit from the users (Howe 2006). These studies reported that this was often only temporary at the initial stages of the research. The confidence of the users in conducting research and feeling they were contributing, grew as the study progressed. However, one study did report that the lack of preparation of the user through training and induction left them feeling inexperienced (Clark 2004), and anxiety about attending group situations led to low attendance rates throughout one study of mental health users (Truman 2001).

Furthermore, in one study users reported believing that by getting involved in the research they would be given additional support to help them manage their condition, which led to disappointment when they realised that this was not necessarily the focus of the research and researchers (Abma 2005).

Users reported unease at the changing roles between users and health professionals (e.g. changing from doctor-patient relationship to meeting as colleagues) (Hewlett 2006), and concern that close working relationship with clinicians may lead other patients to assume they receive preferential clinical care (Hewlett 2006).

When involved on a consultative basis, users reported the frustration of only commenting on pre-developed information, rather than being involved in the development of information from the outset of the study (Rowe 2006), and also frustration at not being involved from initial stages of research (Cornes 2008).

Some users reported distrust of the research being conducted (Sainsbury 2008, Abma 2005, Oliver 2001, Dickson 2001), for example aboriginals traditionally distrusted researchers because they were used to research being done to them, and then the results being used to detrimentally affect the way they were allowed to live their lives (Dickson 2001).

Users reported frustrations of having to go through formal procedures of research, for example, having to use interview schedules instead of gaining data through more informal discussions with interviewees, or not being able to comment or offer advice when they want to help patients directly were reported by users (Rowe 2006, Meyer 2003). Users also commented that the involvement in the research was a reminder of what they went through (Maslin-Prothero 2003), and in some cases, for example when drug users were interviewing drug users, the risk of returning to ‘patient’ status by becoming an addict again (Coupland 2005, Elliott 2002) .

Users also talked of the burden of responsibility at being a ‘bridge’ to health care systems in the community and the burden of ‘duty’ to the research community (Dyer 2004, Meyer 2003), and taking on emotional burden of participants in research (e.g. interviewees) (Rowe 2006, Cotterell 2007) . Furthermore, users could be given too much work, or not given long enough to read documents or take in information. This over-burdening of tasks led to stress in the users involved in the research (Abma 2005).

Negative impact of PPI on skills

Insufficient provision of training in research methodology and in the medical/social conditions researched, or training at the wrong time, led to users feeling not able to research/contribute, or led to confusion and misunderstanding among users (Ghulum & Robinson 2007, Rowe 2006, McCormick 2004) . Users often found it difficult to commit to the training courses because of the other commitments (Taylor 2006).

Furthermore, users reported confusion and conflict due to lack of clarity about their roles in the research (UKCRC 2009, Dewar 2005, Dyer 2004, Royle & Oliver 2004, Dobbs 2002, Oliver 2001, Gooberman-Hill 2008) . However, one study reported that the pre-defined role given led to less control over the research process (Gooberman-Hill 2008). This study reported on users involvement in research juries, that help set research agendas, but the users did not define their own topics or questions, as the funders commissioned juries to address specific issues that matched their own remit.

Users were taught the traditional methods of research, yet found that the non-conventional methods collected more in depth data (Dewar 2005, Dickson 2001). For example, where elderly people were interviewing elderly people, the interviewer found they obtained more 'rich' data by having an informal chat with the interviewees rather than following the interview schedule. However, this caused concern among the researchers who felt their research integrity was threatened.

Negative impact of PPI on knowledge

Lack of understanding in research methodology and unfamiliar processes, acronyms, and technical language led to concerns about the research being conducted (Morris 2004, Royle & Oliver 2004). For example, lack of understanding of randomised controlled trials led users to be concerned that some children would not receive the treatment under research after resuscitation from inpatient paediatric cardiac arrest ((Morris 2004).

The failure of researchers to feedback to users about the impact of their involvement meant that users were not able to learn how useful their input had been, which led to lack of motivation to be involved in future research projects (Howe 2006).

The negative impact of PPI due to poor communication

Effective communication between parties involved in a research study is vital, as it can lead to an environment of trust, mutual respect, and understanding, and helps minimise some of the challenges to involvement in health and social care research (Colins 2006). Studies reported that users felt left out of regular communication within research teams, as routine use of e-mail, corridor meetings by researchers, and attendance at academic conferences could exclude users (Hewlett 2006, Savage 2006, Barnard 2005) . Another study reported that users perceived more weight was put on issues expressed by those who were able to present their views more cogently than others ("*Posh articulate got more attention*") (Gooberman-Hill 2008).

Other studies reported users' concerns with unfamiliar processes, acronyms, technical language (Abma 2005, McCormick 2004, Royle & Oliver 2004, Oliver 2001), and general communication issues (Corner 2007, Ross 2005, Oliver 2001).

The negative impact of the time burden of PPI

Studies reported that users' involvement in research was time consuming, which may discourage them from being involved in research (UKCRC 2009, Gooberman-Hill 2008, Hewlett 06, Sainsbury 2008, Langston 2005, Reed 2004, McCormick 2004, Rees 2004, Meyer 2003, Rhodes 2002, Minkler 2002). Two studies reported users' concerns of the lack of time to read through unfamiliar documents before meetings (Hewlett 06, McCormick 2004). Two studies reported that users were overburdened with tasks (Cornes 2008, Clark 2005), with one study reporting that the lay researcher went on long-term sick leave caused by the large amount of reviewing work, with little experience in this area (Clark 2005).

The negative impact of the financial burden of PPI

If funding is not provided by funders for the PPI in research, then the financial burden of covering travel, child care, or respite care, in order to be involved in different aspects of the research project lands on the users (Maslin- Prothero 2003). For user-led research, individuals may find difficulties in securing funding from funders and, in the case of one study, has led to self-financing involvement in the study (Reed 2004).

The negative impact of PPI on practical issues

A number of studies reported practical challenges for users involved in research. These difficulties include: travel difficulties (for example, getting to meetings, travelling to conduct interviews and focus groups, particularly for users in wheel chairs) (Abma 2005); issues of returning to employment (for example, for unemployed or retired users) (Howe 2006); concerns of putting themselves at risk (for example, home-visiting, interviewing people under the influence of drugs) (Coupland 2005, Elliott 2002); lack of traditional employment rights and benefits (Elliott 2002); and lack of equal opportunities for individual appraisal, support and personal and professional development (Cornes 2008).

4.10.3 Summary of impacts on users

The evidence reports beneficial and challenging impacts on health and social care research in the following research areas:

Benefits

Personal: Users reported that PPI made them feel valued and listened to. They reported feeling empowered to do something for their community, felt improved self-confidence and self worth, and felt more control over helping themselves to recover. Users reported the sense of being able to give something back. Users reported they felt mutual support from fellow users, and with their increased knowledge of the condition/disease, they reported a more open communication with their clinician over treatment options.

Knowledge: PPI helped improve direct access to general research knowledge and helped demystify research. Furthermore, it improved users' knowledge of their condition, through training and through exchange of information with other users and researchers, and helped users to reflect and re-evaluate their own assumptions of the condition.

Skills: Users reported that they gained skills through training in research methodology and in management and treatment of their disease/condition.

They also reported gaining skills such as confidence in speaking in groups and confidence in public speaking, and they improved their listening skills. They also reported gaining skills which may improve their chances of future employment (e.g. computer skills, working as a team), and, in the case of mental illness, resurrect skills which appeared to be lost during illness.

Challenges:

Personal: Users reported frustration at not being listened to by researchers, and feeling marginalised within the research team. They reported frustration at the rigid beliefs of some 'experts' and at the assumption that they lack knowledge, and therefore their views are not taken seriously. Furthermore,

users felt their contribution was not valued, often being asked to comment on developed materials, rather than be involved in the development of them.

Users reported the frustration that the research they were involved in could not immediately solve their daily problems, and yet they felt the emotional burden of having to re-live their experiences, the burden of 'duty' to their community, and time burden of reading through documents and contributing to the research.

When training was not given, users felt thrown in at the deep end due to lack of preparation and felt inexperienced. Users felt restricted by the formal procedures of research, such as not being allowed to offer advice in an interview when they wanted to help patients directly.

Some ethnic groups reported distrust of research and researchers, especially at the initial stages of the study.

Other studies reported the perceived insensitivity of researchers, the unease of users at talking about their experiences, feeling intimidated at being the only lay researcher involved, and unease at close working relationships with clinicians.

Communication: Users reported feeling left out of regular communication within the research team, for example, the routine use of e-mail, conferences, and corridor meetings by researchers could exclude users. Users reported the difficulty of unfamiliar processes, acronyms, and technical language, and the feeling that those who articulated their opinion better were listened to more,

Knowledge & Skills: Users reported that their lack of training in research methodology and lack of training in issues of treatment and management of their condition led them to feel they could not contribute. Furthermore, users reported feelings of confusion and conflict due to the lack of clarity about what their role was.

Financial: Financial and time costs: users reported the financial burden of travelling, child care, and respite care if financial backing is not provided, and the time consuming involvement often without payment. In the case of user-led research, lay researchers had difficulty in being taken seriously by funders.

Practical issues: Other practical issues which negatively impacted on users included: difficulties with travel arrangements to study meetings, issues of returning to employment (e.g. for unemployed or retired), concerns of putting themselves at risk (e.g. home-visiting, interviewing people under the influence of drugs), the lack of traditional employment rights and benefits for users, and the lack of equal opportunities for individual appraisal, support and personal and professional development.

4.11 Impact of PPI on researchers

In total, 33 papers reported impacts of PPI on health and social care researchers, of which 15 reported beneficial impacts, and 26 reported negative impacts. The latter was mainly due to lack of funding and other resources.

4.11.1 Beneficial impacts of PPI on researchers

One study reported that when seeking research topics, face-to-face discussion with a user group was more productive than scanning consumer research reports or contacting consumer health information services (Oliver 2001). The evidence reports that through involving users in the research, researchers gained fresh insights into issues (Wyatt 2008, Hewlett 2006, Clark 2004, Meyer 2003, Andejeski 2002b). Beliefs and attitudes could be challenged (Hewlett 2006), researchers gained a greater understanding of the community health needs, barriers to research could be identified, and researchers developed skills to resolve differences (Sainsbury 2008, Meyer 03).

In collaborations with users, researchers found that by spending time with community members, they built a good rapport with users (Coupland 2005) and one study reported that researchers found their pre-conceived assumptions of the research community were challenged. Researchers were given insight into how users think and feel (Clark 2004), as well as gaining experience from users to give background knowledge to the project, which may have led to greater respect towards the community they were studying (Rhodes 202). In turn, researchers worked with committed lay researchers who wanted to make a difference, and often committed to helping further research (Gooberman-Hill 2008, Langston 2005, Morgan 2004). Researchers remained focussed on the issues important to the community they were researching, while by listening to questions and concerns of client organisations, researchers improved trust and confidence with community collaborators (Abma 2005). PPI provided greater diversity within the research team, and in the case of collaborative work or user-led research, often lightened the workload for the researchers, whose role became one of more professional advice and support (Morgan 2004, Truman 2001).

4.11.2 Negative impact of PPI for researchers

The more negative impacts for researchers are divided into two main categories: negative attitude towards PPI in research, and limitations of time and cost.

Negative impact of PPI on researchers

Some of the impacts reported in this section could be due to poor previous experiences of PPI, and could be said to be part of the previous context of PPI and not necessarily originate from the study being reported, although this was not always made clear in papers. They are reported as impacts because of the potential for studies to have these types of effects on researchers after involving users. The evidence reports that researchers can be sceptical about PPI, leading to a lack of commitment and a tokenistic attitude towards involving users in their research (Cornes 2008, Hewlett 2006, Collins 2005, Minogue 2005). Researchers reported having concerns about what contribution users can make to a research project (Howe 2006) and concern over competence of users to assist with research (Abma 2005, Dyer 2004). They were also concerned that users may come with their own lobbying agenda (Andejeski 2002b). This may be reported either due to researchers' lack of understanding about PPI or because user involvement is avoided because researchers believe there is no added value or benefit from the involvement of users e.g. research around diagnostic testing or clinical research (Hailey 2006, Chambers 2004).

In addition, difficulties arose for researchers when there was a lack of pre-defined roles for lay researchers and academic researchers. These could lead to misunderstandings of what researchers expected of users (Hewlett 2006, Dyer 2004). Some researchers had difficulty accepting views of users when they did not match that of the academic researchers (Sutton 2008, Gooberman-Hill 2008, Abma 2005), particularly when research deemed worthy and viable by 'experts' was not received so well by users (Truman 2001). Furthermore, studies reported that researchers had difficulty in relinquishing control over or sharing power over research (Sutton 2008, Coupland 2005, McCormick 2004), with researchers feeling users were encroaching on their 'territory' (Elliott 2002). In one study where participants refused to let the lay researchers record the interviews due to the sensitive nature of the content, this led to anxiety from the academic researchers as they could not listen to the original data, an important part of the research process (Elliott 2002).

The evidence also reports that researchers found having to change working practices difficult, which could lead to conflict due to differences in the way academic

researchers work compared to the way users work (Howe 2006, Hewlett 2006, Coupland 2005, Dickson 2001). Tension between what constitutes a good research study (academic criteria vs. user perspectives) also caused difficulties for researchers (Reed 2004). One study reported that the researchers were not convinced the additional effort and resources were worthwhile (Howe 2006).

In another study the health professionals involved in interviewing with the users reported that they found that what they saw as constant criticism from users was difficult to take (Hewlett 2006).

The negative impact of time and cost of PPI

Evidence reports that researchers found the additional time and resources need for PPI challenging (Wyatt 2008, Wright 2006, Langston 2005, Morgan 2004, Maslin-Prothero 2003, Rhodes 2002, Trivedi 2002, Dickson 2001).

Researchers found that PPI increased the time and cost of the project by developing working relationships with users (Maslin-Prothero 2003, Dickson 2001), supporting them throughout the project (Morgan 2004), with(?) the time and cost of the practical elements of PPI, such as training users to be researchers, in gaining honorary contracts for users, and the conflicting time frames of researchers and users (Langston 2005, Wright 2005, Dickson 2001). While these might be positive impacts for the users involved in terms of enabling their involvement, they also have the potential to be negative for researchers, particularly if they had not planned for the extra time or costed additional activity into their proposals.

4.11.3 Summary of impacts on researchers

The evidence reports beneficial and challenging impacts on health and social care research on researchers:

Benefits

Researchers reported the benefit of building friendships and a good rapport with users. They gained fresh insights into the issues of the study, and had their beliefs and attitudes challenged. This helped researchers gain a greater commitment to the community under research, and ensured that the researchers remained focussed on the users.

Researchers gained respect for users' knowledge and commitment to the study, and learnt more appropriate interpersonal skills and sensitivity towards the community under research.

From a practical point of view, researchers' role became more about technical advice in the study and one of support for users, particularly in user-led research or in collaborative research. PPI gave researchers the opportunity to have a number of work partners, and provided a more representative team.

Challenges:
Researchers reported concerns about the contribution that users could make to the research study, and researchers' lack of commitment to user involvement could lead to tokenistic involvement. Researchers felt uncomfortable relinquishing control/sharing power over the research, and had difficulty accepting views of users when they did not match their own.

The lack of pre-defined roles led to misunderstanding of what was expected from PPI, and the researchers were not always convinced the additional effort and resources were worthwhile

Other challenges reported by researchers included having to change working practices to accommodate PPI, and their worry that users were encroaching on their 'territory'.

Researchers reported the issue of additional time and cost needed to develop working relationships with users, to train users, and the time needed to get honorary contracts for users. They also reported the time needed to support users, keep them well-informed, and the difficulty caused by the conflicting time frames of researchers and users.

4.12 Impact of PPI on research participants

In total, 13 papers reported impacts of PPI on health and social care participants, of which 12 reported positive impacts and 1 reported a negative impact.

4.12.1 Beneficial impacts of PPI on participants

Research participant is defined here as someone who provides data for a study. The evidence reports that PPI provides participants with access to information about the disease or condition which is being researched (Smith 2006, Coupland 2005, Marsden and Bradburn 2004, Meyer 2003, Rhodes 2002, Oliver 2001). It may also provide a more 'friendly' approach to data collection (Cornes 2001, Dickson 2001,

Hanley 2001), and provide emotional support for participants from someone who has been through a similar experience (Rowe 2006, Miller 2006, Minogue 2005).

4.12.2 Negative impacts of PPI on participants

Only one published paper reported on more negative impacts on participants. This study reported that challenges may arise if participants do not want to share personal experiences with people they know well (Godfrey 2004), for example if users are interviewing other participants.

4.12.3 Summary of impact of PPI on participants

The evidence reports beneficial and challenging impacts on health and social care research on participants:

Benefits

Participants reported the benefit of being provided with access to information about their condition, they appreciated the more 'friendly' approach to data collection, and felt emotional support from lay researchers who has been through a similar experience

Challenges:

Participants described the tension that could build up between lay researcher and participant, and participants reported not wanting to share personal experiences with people (lay researchers) they know well.

4.13 Impacts of PPI on the community

In total, 20 papers reported impacts of PPI on the community involved in research, including researchers, users and the broader public. 16 reported beneficial impacts, and 5 reported negative impacts

4.13.1 Beneficial impact of PPI on the research community

Studies report that a mutual respect/coalition between researchers and the community may develop as a result of PPI, (McCormick 2004, Meyer 2003, Dobbs 2002, Dickson 2001, Burrus 1998), increasing the acceptability and trust of the research in the community (Dickson 2001, Burrus 1998), resolving conflict between researchers and the community (Dobbs 2002, Burrus 1998), and therefore aiding the success of the research. The improved trust may in turn build a more research co-

operative spirit within the community (Shea 2005, Dobbs 2002, Burrus 1998), and give research credibility in the community (Rhodes 2002, Burrus 1998).

PPI helped increase the awareness of the disease or condition in the community (Guarino 2006, Langston 2005, Angel 2003, Oliver 2001, Burrus 1998), which led to greater knowledge of and better distribution of information on diagnosis and treatment in the community (Langston 2005, Shea 2005, Angel 2003), leading to a well informed patient population (Langston 2005). PPI also led to increased membership for community groups (Langston 2005), and to gaining greater inter-cultural understanding by all parties involved in the research about issues of the disease or the condition within the community, such as the taboo of diabetes in Asian communities, and why health promotion appears to be challenging with Hispanic communities (Meyer 2003, Rhodes 2002).

User collaborations with researchers provided a new interface by which research is fed back to the community (Howe 2006, Angel 2003), as users became advocates of the research in the community (Ross 2005, Hanley 2001). PPI also led to a sense of community ownership when a community panel was set up to work with researchers focusing on delivery planning, housing management arrangements, services for families, healthy living networks, public transport planning, and training and employment needs in one area of the UK. Parties worked together to develop a better action plan for dissemination of research findings (Dobbs 2002).

PPI activity may also have other community benefits, such as relating the research more directly to the illness experiences of the community (Morgan 2004, McCormick 2004, Angel 2003), broadening the research agenda beyond that set by clinicians and researchers (Morgan 2004), and making science more accountable to the community (McCormick 2004, Meyer 2003). Users involved in the research may have links to specific seldom heard communities, and these communities may therefore receive better health promotion, increased diagnosis, and better treatment through the research project that they may not have received otherwise (Meyer 2003, Dickson 2001, Burrus 1998).

Furthermore, the greater mutual trust and respect helped increase the likelihood that community members comply with treatment and care plans (Clark 2004).

The evidence reports that PPI may help overcome resistance to new ideas in the research community, as seen in a study which aimed to measure progress in relation to a range of issues including delivery planning, housing management arrangements, services for families, healthy living networks, public transport planning, and training and employment needs in the Tyneside area, through the establishment of a diverse community group (Dobbs 2002). PPI can also contribute to a change in the health care practice, as seen in a study to assess schizophrenic people's experiences with medical professionals, particularly in relation to communication. In-depth interviews with people with schizophrenia were conducted by schizophrenic patients, and the results were presented to health professionals in the form of a theatre performance (Schneider 2004). PPI may also lead to better targeted services based on the identified needs in the community, as seen in collaborative PPI studies around aboriginal health needs, and around improving mental health services (Clark 2004, Dickson 2001).

4.13.2 Negative impacts of PPI on the community

Five published papers reported the challenging impact of PPI on the researched community. The evidence reports that PPI may uncover conflict within the community, as one study evaluating health care programmes in an aboriginal community discovered (Dickson 2001). It may also increase time and cost to the community organisations involved, with meetings of core groups of community members over an extended period of time, having clients review the proposal, research methods and tools to provide feedback, and for users who become involved as lay researchers (Plumb 2004, Paterson 2003). Furthermore, some researchers have expressed concerns that users involved may not be representative of the community being studied because of the difficulty in recruiting users from the seldom heard groups. For example, in a study identifying a stroke injury research agenda, there was difficulty representing those that were severely disabled or severely ill, possibly because of their health status (Abma 2005). The issues of representativeness has been extensively discussed in PPI and some see it as a red herring, distracting from the real aims of involvement (Beresford et al 1993).

4.13.3 Summary of impacts on the community

The evidence reports beneficial and challenging impacts on health and social care research on the community:

Benefits:

The evidence reports that mutual respect can develop between researchers and the community, leading to greater inter-cultural understanding about issues of disease or conditions within community. PPI can broaden the research agenda beyond that set by health professionals and researchers.

Users became advocates of the research to the community and increased their awareness of the disease/condition in the community, which provided a greater knowledge of and a greater distribution of information on diagnosis and treatment. It also increased awareness, credibility and recognition of the research study in the community This helped raise acceptability and trust of the research in the community, and built a more research co-operative spirit within the community.

Other benefits of PPI to the community included better targeted services, based on identified needs in the community, more successful health promotion, and greater community empowerment, and increased membership to community groups.

PPI created a well informed patient population, and the opportunity to share knowledge and learning.

PPI provided the introduction of services and changed practice as a result of study results, potentially leading to improved services in the community.

Challenges:

Evidence reports the difficulty of involving seldom heard groups, although this is also a wider issue in health research. Conflict within the community could occur as a result of PPI, and the community organisations reported increased time and cost involved to them.

The other challenge reported was how to combine the research agenda important to the community with the agenda that was important to the researchers.

4.14 Impact of PPI on funders

In total, 3 papers reported impacts of PPI on funders of health and social care research, of which one reported beneficial impacts, and 2 reported negative impacts.

4.14.1 Beneficial impact of PPI on funders

The evidence on impact of PPI on funders is very limited. Only one study reported the benefits of PPI to the funders of the research. This study reported that PPI helps ensure that research funded is of relevance and importance to the community (O'Donnell & Entwistle 2004), makes allocation of funds more transparent (O'Donnell & Entwistle 2004), and makes funding organisations more accountable (O'Donnell & Entwistle 2004). There is need for further research on funder impact.

4.14.2 Negative impacts of PPI around funders

The evidence reports that the lack of support from funders for PPI in research can affect the success of research collaborations with users (McCormick 2004). Furthermore, funders may only want to fund specific projects to fit their own remit, therefore leaving little room for user involvement in agenda setting for research (Gooberman-Hill 2008).

4.14.3 Summary of impacts on the funders

The evidence reports beneficial and challenging impacts on health and social care research on the funders:

Benefits:

PPI helps ensure that research funded is of relevance and importance to the community, it makes allocation of funds more transparent, and it makes funding organisations more accountable.

Challenges:

The evidence reports that funders need to be more supportive of PPI, and to take PPI more seriously. One problem encountered was that funders and ethical committees looked for scientific integrity, whereas user-led research focussed on making research 'real'.

Furthermore, funders want to fund specific projects to fit their own remit, and therefore there is often little room for user involvement in agenda setting for research.

4.15 Impact of PPI on policy makers

In total, 2 papers reported impacts of PPI on health and social care policy makers, both of which reported beneficial impacts, and one of them reports a negative impact.

4.15.1 Beneficial impact of PPI on policy makers

The impact of PPI on policy makers was also underpinned by a small evidence base with only one published paper reporting the impact of PPI on the policy-makers in health and social care. This study found that PPI may bring additional insight into policy decision-making by helping legitimise research findings among policy makers, which may lead to more patient-centred health and social care services (O'Donnell and Entwistle 2004). As with the impact on funders, there is a greater need to understand the impact that PPI can have on policy makers and the policy agenda. Complexities of goals within the health and social care services and the constant changes of health and research processes leads to uncertainty of how policy makers can take forward recommendations from research involving users (Marsden & Bradburn 2004).

4.15.2 Negative impacts of PPI on policy makers

The complexities of conflicting clinical and health system goals between clinicians, researchers and service users (e.g. quality of life versus research rigor), and constant changes of health and social processes lead to uncertainty of how policy makers can take recommendations from research involving PPI forward (Marsden & Bradburn 2004).

4.15.3 Summary of impacts of PPI on policy makers

The evidence reports beneficial and challenging impacts on health and social care research on the policy makers:

Benefits:

PPI brings additional insight into decision-making for policy-makers, and helps legitimise research findings used to change policy.

Challenges:

The challenges that PPI brings to policy makers are the complexities of conflicting clinical and health system goals between clinicians, researchers, and users, and the constant changes of

health and research processes and systems leading to uncertainty about how to take the study recommendations forward.

4.16 Impact of PPI on publishing in academic journals

Two studies reported on the impact of PPI on publishing in academic journals, both of which reported negative impacts.

4.16.1 Beneficial impacts of PPI on publishing in academic journals

No studies reported beneficial impacts of PPI on publishing in academic journals

4.16.2 Negative impact of PPI on publishing in academic journals

Two published papers reported the negative impact of PPI on the publishing of data from PPI studies, and in the dissemination of the data.

Academic researchers need to follow a range of rules and conventions in order to get their papers published in peer reviewed journals, which is important for academic recognition. One study reported that this can create challenges for involving users in the writing-up phase of the study. Furthermore, convention often diminishes the user perspective (Reed 2004). Small word limits on journal articles lead to user-involvement not being reported in peer-reviewed journals (Chambers 2004).

4.16.3 Summary of impacts on publishing in academic journals

Challenges:

Small word limits on journal articles leads to PPI activities not being reported in peer-reviewed journals. The conventions of publishing can create challenges for how users are involved in publication and dissemination.

4.17 The outcomes of PPI

In developing the study aims, the advisory group and users involved suggested that some differentiation was made between impacts of PPI and the outcomes of studies, that is the results of PPI in study outcomes. However, the distinction between impact and outcomes, while clear in some studies, is more blurred in others. In some respects outcomes form part of the impact picture, but are presented separately in this report to enable clarity about all aspects of impact. To enable easier understanding of the outcomes identified, these are presented as summary tables for groups of studies.

4.17.1 Outcomes for agenda setting

Nine published papers reported on outcomes of PPI for setting research agendas in health and social care research (Gooberman-Hill 2008, Abma 2005, Burhansstipanov 2005, Mosavel 2005, Wright 2005, McCormick 2004, Flinterman 2004, Ong & Hooper 2003, Cohen 1999). Six of these studies were consultations with users (Abma 2005, Burhansstipanov 2005, Mosavel 2005, Flinterman 2004, Ong & Hooper 2003, Cohen 1999), one involved users in consultation and collaboration (McCormick 2004), one study involved users in a collaboration with researchers (Wright 2005), and one study was led by the users (Gooberman-Hill 2008).

All but one of the studies that consulted with users were setting agendas for clinical issues, including biomedical issues, back pain, spinal cord injury, breast cancer, and cervical cancer. One study consulted users over agenda setting for homeless programmes (Cohen 1999). One study used consultation and collaboration to set the research agenda for breast cancer research (Burhansstipanov 2005), one used collaboration for agenda setting in cancer research (Wright 05), and one user-led study reported on a jury of users who identified the health and social care research agenda for one region in the UK (Gooberman-Hill 2008).

All studies reported beneficial outcomes to the agenda setting. 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. Table 3 give a summary of the results of each study:

	Table 3 Outcomes of PPI on agenda setting
	Biomedical (Flinterman 2004) This study conducted a review of evidence on patient experiential knowledge influencing biomedical research agendas, and reported the following main results: • Users formulated prioritisation criteria for research into chronic illnesses, dementia, national programme on pain • Users' questions from patients with neuromuscular diseases about severe fatigue led to new research on central and peripheral aspects of muscular fatigue • Users' reports on restless leg and insomnia led to a research proposal in this area for kidney patients • Users with Addison's disease complaining of having to get up in the night to take medicine led to study about new delayed release hydrocortisone tablet
	Back pain (Ong & Hooper 2003) Consultation This study involved users in the design of a research project to assess research agenda for lower back pain They reported the following main results: • Users suggested research around the recognition of vague symptoms of back pain, as felt frustrated that GPs were able to work better with patients with obvious trauma "*I've got a full face of make-up on. I've done my hair – I look great…but I have had to get up at 6.30 this morning, have a couple of baths, have loads of drugs. Fiddle about with myself so that I look wonderful- because I look bloody awful when I get up in the morning because I've had no sleep. People look at you and there is no plaster on it* […]" • Users suggested research around proving the pain - users suggested developing a diagnosis around fitness to do certain activities, not on level of pain. They also suggested cultural differences in proving pain should be researched. • Users suggested research into quality of life, giving the example of the GP just giving pain relief, but patients have to live with the side-effects of these. • Users suggested research into more flexible application of medical categories to avoid GPs inflexible application – "you are working therefore you are not serious enough for pain relief on the NHS".
	Spinal Cord injury (Abma 2005) This study aimed to develop a list of research topics that are considered relevant to users from the Spinal Cord Injury Association. Users suggested the following areas of research: • The inflexibility of standard patterns of defecation • The ineffectiveness of antibiotics in case of infections of the bladder • The social isolation and experiences of aloneness • The negligence of the psychosocial needs of the partner and family • The arrogant attitude of doctors and the fact that the "wisdom" of people with spinal cord injury is not acknowledged and taken seriously • The focus on activities and mobilities in rehabilitation, and short time frame, and hence inadequate anticipation of secondary problems occurring later in life, such as obesity, decubitus, bladder infections, and defecation problems
	Breast cancer- Native Americans (Burhansstipanov 2005) This study aimed to identify the National American Cancer survivors' quality of life research priorities. Users suggested the following areas of research: • Make pain medication more accessible, as Native American will not travel long distances to get medication if they are in pain or the travel is too expensive. • How pain assessment tools be made culturally acceptable to Native Americans. One user commented when shown a sad face to indicate his pain "I'm in pain not sad!" • Issues of addiction to pain medication, as this is more common in Native Americans • Issues of cultural ways of asking about pain, for example, not ask 'have you got pain?', but 'how does the pain affect your daily life?'. • Impact of cancer on an individual who is also a diabetic, as the cancer and diabetic clinics may be in opposite directions/long distance apart, and therefore they need help managing both conditions. • Integration of traditional/spiritual healing with western medicine. • What resources will improve the quality of care of the patient • What training support is needed to avoid 'burnout' of carer. • What culturally respectful palliative care can be provided to reduce unnecessary distress for patient and family (e.g. not want to die in hospital, 'preparation for death' ceremonies) • What behaviours or environmental exposures have resulted in increased cancer rate in Native Americans? • What are long-term side effects of cancer and cancer treatments.
	Health and social care in one UK region (Gooberman-Hill 2008) This citizen jury was used as an example to show how key research topics for the health and social care programmes in one region of the UK could be identified.

	The key research topics they identified were: • approaches to research in health and social care • older people • public health needs in Bristol • social care and mental health • general practice • patient complaints
	Cervical cancer - health promotion behaviour (Mosavel 2005) This study aimed to involve users to identify research questions for cervical cancer health promotion in South Africa. The key research areas identified were: • Issues influencing health promotion behaviours including poverty, crime, violence and unemployment • Research agenda should be broadened to include cervical health to reflect these wider concerns.
	Breast cancer (McCormick 2004) Studies involving users to set the research agenda identified the following issues: • need to identify environmental causes of breast cancer • Research agenda shifted away from biomedical model towards environmental and political model, better reflecting users interests (e.g. look at radiation exposure).
	Homeless services (Cohen 1999) This study aimed to identify the 5 most and the 5 least important research topics for homelessness services The most important research topics identified were: • There were significant differences between the homeless clients and the staff concerning the following items: • Clients were significantly more likely than staff to be interested in research into how funds for homeless are used (49.4 vs 17.9, $\chi 2$ 8.68, $p<0.01$) • Clients were significantly more likely than staff to be interested in research into whether the homeless programmes help veterans to obtain benefits (52.9 vs 17.9, 10.52, $p<0.001$) • Clients were significantly more likely than staff to be interested in research into whether the homeless programmes help clients to obtain employment (44.8 vs 17.9, 6.52, $p<0.01$) • Staff were significantly more likely than clients to be interested in research whether the homeless programmes helped veterans to stay clean and sober (40.2 vs 64.3, 4.93, $p<0.05$)
	Cancer (Wright 2005) Patient forums in 40 Cancer Networks were contacted to ask for volunteers for the reference group. This study reports users' involvement in the design and conduct of a cancer research study and in identifying their research priorities ('Listening to the Views of People Affected by Cancer about Cancer Research) The following issues were identified by the reference group: • There is a need for more drug to drug comparisons rather than drug to placebo comparison. • They provided valuable feedback on the clarity of review • They identified possible research gaps
	Research priorities (Owens, Ley, Aitken 2008) To involve users in a Delphi style panel meeting to assess research agenda priorities with other stakeholders. **Important research topic agendas:** **Carers:** • Impact of mental illness of the health and lives of carers • Respite and practical support for carers • Residential care/supported living: effectiveness and adequacy of provision • Access to crisis services, especially out of hours • Alternative to hospital: safe environments of sanctuaries for people to recover in • How to improve communication between carers and health professionals • Factors affecting carers' and professionals' motivation and effectiveness • Users' and carers' understanding of diagnosis; access to information • Aftercare following acute episode • Putting care plans into practice • Effective methods of preventing crisis • Helping users to recognise onset crises and seek help early • Early detection of mental disorders (e.g. at school) • Length of time between first onset of symptoms and diagnosis • Public education about mental health • Causes and triggers of serious mental disorders • Implementing available research evidence and cost of doing so **Users:** • How to find the meaning and purpose in everyday life; battling hopelessness • Alternative places to go when ill or recovering: sanctuaries • Crisis prevention • Challenging stigma; changing public attitudes towards mental illness

	• Which aspects of services do users perceive as enhancing or undermining their personal autonomy and dignity **Health professionals** • Quality of life of in-patient environment and care • Brief psychological interventions: what components are helpful **Managers**: • Admissions to hospital: how are decisions taken • What do patients see as central to their recovery • Effective self-management packages for chronic mental illness • Good customer service skills: impact on users, staff & visitors • Performance monitoring: impact on service delivery and patient experience All groups identified and attached high importance to issues relating to the promotion of independence, self-esteem, and recovery. The quality of in-patient care, the place of psychological therapies and relationship between physical and mental health also emerged across the board.
	Ulcerative Colitis (Welfare et al 2006) **To involve users in the identification of a research agenda for people with ulcerative colitis.** Topics identified were grouped into main categories: • Finding the cause of colitis • Cure of colitis • Prevention of colitis • Living with colitis • Treatment (conventional, complementary and surgical) + complications • Control over particular symptoms • Information provision • Communicating with health professionals • Methods of service delivery

4.17.2 Outcomes for ethical decisions

Two published papers reported on outcomes of PPI in assisting with ethical decisions (Koops & Linley 2002, Marsden & Bradburn 2004), both of which involved users in consultations, one in a trial with treatment for stroke patients, and one for treatment using HRT. Both studies reported beneficial outcomes to ethical issues in the trials and also to trial design. One study enabled researchers to develop a better understanding of how participants perceived risk and what to do if a participant cannot communicate in terms of next of kin, the other led to an improved trial design which included outcomes of more relevance to participants.

Table 4 gives a summary of the results of each study:

	Table 4 Outcomes of PPI on ethical and design issues
	Stroke (Koops and Linley 2002) To involve users to help solve some of the ethical problems associated with research into thrombolysis for acute ischaemic stroke, with its inherent risk of fatal intracranial haemorrhage. The following suggestions were identified: • Most users were prepared to accept treatment in the trial, despite the risk of thrombolysis. • Many users were comfortable with risk • "*Four people in 100 is a very small risk compared to living a vegetable life, I think at my age I have nothing to lose*" • Users were unanimous that if the patient is unable to communicate, the next of kin was the appropriate person to decide on treatment, although some people worried about the consequences of this: "*The implications of that though are… think of the guilt that someone signing and then the person died and*

	they were aware they had been party to doing that".. "*I would not want to put someone in that position*". Most were happy for assent by the attending doctor "*it's up to the doctor*," "*you should use your discretion, and if you think it is going to work, go for it*".
	Breast cancer & HRT (Marsden & Bradburn 2004) This study involved users in focus groups to improve the design of a national randomised trial of hormone replacement therapy (HRT) in symptomatic breast cancer patients in order to increase accrual • Women were in favour of going ahead, despite the ethical issue of giving women with breast cancer HRT • Should include quality of life measures • Should include measurement of side effects of treatment

4.17.3 Outcomes for methodology and data collection

Thirteen published papers reported on outcomes of PPI during the methodology and data collection stage of health and social care research (Sutton & Weiss 2008, Corneli 2007, Guarino 2006, Ali 2006, Ali 2005, Langston 2005, Rose 2005, Morris 2004, Paterson 2004, Marsden & Bradburn 2004, Maslin-Prothero 2003, Donovan 2002, Lloyd 1996). Eight of these studies were consultations with users (Sutton & Weiss 2008, Corneli 2007, Guarino 2006, Ali 2006, Ali 2005,Langston 2005, Morris 2004, Paterson 2004, Marsden & Bradburn 2004, Maslin-Prothero 2003, Donovan 2002, Lloyd 1996), three involved users in consultation and collaboration (Guarino 2006, Paterson 2004, Lloyd 1996), and one study involved users in a collaboration with researchers (Langston 2005). One study was a review that reported on studies with all levels of involvement.

All the studies that involved users in consultation for methodological issues were researching for clinical issues, including cardiac arrest, breast cancer and HRT, prostate cancer, stroke, and prescribing drugs. Those studies that involved users in some form of collaboration during the study were researching areas such as massage for patients with Parkinson's disease, service needs for disabled people, nutrition during pregnancy, and CBT and exercise therapy for Gulf war veterans. All 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. All these aspects represent important ways of improving the quality of research.

Table 5 give a summary of the results of each study:

	Table 5 PPI Impact on methodology of study and data collection **Paediatric cardiac arrest (Morris 2004) Informed choice** This study involved users in focus groups to determine the applicability of exception from informed consent to a randomised, controlled trial of emergency interventions after resuscitation from inpatient paediatric cardiac arrest. Users identified the following issues: • Agreed with the applicability of exception from informed choice for parents of the child, due to emotional state of parents & and the volume of information to absorb at this stressful time. This was agreed by 21/27 parents and 21/42 hospital staff. • As an alternative, parents suggested seeking informed choice from all parents at the time of hospitalisation, although some users were concerned this would add to parents' anxiety at this time, and increase staff work load. Agreed timing of intervention (emergency interventions after resuscitation) should be within 30 minutes of cardiac arrest. **Breast cancer & HRT (Marsden & Bradburn 2004)** **Informed consent & Support** This study involved users in focus groups to improve the design of a national randomised trial of hormone replacement therapy (HRT) in symptomatic patients in order to increase accrual. The following issues were identified: • Ensure thorough informed consent and good support for those in control group, as they are denied a potentially effective treatment. • Provide adequate information about the trial (e.g. treatment side-effects, types of HRT, access to research papers) • Provide good patient support during the trial (e.g. GP & hospital based) Action points that came from of the involvement of users were: 1) Is HRT a research priority? 2) Is the climate right for the study? 3) How can informed consent be ensured? 4) Should women who are not suffering from severe symptoms be recruited to a trial where the end result is survival? 5) Will the study give meaningful answers?
	Electroconvulsive Therapy (ECT) (Rose 2005) **Informed consent** Review of evidence comparing studies where health professionals sought informed consent and views of ECT vs. users who sought informed consent and views of ECT Analysis of papers concluded that academic papers were over-estimating satisfaction. Patients tended to be positive about ECT because they didn't want to criticise the health professionals interviewing them or affect their future care. Patients tended to be more negative about ECT when interviewed by users, indicating that user led research reported inadequacies in informed consent.
	Breast cancer (Maslin-Prothero 2003) **Improve recruitment to trial** Users participated in focus groups to help improve recruitment to breast cancer trials. The following issues for improving recruitment were identified: • Eligible participants were approached for recruitment at the wrong time. Patients were approached just after they were given their results, which is a stressful time to take in additional information about the trial. • Staff recruiting needed to be more supportive and interested in the patient. • Verbal information should be backed up with written information for patients to take away with them. • Avoid inconsistent information given by the clinic staff and the trial staff. • Importance of access and choice. For example, providing treatments and check-ups in a clinic close to the patient's home, covering travelling costs and other expenses incurred, and, if possible, allowing participant to choose which treatment they have.

Prostate cancer (Donovan 2002)

Improve recruitment to trial

Users were interviewed to improve recruitment to a RCT for treatment of prostate cancer. The following issues were identified:

- The order of the information was presented was wrong. The information had a lot of data about surgery and radiotherapy first, then just mentioned watchful waiting briefly. Users suggested equal weighting should be given to all interventions. They also suggested that the order should be changed to watchful waiting, radiotherapy, and then surgery.
- Clear explanations of clinical terminology used to avoid the wrong interpretation. For example, the word 'trial' was often interpreted as meaning watchful waiting or 'try and see'.
- Check lay interpretation of sentences in the information sheet, for example, 'the majority of men will be alive in 10 years time' was interpreted as 'they might be dead in 10 years', so it was changed to 'most men with prostate cancer live long lives even with the disease'.
- 'Watchful waiting' was interpreted as 'no treatment' or 'watch while I die'. It was therefore changed to active monitoring every 3-6 months, and the slow growing nature of the cancer was emphasised.

Stroke & Oxygen supplementation (Ali 2005)

Design of study

This study involved stroke patients and carers in focus groups and the completing of a questionnaire to assist in the design of a study of oxygen supplementation in acute stroke.

The following recommendations were identified by users:

- Suggested the following additional outcome measures: movement scores, concentration, measure of intelligence, handwriting skills, tiredness and fatigue, speech, vision, and enjoyment of hobbies.
- Agreed consent from family or carer is acceptable.
- Most users agreed the doctor could recruit patients to the study and seek consent later.
- Agreed to 6 month follow-up time.

Pharmacist supplementary prescribing (Sutton & Weiss 2008)

Design of study

This study involved the users with a chronic condition as advisors in a research project exploring pharmacist supplementary prescribing (supplementary to GP).

The users identified the following issues:

- Concerns about prescribing on shop floor environment because of issues of confidentiality.
- Further refinement to topic guide, for example suggested discussing the concerns of combining dispensing on the shop floor with prescribing.
- Other queries raised by the users – training of pharmacist, who does pharmacist go to for support, time allowed for consultations with pharmacist.
- Need clear guidelines regarding the pharmacist's relationship with other health professionals, for example, with GPs. Management structures and care pathways should be in place.
- Awareness of sensitivity towards other health professionals (e.g. nurse practitioners and GPs) who may feel threatened by the new role of the pharmacist.
- Users suggested the following additional questions for interview with GPs (Phase 2 of study):
  How do you share the responsibility for patient care?
  Do you feel there are clear lines of responsibility?
  How do you decide which patients will be given to the pharmacist as supplementary prescriber?
  Do you meet regularly with the supplementary prescriber?

Disabled (Lloyd 1996)

Design of study

To develop, with users, a postal questionnaire for gathering data to survey the needs of physically disabled people in a metropolitan borough in order to address deficits in service provision and inform community care and health service planning. After observation of other questionnaires used in previous studies, a new questionnaire was developed using the observations of the group members.

The following issues were addressed in the new questionnaire: accommodation, environment (including access to buildings), needs assessment, met and unmet needs, lifestyle, services, information provision, employment, costs and income costs.

Stroke - Oxygen supplementation following stroke (Ali 06)

Design of study

The study aimed to involve stroke patients and carers in the design of a study of oxygen supplementation in acute stroke.

The users suggested the following recommendations:

- There was general approval of the study.
- Additional outcome measures considered relevant were: communication (ability of patient to speak), mood and depression, mental function, swallowing, tiredness/sleep, and 1 to 10 score of how much the patient is back to their old self.
- They agreed the family or doctor could give consent for the patient.
- Issues of family giving consent, then patient does not pull through were discussed (i.e. guilt). They agreed that consent from relatives or a friend would be acceptable, as stroke patient unlikely to give fully informed consent at this stage.

	• They agreed with the proposed 6 month follow-up, and they agreed it is acceptable to contact the GP to obtain information on the health status of the patient. • The first focus group of users accepted the follow-up method by postal questionnaire, interview or contact with GP. The second two focus groups (from dysphasia support groups) preferred personal contact (home visit) to a postal questionnaire. • Other outcome measures suggested from responses to the questionnaire were: movement scores, concentration, measure of intelligence, handwriting skills, sleep, tiredness and fatigue, speech, vision, and enjoyment of hobbies.
	Parkinson's disease – therapeutic massage intervention (Paterson 2004) **Design of study** This study involved users in the design, timing, and adequacy of outcome measures for assessing therapeutic massage for people with Parkinson's disease. Users identified the following issues: • The time of day the massage is given is important. • Attention is needed for the administration of the questionnaire to those with disabilities (e.g. poor eye sight, speech problems) or those where questions raise distress. • PDQ-39 is a suitable quality of life measure to use in the study. • Add in objective assessment of change (e.g video of them conducting certain tasks) rather rely on subject reports from participants. • Baseline data should be collected on several occasions to overcome changes due to anticipation of intervention itself. • Consideration of additional funding for participants to continue massages after study has finished. • Well-being outcome can be 'not getting worse', rather than always 'getting better'.
	Paget's disease (Langston 2005) **Collaboration** **Design and recruitment** This study involved users in the design, conduct and delivery of the PRISM (Paget's disease: a randomised trial of intensive versus symptomatic management) trial • The patient information leaflet was changed by users because they deemed it "too simplified" and "potentially patronising", which could have a negative impact on the recruitment of patients to the trial. The style and layout of the information sheet were also commented on. • They advised the research team on how to present to a lay audience. • They provided contacts to assist with the recruitment of centres/participants. • They advertised the trial in the user newsletter, and at user conferences.
	Safety and efficacy of antiretroviral and nutrition interventions to reduce postnatal transmission in HIV, Malawi (Corneli 2007) **Consultation** **Design of study** The study involved users to assess the attitudes and concerns of the local community on the study. The following issues were identified: • Users accepted the study, but while they understood that the purpose of providing antiretroviral drugs was to prevent the infants getting HIV, few recognised the purpose of the research was to determine whether the drugs were indeed safe and efficacious for this use. They believed the medicines would prolong their lives, and that they would be able to share their medicines with their husbands who were presumed to be HIV positive. • Misunderstanding of randomisation: they thought it would be unfair that some women would not receive antiretroviral drugs or nutritional supplements. • Concern raised by the amount of blood which would be drawn – they were concerned that the baby or the mother would fall sick if too much blood was taken. The mothers were asked to identify a suitable amount of blood quantity that would be acceptable to be drawn at each study visit, and this was changed in the protocol. • Identified culture is to share nutrition with family so named the supplement 'Nutrition for Breastfeeding Mothers' to minimise the stigma associated with its use in the context of the study and to possibly reduce sharing. To further offset supplement sharing, all families are provided with a small bag of maize from the study.

4.17.4 Outcomes for writing up and dissemination

Although studies reported that users were involved in the write-up phase of the study, only one study reported the outcomes of PPI at this phase of the study (Sutton & Weiss 2008). Users were involved in a consultation with researchers about

pharmacy prescribing services, and added their comments to the phase 1 final report (see below in table 6).

	Table 6 PPI Outcomes in relation to writing up and dissemination
	Pharmacist supplementary prescribing (Sutton & Weiss 2008) This study involved the users with a chronic condition as advisors in a research project exploring pharmacist supplementary prescribing (supplementary to GP). This is a summary of users comments/questions from their involvement in the write up of the phase 1 study report. • Is the supplementary training too intensive and, in reality, will it meet the needs of the individual prescribing? • The transcripts of the interviews with pharmacists reflected the pharmacists' desire to move towards independent prescribing (which worried patients). • Users were concerned that they might lose contact with their GP. • Users were concerned about the accountability of pharmacists i.e. should they prescribe without guidance from the doctor? • Would pharmacists have sufficient knowledge to make judgements about patient care in all cases? • Would they still refer to the GP if necessary?

4.17.5 Outcomes for dissemination of results/implementation of results

Two studies reported on outcomes in relation to the dissemination and implementation of results, included in table 7.

	Table 7 – Outcomes on dissemination of results/implementation of results
	Write-up and publishing – review of journals (Chambers 2004) This study investigated if researchers publishing in international general medical journals had actively involved consumers in their research and the extent to which authors perceived that they had done so. The following summary of results is reported: • Consumer involvement was reported as being integral to the research undertaken in 6/200 original published papers (2 in BJGP, 2 in BMJ, 1 in Lancet, 1 in N Engl J Med). • 41% (54/132) reported that they had involved consumers in their research. • 72% (39/54) thought that consumer involvement was beneficial. • Misunderstanding of consumer involvement was reported by 26 respondents (e.g. research question to elderly people, featured in mass media).
	Disability (Lloyd 1996) Dissemination of findings This study involved users in a survey of the needs of physically disabled people in a metropolitan borough in order to address deficits in service provision and inform community care and health service planning. Users assisted in dissemination by participating in workshops of users, carers and providers which were held to disseminate the findings and to use these as a basis for the service planning.

4.17.6 Outcomes of PPI when users are involved in most stages of research

Ten published papers reported on outcomes of PPI involved in most parts of health or social care research study (Wyatt 2008, Shea 2005, Schneider 2004, Morgan 2004, Phillpot 2004, Reed 2004, Angell 2003, Meyers 2003, Trevedi & Wykes 2002, Burrus 1998). Two of these studies were led by users, which included one study that elicited users' views of electroconvulsive therapy (ECT) in two mental health trusts (Philpot

2004), and another that developed and disseminated a breast cancer work-book to reduce anxiety (Angell 2003).

A range of studies reported on communication issues between health professionals and schizophrenic patients, on health promotion in the Hispanic community, on awareness and knowledge of stroke, on issues with older people, and on primary care study programmes (Wyatt 2008, Schneider 2004, Morgan 2004, Reed 2004, Meyer 2003).
Three of the studies were collaborative studies reporting on mental health issues, prevention of diabetes, and the Cochrane user group. All studies reported beneficial outcomes.

Table 8 gives a summary of the results of each study:

	Table 8 Outcomes of PPI when users are involved in most parts of research
	Schizophrenic services (Schneider 2004) **Design, recruitment, conducting, analysis and write-up** The study involved users to assess schizophrenic people's experiences with medical professionals (MPs), particularly in relation to communication. The following issues were raised: • Diagnosis takes too long, causes frustration for users. • Lack of clear communication from health professionals about patients' conditions lead to distress "*with heart attacks or cancer … they tell you…only with mental illness they won't tell you*". • Lack of communication about side-effects of drugs. • Information and support for patients is needed. • Health professionals should listen to patients when discussing treatment. • Health professionals should treat patients with dignity and respect. *"…it's like hitting a brick wall. It's very frustrating and I'm tired of felling that way. I just want to be heard …"* If treated with respect, given information about treatments, and supported, patients are more able to accept their situation. • If patients have good communication from doctors, they are more likely to understand their need to take their medication, look after themselves, and start to see ways to deal with their situation. The users developed and performed a readers' theatre presentation of the results and their recommendation for of how they would like to be treated by medical professionals.
	Health promotion in Hispanic population (Meyer 2003) **Design, recruitment, conducting, analysis** The study involves users at most stages of the research to explore how lay Hispanic women want to receive health promotion. The following issues were identified: • Isolation of hispanic women. • Hispanic women feeling they are not able to talk about their health needs. • Dealing with cancer in the family. • Immigration issues. • School system issues. • 90% of women saw the project as very beneficial to the future of the community.
	Stroke – awareness and knowledge (Morgan 2004) **Proposal, design, conducting, dissemination** The study aimed to involve and enable lay people to identify and direct a research study as co-researchers consulting members of the general public about their awareness and knowledge of stroke and stroke risk. The following results were reported:

	• Knowledge of stroke and stroke risk was good. • 90% knew stroke occurs in the brain and most correctly identified the causes as related to impaired blood supply to the brain. • 96% said it was extremely important to get immediate treatment for someone who may have suffered a stroke. • 78% stated they would like further information about stroke. Most popular sources of information identified were: general practice (51%); TV and radio (36%); and friends and family (33%).

	Primary Care Studies Programme (Wyatt 2008) **Design, recruitment, conducting, analysis and write-up** The study set out to evaluate user involvement in the London Primary Care Studies Programme (LPCSP) and understand what impact consumers had on the research process and outcomes. The following results were reported: Eight studies reported impacts on initial design of study, recruitment of the research subjects, developing data collecting tools, collecting data, analysis and dissemination of the findings. Some projects achieved 'partnership' style consumer involvement, while the involvement felt tokenistic for some users and carers. Greatest impacts were where the projects achieved 'partnership' style consumer involvement.
	Breast Cancer (Angell 2003) **Design, recruitment, conducting** The study assessed a workbook journal developed by users to improve psychosocial functioning of patients. Three significant results reported: • Women treated in rural practices reported decreased fighting spirit ($t=-2.64$, $p<.01$) if they did not receive the WBJ. • Women treated in rural practices reported decreased emotional venting ($t=1.85$, $p<.07$) if they received the WBJ . • Women treated in rural practices reported decreased posttraumatic stress disorder symptoms if they received the WBJ ($F(6,79)=3.42$, $p<.01$). • No other significant results reported. With those who received the WBJ, 44% (20/45) said that they were better able to cope with breast cancer. However, 53% reported no difference in their coping as a result of the WBJ. 74% (32/43) reported feeling more supported by the WBJ.
	Older people (Reed 2004) **Design, recruitment, conducting, analysis and write-up** Reflection of issues that have arisen in 3 projects where older people were involved in research at different levels (from sources of data to independent researchers). Issues raised were the following: • Importance of reflecting older people's views in research questions asked, but still have to formulate them for funders/reviewers. • Need to educate users in research methodology – so it can be challenged by users. • Need support and training for users if they are data collecting. Advantage of users collecting data include better rapport with participants. • In analysis and interpretation – need to take ideas to users and debate with them. • Problems of project management because academic researchers have responsibilities and accountability to the funders (difficult to defend decision which you do not support), so get hierarchical model of management. • Problems with writing up, as academic researchers write up for peer-reviewed journals, whereas users write up for other users.
	Mental Health (Trevedi & Wykes 2002, Trevedi 2003) **Collaborative** **Focus of research/outcome measures** The study aimed to improve education and knowledge about medication on in-patients in our local psychiatric intensive care unit (PICU), as clinicians were concerned with compliance to treatment. Users identified the following issues: • They did not like the outcome measure of insight and compliance. Insight was seen as 'agreeing with the health professionals', and being compliant as 'doing what you are told to do by the health professionals'. • Users changed the focus to empowerment around decision making in treatment to encourage compliance. • They suggested providing patients with medication education. • The outcome measures were changed to be more user-friendly to reflect real life e.g. remember items on a shopping list/test day-to-day skills of patients rather than use neuropsychological tests. • Users pointed out that since clinical teams in the hospital were known to have very different attitudes to medication information, this could markedly affect how the patients responded to the medication education sessions, which led the researchers to make specific use of matching procedure to improve the scientific method of the investigation. Two papers written, one on actual medication education study, and one on user involvement in the study. For the dissemination the study followed the policy of the Centre for Recovery in Severe Pschosis (CRiSP),

	south London by using newsletters and web-pages to disseminate the results to users.

	Cochrane systematic reviews user group. (Shea 2005) This study aimed to assess the benefits of the development of a Cochrane network of consumers to guide research priorities, peer review systematic reviews, and promote and facilitate consumer-appropriate knowledge dissemination for people with musculoskeletal diseases (CMSG – Cochrane Musculoskeletal group). User involvement led to the following: • identified research needs e.g. more drug to drug comparison rather then drug to placebo comparison. • Provided valuable feedback on clarity of review e.g. Concerns about generalisability of review. • Identified research gaps. • Identified what information is most important to tell the consumer (identified that consumers need different amounts of information to make health care decisions, so format now – short consumer summary, long summary, and decision aid). • Consumers identified need for more information about complementary and alternative therapies. • Development of the format for consumer summaries.
	Mental Health (Philpot 2004) The study aimed to elicit users' views of electroconvulsive therapy (ECT) in two mental health trusts with a user-designed questionnaire. Data collection was conducted by users. • Users reporting they would 'never have ECT again' had significantly lower satisfaction scores and higher adverse effect scores (p=0.024, p=0.033), than those who had had ECT before and were more prepared to have it again. • Those respondents who had had ECT before went on to say they would agree to it again (α^2=4.91; df=1; p<0.05). Those receiving care at Maudsley Hospital had significantly lower satisfaction scores (p=.007). • Those who said they would have an ECT again were significantly younger than the remainder (54.8±16.1 years vs 66.4±13.2 years, F=5.26, df=1, 42, p=.0286). Qualitative responses: • Feeling compulsion (no choice): patients reported they were 'not given another alternative by staff', or 'felt for themselves that there was no alternative', either because ECT had worked before or because they were at the end of their tether, or prepared to try anything. • Informed choice: reported that even though she had tried to make an informed choice, felt at the end of the day the information was wrong because the treatment did not work and she had memory loss. • Most severe side effect was memory loss.
	Diabetes (Burrus 1998) This study aimed to assess community interest and willingness to give support to issues associated with preventing and mitigating adverse health effects associated with diabetes. Users' involvement included: • Creating the name for the study (DIRECT – Diabetes Interventions Reaching and Educating Communities Together). • Input to the promotional brochure for study (e.g. development, layout, literacy level, agreed to have their names on the back of the brochure to show their commitment to the study). • Helping to raise awareness through mass brochure distributions, presentations, mass media coverage (radio, newspaper, television). • Teaching interviewers cultural sensitivities.

	Death with Dignity in Severely Disabled (Minkler et al 2002) This study explored the issue: death and dignity or physician assisted suicide legislation for severely disabled people led by a Community Advisory Group. Users conducted the research study, and reported the following issues of concern on this issue: • The existence of great breadth of opinion with respect to attitudes towards death with dignity (DWD) legislation: "*There seems to be one public position on behalf of people with disabilities about DWD legislation put forward by disability community spokespersons and groups, but when you go deeper into the community there are many different opinions. And individual's' opinions seem to depend on their own character, personal experience [of self or loved one] with near-death or death, among other things*". • The importance attributed to self-determination and autonomy in the way people with disabilities live and die. Regardless of their opinions on DWD, all respondents reported wanting their independence and autonomy in life choices to be respected. All but one reported that, if they were close to death or experiencing intractable pain or loss of cognition, they would want to have their own opinion about ending or continuing their life respected. • The pervasiveness of discrimination based on disability. 90% experienced discrimination based on their disability "I have heard people say to disabled people, 'why don't you die?'".

	• Contradictions between personal experiences and abstract or political beliefs shaping attitudes towards DWD legislation. That is participants reported having personal experiences or anticipated changes in their own life that would cause them to have opinions at odds with their abstract or political beliefs regarding DWD. • Misinformation about the law on DWD (passed in one state in the USA): e.g. "could be used to hasten death in people with disabilities" "once suicide was legalised, an expensive drug for pain was not covered by the insurance company". • Fear of criticism from other disabled people in relation to the expression of attitudes towards DWD legislation is common. 24/45 participants either had experienced, knew someone who had experienced, or feared they would experience criticism if they spoke out in favour of DWD legislation. • Lack of association between attitudes towards DWD legislation and a host of factors, including disability identification, religion, race, class, social support, and relationship with one's own physician.

4.17.7 Outcomes of PPI in large research programmes (e.g. HTA)

Four studies reported on the involvement of users in large research programmes, including the Canadian HTA programme, the UK NHS programme, and the UK clinical trials programme, reported in table 9 (Hailey 2006, Telford 2002, Hanley 2001, Kelson 1999). User involvement appeared to be greater in the Canadian HTA programmes compared with the UK NHS programmes or the UK clinical trials programmes, although the UK studies were conducted 4 and 5 years before the Canadian project, so the increased involvement in the latter may reflect the growing acceptance of PPI in those 5 years.

	Table 9 Outcomes of user involvement in large research programmes
	HTA (Hailey 2006) The study aimed to obtain information from members of the International Network of Agencies for Health Technology Assessment (INAHTAA) on their involvement of consumers (patients, carers, and related organisations) in their programmes. The following results were reported: • 21/37 indicated that consumers were involved in HTA programme. 20/21 reported they involved consumer or patient organisations, 10/21 reported they involved individual consumers. • 19/21agencies contacted consumers by invitation, 14/21 accepted requests from consumers for assessment of specific topics, and 5/21 were in response to publicity on forthcoming assessments. • 4/21 provided users with some form of training. • 5/21 agencies gave details of when user involvement is avoided because there is no added value or benefit from the involvement of consumers e.g. diagnostic test, horizon scanning products. • 14/21 used consumers in the formulation of topics for assessment, 8/21 in prioritising topics for HTA, and 6/21 sought comment in refining the scope and nature of the HTA, and 6/21 involved consumers in development of the protocol. • All agencies that responded intended to involve consumers in the future process of HTAs. • 12/37 prepared lay reports for consumers in the dissemination phase of the study.
	NHS (Telford 2002) The study aimed to investigate the extent to which user involvement is incorporated into NHS Research projects in one NHS region. The study reported the following results: Only 7 research teams (13%) representing just 5 trusts (less than ¼ of trusts) were actively involving consumers in the research process. These projects addressed maternity care issues, cancer, disability, respite needs of people with dementia and their carers, Cochrane Collaboration research activities. Consumers were involved in research at all 3 levels: user-controlled, collaboration, and consultation.

	UK Clinical Trial Centres (Hanley 2001) The study aimed to assess the extent to which consumers are involved in the work of clinical trial co-ordinating centres in the UK, and the nature of the consumers' involvement in randomised controlled trials is co-ordinated by these centres. Of the 62 eligible centres, 23 reported that consumers had already been involved in their work, and most respondents were positive about this involvement. 17 centres planned to involve consumers. 15 centres had no plans to involve consumers, but only 4 of these considered such involvement irrelevant. Responses from investigators about the 48 individual trials were mostly positive, with respondents commenting that input from consumers had helped refine research questions, improve quality of patient information, and make the trial more relevant to the needs of the patients.
	Cochrane Research Group (Kelson, 1999) This study aimed to identify the extent to which the Cochrane Collaboration involves users as members of the Cochrane Review Groups (CRGs). The following results were reported: 10/33 (30%) had no user representatives 4/33 (12%) had one user representative 6/33 (18%) had two user representatives 12/33 (36%) had three or more user representatives. 19 (58%) indicated that they had discussed the issue 5 (15%) had carried out a search for literature on patient defined outcomes 3 (9%) had produced a bibliography, summary or review. Reported contributions included informing the methodology, development and reporting of reviews, participation in working groups, suggesting outcomes and/or identifying areas of interest that patients would like the CRG to address.

4.17.8 Summary of themes from outcomes of PPI from research

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 also shows user-led and collaborative studies tended to be more in the areas of mental health, older populations, disability studies, and health promotion. In addition, 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 collaborations with users were more likely to include users throughout the research project, from proposal, methodology through to writing up and dissemination of results.

5 Discussion and Conclusions

5.1 Introduction

This section discusses the key results which have emerged from the review and considers the strength and limitations of this evidence base. It builds on the results and considers how to strengthen the future PPI evidence base, particularly in relation to the quality of reporting. It also recommends future areas of research to help strengthen the quality of the PPI evidence base.

The emphasis on patient and public involvement in health and social care research in the UK has emerged over the last decade, gaining strength and recognition and reflecting the increasing international focus on research in this area (Staniszewska 2009). The policy support for involvement has also strengthened and funders are increasingly building PPI into the systems for commissioning and funding research. For example, the National Institute for Health Research aims to ensure all research projects have active involvement from the start. With the significant level of patient and public involvement in health and social care research, this systematic review provides a timely synthesis of evidence over the last 15 years. The overall aim of the systematic review was to identify the impact of patient and public involvement (PPI) on health and social care research. In order to examine this question it was also necessary to consider how PPI was being defined, how it was being conceptualised and theorised, how it was being measured or captured and what the outcomes of PPI studies were. In addition, economic evaluations were also sought to understand the financial impact of PPI activity in research. By utilising systematic review principles it has been possible to thoroughly search for and assess relevant studies and to draw out key themes and recommendations. These recommendations focus on the content and quality of reporting of PPI activity, in order to strengthen the future quality of the PPI evidence base. Specific guidelines for reporting PPI impact are provided for academic papers, and could also be used for grey literature.

5.2 Quality assessment

Before discussing the study findings it is important to contextualise them within a discussion of quality assessment. Systematic reviews usually evaluate the quality of the sources of evidence they utilise. This is undertaken using a range of different checklists suitable for particular study designs. There is debate about the value of quality assessment, with some researchers viewing it as a necessary part of the systematic review process, while others question its value and subjectivity, particularly for systematic reviews which do not synthesise data on effectiveness (Brouwers et al 2005). Furthermore, the quality assessment tools are developed to measure the quality of the main study, not the quality of the PPI activity within the study, which can be designed in a different way to the main study. In this review, using the CASP criteria, if papers passed the first two fielding questions, that is, the paper reported a clear statement of aims, stated clear, appropriate methodology, and reported results, then the study was included, but quality assessment was reported as 'partial'. If the papers passed the first two fielding questions and scored 7/10 or more on this quality assessment sheet, they were scored as 'adequate'. These assessments are in the data extraction tables. However, there was very little difference between these two groups of papers, so the utility of describing the evidence in terms of quality was limited and not used to discuss the results. If studies had been fatally flawed in terms of their quality, they would have been excluded.

Grey literature provides further challenges with no agreed ways of assessing the quality of such sources, which can be very variable in their nature, making consistent evaluation difficult (Personal communication Iveta Simera 2009, EQUATOR, Personal communication Maggie Westby 2009, RCP NICE Collaborating Centre). 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.

At this point in the development of the PPI evidence base, it was felt to be too early to exclude studies just on the basis of design and to weight evidence in this way. The CRD (2001) guidance for systematic reviews places emphasis on a hierarchy of evidence that places experimental studies such as RCTs (with concealed allocation) at the top of the hierarchy. However, with the complexity of PPI as a concept, the RCT study design may not be appropriate as an indicator of the best quality PPI

study. In this review, PPI studies were characterised by variability in the study designs used and included qualitative, cross-sectional and case studies, reflecting the diversity and complexity of PPI activity. With the diverse study designs included in this review, the CASP checklist was selected, a generic tool that can be applied to different study designs. This also ensured consistency with the approach utilised by the National Centre for Involvement, which successfully used the CASP checklist in its review of the impact of PPI in health and social service provision (NCI, 2009). Overall, CASP worked well for qualitative studies and case studies, which make up most of the PPI evidence base, but was less was helpful for cross-sectional studies, although these were less common. Each study was assessed for quality and any that were felt to have a fatal flaw in terms of this quality assessment would have been excluded. While CASP was helpful in an overall assessment of quality, it was not possible to evaluate the quality of PPI within a study as no specific quality assessment tool is available, although one is currently being developed (Personal communication, Jim Elliott 2009). At the time of data extraction this tool was still undergoing development and not yet published. It is hoped the results of this review will help with deliberations about the content of quality assessment in PPI. It is important to note that even if a quality assessment tool for PPI had existed, this evaluation would be hampered by the variable and often poor reporting of PPI activity within studies. This difficulty points to the need for more consistent reporting of PPI activity and possibly separate PPI methods papers, which would facilitate quality assessment.

While quality assessment can be helpful in assessing a body of literature, and in understanding its strengths and weaknesses, it should be noted that current forms of quality assessment are very much driven by a research perspective. To date, users have not been routinely involved in the development of quality appraisal checklists and consequently it is not clear whether they reflect the aspects of quality relevant for users. This is an important area for future collaborative work with users and researchers working together to identify how the quality of PPI should be assessed.

5.3 Searching databases

The searching of databases to identify potential papers for this review provided a number of challenges. In addition, impact is rarely featured as a keyword in papers

that attempt to capture impact, making it difficult to identify these papers. A key issue is the lack of a MESH term for PPI to enable consistent searching. In addition, the variability in keywords used by papers resulted in long and complex search strings (the list of terms used for searching databases). It is important that the managers of research databases and the editors of the journals they index can work together to create more consistent ways of searching for and locating relevant papers in this field. These limitations may mean that relevant studies have been omitted.

5.4 Defining PPI

A range of helpful definitions of PPI already exists including INVOLVE's definition of PPI as an active involvement with research as a partnership between users and researchers (INVOLVE 2004), which was utilised within this review. In terms of the overall evidence base, some studies provided definitions of PPI, often variations of the INVOLVE definition, while others did not attempt explicit definitions but seemed to rely on a common understanding of what PPI is. Fewer studies included a discussion of the importance of defining PPI or how their definition related to other definitions. While the implicit definition of PPI may seem obvious to many, a clear definition provided within a study is important because it can help to ensure a consistent understanding of a concept or an activity, particularly important in a diverse and complex area such as PPI where individuals can have different philosophical approaches. This does not necessarily mean studies have to adopt the same definition of PPI, but it does mean that clear definitions, explained within the paper, are an important part of developing a clear and coherent evidence base. In addition, when studies do provide their own definitions of PPI, it is helpful to link that definition to a broader body of work to provide a rationale for that definition. This will help identify a clearer picture of the way in which PPI is being operationalised within a study and so will contribute to a strengthening evidence base. Thus, it is important that future studies provide an explicit definition of PPI, comment on how effectively this has been operationalised within their study and make any suggestions for how future studies should define PPI.

5.5 Conceptualisation and theorisation of PPI

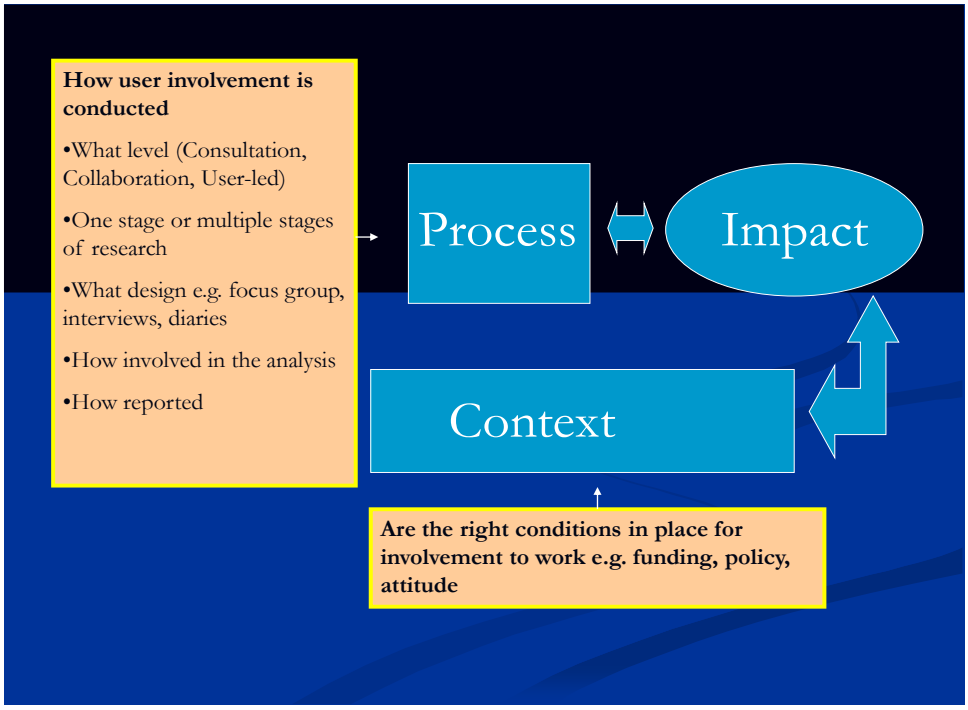
Compared to the many studies that report some form of PPI activity, there are relatively few papers that focus on the conceptualisation of PPI, with many relying on

personal reflections. Conceptualisation refers to the way in which a phenomenon is described, defined and understood. This can build a greater understanding of the concept which can be shared. For example, in quality of life research, a clearer understanding of the concept has emerged over time, with studies presenting their own definitions of quality of life and suggesting its content through the identification of key dimensions of quality of life, which include physical functioning, emotional well-being, social functioning among others (Streiner and Norman 2005). In PPI, conceptual and theoretical development has been relatively limited. Studies undertaken to develop our conceptual thinking have varied in their focus and approach. At a broad but very useful level, the INVOLVE classification of user-led, collaboration and consultation offers a way of grouping PPI into different types of activity. Work has been undertaken by Pivok (2003), Abelson (2007), and McCormick (2004) attempted to identify the processes, obstacles and benefits of lay involvement from previous experience of PPI. Telford et al (2005) attempted to ascertain the principles and indicators of successful involvement through a more formal Delphi process. Such work is very helpful in starting to develop a deeper understanding of PPI and start to unravel the components of PPI and the ways in which these different components could be captured or measured. More recently, there have been attempts to develop a multidimensional framework to help draw out the implications of PPI for policy and practice (Oliver et al 2008). These more complex attempts to conceptualise and model PPI are important because they illustrate the trajectory required for future conceptual and theoretical modelling of PPI, which needs to go further in capturing the complexity of this activity. A conceptual model or theory can be helpful in explaining a concept by offering a model of how it might work. For example, a theory could identify the components or variables that influence PPI, or the variables that might be influenced by it. Theoretical models are also helpful because they can be tested empirically to establish their trustworthiness and utility. Theoretical models can also be helpful in guiding the capture or measurement of impact, as they essentially provide a ‘blueprint’ for developing instruments to measure impact. To date, there have been no attempts to develop a comprehensive theory of PPI which has been tested. Future studies need to consider how their collaborative work with users could contribute to furthering conceptual thinking and theory development and testing.

5.6 The importance of context and process

Before discussing the results of the review in relation to impact and outcomes, it is important to contextualise these results within a broader framework. The User Involvement Seminar, held in October 2009 as part of this study, provided an opportunity for users and others to contribute to the synthesis of initial results. A key outcome from this seminar and from the synthesis of review data was the need to consider the impact of PPI in a framework which includes the context and process in which PPI occurs (see figure 1).

Figure 1. The architecture of PPI impact: The role of context and process



The context refers to the environment in which PPI is undertaken, that is, whether the right conditions are in place for involvement to work. It could include funding, policy or the attitude of those involved, the broader underpinning factors that can affect PPI. The process of involvement refers to more specific factors. For example, it could refer to the level of involvement that users have, how they are involved, when they are involved and what procedures are put in place to improve the likelihood of success. In many ways these contextual and process factors, when taken together, could be described as the 'architecture of involvement' as they reflect the structures and landscape that is likely to be needed to enable PPI activity to have an impact. A list of

possible factors (extracted from the studies included in this review and included as recommendations) is included in table 4.2 in the results section. If the context and process are not appropriately established then the chances of beneficial PPI impact appear to diminish.

The evidence shows that the better the training, planning and procedures that are put in place, the clearer the definition of roles, the more positive the attitude towards PPI and the greater the trust and respect that parties (users, researchers, clinicians, funders, policy makers) have with each other, the more potential for beneficial impact. The less involved the users are in the research, for example, if there is a lack of training, poor planning and unclear procedures and roles put in place, a more negative attitude, and a lack of trust and respect between parties, the more challenging the involvement can be, and possibly less chance of beneficial impact.

In many ways this need to consider the broader areas of context and process in evaluating PPI echoes the guidance provided by the Medical Research Council (2009) on the evaluation of complex interventions, which are viewed as having several interacting components, which can present special problems for evaluators. Many of the problems relate to the difficulty of standardising the design and delivery of such interventions, their sensitivity to features of local context and also the length and complexity of the causal chains linking interventions with outcomes. All of these elements fit with PPI, which is made up of many interacting components, can differ according to local context and can be very complex as an activity, which all makes consistent evaluation difficult at present. The future evaluation of PPI impact needs to consider not only the specific impacts and how they are identified, but in some way capture the broader context and process in order to evaluate what works, for whom and in what circumstances. Further collaborative work with researchers and users needs to be undertaken to identify what data would need to be collected to enable such an evaluation to occur. At present studies are very variable in the context and process information they report and perhaps do not recognise the importance of reporting this information in adequate detail, alongside impact and outcome results. In addition most studies tend to be retrospective reflections, examining impact at one point and there is an important need to undertake prospective longitudinal studies to capture how impact changes over time.

5.7 Capture or measurement of impact of PPI

This review has aimed to identify the impact of PPI on health and social care research. It has been possible to identify a range of impacts and outcomes, although they are based on often brief descriptions in studies. It is often not clear whether all impacts have been reported or whether studies have selected some impacts that the researchers regard as particularly noteworthy. As a result it is difficult to be confident about the 'content validity' of these studies, that is, whether they have explored all the potentially relevant impacts (Streiner and Norman 2005). Data contained in the literature, that is the content of impact and different aspects identified, only provides an initial insight. Because of concerns about its quality, it does not provide an adequate enough foundation for the development of an instrument designed to measure impact. It provides some initial ideas of dimensions, or aspects of impact, but not the detailed content which would be required for instrument development, pointing to the need for a qualitative study to explore understanding of impact in a more detailed way.

In attempting to identify PPI impact, this review also searched for studies that robustly measure impact. However, this is an area that is characterised by an absence of measurement, with only two studies attempting measurement in a crude way. It is clear that while considerable progress has been made in PPI in many ways, the capture or measurement of impact has lagged behind significantly. In the User Involvement Seminar the use of the term 'measurement' was discussed and an alternative 'assessment' was proposed. Within this review 'measurement' has been used to reflect a particular approach to assessing impact which reflects the principles of robust measurement in research and so the term measurement has been retained. The term 'capture' has been used to try and reflect the potential to include qualitative assessment as well as quantitative measurements. However, it is recognised that with further discussion and debate, alternative terms such as assessment may be more helpful in the future to describe collectively forms of impact assessment.

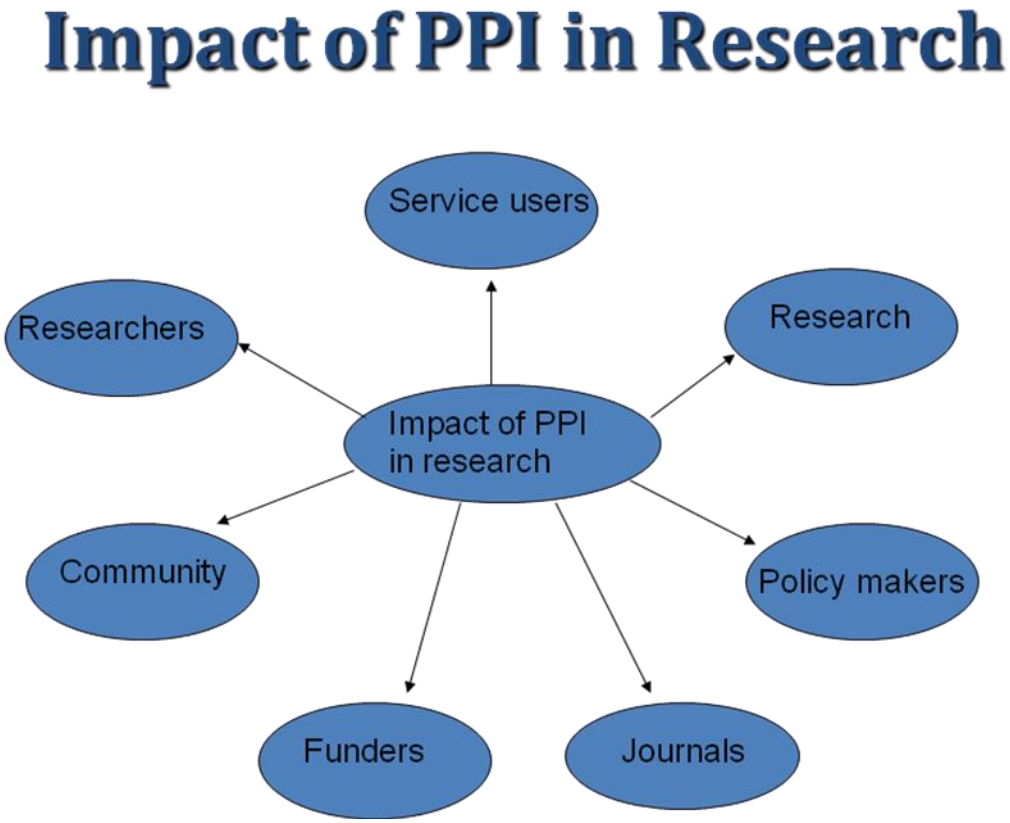
There is a need in the next few years to develop collaborative studies with users to identify the 'content' of impact, that is, the dimensions or aspects of impact that are relevant to impact and also to consider how the concept of PPI impact can be best

captured or measured. With the previous discussion of PPI as a complex intervention, it is likely that both qualitative and quantitative forms of capture, description or measurement will be required, with some standardised approaches combined with more individual measurement of impact to ensure that both generic impacts and those specific to an individual are captured. There is potential for PPI to 'borrow' from areas such as patient reported outcomes in adopting robust principles of measurement such as reliability, validity and responsiveness. Further research is needed to explore the potential applicability of the principles that underpin PROMS to the field of PPI, but this could offer a helpful way forward in developing both qualitative and quantitative forms of capture and measurement. This endeavour should not be underestimated as it represents a significant future challenge, but the successful development of a conceptually clear, methodologically robust instrument that measures PPI impact in research will enable the 'true' impact to be fully assessed and considered.

5.8 The impact of PPI in health and social care research

The review has identified a range of impacts that PPI has on a number of activities and a number of groups, see figure 2 which summarises the different areas and which was discussed at the user involvement seminar. Most studies have reported impact on research and the research process and on users, with comparatively less published in the other areas of impact.

Figure 2



5.9 Impacts on research and the research process

Many studies report the impact that PPI has had on research and the research process, including the design of studies, research methods and instruments, recruitment, data collection, analysis and dissemination. These impacts vary in nature, with some overarching impacts and other more specific impacts. The overarching benefits are characterised by impacts that help refine research and make it more relevant and appropriate from a user perspective, with the possibility that the results of such studies have a greater utility when implemented, although this has not yet been tested. More specifically, there is evidence of the impact of PPI in the initial stages of research, particularly around setting research agenda and research questions with users helping to identify user relevant topics for research agenda grounded in their own experiences. In addition there was extensive evidence of the impact of users involved in undertaking research. For example users commenting on research protocols had important impacts in trying to develop research that is relevant to users. This represents a critical area for user involvement as it can shape

an entire study and users may have more freedom to influence the aims and methods at this initial stage (Staniszewska et al 2007).

Adapting research language to suit users was another important impact from some studies where users also helped improve the sensitivity of wording. Such impacts are important in ensuring the acceptability of research to research participants and ultimately to the success of the research. In addition PPI can help researchers to recruit to studies, by identifying more effective ways of accessing participants and so improve response rates. They can also improve recruitment from communities that might be harder for researchers to reach and enable greater empathy to develop with potential participants. These impacts could be particularly helpful in a clinical trial study setting where recruitment poses significant challenges. By reaching out to the community, researchers may find that the research process becomes more accessible and open to users and to research participants, and so potentially a wider public, building community communication and understanding and perhaps contributing more broadly to a wider public understanding of science and research. A more informed public may aid informed consent as potential participants start from a better basis of information.

The potential for PPI to assist with assessing the appropriateness of research tools is another important area. Sometimes these impacts can be small but immensely significant in the research process. For example, PPI can lead to better wording in a questionnaire, identification of appropriate content, thus aiding content and face validity of measurement tools and to the identification of lines of enquiry not previously considered. In these ways PPI is providing important contributions to improving the quality of the research process and theoretically the data collected. As part of the appropriateness of research and research questions, PPI was also found to have important impacts in ensuring the cultural relevance of studies and by providing a broader cultural understanding which could inform protocol development.

There are also studies that support users as active researchers and the impact this can have on the research process. Some studies found that deeper and more insightful data was gained within research interviews, possibly because of a better rapport between interviewer and interviewee if participants felt more at ease. From a

research perspective there is a potential for this impact to work in the opposite direction, with participants withholding sensitive information from people they know.

Overall, such potential to improve the quality of research and the research process could be very appealing to those researchers who have not yet collaborated with users and wish to consider that possibility. In addition to these specific impacts, research studies rely on good relationships with a broader community and some evidence suggests that PPI can help to strengthen these relationships, in terms of better community links, greater understanding of research, better recruitment rates and better credibility with stakeholders. Such positive impacts illustrate how PPI can help to strengthen relationships between communities and researchers.

The analysis of study findings can be a critical stage where the interpretation of data can focus on certain key aspects of the study, which are then reported in subsequent dissemination. This stage offers important opportunities for PPI to have an impact. Studies have found that PPI can help to broaden the interpretation of data; providing a different insight and helping to identify the aspects of research that have most relevance to users. The results of studies, when developed with users, can also help with establishing the credibility of findings with stakeholders, particularly important when attempting to implement study findings. If a study has been conducted collaboratively with users and the community, the chances of successful implementation may be enhanced. In addition, users can help to identify gaps in research that future studies need to address, to ensure that users have continued input into the research agenda.

Dissemination and uptake of findings can provide significant challenges for researchers. Researchers focus on publishing results in peer-reviewed journals, with less focus on the implementation of findings. However, with the renewed focus of the Higher Education Funding Council (HEFCE) on the impact of research, researchers are now placing much more emphasis on the impact of their research through appropriate dissemination which may be broader than the traditional routes of peer-reviewed journals and offer opportunities for PPI. There is already some evidence that PPI can achieve better dissemination and implementation of research findings due to the dedication and influence of users. PPI can also strengthen aspects of

dissemination by making it more accessible and poignant. There is also an important role for users in the rapidly developing implementation research agenda, which is focusing on getting evidence into practice.

5.10 Negative impacts

While many papers reported on the positive impacts on research and the research process, fewer reported on negative impacts, although the assessment of whether an impact is negative is, to some extent, in the eye of the beholder, and what some researchers may view as negative may actually represent a positive impact for the user. In the User Involvement, seminar some participants felt uncomfortable with the term ‘negative’ impacts, although an alternative framework for representing positive and negative impacts did not emerge from this discussion. We have used the term negative within the review for the purpose of clarity but recognise that an alternative term might have been ‘challenges.’ However, in this phase of developing a clear evidence base in PPI, on balance, it was felt that for now, the term negative most clearly conveys the concept of adverse impacts. The review identified the potential for very different aims to emerge, with the potential for research methods accepted by the research community to conflict with user perspectives. This was a common theme among studies that reported a range of more negative impacts. For example, one study found that users felt restricted by an interview schedule and departed from it, leading to what the researchers saw as inconsistencies in the data collection. While there might have been good reason for the users’ actions and it could be argued that the researcher might have included them in the construction of the interview schedule, the negative impact on the data collection from the researchers’ perspective still needs to be acknowledged.

An important theme which emerged from studies as a potentially negative impact was the extra time needed to undertake PPI. The time limits imposed on studies can often form an important barrier to activity and so potentially impede impact. Studies need to build in appropriate time and funders and commissioners should acknowledge this need as part of providing an appropriate context for PPI to have a potential impact. A further potentially negative impact for the research process relates to the release of findings before formal publication, which some users may prefer, particularly as formal publication can take a long time. While helpful for users to ensure key

messages are disseminated early, it may mean that researchers may not be able to publish their research, as findings are already in the public domain. This can preclude publication in a peer reviewed journal and so prohibit that study from becoming part of the PPI peer-reviewed evidence base. This is only one example, but the issue of how user perspectives are reconciled with research processes, methods and principles recognised by the research community, by editors and by funders is an ongoing but vital issue for the future and an important part of the context of understanding and evaluating PPI impact. It needs careful exploration with everyone supported in an open and transparent process with an emphasis on understanding the others' perspective.

5.11 Impacts on users

In addition to impacts on research and the research process, the review also identified impacts on users. These two areas of impact represented the main body of research around impact with much less in the other areas identified in figure 2. Most papers reported positive impacts on three main areas for users – personal issues, improved level of knowledge, and increased skills. Studies reported a wide range of personal benefits, with users feeling empowered, valued, listened to and generally feeling more positive about their experiences. There were many descriptions of the significant benefits that involvement can have for users. In addition to personal benefits, studies reported that users developed their knowledge about research, about their illness and about community issues. Users also benefited by gaining broader skills such as confidence in speaking, listening skills and in working as a team. While many positive impacts were identified, studies also highlighted the more negative impacts that PPI could bring. These were divided into three similar areas – personal impacts, lack of skills, and limited knowledge. Many of the negative impacts related to the phenomenon of colliding worlds, where the values and assumptions that underpin research meet with the needs and aspirations of users, and do not necessarily mesh well. Some users experienced researchers' negative attitudes and perceptions where users were feared as lobbyists with their own specific agenda. Some users felt that their contribution was not valued and they felt excluded from the process. There was also evidence of the emotional burden or emotional labour of PPI could bring with different experiences reported, including having to re-live past experiences which could cause distress. Limited feedback could also have a negative

impact with users unclear of the contribution they had made to a research study which could lead to a lack of motivation for further involvement. Other negative impacts were also identified concerning issues of time burden and the practical impacts when users are expected to contribute to studies, often in a substantial way but with relatively little financial support.

5.12 Whose negative impact?

Overall the evidence of the impact of PPI on research and research process and on users demonstrates a range of positive impacts which can benefit the research and users. However, the evidence also highlights the more negative impacts which can be important. To date, there has been much less focus on negative impacts, but the future research agenda needs to consider both positive and negative impacts and studies need to consider how negative impacts are identified and mitigated during the process of PPI. It also needs to acknowledge that a positive impact in one situation may not be a positive impact for another situation, and the context may be important for the interpretation of impact and whether it is positive or negative. This variation in interpretation poses a challenge for how such impacts are assessed in a standardised way.

5.13 Impact on researchers

Most of the literature focuses on impact in relation to research and research process and on users. Comparatively there are fewer studies that examined evidence of the impact of PPI on researchers. The distinction between impact on research and impact on researchers could sometimes be blurred. Many of the positive impacts on research such as developing good rapport with users could also benefit the research. Studies also found that researchers gained new insights into their work and their assumptions were challenged. Researchers found possibilities for working in new ways, such as being the facilitator and providing support and advice.

The negative impacts identified for researchers could be grouped in similar ways to the positive impacts and related to ways of working and the extent to which researchers were willing to consider challenges to their accepted ways of working. Many aspects of negative impact were concerned with researchers feeling that the integrity of their research was under threat, which could have important personal implications for research careers. In addition, unless researchers had already

planned for PPI within their budget and project time-line, there could be a significant negative impact on time and budget.

5.14 Impact on research participants

While PPI implicitly involves users in different ways, the studies undertaken can also include research participants, those individuals who provide the data or information for a study. These two groups can be different, although it is possible for users to be research participants. Studies have identified a small number of positive impacts that PPI can have on research participants. These include the potential for PPI activity to provide opportunities for accessing information about the condition that otherwise may not have been available. Users can also help develop more friendly approaches to data collection and also provide support to other participants in similar situations. Only one paper considered more negative impacts of PPI on research participants and this identified the possibility that some participants may not want to share personal experiences with someone they know.

5.15 Impact on community

The impact of PPI on the community was also considered. Important positive impacts included the development of closer coalition between researchers and the community which could increase the acceptability of the research, help to resolve conflict and possibly lead to the community becoming more engaged with research and also with other community activities. PPI could also enhance the knowledge of communities about particular conditions, and so in many ways contribute to enhancing public health. The development of mutual understanding between communities and researchers could also be important as users became community advocates for research and communities developed a sense of ownership of the research. Broader benefits for the community also included ensuring that the research agenda was more clearly connected to community issues, services might be better targeted at need, and the community felt ‘science’ was more accountable to them. In addition to these beneficial impacts, studies also identified the potential for negative impacts. These included the potential for conflict to occur, the increased time that is needed to develop close connection and the difficulty of recruiting users from seldom heard groups.

5.16 Impact on funders and policy makers

The review searched for evidence of impact on funders and policy makers and very few papers were identified. Overall evidence of the impact on the funder is very limited. There is some suggestion of benefit as it can help to ensure research is commissioned in a more transparent way and has greater relevance for the community, and so theoretically a more appropriate expenditure of public monies. In terms of policy makers, one study identified the additional insights into policy making that PPI could bring which could ultimately lead to more patient-centred health and social care services. There is also an important need to consider how the results of studies on PPI can be most effectively translated into policy in the context of the constantly changing health and social care systems.

5.17 Understanding the nature of impact

The various impacts identified in this review provide a useful contribution to our understanding of the nature of impact in terms of its content, that is, the possible dimensions or aspects of PPI impact that would need to be considered by any theoretical model or by any attempt to develop an instrument to measure impact. However, while the review has been helpful in identifying the range of impacts that exist in the literature, studies often provide a relatively brief description of the impacts and rarely indicate whether they have omitted any impacts they viewed as less relevant. As a result it is difficult to gauge the ‘content validity’ of the evidence base, that is, the extent to which all relevant impacts have been reported. The absence of evidence may not mean absence of impact and some PPI impacts may not have been reported at all, which can be a concern when there is evidence of poor quality reporting. As such the evidence base is still relatively weak and requires further substantive development in terms of the way in which impact is reported. In order to guide future theoretical development (and subsequently instrument development for the measurement of impact), there is still a clear need to develop a better understanding of the nature of different impacts and how these different impacts may relate to each other. Data extracted from papers contained in this review is not adequate for developing the content of an instrument designed to measure impact. It provides some initial ideas of dimensions but not the detailed content which would be required and could be gained through a qualitative study which explores the nature of impact in more detail. To date, relatively few studies have focused on collecting

qualitative in-depth data on impact to enhance our understanding of its nature as a primary outcome of the study, rather than a secondary one. Such data could be used to inform the development of a theoretical model of PPI impact that could be empirically tested in future studies and underpin the development of instruments designed to measure impact.

5.18 Outcomes of PPI in health and social care research

In addition to examining impacts, this review also included the outcomes of the research studies, that is, the end results of the study and the ultimate outcome. While they are described as outcomes in this review, they do form part of the landscape of impact and the difference PPI makes to health and social care research and there are some overlaps between some of the outcomes and the impacts. However, they offer important evidence of the difference PPI can make to research. For example, 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. In addition, 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. These aspects are all important ways in which users contributed to the quality of the research and its relevance. Some interesting trends have also emerged from this synthesis of outcomes data. For example, clinically-focused studies tend to involve users at a consultative level at one stage in a study. User-led and collaborative studies tended to occur in the fields of mental health, older populations, people with disabilities and health promotion where the involvement was more likely to continue throughout key stages of projects.

The studies that focused on outcomes of PPI represent a smaller body of evidence than those that were more focused on impact. Nevertheless the beneficial outcomes

that can result from PPI were clear in many of these studies. Interestingly, few considered negative outcomes, which may reflect the tendency of researchers to often only report positive outcomes. There are some examples of potential negative outcomes that were addressed, such as cultural differences in interpretation of a study. Overall, the studies focusing on outcomes provide a range of evidence in different areas. A key area of outcome focuses on setting the research agenda for studies or for programmes of research. Some studies involved users in considering how future studies should be designed. These found that users can have a beneficial effect on shaping research questions and research methods, including the type and nature of outcome measures used to collect data within studies, such as quality of life measures and measurement of the side effects of treatment. In one study users were able to suggest a range of outcome measures which future studies should consider including in their design. Users were able to consider the design of future studies in terms of optimising future participation and recruitment. PPI has clearly resulted in novel research in a wide range of areas, including clinical research, including examples such as involvement in the design of the way in which medication is delivered, demonstrating the potential of PPI in clinical research. In addition, there were important outcomes in relation to ethical issues. When considering the design of trials, PPI could be particularly important within clinical trial settings where issues of consent and assent proved challenging. Users were able to advise researchers on the most appropriate course of action when ethical issues arose. In one study the vital role users played in ensuring the viability of a study is demonstrated, which might otherwise have failed because of a poor understanding of the community.

It is clear that PPI can affect the outcomes of studies, although, as already noted, while outcomes have been defined as the end result of a study, there is still overlap with some of the impacts identified in earlier sections. In some respects outcomes represent one part of a broader picture of impact and could be represented in this way in future theoretical modelling of PPI.

5.19 Summary

The discussion has provided an important opportunity to consider the key issues that have emerged from this review. There is a clear need to develop a much more consistent and robust base by enhancing the quality of reporting, to enable impact to

be fully identified and evaluated. The next chapter provides recommendations on key ways to enhance the PPI evidence base.

Chapter 6 PIRICOM Recommendations

The aim of these recommendations is to improve the clarity, consistency, detail and overall quality of PPI impact reporting, in order to strengthen the future quality of the PPI evidence base. There are also recommendations for strengthening the PPI evidence base more broadly, as part of developing the quality of reporting. The rationale for each recommendation is presented alongside the recommendation, which is underlined. Some researchers may consider reporting their PPI activities as separate methods papers, which would allow this evidence base to develop in the detail required. Specific guidelines for papers reporting impact are provided in chapter 6 to guide future reporting.

Recommendation 1 – Searching for and locating studies of PPI impact

a) It is difficult to search for and locate studies which report PPI impact. The keyword 'PPI impact' or a derivation is rarely used as a keyword in papers. When studies have attempted to capture or measure PPI impact, they should include 'impact' as one of the key words listed in the paper to enable easier location of relevant studies.
b) Databases are not consistent in their indexing of studies relating to PPI, PPI definitions, conceptualisation, theory, impact or outcomes which poses many challenges for developing search strategies that aim to locate these papers. Databases also vary in the search terms they utilise, which means that search strategies need to vary according to the database, increasing the complexity of searching and the potential for error. It is important in reviewing their indexing terms, health and social care research database managers need to consider developing MESH terms on PPI and 'PPI impact' and derivations, to help develop more sensitive ways of searching.
c) Even when a potentially relevant paper is located, the first appraisal for relevance in a systematic review, using only the abstract, can be difficult because impact information is not always reported in the abstract as a key result, which means the whole paper needs to be read, significantly increasing the time required to locate relevant papers and extending the time required for a systematic review. Researchers need to include key impact information in

the abstract as part of the results section, to ensure that relevant papers are easier to identify and include in future reviews.

d) Editors need to consider working with those responsible for the indexing of studies in research databases, to agree consistent approaches for PPI search terms.

Recommendation 2 - Definitions

a) Relatively few studies attempt to define PPI or link a definition to other studies. This hinders understanding of how PPI is regarded or operationalised within a particular study. It would be helpful if studies provided a definition of PPI and linked this to other definitions to enable similarities and differences with other study definitions to be identified and discussed, comment on how effectively it has been operationalised and make suggestions for how future studies should define PPI, and so contribute to a more connected body of evidence.

Recommendation 3 - Conceptualisation and theoretical underpinnings

a) Studies do not always provide a clear account of the way they are conceptualising PPI or whether they are utilising any theoretical influence. Clarity in theoretical influence will allow the reader to judge the way in which a study has been framed and the way it has approached impact. Studies need to clearly report whether they are utilising any conceptual or theoretical thinking and to provide adequate detail and rationale.

b) Studies do not often describe how their results contribute to conceptual or theoretical understanding of PPI. Studies need to report how their findings contribute to broader theoretical thinking, for example, how their study builds on others, to enable a more coherent theoretical body of work to emerge.

c) There is very little development of explanatory conceptual or theoretical models to guide capture or measurement of impact. An explanatory model of a concept can be tested, refined and ultimately provide a blueprint for developing instruments that measure impact or change. Studies need to clearly report any conceptual or theoretical modelling and testing, to inform future attempts to develop instruments which capture or measure impact.

Recommendation 4 - Context

a) Studies tend not to report the level of detail required to assess the context underpinning PPI activity. Those reading a study need to assess whether the appropriate contextual factors are in place for involvement to work e.g. funding, policy, attitude, knowledge of PPI, effective communication (to manage conflict and avoid isolation), organisational 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.
b) Studies also need to comment on the way in which they believe any of the contextual factors identified in their study have enabled or hindered PPI activity, impact and outcomes.

Recommendation 5 – Process or method of PPI

a) Studies do not always report sufficient detail about the process of involvement to enable a full understanding of PPI activity. In addition to the methods studies might routinely report as part of research, they also need to report detailed information about the PPI process and method. This would enable the quality and appropriateness of PPI activity to be judged. It may be appropriate for the process and methods information to be published separately, but as a linked paper to the main results paper. The process and methods information needs to consider the following elements as a minimum level of detail:

- A clear description of all involvement activity
- The aims of the PPI in the study
- A description of participants, both users and researchers
- What level of PPI was utilised (consultation, collaboration, user-led)
- Whether PPI occurred at one stage or multiple stages of research
- A detailed description of PPI at each of the research stages including developing aims, selecting methods, data collection, data analysis, writing and dissemination
- What research design was used e.g. focus group, interviews, and diaries.

b) Studies need to report whether and how any process or methods related factors have enabled or hindered PPI activity, impact and outcomes.

Recommendation 6 – Impact and Outcome

a) The impacts and outcomes of PPI activity are often poorly reported, making it difficult to assess whether PPI activity has had an impact or the detailed nature of the impact. PPI is most commonly reported as a secondary outcome or a reflection, not as a primary outcomes measure. Each impact and outcome needs to be reported in adequate detail to enable an understanding of the difference PPI has made and studies need to consider including PPI as a primary outcome.

b) The impacts and outcomes of PPI need to be reported in a consistent place, ideally in an impact or outcomes section of results and included in the results part of the abstract, to enable others to easily find this data. The discussion section of a paper also needs to include some discussion of impact or outcomes, ideally in a broader discussion of context and process and their influence on impact and outcomes. Clearer, more detailed reporting of impact and outcomes will enable a better understanding of the difference PPI makes. It will also make it easier to compare impact across studies.

c) To enable an understanding of PPI impact to develop in terms of its content validity (that is, our understanding of all aspects of PPI relevant to impact), all impacts must be reported, including the impacts researchers and users consider important and also smaller less significant ones.

d) To enable a fuller understanding of the nature of PPI impact to develop, both positive and negative impacts should be reported.

e) To enable a fuller understanding of PPI impact to develop, prospective longitudinal studies are required to understand if and how impact changes over time.

f) If studies believe there is a strong relationship or association between PPI activity and a specific impact, they should report this, clearly justifying this view to enable critical reflection by others.

Recommendation 7 – Capture and measurement of impact and outcomes

a) Studies have rarely focused on the formal process by which they capture or measure the impact and outcomes of PPI. In arguing that a PPI activity has had an impact, studies should critically evaluate the adequacy of the method used to capture or measure impact.

b) There is a need to develop the methods by 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 and this poses a significant challenge for PPI in the next decade. It is important that the approach to measurement considers concepts such as validity, reliability and responsiveness to change to ensure a robust approach. This approach demands a clear conceptual understanding of PPI and ideally a theoretical model to offer a blueprint for instrument development. In addition it demands an understanding of the content or aspects of PPI that would need to be measured to ensure the content validity of any quantitative tool. There is a need for further qualitative research to identify all relevant aspects of impact as the evidence currently does not provide the level of detail required for a full understanding of all aspects of impact. Also, there would be a challenge for how such an instrument captures or measures context and process factors as part of the evaluation of impact.

Recommendation 8 – Developing critical perspectives

a) PPI is sometimes characterised as a worthwhile activity that has an inherent benefit. While this may be the case in many situations, this may have prevented the development of a more critical, reflective body of literature. 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.

Recommendation 9 - Economic evaluation

a) PPI is characterised as an area with no economic evaluation. Economic aspects are important aspects to consider in developing the ‘business case’ for PPI and methods by which to assess economic impact need to be developed.

The development of such approaches would need to be balanced with social impacts and the public good.

Recommendation 10 – PPI publishing

a) A key difficulty facing researchers and users who try to publish their studies in PPI is the limited word counts that journals impose. One way forward might be for the publication of linked papers that report findings separately from methods, to enable adequate reporting of PPI impact.
b) Currently the guidance provided by journals and editors on publishing PPI studies in peer-reviewed journals is limited. 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.

Chapter 7 PIRICOM Guidelines for reporting PPI Impact

These guidelines are for studies that have examined PPI impact as one of their aims. The aim is to encourage researchers and users to include the following information, depending on how the study was conducted, to help strengthen the quality of reporting and thus the quality of the future PPI evidence base.

Abstract:
• **Aims:** The specific aim of capturing or measuring impact of PPI must be included.
• **Results:** State that impact has been assessed and report any key impacts.
• **Keywords:** Include 'PPI' or a derivation and 'impact' as keywords.
Main body of paper:
• **Background/literature review**
• **Definition:** Provide a definition of PPI and ideally link this to definitions provided by other studies, providing a rationale for that definition.
• **Conceptualisation and theoretical development:** Provide a clear account of the way in which PPI is being conceptualised and whether the study is drawing on any conceptual or theoretical underpinnings, including any theoretical models or influences.
• **Aims:** The specific aim of capturing or measuring impact of PPI must be included.
• **Methods:** Report the detail of the PPI activity, in terms of a clear description of all involvement activity, description of participants, both users and researchers, what level of PPI was utilised (consultation, collaboration, user-led), whether PPI occurred at one stage or multiple stages of research, a detailed description of PPI at each of the relevant research stages, for example, developing aims, selecting methods, data collection, data analysis, writing and dissemination, what research design was used e.g. focus group, interviews, and diaries.
• **Capture of PPI Impact:** Report how impact has been captured, for example, when qualitative, describe this process.
• **Measurement:** Report how any quantitative assessment of impact has been made and on the robustness of this assessment, justifying this approach**.**
• **Economic appraisal:** Include any information on the economic cost or benefit of the impacts identified.
• **Analysis**: Report how users have been involved and how they influenced the analysis, interpretation and synthesis of impact data.
• **Results**:
• **Context:** Report results in a broader framework that considers the contextual factors underpinning the study. Comment on the way any contextual factors have enabled, hindered or otherwise influenced PPI activity, impact and outcomes.
• **Process:** Report results in a broader framework which considers process factors that may have affected impacts.
• **Conceptualisation/theoretical development:** Report any comments on conceptualisation of PPI, as operationalised in this study and any key messages for future studies, particularly for those who wish to utilise conceptual or theoretical models to develop instruments to measure impact.
•**Testing of conceptual or theoretical models**: This needs to be reported in extensive detail as there is so little testing.
• **Impacts and outcomes:** Report all aspects of impact and outcomes, both important impacts and more minor ones. Report both positive and negative impacts and consider the possibility that positive or negative impacts may be in the eye of the beholder and so interpretation will vary. If capture of impact is qualitative include adequate detail of the impact, its nature and any influences from or relationships with context and process factors. Also comment on how adequately qualitative data has been collected and used.
• **Measurement:** If an instrument to measure PPI impact was developed or utilised, report all aspects of instrument development and testing, including how users influenced it, how well the instrument performed, justification of content and face validity, any data on reliability, validity and responsiveness to change (in impact).
• **Economic appraisal:** Report any information on the economic cost or benefit of PPI.
Discussion and conclusions:
• **Definition:** Comment on how effectively the definition of PPI adopted in this study has been operationalised, and make any suggestions for how future studies should define PPI.
•**Conceptualisation/theoretical development:** Report how the findings contribute to a broader theoretical thinking, how their study builds on others and how future studies could utilise the conceptual information contained in this study.
• **Context and process**: Comment on the importance of context and process factors and any relationship with any aspects of impact.
• **Impact and outcomes:** Comment on the nature, content and extent of impact, and how impacts identified in this study contribute to the broader knowledge base of impact, and the relationship between specific impacts and specific context and process factors, clearly justifying this.
•**Measurement:** Comment on how adequately impact has been measured and any key limitations. Make any suggestions for future instrument development.
• **Economic appraisal:** Discuss any information on the economic cost or benefit of PPI, particularly any suggestions for future economic modelling.
• **Critical perspective:** Comment critically on the study, reflecting on the things that went well and those that did not.

User version of PIRICOM Guidelines for reporting PPI Impact

Peer-reviewed research papers form the building blocks of the PPI evidence base. Grey literature also makes an important contribution. It is important that these papers report on the impact of PPI to allow this evidence base to develop and flourish. At present the reporting of impact is not good enough, with not enough detail. The PIRICOM Guidelines attempt to guide researchers in how they report PPI in different parts of research paper. Such papers need to consider the following:

Abstract (or summary)
• **Aims:** The paper should mention that one of their aims is to understand PPI impact.
• **Results:** There needs to be a mention of the impacts, or the difference PPI has made, in the study.
• **Keywords:** (Papers include key words to help people find them more easily in the databases). Studies should included 'PPI' or something similar and 'impact' as keywords.
Main body of paper:
• **Background/literature review**
• **Definition:** It is important that studies attempt to define how they view, or think about, PPI and maybe refer to previous studies, comparing their definition with others and providing a reason why they have defined it in this way.
• **Conceptualisation and theoretical development:** Clear concepts and theories (or ways of thinking about something) can help us to develop a better understanding of PPI and so it is important that studies start to report on whether and how they have used theoretical thinking.
• **Aims:** This section should include the aim that says the study wanted to assess impact of PPI.
• **Methods:** The way in which PPI is carried out within a study needs to be reported. There needs to be information about who took part, who the participants were, what level of PPI occurred, whether PPI happened at just one point or all the way through, and what these stages were.
• **Capture of PPI Impact:** Studies need to say what approach they used to try to identify impact, for example, whether they asked people to describe it and in what detail.
• **Measurement:** If any questionnaires or number-based approaches have been used, the details need to be reported, why this approach was used and how well it worked.
• **Economic appraisal:** The economic impact of PPI needs to be reported, if any of this information was collected.
• **Analysis**: It is important that the way in which users have been involved in analysing or thinking about the data, or information from the study, is reported.
• **Results**:
• **Context:** The broader issues that underpin PPI, for example whether there is a budget, need to reported, as these can sometimes affect the impact of PPI and whether it is successful.
• **Process:** Like context, information about the process of PPI (e.g. training, support) is important as it can affect impact and studies need to say something about this..
• **Conceptualisation/theoretical development:** Studies need to report how well any theoretical thinking has worked, whether it has helped to clarify things and how future studies should try to develop our understanding of PPI impact.
•**Testing of conceptual or theoretical models**: If a study tries to test a theory this should be reported in detail as there is very little information about this.
• **Impacts and outcomes:** It is important that studies report everything they find about impact; to help us develop our understanding of what is important to different people and different situations. It is also important that this includes impacts that are positive and those that are more negative, maybe things that have not gone so well. Also, studies need to consider that the impact or outcomes of PPI can be in the eyes of the beholder and what is a positive impact for a user may be a negative impact for a researcher.
• **Measurement:** If a study tried to measure impact, the paper needs to say how well this worked and whether the information was meaningful.
• **Economic appraisal:** If a study collected any information about financial impacts of PPI this needs to be reported.
Discussion and conclusions:
• **Definition:** Studies need to say how well their definition of PPI has worked and make any suggestions for how others define it in the future.
•**Conceptualisation/theoretical development:** Studies need to talk about whether and how the theory of PPI has helped understanding, and whether and how future studies think about theories.
• **Context and process**: Studies need to talk about how things to do with context and process of PPI have affected impact, for example, whether budgets have stopped impact taking place.
• **Impact and outcomes:** Studies need to talk about what they think of the impacts they have found and how they have been affected by other things.
•**Measurement:** Studies need to talk about how well the measurement worked and how studies should do this in the future.
• **Economic appraisal:** Studies need to talk about any information they found about financial aspects of PPI.
• **Critical perspective:** Studies need to think about the things that went well and the things that did not go so well, so others can learn from this experience.

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Appendix 1: Search Strategy

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1 patient*.ab,ti. (3167756)
2 user*.ab,ti. (63935)
3 carer*.ab,ti. (4486)
4 caregiver*.ab,ti. (16663)
5 public.ab,ti. (150044)
6 citizen*.ab,ti. (7720)
7 client*.ab,ti. (26707)
8 consumer*.ab,ti. (24616)
9 Stakeholder*.ab,ti. (4811)
10 representative*.ab,ti. (67458)
11 relative*.ab,ti. (646798)
12 Famil*.ab,ti. (508766)
13 survivor*.ab,ti. (41860)
14 lay people.ab,ti. (478)
15 or/1-14 (4237335)

16 Involv*.ab,ti. (1048245)
17 Participa*.ab,ti. (347335)
18 Engag*.ab,ti. (42740)
19 Evaluat*.ab,ti. (1372007)
20 Consult*.ab,ti. (53501)
21 Partnership*.ab,ti. (11565)
22 audit.ab,ti. (14591)
23 collaboration.ab,ti. (21413)
24 consumer panel*.ab,ti. (56)
25 advisory group*.ab,ti. (605)
26 or/16-25 (2642702)

27 (skill or skills or skilled).ab,ti. (70182)
28 Knowledge.mp. or exp Knowledge/ (251055)
29 exp attitude to health/ (197703)
30 27 or 28 or 29 (454638)
31 Empower*.ab,ti. (6916)
32 experience*.ab,ti. (461505)
33 reform*.ab,ti. (26595)
34 develop*.ab,ti. (1804909)
35 Economic*.ab,ti. (92214)
36 Cost*.ab,ti. (219449)
37 Chang*.ab,ti. (1508356)
38 Reconfig*.ab,ti. (1098)
39 redesign*.ab,ti. (3572)
40 Impact*.ab,ti. (273139)
41 Outcome*.ab,ti. (484558)
42 exp "Outcome and Process Assessment (Health Care)"/ (417587)
43 effect*.ab,ti. (3205547)
44 exp Decision Making/ (80039)
45 health priorities.mp. or exp Health Priorities/ (7162)

46 policy making.mp. or exp Policy Making/ (14496)
47 decision making.ab,ti. (36030)
48 or/31-47 (6196884)

49 exp Great Britain/ (237281)
50 (GB or UK or Great Britain or United Kingdom).ab,ti. (61140)
51 (Birmingham or Leicester or Bradford or Leeds or Manchester or London or Glasgow).ab,ti. (29135)
52 (England or Scotland or Wales or Ireland).ab,ti. (42811)
53 (Coventry or West Midlands or East Midlands or Nottingham).ab,ti. (3381)
54 (Europe or Australia or Canada or Spain or Portugal or France or Germany or Switzerland or Italy or Sicily or Belgium or Denmark OF Sweden or Finland).ab,ti. (216807)
55 North America.mp. or exp North America/ (999239)
56 exp United States/ (889129)
57 or/49-56 (1459725)

58 research.ab,ti. (468081)

59 Health service.mp. or exp Health Services/ (1187988)
60 Social service.mp. (1831)
61 Health service*.mp. (250376)
62 social service*.mp. (4880)

63 57 and 26 and 15 (137469)

64 59 or 60 or 61 or 62 (1247457)
65 64 and 58 (78723)
66 63 and 65 (9089)
67 limit 66 to (english language and humans and yr="1997 - 2009") (6731) = with limits and basic research set

68 from 67 keep 1-20 (20)

Appendix 2 Quality assessment

Quality Assessment for published studies:

Please note that if papers passed the first two fielding questions, that is the paper reported a clear statement of aims, stated clear, appropriate methodology, and reported results, then the study was included, but quality assessment was reported as 'partial'.
If the papers passed the first two fielding questions and scored 7/10 or more on this quality assessment sheet, they were scored as 'adequate.'

A) Critical Appraisal Skills Programme (CASP) (Qualitative, case studies, case control studies)

Screening Questions

1. Was there a clear statement of the aims of the research?

Consider:

– what the goal of the research was

– why it is important

– its relevance

2. Is a methodology appropriate?

Consider:

– if the research seeks to interpret or illuminate the actions and/or subjective experiences of research participants

Detailed Questions

3. Was the research design appropriate to address the aims of the research?

Consider:

– if the researcher has justified the research design (e.g. have they discussed how they decided which methods to use?)

4. Was the recruitment strategy appropriate to the aims of the research?

Consider:

– if the researcher has explained how the participants were selected

– if they explained why the participants they selected were the most appropriate to provide access to the type of knowledge sought by the study

– if there are any discussions around recruitment (e.g. why some people chose not to take part)

5. Were the data collected in a way that addressed the research issue?

Consider:

– if the setting for data collection was justified

– if it is clear how data were collected (e.g. focus group, semi-structured interview etc)

– if the researcher has justified the methods chosen

– if the researcher has made the methods explicit (e.g. for interview method, is there an indication of how interviews were conducted, did they used a topic guide?)

– if methods were modified during the study. If so, has the researcher explained how and why?

– if the form of data is clear (e.g. tape recordings, video material, notes etc)

– if the researcher has discussed saturation of data

6. Has the relationship between researcher and participants been adequately considered?

Consider whether it is clear:

– if the researcher critically examined their own role, potential bias and influence during:

– formulation of research questions

– data collection, including sample recruitment and choice of location

– how the researcher responded to events during the study and whether they considered the implications of any changes in the research design

Ethical Issues

7. Have ethical issues been taken into consideration?

Consider:

– if there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained

– if the researcher has discussed issues raised by the study (e. g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)

– if approval has been sought from the ethics committee

B) Critical Appraisal Skills Programme (CASP) (Randomised control trials)

Screening Questions

1. Did the study ask a clearly-focused question?

Consider if the question is 'focused' in terms of:

– the population studied

– the intervention given

– the outcomes considered

2. Was this a randomised controlled trial (RCT) and was it appropriately so?

Consider:

– why this study was carried out as an RCT

– if this was the right research approach for the question being asked

Detailed Questions

Screening Questions

3. Did the study ask a clearly-focused question?

Consider if the question is 'focused' in terms of:

– the population studied

– the intervention given

– the outcomes considered

4. Was this a randomised controlled trial (RCT)

and was it appropriately so?

Consider:

– why this study was carried out as an RCT

– if this was the right research approach for the question being asked

Is it worth continuing?

Detailed Questions

5. Were participants appropriately allocated to intervention and control groups?

Consider:

– how participants were allocated to intervention and control groups. Was the process truly random?

– whether the method of allocation was described. Was a method used to balance the randomization, e.g. stratification?

– how the randomization schedule was generated and how a participant was allocated to a study group

– if the groups were well balanced. Are any differences between the groups at entry to the trial reported?

– if there were differences reported that might have explained any outcome(s) (confounding)

6. Were participants, staff and study personnel 'blind' to participants' study group?

Consider:

– the fact that blinding is not always possible

– if every effort was made to achieve blinding

– if you think it matters in this study

– the fact that we are looking for 'observer bias'

7. Were all of the participants who entered the trial accounted for at its conclusion?

Consider:

– if any intervention-group participants got a

control-group option or vice versa

– if all participants were followed up in each study group (was there loss-to-follow-up?)

– if all the participants' outcomes were analysed by the groups to which they were originally allocated (intention-to-treat analysis)

– what additional information would you liked to have seen to make you feel better about this

8. Were the participants in all groups followed up and data collected in the same way?

Consider:

– if, for example, they were reviewed at the same time intervals and if they received the same amount of attention from researchers and health workers. Any differences may introduce performance bias.

9. Did the study have enough participants to minimise the play of chance?

Consider:

– if there is a power calculation. This will estimate how many participants are needed to be reasonably sure of finding something important (if it really exists and for a given level of uncertainty about the final result).

10. How are the results presented and what is the main result?

Consider:

– if, for example, the results are presented as a proportion of people experiencing an outcome, such as risks, or as a measurement, such as mean or median differences, or as survival curves and hazards

– how large this size of result is and how meaningful it is

– how you would sum up the bottom-line result of the trial in one sentence

9. How precise are these results?

Consider:

– if the result is precise enough to make a decision

– if a confidence interval were reported. Would your decision about whether or not to use this intervention be the same at the upper confidence limit as at the lower confidence limit?

– if a p-value is reported where confidence intervals are unavailable

10. Were all important outcomes considered so the results can be applied?

Consider whether:

– the people included in the trail could be different from your population in ways that would produce different results

– your local setting differs much from that of the trial

– you can provide the same treatment in your setting

Consider outcomes from the point of view of the:

– individual

– policy maker and professionals

– family/carers

– wider community

Consider whether:

– any benefit reported outweighs any harm and/or cost. If this information is not reported can it be filled in from elsewhere?

– policy or practice should change as a result of the evidence contained in this trial

C) Quality assessment for grey literature – Dixon-Woods et al, 2005

Documents were rated 5 if all three questions were answered in the affirmative and 4 if one of the questions was not answered affirmatively and 3 if none of the questions were answered affirmatively.

1. Are the aims and objectives of the activity to include people affected by cancer clearly stated?
2. Do authors provide a clear account of the process by which they included people affected by cancer?
3. Do the authors display enough evidence to support their interpretation and conclusions?

Dixon-Woods M, Kirk D, Agarwal S, AnnandaleE, Arthur T, Harvey J, HSU R, Katbamna S, Olsen R, Smith L, Riley R, Sutton A. Vulnerable groups and access, to health care: a critical interpretative review. London: National Co-ordinating Centre for NHS Service

Appendix 3 – Data extraction and quality assessment

Key for data extraction

NR=Not reported

• Authors, year, country: The first author is listed, date of publication and country of publication.

• Aims: This reports the aims as described in the study.

• Methods: This reports the methods used in the study.

• Patient and public involvement: This reports the methods used for patient and public involvement in the study.

• Level: This refers to the level of PPI: 1=Consultation, 2= Collaboration, 3= User-led

• No of users: This relates to the number of users involved in the study.

• C& D refer to any discussion of conceptualisation and definition in the study

• M refers to any discussion about measurement in the study

• Impact: This reports all impacts listed in study.

• Outcomes: This reports all outcomes that have resulted from the PPI in the study.

• Limitations of study – This reports any limitations identified by the author or by the reviewer undertaking this study.

• Quality assessment – This refers to the quality assessment rating calculated according to the quality checklist utilised.

Data extraction tables for PPI in research

A: Published papers

Authors, Year, Country	**Abelson, 2007, Canada**		
Aims	To offer a framework of public involvement in technology assessment and health policy		
Methods	Review This reviews the current evidence and lessons learnt from HTAs in other countries to develop a framework for involving patient and public in HTA research. Demographics not reported		
Patient and public involvement	Patient, public and carer. Mixed population Public representation: • In developing and applying assessment criteria • In formulating assessments • Public involvement: • In setting assessment priorities • In developing and applying criteria • In formulating assessment priorities • Accountability (through answerability) • Assessment reports • Assessment methods (replicable) • Recommendations for decisions • Rationales for recommendations • Accountability through citizen engagement • Accountability (through sanction or appeals) - although should avoid if possible because creates antagonistic relationships.		
Level	**No. of users**	**C & D**	**M**
1 or 2	NR	C= √ Level of involvement D= X	NR
Impact	NR		
Outcomes	Framework of how to involve patient and public in HTA assessment research		

	See PPI above Public representation: • In setting assessment • In developing and applying assessment • In formulating assessments Public involvement: • In setting assessment priorities, can propose topics, e.g. via web or in writing • In developing and applying criteria • In formulating assessments • Accountability (through answerability) • Assessment reports • Assessment methods (replicable) • Recommendations for decisions • Rationales for recommendations • Accountability (through citizen engagement) • Accountability (through sanction or appeals)
Limitations of study	1. Author: NR 2. Reviewer Not tested or evaluated. Descriptive suggestion of framework
Quality assessment	Partial

Authors, Year, Country	**Abma, 2005, Holland**
Aims	To recruit patients from the Spinal Cord Injury Association in order to develop a list of research topics that are considered to be relevant among the stakeholder parties and to obtain a shared agreement on two or three research proposals.
Methods	Qualitative study Recruitment through Spinal Cord Injury Association (SCIA)/Society. Demographics not reported. • 4 x in-depth interviews (changed method from workshops to help with barriers to participating – see outcomes) • 2 x workshop focus groups (n=11) • 2 x storytelling workshops • 1 x meeting of Spinal Cord Injury Association • Forum for discussion on website of the SCIA Interviews and workshops were recorded and transcribed.

Patient and public involvement	To help formulate a new research agenda for spinal cord injury patients and clients.		
Level	**No. of users**	**C & D**	**M**
2	Interviews = 4 Focus groups (n=2) = 11	C=NR D=NR	NR
Impact	**Community** <u>Challenges (differences in priorities of what important to community):</u> • Mismatch of research topics derived between researchers/clinicians and Service users. The former focussed on movement; the latter focussed on quality improvement in rehabilitation ("best practices"), experiential knowledge to prevent secondary problems, on the effectiveness of standard treatments, and the socio-psychological well-being of patients and relatives. • Service users involved may not be representative of the stroke community, because of the difficulty in recruiting service users from the harder to reach groups within the stroke community (e.g. disabled, seriously ill). **Service users** <u>Benefits:</u> • Gained more open attitude to research as a result of this study • Felt listened to • Financial reward <u>Challenges:</u> • Not traditionally involved in research and distrust of what researchers trying to do. • Frustrated that research cannot solve daily problems of patients • Researchers speak a different language • Researchers often have a ready-made story why their research is relevant. • Ethical issues/sensitivities of exclusion and confidentiality. • Issues of overburden with tasks • Travel difficulties (most in wheelchairs) and work commitments of service users were barriers to participating **Research team** <u>Benefits</u>: • Awareness has grown that collaboration with clients can be relevant • Gained topics for research that were grounded in the day-to-day reality of these patients but often not accessible by researchers and clinicians • Listening to questions and concerns of client organisations improves trust and collaboration. • Use of clients as co-researchers can contact and motivate I recruitment • Financial triggers motivate researchers		

	Challenges: • Difficulty in gaining interest from members of SCIA in workshop because traditionally they were passive members (only recently changed from a foundation to an association where members could be active in issues). • Travel difficulties (most in wheelchairs) and work commitments of service users were barriers to participating. • Active members of SCIA had different priorities to non-active members, e.g. the latter suffered more from social isolation. • Difficulty in recruiting from the diverse selection of service users • Conflicting time frames between researchers and service users. • Concern over competence of patients to assist research (concern that individuals can take an objective position/more general role as spokesperson, and distance themselves from their own specific problems).
Outcomes	The following issues were put forward for the research agenda for Spinal Cord Injury: • The inflexibility of standard patterns of defaecation • The ineffectiveness of antibiotics in case of infections of the bladder • The social isolation and experiences of aloneness • The negligence of the psychosocial needs of the partner and family • The arrogant attitude of doctors and the fact that the "wisdom" of people with spinal cord injury is not acknowledged and taken seriously • The focus on activities and mobilities in rehabilitation, and short time frame, and hence inadequate anticipation of secondary problems that occur later in life, such as obesity, decubitus, bladder infections, and defaecation problems
Limitations of study	1. Authors: NR 2. Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Ali & Combe (also Ali, Roffe and Crome in Stroke, 2006; 37;865-871), 2005, UK**
Aims	To involve stroke patients and carers in the design of a study of oxygen supplementation in acute stroke.
Methods	Qualitative/ descriptive study • Three focus groups with individuals who had personal experiences of stroke and their partners or carers. • Sample from two dysphasia support groups, and one young stroke sufferers association. • Participants of the focus group were also asked to complete a questionnaire on their views on the study. • Age range 31-86 years. Mean age 64 years, 34 males, 39 females; 49 stroke patients and 24 carers.
Patient and public involvement	Stroke patients and carers • Participated in planning stages study, inputting into aims, design and proposed outcome measures

Level	No. of users	C & D	M
1	73	C=NR D=NR	NR
Impact	**Research team** <u>Benefit:</u> • Consumer involvement helped make the study more relevant to stroke population, but led to difficult scientific and ethical conflicts in protocol design.		
Outcomes	Seventy-three people attended three focus groups (n=34; 19; 20): 67% stroke patients, 33% carers; mean age 64 (range 31 to 86 years), 47% male) <u>Relevance of research:</u> • General approval by participants • Outcome measures considered relevant: communication (ability of patient to speak), mood and depression, mental function, swallowing, tiredness/sleep, and 1 to 10 score of how much the patient is back to their old self. • Consent issues (to give oxygen within 24 hours of the stroke): agreed that consent from relatives or a friend would be acceptable, as stroke patient unlikely to give fully informed consent at this stage. • "The last person capable of making the decision is the stroke patient. After I had my stroke, I lost about 18 months of my life when I was incapable of making any rational decision". • "Relatives are emotionally involved and therefore it might be better for the doctor to take the lead. Therefore the doctor gives their opinion, but gives the relatives the choice. Relatives don't know the implications of recruiting or not recruiting" • "I believe doctors are best to decide on recruitment" <u>Follow-up arrangements:</u> • Agreed with six month follow-up, and agreed acceptable to contact the GP to obtain information on the health status of the patient. • 1st focus group accepted follow-up method by postal questionnaire, interview or contact with GP. The second two groups (from dysphasia support groups) preferred personal contact (home visit) to a postal questionnaire. • 51/73 (70%) of focus group also responded to the questionnaire. The majority of respondents agreed that the oxygen supplementation study was a worthwhile study and that the suggested outcome measures were relevant. Other outcome measures suggested were movement scores (n=9), concentration (n=8), measure of intelligence (n=6), handwriting skills (n=6), sleep (n=5) tiredness and fatigue (n=5), speech (n=6), vision (n=5) and enjoyment of hobbies (n=3). Thirty-eight (75%) thought it was appropriate for the family or carer to give consent on behalf of an incompetent patient to be included in the study. Forty-seven (92%) would allow a doctor to recruit a patient into the study and seek consent later on.		

Limitations of study	• Authors: 1st focus GP known to researchers, therefore may have been bias. • The sample was younger and more socially active than average stroke patient. More frail individuals who did not have access to private transportation would not have been able to attend the meetings. • Researcher: Questionnaires sent to the sample that were involved in focus group. May have achieved greater representation if questionnaires sent to different sample of stroke patients. Questionnaire answers may have been influenced by discussions in the focus group.
Quality assessment	Adequate

Authors, Year, Country	**Andejeski et al., 2002, USA**		
Aims	To assess the involvement of breast cancer survivors as lay representatives in a scientific and technical merit review of proposals for the 1995 Department of Defence Breast Cancer Research Programme		
Methods	Pre-and post-test survey and qualitative study. • A pre-panel and post-panel survey was conducted to elicit feedback on attitudes, perceptions and beliefs towards consumer participation in scientific merit review. • Qualitative methods were used to describe the responses of consumers and scientists, to explore the significance of this interaction and to gain an understanding of the benefits and disadvantages of bringing these participants together.		
Patient and public involvement	Eighty women who have had breast cancer were involved in the scientific and technical panel to decide the research agenda. 75/80 women were white. All but one had a higher than college education.		
Level	**No. of users**	**C & D**	**M**
1	NR	C=NR D=NR	NR
Impact	**Community** <u>Benefits:</u> • Service users educate other individuals who have, are at risk of, or are interested generally in breast cancer • "Consumers can educate more people, especially those affected by breast cancer, about the complexities of the disease" • "Scientists and consumers must work together to eradicate breast cancer. The scientific knowledge and the breast cancer experience will make it happen" **Service users** <u>Benefits:</u>		

	• "It is beneficial for consumers to see what research is going on and how tax dollars are spent….It validates the importance of advocacy efforts" Limitations: • Service users opinions might not be taken seriously (views pre-panel meeting) **Researchers** Benefits: • "Consumers were able to put things about some of the studies in practical perspective for the scientists" • "consumers provided insight into major concerns of a patient and reflect their experience in dealing with disease" • "consumers should become scientists' translators to the lay advocates and political lobbying" • Service users help disseminate medical research information and knowledge gained about procedures of scientific merit review to the lay community. • "consumers were able to explain how certain procedures would affect women being tested for breast cancer from a clinical and experienced point of view" Limitations: • It will be beneficial…."if consumers as advocates are not biased in their views" • "If consumers have a specific agenda in terms of what they want, it could be problematic" • "Consumers come as lobbyist for a particular view point. Scientific reviews should be based on science, not the politics involved"
Outcomes	Results of question: Are/Were their drawbacks on to having service users on peer review panels? Pre-panel results: • Scientists: 207/389 (53.2%) said yes • Service users: 26/75 (34.7%) said yes Post-panel results: • Scientists: 84/329 (25.5%) said yes • Service users: 9/59 (15.3%) said yes Both service users and scientists had greater concerns about having consumers on the peer review panel pre-panel meeting compared to the post-panel meeting. Concerns that there may be drawbacks of having service users on the panel were greatly reduced by the post-panel meeting.
Limitations of study	Author – NR Reviewers- NR
Quality assessment	Adequate

Authors, Year, Country	Andejeski et al., 2002, USA		
Aims	To evaluate the impact of having breast cancer survivors with advocacy experience (consumers) participate as voting members of scientific review panels for proposals on breast cancer research.		
Methods	Cross-sectional study • Evaluation calculated by assigning proposal scores ranging from 5.0 (acceptable) to 1.0 (outstanding);and before (pre-panel) and after (post-panel) questionnaires • Outcome measure: proposal merit score and opinions concerning perceived benefits and drawbacks of consumer involvement. • 42 panels with 85 consumers and 638 scientists.		
Patient and public involvement	85 consumers participated in research proposal panels		
Level	**No. of users**	**C & D**	**M**
1	NR	D=NR	NR
Impact			
Outcomes	Voting patterns of consumers was similar to scientists Final proposal scores were the same as those that would have been obtained without consumer voting for 76.2%, more favourable for 15.2%of proposals, and less favourable for 8.6%of proposals. Pre-panel opinions regarding consumer involvement were generally positive. Pre-panel and post-panel opinions almost always showed that significantly greater proportions of participants had positive post-panel opinions than negative post-panel opinions. Having consumers on the review panels was reported to be both beneficial (83% and 98% for scientists and consumers, respectively) and without drawbacks (74.7% and 87.3%, respectively).		
Limitations of study	Author: NR Reviewer: Scientists sitting on the panel may have influenced the consumers, leading to high level of agreement between them.		
Quality assessment	Adequate		

Authors, Year, Country	Angell et al., 2003, USA
Aims	To evaluate a low cost community-based Workbook Journal (WBJ) developed by breast cancer survivors for improving psychosocial functioning in geographically and economically isolated women with primary breast cancer
Methods	RCT

<table>
<tr><td></td><td colspan="3">Breast cancer survivors formed a partnership with academic researchers.
RCT compared the WBJ intervention plus educational materials to educational materials alone (usual care)
68 enrolled from SNCC, 32 women referred from other rural practices. Average age was 58.6 years.17% had no education, 31% had a college degree. 19% earned less than $20,000, 22% earned more than $60,000. 52% had stage 1 disease, 46% were treated with mastectomy, 66% received radiation, 48% underwent chemotherapy. 47% lived more than 10 miles from their breast cancer treatment provider.
One rural cancer centred plus several private medical practices in seven rural counties in the Sierra Nevada Foothills in California</td></tr>
<tr><td>Patient and public involvement</td><td colspan="3">Development of WBJ
Recruitment strategy
Conducting assessments
Designing strategies to reduce rural women’s fears about participating in a clinical trial</td></tr>
<tr><td>Level</td><td>No. of users</td><td>C & D</td><td>M</td></tr>
<tr><td>3</td><td>4
(98 took part in study)</td><td>C=NR
D=NR</td><td>NR</td></tr>
<tr><td>Impact</td><td colspan="3">Community
<u>Benefits</u>:
Community-research partnerships bridge between community experience and academic knowledge, improving their ability to develop interventions that are more effective for more people.
Research team
<u>Benefits:</u>
Attribute the success of the participant-focussed recruitment model to four factors: 1) integrating insights and experience from community partners into the model; 2) allowing and budgeting for several interpersonal contacts between recruiters and potential participants; 3) the high skill level of the community recruiters; 4) the endorsement of the study by the community.
Community recruiter enthusiasm, combined with education and supervision, can reduce tension in the recruitment process, and lead to excellent recruitment and retention rates.</td></tr>
<tr><td>Outcomes</td><td colspan="3">Research
Three significant results reported:
Women treated in rural practices reported decreased fighting spirit (t=-2.64, p<.01) if they did not receive the WBJ.
Women treated in rural practices reported decreased emotional venting (t=1.85, p<.07) if they received the WBJ .
Women treated in rural practices reported decreased posttraumatic stress disorder symptoms if they received the WBJ</td></tr>
</table>

	(F(6,79)=3.42, p<.01) No other significant results were reported. With those who received the WBJ, 44% (20/45) said that they were better able to cope with breast cancer. However, 53% reported no difference in their coping as a result of the WBJ.
Limitations of study	Author: NR Reviewer: a qualitative methodology might have been a better design for this study in order to report differences
Quality assessment	Adequate

Authors, Year, Country	**Beresford, 2007, UK**		
Aims	To explore the potential contribution of service user knowledge and service user research to the development of evidence-based policy and practice in health and social care. This is done in context of competing research ideologies and broader history of user involvement, and draws on the views of service users.		
Methods	Qualitative study • Review of evidence • Interviews • Demographics not reported • Discussion of a collection of evidence		
Patient and public involvement	Patients, carers and public Mixed population Reflections of user's experiences of user-led research		
Level	**No. of users**	**C & D**	**M**
1	NR	C= theory reported D=NR	NR
Impact	**Service user** <u>Benefits:</u> • Emphasised that user-led research was a positive experience: "*A lot of user-controlled research has a struggle to make things better for people's lives. But it can have a particular benefit in that it is much more positive experience for people to be involved in. It's a positive experience in that for people to have other service users with skills doing it with them on the basis that they have a sense the [the researcher] will have a belief in what they say and understand them"* • Emphasised the user-controlled research had a particular capacity to deliver empowerment to users. **Group** <u>Benefits:</u> • Emphasis is on the usefulness of user-controlled research. More likely to address relevance to service users because		

	it followed their concerns: "*User-led research can enable intervention to become effective and economically efficient. I did a study of wheelchair users and interviewed 143 consumers. Every single one of them said that there were bits of their lives that they could do if they wanted to do if they had a right wheelchair, but nobody ever asked them what they wanted to do, so they never had the right wheelchair. They couldn't get around their houses. They couldn't get to work, they couldn't look after their kids, they couldn't do their shopping. They'd been given wheelchairs that fitted the medical criteria and clinical judgement but nobody actually asked the consumer what they wanted to do and where they wanted to go".* • More inclusive approach to research that encourages more diverse involvement: "*User research is a way of advocating on a wider scale. I can go along to a meeting and talk about my problems and they can just say that is my individual experience. But if I go and research it thoroughly and come up with some findings, then they have to listen…"* **Organisation** <u>Benefits:</u> • Participants highlighted how user-controlled research had already opened up new areas for development, such as the NHS adopting alternative and complementary approaches to health in light of evidence provided by service users: "*…user-controlled research is working from the inside and going out, whereas most research is people looking at something from the outside and going in, so the perspective is very different in user-led research because it starts from the inside*"
Outcomes	• Problems of measuring user-involvement because user involvement research is unlikely to be amenable to the production of neutral and agreed findings. The issues it raises are philosophical, moral and methodological, rather than technical and objective (essentially value-based). • User-led research creates knowledge in areas that have been overlooked and engages a wider range of user-perspectives. Service users can fill gaps that may be left by other research approaches. • Difficulties of user-led research (from Involve report):continued dominance of medicalised research, the perception of user research as inherently biased, and ongoing difficulties that it faces in securing funding, e.g. from Nature (2004), which ran a discussion entitled 'Necessity or nuisance? The role of non-researchers in research'.
Limitations of study	1. Review does not include the perspectives of all interested stakeholders. 2. Review of evidence not systematic?
Quality assessment	Difficult to assess as not systematic review – good overview of evidence

Authors, Year, Country	**Burhansstipanov, 2005, USA**		
Aims	To identify the National American Cancer survivors quality of life research priorities.		
Methods	Qualitative study Data about Quality of Life (QOL) research priorities was collected from the following: • Meeting notes with cancer survivors participating as a working group to develop QOL education modules (n=12); • Video tape/and or notes collected documenting what was being said and by whom at the 1st National Native American Cancer Survivors'/ Thrivers' Conference (n=90). • Findings of the National Native American Cancer Survivors' Support Network QOL survey (n=380). Criteria for including QOL research priorities: • Issues raised eight or more times • Issues clarified how QOL was affected Issue a common area of concern, even though not directly affecting QOL (e.g. survivor worried family were at greater risk of developing cancer.		
Patient and public involvement	Service users were used to set research priorities around QOL of survivors of cancer		
Level	**No. of users**	**C & D**	**M**
2	482	C=NR D=NR	NR
Impact	NR		
Outcomes	• How can we better deal with Cancer Pain in Indian Country? o Make pain medication more accessible: e.g. often pain medication is not available in Indian pharmacies. Often the Indians have to travel long distances, which is not possible when ill or often too expensive for them. • How can Pain Assessment tools be improved to be culturally acceptable and accurate? o Smiley-face scales not seen as culturally acceptable ("I'm in pain, not sad") • Worries of taking too much pain medication (addiction more common in native Americans) o Methods of asking about pain and assessing levels of pain need to be modified e.g. instead of asking, "Do you have pain? Ask "How does your pain change your daily life?" • What is the impact of Cancer on the individual who is a Diabetic? o Sites where cancer care is provided are typically long distances from those that provide diabetic care o Service users need help in managing cancer and diabetes concurrently. • How does integration of traditional/spiritual healing with western medicine affect healing and QOL? o Spiritual healing helped Native Americans to continue doing daily activities without bitterness and anger and with a constructive attitude toward their recovery.		

	○ Questions reported included: How does spiritual healing affect the body's immune system? How does participation in traditional Indian medicine affect medication effects? Can spiritual healing increase the efficacy of the cancer medication? What impact does spiritual healing have on long-term fatigue? How can the impact o spirituality on QOL be measured? • What type of local, Regional, and National resources can improve the quality of care of the cancer patient? ○ Access to state of the art treatment and medication; provision of local advocates who could assist cancer patients to navigate the local health care system as well as help communicate with cancer therapeutic providers; local Native-specific cancer survivor support programmes; Local easy to understand information, QOL long-term care; culturally appropriate palliative care; QOL programmes that integrate western medical care with traditional Indian medicine and spirituality • What kind of training support are needed to reduce the "burnout" and improve QOL of caregivers? ○ Service users reported that cultural practices resulted in carers feeling uncomfortable in asking for help, and therefore more at risk of burnout. Often the poverty further exacerbates the suffering. Therefore training and support resources are needed for the family caregivers. • How can culturally respectful palliative care be provided to reduce unnecessary distress of the dying patient and loved ones of the cancer patient? ○ Native Americans did not want to die in hospital. They wanted Westernised home palliative care with pain medication, but with Native American 'preparation for death' ceremonies, Indian medicines, and spirituality (e.g. drumming, sacred passing tribal practices). Often the patient passed at home without pain medication or palliative care because of the distance to obtain these services. • What behaviours or Environmental Exposures Have resulted in elevated numbers of cancer diagnoses with native families? ○ Native American communities were concerned of raised risk of cancer in their communities and wanted research to investigate the cause of this (e.g. raised environmental contaminants? Carcinogens in abundance in selected fish eaten in the community? ○ Although this is not directly QOL, it affects the mental health of the service users. • What are the long-term side effects of cancer and cancer treatments? ○ Native American wanted to know which symptoms they were suffering was due to cancer treatment (e.g. long-term fatigue and weakness, lack of sexual interest, memory problems). ○ Health providers had not provided them with this information.
Limitations of study	1. Authors: NR 2. Reviewer: Lack of formal data collection (e.g. interviews and focus group
Quality assessment	Partial

Authors, Year, Country	**Burrus B, Liburd L, Burroughs A, 1998, USA**
Aims	• To assess community interest and willingness to give support to issues associated with preventing and mitigating

<table>
<tr><td></td><td colspan="3">adverse health affects associate with diabetes

• To field test survey methods, to determine their acceptability to community

• To assess the race-specific prevalence of diagnosed and undiagnosed diabetes and its behavioural risk factors in the general community by race.</td></tr>
<tr><td>Methods</td><td colspan="3">Qualitative study

• Hire community organiser who is community champion (accepted and respected in community) to provide ‘entry’ into the community
• Recruitment of community to community advisory board (CAB)
• Interviews conducted to achieve diverse group in CAB. At interviews, community members were asked to recommend other possible members (snow-balling effect).
• Recruitment of community members to Pilot study</td></tr>
<tr><td>Patient and public involvement</td><td colspan="3">• Created name for study (DIRECT – Diabetes Interventions Reaching and Educating Communities Together)
• Input to promotional brochure for study (e.g. development, layout, literacy level, agreed to have their names on the back of the brochure to show their commitment to the study)
• Helped raise awareness through mass brochure distributions, presentations, mass media coverage (radio, newspaper, television)
• Taught interviewers cultural sensitivities.</td></tr>
<tr><td>Level</td><td>No. of users</td><td>C & D</td><td>M</td></tr>
<tr><td>2</td><td>25
CAB members</td><td>C=NR
D=NR</td><td>NR</td></tr>
<tr><td>Impact</td><td colspan="3">Community
<u>Benefits:</u>
• Community mobilisation activities resulted in high response rate and commitment from CAB for subsequent activities associated with Project DIRECT
• Successfully built a strong community coalition interested in confronting the problems of the community that were associated with diabetes
• Community and researchers had a better understanding and appreciate the goals and objectives of the other.
• Trust developed by different groups listening and responding to each other.
• Distribution of resource list and sources of care from researchers lead to greater awareness of diabetes
• Viewed the study as having positive benefits for participants with non-normal biological measures, because these individuals were receiving screening which they may not have got without participating in the study.</td></tr>
</table>

	Service users (CAB members): Benefits: • Viewed themselves as guardians to the community (ensure research was giving back to community) • Gained knowledge about diabetes through training given at each meeting **Research team** Benefits: • Gained invaluable cultural perspectives of diabetes e.g. diabetes concealed because of social stigma, which helped in development of survey protocol • Achieved a greater response rate to study • Gained greater trust and credibility of community through CAB • Distrustful rumours were dispelled
Outcomes	• 77% response rate (household survey and comprehensive medical). • 72% (72/315) had heard about the study through other sources other than the lead letter (which authors report reflect success of CAB activities.
Limitations of study	1. Authors – NR 2. Reviewer: - NR
Quality assessment	Adequate

Authors, Year, Country	**Caron-Flinterman, 2005, Netherlands**
Aims	To investigate the usefulness or practical value of the experiential knowledge of patients with respect to its (potential) beneficial contribution to the relevance, quality, or content of biomedical research.
Methods	Review of evidence and qualitative Extensive literature and internet search was conducted to identify cases of patient involvement in biomedical research. • 42 in-depth interviews with patients and patient representatives (n=16), biomedical scientists (n=7), other research professionals (researchers, funding bodies, research councils). Demographics not reported. • Interviews identified 21 cases of patient involvement in studies, and after further interviewing, nine were reported as clear cases of patient experiential knowledge in biomedical research processes. Results are based on these **nine** cases.
Patient and public	• Concerning new research priorities or new research topics.

involvement	• Ideas on etiological or therapeutic aspects of diseases or symptoms • Relevance of research priorities or projects		
Level	**No. of users**	**C & D**	**M**
1, 2	NR (but 16 interviewed about research)	C=NR D=NR	NR
Impact	NR		
Outcomes	Research input: • To formulate prioritisation criteria for part of an integral programme for research into chronic illnesses. • Decide on research priorities for the programme of quality research on dementia • Influenced priorities in national research programme on pain • Questions from patients with neuromuscular diseases about severe fatigue led to a new research project on central and peripheral aspects of muscular fatigue. • Kidney disorder patients reports 'restless legs' and insomnia; lead to a research proposal on this topic, • Patients with Addison's disease complained of having to get up in the night to take their medicine, which was to be taken every few hours. This lead to a study about a new delayed release hydrocortisone tablet. Ideas from individuals: • Mother whose daughter had adenocarcinoma of the vagina suggested to the doctor that this might be because the mother took diethylstilboestrol during her pregnancy. This lead to a systematic review of this, and she was proved right. • A woman with Crohn's disease who took metronidazole for a vaginal infection commented on the improvement in their bowel disease too. A study on this proved her correct, and is now used to treat inflammatory bowel diseases. • Hyperactive Children's Support Group hypothesised that hyperactivity in children could be due to a deficiency in essential fatty acids. This hypothesis has received a lot of support to date.		
Limitations of study	Author. NR Reviewer-small sample, therefore could not representative of population.		
Quality assessment	Partial		

Authors, Year, Country	**Caron-Flinterman et al., 2005, Netherlands**
Aims	To assess the ability of asthma and chronic obstructive pulmonary disease (COPD) patients to prioritise research in a well argued way
Methods	Qualitative and cross-sectional

<table>
<tr><td></td><td colspan="3">Seven focus groups (n=61) to explore entire breadth of patients' problems experienced in relation to their diseases.
42 female, 19 male. Mostly over the age of 30 years. Asthma (n=28), COPD (n=18), Asthma & COPD (n=10), patient relatives (n=5).
Questionnaire (n=244/1042, 23.4%) aimed to investigate the prioritisation by patients of possible research targets focussed on solving these problems.
All age groups, mainly over 30 years. 40% had asthma, 40% had COPD, 10% had both, 10% were relatives. Sept 2003 – Feb 2004</td></tr>
<tr><td>Patient and public involvement</td><td colspan="3">Involved in prioritising the research topics for COPD, in order to set the research agenda in this area</td></tr>
<tr><td>Level</td><td>No. of users</td><td>C & D</td><td>M</td></tr>
<tr><td>1</td><td>61 in seven focus groups
244/1042 questionnaires</td><td>D=NR</td><td>NR</td></tr>
<tr><td>Impact</td><td colspan="3">Community
<u>Benefits:</u>
Success at setting research agenda for COPD, led to prioritising some research topics that are not covered by the current Dutch research programmes (e.g. co-morbidity, side-effects of medication, and mutual effects of medication), therefore PPI broadened the research agenda beyond that set by health professionals.
Service users
<u>Benefits:</u>
Considered their research agenda setting to be relevant
Prepared to be involved in future consultations
Most preferred questionnaire, while ¼ of respondents were willing to be interviewed or to participate in workshops or committees as well
Research team
<u>Benefits:</u>
Focus groups were good for identifying topics
Questionnaire was good for prioritising topics
<u>Challenges</u>:
In focus groups, patients will influence each other, easily resulting in potential (unintentional) over-emphasising of a particular problems (questionnaires may overcome this issues)</td></tr>
<tr><td>Outcomes</td><td colspan="3">Success at setting research agenda for COPD, with topics that would have been missed from the agenda if users had not been involved in the process.</td></tr>
</table>

Limitations of study	Author : NR Reviewer: Low response rate to survey; could have led to a biased sample of responders.
Quality assessment	Adequate

Authors, Year, Country	**Cashman et al., 2008, USA**		
Aims	• To assess the benefits and challenges of engaging service users in data analysis, interpretation, or both. • To develop tribal capacity to address their own health issues and increase detection of breast and cervical cancer to reduce disparities in cancer mortality rates.		
Methods	Case study • Four cases studies of community-based participatory research		
Patient and public involvement			
Level	**No. of users**	**C & D**	**M**
1, 2	NR	D=NR	NR
Impact	<u>Research:</u> <u>Benefits</u> • University researchers changed the wording of the questionnaire, as the instrument used too much professional jargon • Service users helped analyse the data • Helped understand broader context in community which helped with analysis Service users: Benefits • Able to enhance their own understanding of issues in the community		
Outcomes	<u>Building public health infrastructure and assessing capacity in a tribal community:</u> • The community developed a diverse committee of providers and community members from different professionals. • Had four meetings stretched over a two-month period. One meeting changed wording of questionnaires, which service users said were too full of professional jargon. • Service users were involved in the analysis of the data. This was by producing bar graphs of priority scores, and a summary of the strengths and challenges of the data in a all day meeting. Immediate action taken: develop a culturally appropriate video on breast and cervical cancer. <u>Developing the East Side Village Health Worker Partnership:</u>		

	• Steering group set up which included six community organisations and 6 health representatives. • Steering committee conducted random sample survey in community to assess community needs and assets to guide interventions, and test a stress process model that links to stressors and protective factors enduring health outcomes in Detroit's east side. • Benefits included users having a deeper understanding of context in community which helped in the design and analysis of data. Improving Latino men's health: • Focus group study to explore social-cultural determinants of sexual risk among non-english speaking Latino men living in N Carolina, and identify approaches that would be context sensitive and gender relevant. • Participatory data analysis and interpretation of findings • Helped in receipt of funding for health promotion schemes in this population. Tackling environmental health issues in an urban community (Brooklyn, New York) • Community mapping project – by walking through neighbourhood with city's department of environment protection agency and mapped pollution emissions. • 200 residents attended a Radiac hearing • The community mapping efforts helped activists in Brooklyn to convince the EPA to pilot its first community-based exposure project in the neighbourhood.
Limitations of study	Author: NR Reviewer: description of events rather than using formal methods.
Quality assessment	Partial

Authors, Year, Country	**Chambers et al., 2004, UK**
Aims	To investigate if publishing in international general medical journals had actively involved consumers in their research and the extent to which authors perceived that they had done so. <u>Definition of consumer involvement</u>: • Consumers were involved at any or all stage of the research process(setting research agenda, commissioning research, undertaking research, interpreting research, and disseminating the results of research)
Methods	Two researchers independently identified the extent to which there was consumer involvement in the research process in 200

<table>
<tr><td></td><td colspan="3">published papers, which were randomly selected from four international journals: British Journal of General Practice, BMJ, The Lancet, and the N Engl J Med.

Corresponding authors of the published research were contacted and sent a questionnaire to establish the extent to which they perceived they had involved consumers in their studies.

200 papers selected between Jan – Sept 2000, original research of over 2000. Not SR, MA, or case reports.</td></tr>
<tr><td>Patient and public involvement</td><td colspan="3">Extent of consumer involvement:
Two studies used consumers to set priorities for health services through needs assessment and other activities (reviewing questionnaire and research design).
One study used consumers at the commissioning, funding or reviewing proposals stage ‘patient advocate’.
Two studies used consumers in the data collection stage
One study used consumers to monitor or audit existing health services.</td></tr>
<tr><td>Level</td><td>No. of users</td><td>C & D</td><td>M</td></tr>
<tr><td>1</td><td>NR</td><td>D=NR</td><td>NR</td></tr>
<tr><td>Impact</td><td colspan="3">Research team
Benefits:
Increased response rate from subjects (6)
Help in design (4)
Additional funding (4)
Another perspective to research study (3)
Identified problem for research (3)
Influence of Government to take research findings seriously (2)
Influence on media campaign (2)
Conveying information (1)
Challenges
Reasons for consumer involvement not being reported: Word limits of journal paper
Information was not perceived as important
Study was written up and published before consumers involved in the dissemination of the results.
Service users
Challenges:
The majority of service users did not believe that consumer involvement had influenced the outcome of their study.</td></tr>
<tr><td>Outcomes</td><td colspan="3">Consumer involvement was reported as being integral to the research undertaken in 6/200 original published papers (2 in BJGP, 2 in BMJ, 1 in Lancet, 1 in N Engl J Med).</td></tr>
</table>

	• 66% (132/200) responded to the survey questionnaire • 41% (54/132) reported that they had involved consumers in their research. • 72% (39/54) thought that consumer involvement was beneficial. Misunderstanding of consumer involvement was reported by 26 respondents (e.g. research question to elderly people, featured in mass media). <u>Challenges</u>: • Only four journals – might not be representative of all paper published. • Papers published in specialist journals might involve consumers more (and report it)
Limitations of study	1. Authors: NR 2. Reviewers: NR
Quality assessment	

Authors, Year, Country	**Clark et al., 2004, UK**		
Aims	• To describe the experience of involving mental health service users in research on adult mental health services. • To describe the benefits and limitation of user involvement in the research process.		
Methods	Qualitative study: observation and descriptive reflection		
Patient and public involvement	• Collaboration between university departments with SURE search (a body of mental health service users who conduct user-controlled research) • Interview for funding after bid was short-listed • Expert panel • Defining initial search terms • Member of research team to assist in identifying themes, reading literature and producing report • Inclusion of anecdotal literature from service users • Critical commentaries in report by individual service users to provide individual response to our findings • Active involvement at launch conference		
Level	**No. of users**	**C & D**	**M**
2	3 plus SURE search and	C=NR	NR

	user anecdotal literature.	D=NR	
Impact	**Community** Benefits: • More effective partnerships of care/better working relationships between service users, carers and professionals. • Better targeted services based on identified needs • More likelihood of service users complying to treatment and care plans **Service users** Benefits: • Feeling empowered, confident, and valued, thereby feeling more in control and so enhancing the quality of their lives • Opportunity to interact with other people in the context of their work • Resurrect skill which appeared to be lost from some many years of concentrating on recovery from mental breakdown • Acquire new skills • Apply knowledge and experience of mental health issues • Earn money **Research team** Benefits: • Better understanding of the effects of disability or illness on service users and their families. • Critical light being thrown on the effectiveness of particular interventions. • Ensured that emerging themes and trends were interpreted not merely from an academic or professional perspective, but from a wide range of perspectives. This is particularly important in narrative reviews, which are more subjective. • Challenge own assumptions and consider how users think and feel in mental health services. • On-going collaboration in future projects. Challenges: • Only recruited one service user. • Service user researcher had to carry out a large amount of reviewing work, with little experience in this area, and little back-up help. This resulted in the service user becoming unwell and taking time out from the study. • Guilt at not providing more support to service user researcher. • Difficulty in providing payment that recognised their expertise and knowledge, but without affecting their incapacity benefits • Lack of understanding led to people not understanding that people could be involved in working on a research project while still recovering from mental illness.		
Outcomes			

Limitations of study	1. Authors: not sufficient support given to service users. 2. Reviewer:NR
Quality assessment	Adequate

Authors, Year, Country	**Cohen, 1999, USA**		
Aims	• To identify the five most and the five least important research topics fro staff and clients of homelessness services. • To compare the difference between research preferences of staff and clients.		
Methods	Cross-sectional: a 15 item questionnaire requested the five most important and the five least important research topics. • Completed by 87/92 homeless veterans and staff of the homeless services. • Characteristics of homeless veterans: mean age = 41 years, 74% were African-American, 10% were Caucasian, 10% Latino, and 6% other. Their principle diagnosis were substance abuse (62%), mood disorder (18%), post-traumatic stress disorder (13%), schizophrenia (11%), and dual diagnosis (42%)		
Patient and public involvement	NR		
Level	**No. of users**	**C & D**	**M**
1	87	C=NR D=NR	NR
Impact	NR		
Outcomes	Most important research topics: • There were significant differences between the homeless clients and the staff the following items: • Clients were significantly more likely than staff to be interested in research into how funds for homeless are used (49.4 vs. 17.9; $\chi 2$: 8.68, $p<0.01$) • Clients were significantly more likely than staff to be interested in research into whether the homeless programmes help veterans to obtain benefits (52.9 vs. 17.9; $\chi 2$: 10.52, $p<0.001$) • Clients were significantly more likely than staff to be interested in research into whether the homeless programme help clients to obtain employment (44.8 vs. 17.9; $\chi 2$:6.52, $p<0.01$) • Staff were significantly more likely than clients to be interested in research if programmes helped veterans to stay clean and sober (40.2 vs. 64.3; $\chi 2$:4.93, $p<0.05$)		
Limitations of study	Author: NR Reviewer: Questionnaire designed by researchers, users not involved		
Quality assessment	Adequate		

Authors, Year, Country	**Collins, 2005, UK**

Aims	To describe the development of consumer panels to become an integral part of the cancer research community, using framework principles described by Telford, Boote and Cooper 2004		
Methods	Case study: descriptive experiences of developing consumer panel using framework		
Patient and public involvement			
Level	**No. of users**	**C & D**	**M**
1	NR	NR	NR
Impact	**Service users** <u>Benefits (after mechanisms put in place):</u> • Training given in research , medical terminology, and structure/role of consumer panel • Support • Mentoring of new members • Role descriptions given on onset • Feel welcomed • Feel a valued member of the team • Able to give something back • Able to make a difference <u>Challenges (initially):</u> • Concerned not able to contribute anything significant to research • Concerned their role would be tokenistic **Researchers** <u>Benefits (after mechanisms put in place):</u> • Clarifying role of the consumer helped dispel the suspicion that they had regarding consumers' perceived agendas • Effective communication to build up trust <u>Limitations (initially):</u> • Concerned service users would have their own agendas		
Outcomes	<u>Principle 1:</u> • Roles of consumers to be agreed between researchers and consumers involved in the research. • Reported that effective communication between parties is vital, as it leads to an environment of trust, mutual respect, and understanding, and helps minimise some of the challenges to consumer involvement in health research. • At the outset both groups were wary of working together, with neither sure of each others roles and responsibilities,		

	or of the skills, expertise and understanding required to successfully establish consumer involvement in the research process. Mechanisms were put in place e.g. provision of support and training, mentoring of new members, and role description for consumers. • Consumers were carefully recruited to the panel Principle 2: • Researcher budget appropriately for the cost of consumer involvement: £7 per hour (max. £50 a day). For this they budgeted £5000 to £11,000 a year. Principle 3: • Researchers respect the differing skills, knowledge and experience of the consumers. T • he study found that the language used in a committee or research project can act as a barrier to effective communication. This can be overcome by sensitive translations of medical terms into non-specialist language. • Also, health professionals/researchers clarify the unique role that consumers have and the unique perspective they bring to research. Principle 4: • Consumers are offered training and personal support to enable them to be involved in research. • From inception, all new members to the panel attend a two-day induction research training programme, which covered: introduction to consumer involvement, an overview of the role of the panel, a basic grounding in research methodology (quantitative and qualitative), terminology, and examples of funded research where consumers have been actively involved. Principle 5: • Researcher have the necessary skills to involved consumers: members of the consumer panel work alongside cancer and palliative care research teams, health professionals and professional bodies to provide the user perspective at all stage of the research projects. Principle 6. • Consumers are involved in decisions about how participants are both recruited and kept informed about the progress of research, e.g. in a study 'patient and professionals factors influencing choice of surgery. • Two panel members made modifications to why patients recruited, and collaborated on the design of patient information sheets, interview schedules, questionnaires, and was involved in the analysis of the data. Principle 7: • Consumer involvement is described in the research reports: consumers have been involved in presenting at local, regional and national conferences, involved in analysis and in dissemination of data.

	Principle 8: • Research funding is available to consumers in formats and language that they can understand. • Panel members have been involved in editing and review of reports, been co-authors on paper publications, set up their own website, and have launched their own newsletter.
Limitations of study	Authors: NR Reviewer: not formal methods used to record data
Quality assessment	Partial

Authors, Year, Country	**Cornes et al., 2008, UK**		
Aims	To explore the involvement of older people in research and inspection, reflecting on the learning from the recent 'joint review' of the National Service Framework for Older People		
Methods	One day seminar to report the reflections of a team of older people who had undertaken training in research methods in later life. • Research: 160 interviews in ten health and social service regions conducted by the Health commission. • Seven lay researchers and six university researchers • Standard approach to publicity and joint working within local voluntary and community groups. • Interviews and focus groups conducted by Older People Researching Social Issues (OPRSI) group.		
Patient and public involvement	Qualitative study • Retired people (OPRSI) were trained in research methodology, and conducted the interviews and focus groups. • Demographics not reported. • Reflections from these older researchers in undertaking the research was ascertained via a day long seminar which was tape recorded and transcribed.		
Level	**No. of users**	**C & D**	**M**
2	7	C=NR D=NR	NR
Impact	**Service user**s Benefits: • Opportunity to work alongside experienced professionals. • More challenging and interesting work than use to in OPRSI, which gave the older researchers the chance to develop.		

	• Helped the OPRSI develop as a team • Payment of consultancy fees Challenges: • Need for clearer lines of accountability • Need for equal opportunities for individual appraisal, support, and personal and professional development as with the university researchers • Intensive review weeks (where researchers interviewed and conducted focus groups) were very demanding for the older researchers (too demanding for retired people). • Tension between contract (project) team and the service users arose when the latter raised concerns about the workload after the contract had been signed (i.e. when not negotiable). This was due to lack of contract knowledge in lay researchers. • Inspection and review weeks took place at different times so older researchers were not able to make a direct contribution or able to see how their findings were being used. They therefore felt their role was tokenistic, and they felt like a "junior partner" to other team members. **Research team** Benefits: • Encourages diversity in the workforce Challenges: • Boundaries between older lay researchers and experienced researchers blurred over the lifetime of the project, so lay researchers became more 'professionalised'. • Some events were poorly attended, while others had too many people • Issues of accessibility of venues for older people. • Issues of late delivery of food and late taxis.
Outcomes	
Limitations of study	1. Authors: NR 2. Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Corneli et al., 2007, USA**
Aims	To learn the attitudes and concerns of the local community on participating in research, infant feeding practices, and maternal nutrition in order to inform the design of a clinical trial in Lilongwe, Malawi on the safety and efficacy of antiretroviral and nutrition interventions to reduce postnatal transmission in HIV
Methods	Qualitative study. • Semi-structured interviews, focus group discussions, home observations, and taste trials.

Patient and public involvement	Consultation with community via interviews, focus groups and observation.		
Level 1	**No. of users**	**C & D**	**M**
1	27 HIV positive mothers 35 Mothers of undisclosed status	C=NR D=NR	NR
Impact	**Research** Benefit: • Without this consultation with the mothers, several significant areas would have been undetected which might have jeopardised the study objectives • Helped participants to understand the research which increased the acceptance of the research.		
Outcomes	• Willingness to participate and perceived benefits: all mothers were willing to participate if they were eligible. • However, these mothers had a limited understanding of the research. They understood that the purpose of the providing antiretroviral drugs was to prevent the infants getting HIV, but few recognised the purpose of the research was to determine whether the drugs were indeed safe and efficacious for this use. They believed the medicines would prolong their lives, and that they would be able to share their medicines with their husbands who were presumed to be HIV positive. • Misunderstanding of randomisation: lead to confusion with women questioning why they would not receive the supplements that [others] have received, which seen as favouritism. They thought it would be unfair that some women would not receive antiretroviral drugs or nutritional supplements. • Concern raised by the amount of blood that would be drawn; they were concerned that the baby or the mother would fall sick if too much blood was taken. The mothers were asked to identify a suitable amount of blood quantity that would be acceptable to be drawn at each study visit, and this was changed in the protocol. • The regional culture is to share nutrition with family, no matter how small the amount. Researchers had to think of ways in which the nutritional supplement would not be shared. To do this they named the supplement 'Nutrition for Breastfeeding Mothers' to minimise the stigma associated with its use in the context of the study and to possibly reduce sharing. • To further offset supplement sharing, all families are provided with a small bag of maize from the study. The protocol was rapidly modified to achieve cultural acceptability while still maintaining the study objectives.		
Limitations of study	Author: NR Reviewer:NR		
Quality assessment	Adequate		

Authors, Year, Country	Corner et al., 2007 (also Wright 2006), UK		
Aims	To involve users in the consultation phase to identify research priorities of patients attending UK Cancer Treatment centres		
Methods	Qualitative study. • Exploratory, qualitative approach combining focus group and nominal group methodology (n=17) with the UK cancer population • Users were recruited from outpatient clinics in seven cancer centres across the UK. To obtain diversity of users, purposively selected users from frequently under researched communities, i.e. South Asian Cancer support group, over 75 year old group, and people with advanced cancer.		
Patient and public involvement	• All elements of the study were developed and designed in collaboration with users (patients, carers, and stakeholder groups). • Community representatives from under-researched sections of society were involved. • Fifteen users were co-researchers, who co-owned the study and had direct influence on all aspects of the study, including data collection, analysis, and dissemination of study findings. Co-researchers were given training. The co-researchers took on greater responsibility as they gained in confidence and expertise.		
Level	**No. of users**	**C & D**	**M**
1 & 3	15 co-researchers 105 in consultation focus groups	C=NR D=NR	NR
Impact			
Outcomes	Fifteen research themes were generated from the consultation groups. The top three priorities to cancer patients were: • Impact on life: o How to live with cancer and related support issues; psychological consequences of cancer (impact on patients and others, influence of mental attitude on recovery, and after care. o Impact on social functioning, work, and other financial impacts; pain management. o Impact on family and others; diet and other issues of managing cancer. • Risk factors and causes: environmental (e.g. electrical pylons, mobile phones, microwave, aerosols; genetic; diet; stress. Early detection and prevention – early diagnosis, detection and prevention; GP awareness, knowledge, training and other related issues; means of prevention, e.g. diet. • Other themes generated by users: o General information needs, use and effectiveness of CAM, general education of the public about cancer, research into different cancer and patient types, research on treatment, experiences of management of side effects, organisation and finding of health and social care services, co-ordination, impact and funding of		

	research, research in recurrence rates, general communication issues, accessing patients views about cancer, services and research, health and safety.
Limitations of study	Authors: NR Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Coupland H, et al., 2005, Australia**
Aims	Study aim: • To conduct a needs assessment of young injecting drug users (IDUs) (16-25), who do not access services in two areas of South Western Australia. • To build service planning, build local capacity in research practice and increase levels of consumer involvement in services Aim of Paper: • Explores the benefits and challenges associated with peer workers (PWs) and health workers (HWs) collaborating for the purposes of the research
Methods	Seventy interviews with IDUs who have injected a drug in the previous six months. • Seven focus groups (n=42). • Grounded theory approach to analysis was used. • Research Team consisted of two PWs, two – four HWs, and two university researchers. • Three PWs had personal experience of injecting drugs, one was in close contact with young new injectors. • Training given in research methods. • Fieldwork was conducted two days a week for three months. • Narratives/ 'stories' were documented – experiences of obtaining injecting equipment and accessing drug health services, and suggestions for enhancing service provision and encouraging IDUs to access local drug health services. • Field notes and narrative data were reviewed by the university researchers, who gave weekly feedback to the rest of the research team. • Seven focus groups were conducted to triangulate data and explore perceptions of broader groups of IDUs (recruited through Needle and Syringe Programmes)
Patient and public involvement	• Assisted in recruitment of study participants. • Assisted with interviews and focus groups with IDUs

Level	**No. of users**	**C & D**	**M**
2	2 PWs 2-4 HWs	C=NR D=NR	NR
Impact	**Service users (PWs)** Benefits: • Supported use of participatory approaches rather than conducting expert driven research. • Gain confidence • Empower Challenges: • Undue monitoring by HWs for 'signs of relapse' • Distrust of HW's led PWs to consult University researchers about sensitive issues, not the whole research team. • HWs tried to supervise the PWs when university researchers were not present (power struggles) **Research team** Benefits: • Built good rapport with rest of research team, particularly with PWs • PWs were able to facilitate the development of relationships between IDUs and HWs, which created a level of trust that would increase the likelihood of future service access by young IDUs • Connections of PWs aided recruitment to the study. Combining the experience knowledge of PWs with the skills and knowledge of HWs aided recruitment and fieldwork • PWs became informal peer educators, by disseminating important information regarding risk reduction and local service availability to participants. • PWs were very reliable and trustworthy, dispelling concerns. • Good quality narrative data collected. • Involvement of PWs improved the quality of the data because of access to 'hard to reach' groups Challenges: • Heavily involved in supervising the narrative data collection to ensure the team understood open-ended, explorative nature of qualitative research • Feeling a loss of control over data collection **Research team (PWs)** Benefits: • Positive experience • Gained knowledge about potential barriers to service access, and the needs of IDUs. • Opportunity to interact with IDUs outside a healthcare setting resulted in a more positive attitude towards IDUs		

	• Provided networking opportunities that were perceived as critical for relationship building with IDUs who do not access the service. • Increased self-esteem and confidence from additional skills learnt. Challenges: • Uneasy about working with PWs • Different ways of working (different perspective, priorities, assumptions, values, beliefs and language. • Concern over employment obligations to report relevant authorities if they were aware of a drug user aged less than 16 years. • Some HWs found it difficult to listen to criticisms of the service, and tired to justify the service rather than collect participants views
Outcomes	*Results of study reported elsewhere*
Limitations of study	1. Authors: NR 2. Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Dewar, 2005, UK**		
Aims	To describe developments to involve support involvement of older people through work at the Royal Bank of Scotland Centre for the Older Person's Agenda, and to identify challenges that this has raised for researchers.		
Methods	Descriptive reflection • Development of a framework of future involvement of older people in research using existing evidence and experience.		
Patient and public involvement	Not specifically described		
Level	**No. of users**	**C & D**	**M**
1, 2	35 completed programme	C=x D=√	NR
Impact	**Service users** Benefits: *From consumers:* • Developing a more critical approach • Learning confidence		

	• Learning to listen to the points of view of others • Increased awareness of social and political issues • Increased ability to confront situations • Learning that we are not alone *From evidence:* • Wanting to give something back • Having time on their hands • Wanting to make a difference. • Researcher (from evidence) Limitations: • Traditional researchers would advocate that reliable and valid knowledge is generated by 'keeping a distance', between the researcher and those being researched. • Nervous about consumers conducting research when a lot of time and money has gone into training to be an academic researcher • Older people come to a partnership working with a researcher who has a set of beliefs and values that may be against traditional notions of research and teaching
Outcomes	The core of the programme 'Education for Participation; The voices of Older People' has developed, implemented and evaluated education that enables older people to feel more confident in partnership working with researchers: • Techniques and approaches to enable older people to participate in research and development activity: • Explore values – of research and process of collaboration working to establish agreed philosophies for working together. • Establishing roles – Learning contracts and job descriptions used to negotiate and determine roles. Interview with each older person helps to establish individual learning needs and goals. • Exploring skills and knowledge of team members – to depict the skills and knowledge that each individual brings to the research project. • Capturing the process – Detailed field notes need to be kept to record input from all team members. Quotes from older people can be used as evidence to support decision-making in proposals. • Moving forward with the framework: • Formalise the role of older people who work in partnership • Education programmes for professionals on how to facilitate involvement • Further development of theory that guides involvement: existing theories do not address different types of support that are required, nor does it reflect organisational and process issues inherent in involvement (Reed 2004). • Explore the concept of 'equal but different knowledge and skills' to process of partnership. • Evaluation of both processes and outcomes of older people in carrying out research is required

	• More opportunities need to be created for sharing experiences about the process of involvement in research and development work with other groups (e.g. disable, people with mental issues, people with learning disabilities. Also further understanding of barriers to involvement • Debates with funding bodies to develop systems to enhance user involvement from the outset • Debates are required with ethics committees to recognise the empowering potential of involvement from older people.
Limitations of study	1. Author: NR 2. Reviewer:Not reported as if based on experience – descriptive only
Quality assessment	Adequate

Authors, Year, Country	**Dickson G, Green K, 2001, Canada**		
Aims	Study aim: to study older Aboriginal women's health needs and respond through health promotion programming. Aim of Paper: to report lessons learned about using participatory research involving older aboriginal women (40-70 years).		
Methods	Qualitative study • Gained trust in the community through Tuesday morning get-togethers and cultural events. • Interview and focus group with aboriginal researchers as facilitators • Participant observation and written documentation • Recorded audio tapes and video tapes of selected activities • Documenting field notes • Diary of academic researchers own impressions, ideas and feelings • Analysed using content analysis and reflection.		
Patient and public involvement	Advisory group was made up of seven aboriginal women: they assisted in all areas of research from aiding recruitment, to endorsing the technical work of researchers in designing the interview guides, consent forms, work plan, and contracts with associates. Associates were two aboriginal women trained to conduct the interviews: they verified the data through member checks, and they did secondary analysis and verified drafts of the assessment report. They also took action on some of the outcomes of the study.		
Level	**No. of users**	**C & D**	**M**
2	25	C=NR D=NR	NR
Impact	**Community**.		

	Benefits: • Growth of trust, respect, and sense of community between researchers and academics. • Made a direct link between research and community action • Better health promotion in community Challenges • Conflict within in community (ignored instead of resolved) **Service users (older aboriginals)** Benefits • Social interaction • Confidence and self-reliance • Strengthen self-worth • Awareness of issues they had not previously questioned. • Demystification of research Challenges: • Study 'owned' by health clinic and Government funders, not by the aboriginal researchers/advisory group. • Resisted being seen as problematic (changed aims from 'needs assessment' to 'health assessment' to make it sound more positive). • Individual social problems of aboriginal researchers often impacted on the data collection. • Unease at expressing their opinions, beliefs and feelings. • Unease at being asked directly about their problems **Research team** Benefits: • Aboriginal researchers added to the profile and advancement of the study, improving feasibility and value. • New knowledge was produced and disseminated. Challenges: • Research carried stigma of exploitation • Research integrated in aboriginal daily rituals and activities to make it more acceptable, resulting in a loss of visibility. • Resisting commitment by aboriginal researchers often made it difficult to access aspects of the research. • Often discomfort with speaking English lead to need to translate into and out of Cree • Time to build confidence and self reliance of aboriginal researchers (e.g. often picked them up and took them to interviews, troubleshooting on their behalf).
Outcomes	*NR*
Limitations of study	1. Authors: NR

	2. Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Dobbs L, Moore C, 2002, UK**		
Aims	To explore the benefits and barriers to encouraging consumer involvement in a range of baseline and impact surveys. The survey aimed to measure progress in relation to a range of issues including delivery planning, housing management arrangements, services for families, healthy living networks, public transport planning, and training and employment needs in the Tyneside area.		
Methods	Cross-sectional Partnerships with University of Northumbria and Regeneration Partnerships recruited, employed, trained (in research methodology and consumer issues), and supported service users to help with the design, administration and analysis stages of a survey. • The consumer research team worked closely with the advisory groups which were set up to oversee the research and to create links back to the overall partnership and wider community. • Consumer research team were able to draw on the expertise of the advisory group members, while the advisory group could ensure that research team plans met the requirements of the advisory groups. • Consumer research team liaised with the local community groups by involving individual members in the planning. • Mail shots provided the whole community with information about the surveys, kept local people informed about progress, and disseminated the results. • Particular care was taken to involve those groups perceived to be hard to reach (e.g. translation of information, special session held with disabled access) • Demographic data were not reported		
Patient and public involvement	• Community research team helped to refine the questionnaire (initially designed by academic research team). • Conducted pilot survey. • Face-to-face interviews, or methods that were sensitive to local needs (e.g. group sessions with members of the Bangladeshi community). • Data entry and involved in some of the analysis.		
Level	**No. of users**	**C & D**	**M**
2	NR	D=NR	NR
Impact	**Community**		

	Benefits: • Sense of community ownership of findings; allowed local people to begin to understand their current position and ultimately to act on issues which have a direct impact on their lives. • Resolved conflict among stakeholders (e.g. one housing survey, subsequent design took account of the needs and wishes of all stakeholders and therefore the survey provided evidence to support a middle-way between the previously polarised positions of the community organisations and the local authority) • Provide a catalyst to enhance partnership working • High level of involvement from alternative stakeholders helped overcome resistance to new ideas and it encouraged all stakeholders to look outside of previously inflexible regulatory frameworks. • Increase in the levels of commitment to community empowerment among local authority. **Service users (consumer researchers)** Benefits: • Employed as university researchers and paid established rates and terms of conditions so they felt valued employees and were committed to the projects. • Gained skills and knowledge of research and local issues • Became more employable (three months after the surveys had finished, 50% had found other employment, whereas they had all been unemployed before. Challenges: • Overt conflict between consumer research team and the local authority relating to the level of control over the research process (in one project). • Conflict over local authorities trying to limit the range of issues to be researched by the consumer research team (one project). **Research team** Benefits: • Raised awareness of projects in local communities and encouraged positive community approach to the research, ultimately encouraging local people to participate in the surveys. • Team were representative of all sections of the community and all major ethnic groups living in the target areas. • Consumer research team quickly grasped the nuances of the research process, and they conducted face to face interviews with skill, managing to draw on their training to remain impartial, give objective information and produce reliable data. • Consumer research team knowledge of the local community meant they were adept at negotiating access and at assessing the best time periods to visit particular areas. • Assisted in recruiting 'hard to reach' groups. • High response rate and good statistical validity. • Data went beyond initial requirements providing insights into issues that were identified as important by the community.

	• Credibility of research results with stakeholders. Challenges: • Bringing consumer research team and advisory groups together was crucial for the success of each project (as could discuss National frameworks and local agendas, ultimately ensuring a degree of openness in the decision-making). • Low attendance of information sessions, forced researchers to access community through shopping centres, playgroups, and community centres. • Reaching 'hard to reach' groups was time-consuming. • Involvement of consumer research team in all process of research was time-consuming.
Outcomes	NR
Limitations of study	1. Author: NR 2. Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Donovan et al., 2002, UK**		
Aims	To improve recruitment to a RCT for treatment of prostate cancer by consulting with service users and carers		
Methods	Qualitative study • In-depth semi-structured interviews with men who had had PSA testing for prostate cancer and given a positive result. • Interviews audio taped and transcribed • Thematic analysis conducted using "constant comparison" in which transcripts were scrutinised for similar themes and then examined in detail within these themes.		
Patient and public involvement	Improving information for recruitment to trial		
Level	**No. of users**	**C & D**	**M**
1	NR Check	C=NR D=NR	NR
Impact	NR		
Outcomes	**Research Results (Results of interviews)** Organisation of study information: • Treatments were presented in standard order of surgery, radiotherapy, and monitoring (watchful waiting). • Surgery and radiotherapy were described in detail, and as aggressive treatments. • Monitoring was only briefly mentioned. • The order of this information was changed so all were described equally, in the order – monitoring, radiotherapy, and		

	then surgery. Terminology used in the study information: • Patients might interpret the word 'trial' and other clinical terminology differently to intended, e.g. trial was often interpreted as monitoring (try and see); evidence of good 10 year survival ('the majority of men with prostate cancer will be alive in 10 years time') was interpreted as the suggestion that they might be dead in 10 years, so the sentence was changed to 'most men with prostate cancer live long lives even with the disease. Specification and presentation of the non-radical arm: • Watchful waiting was interpreted as no treatment, as if clinicians would 'watch while I die'. • It was therefore re-named 'active monitoring', every three - six months, repeat PSA testing, with intervention if required or requested. • Recruiters also emphasised the slow growing nature of the disease. Presentation of randomisation and clinical equipoise: • Patients often believed cancer should be removed, and relayed stories of friends or relatives who had died of advanced disease. • Researchers encouraged discussion about the differences in these stories and their own information and were genuinely uncertain about which was the best treatment.
Limitations of study	1. Author: Controversial nature of the study and the extreme differences in treatment arms might limit the generalisability of the findings to other randomised trials. 2. Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Dyer S, 2004, UK**
Aims	To examine lay members own conceptualisation of lay involvement in a local ethics committee and the contributions they are able to make in meetings as a result of these conceptualisations
Methods	• Ethnographic 'thick' descriptions. • Survey. • Observations of committee meetings • Forty-five interviews with committee members, or with representatives of the Central Office of Research Ethics Committees and those involved in LREC training. Demographics not reported. • Own information of participating on the committee for 18 months
Patient and public involvement	Involved in ethics committee making ethic approval decisions about research studies

Level	No. of users	C & D	M
1	18	C=NR D=NR	NR
Impact	**Service users (lay members of ethics committee)** Benefits: • Proud to represent community • Proud to represent patient experiences: *"…the patient might not have had access to read the protocol and question the researcher, but someone like him (sic) has."; "…lay people are there to protect patients. I think that we have an understanding of what it is like to be a patient, of what patients need and what they might be feeling when they see a doctor".* • Putting something back into the community • Relied on to gain trust between researchers and the public. Challenges: • Have less authority than other members of the ethics committee and more open to dispute from other members (compared to paediatrician, whose 'expertise' is valued more). • Seen as a civic duty • Other members are disparaging about the lay members ability to represent the community: *"No one can ever be representative of their community, can they? There are people from ethnic minorities on our committee and it is a big burden to place on one person, to say that you are going to represent all of the ethnic minorities in (town)…"* • Often viewed as an outsider – not arbiters of review but prompting experts to perform a better review. **Research team (research protocol team)** Benefits: • Checking terminology used: *"…you know if I was presented with this information I wouldn't like it. I don't like the word cancer in there. The information sheet said 'you have been chosen for this research because you might have cancer'*. And to a medical person the word cancer is not a scary word, but to a lay person it is….you'd be petrified". • Local knowledge about the area: *"this hospital is not well served by buses…on paper the extra meetings might not seem a lot. If you have a car, fine. But if patients have to travel by bus, you are asking too much".* • Provide role to report ethical uncertainty, not scientific uncertainty • Ask questions 'you need someone who doesn't know about it (the research) to ask questions. • Challenged expert view. Challenges: • No guidelines for the role of lay members on ethics committees. When we fail to address what we want the public to contribute to, we risk wasting people's time and endangering further the relationships of trust between expert and lay members.		

	• Non-democratic recruitment of lay members (most white, with degree level education) • If people sit on ethical committee for a long time (five years), they may stop looking at the protocols with fresh eyes and start becoming an 'expert'. • This conceptualisation of 'lay member' is difficult because it is difficult to define what makes someone an 'expert member'. • Having specific skills (e.g. medical background, or ethicist) doesn't make a member an expert. • Skills of reading and assessing protocols, as well as their knowledge of ethical guidelines and standard practice
Outcomes	
Limitations of study	1. Author - NR 2. Reviewer – absence of details of how analysed and reported.
Quality assessment	Partial

Authors, Year, Country	**Elliott E, Watson A, Harries U, 2002, UK**		
Aims	To explore issues relating to employment of peer interviewers through reflection of a project designed to explore the views and experiences of parents who use illegal drugs who have not used the drug service on offer (hard to reach groups).		
Methods	Exploratory, qualitative study. • Approached two local community drug teams (CDTs) who had a tradition of involving volunteers or 'user representatives' in projects. • Four 'user representative' were selected, who were capable of controlling their own addiction, and 2 of whom had proven interviewing skills. Demographics not reported. • Training provided according to individual needs. • All service users were asked to tape record the interviews. • Debriefing after interviews to provide support.		
Patient and public involvement	• Development of interview schedule • Recruiting • Conducting interviews • Assisting with initial analysis of data.		
Level	**No. of users**	**C & D**	**M**
2	4	C=NR D=NR	NR
Impact	**Service users**		

	Benefits: • Involved in all areas of research from interview design to discussion of the main themes emerging (to avoid feeling of exploitation felt in previous work with drug groups) • Payment per interview, and hourly for training. • Increasingly confident as gain more control over research. Challenges: • Even though they had control over their drug taking, being put with drug takers was always a risk to temptation. Would have appreciated peer support for this, as researchers not qualified to give them support in this area. • Would have liked regular interviewer team meetings as a forum for information sharing and problem-solving (although appreciated support of researchers in debriefing sessions) • No contract gave them more freedom away from commitment, but had no traditional employment rights or benefits. **Research team** Benefits: • Access to respondents that they could never reach otherwise. • Interviewers were from different backgrounds and geographical areas, so accessed respondents from different networks and communities. • Rapid data collection • Interviewers had a rapport and understood the nature of the encounter more than researchers did. Challenges: • Importance of investing time in developing roles of service users and in building up trust between the researchers and the interviewers. • Evidence that drug users will play down their addiction with their peers (Davies 1987) • Closeness of relationships between interviewers and respondents may constrain or influence the kind of information the interviewers are offered (McKeganey and Barnard 1996); e.g. issues of depression, suicidal feelings and domestic violence were raised in interviews conducted by the researchers with service users but not in interviews conducted by service users (although differences could be due to sex [researchers = female, service users = male] or the status of being a service user or not a service user. • Sense of distance from data by using service users to interview was a source of anxiety to researchers, particularly as most interviewees refused to be recorded, so relied on note taking of interviewers. Reported that in future they would use service users to find the participants, but interview them themselves. • Interviewers encroaching on the territory of the research team by claiming a certain expertise as fieldworkers in this domain. • Authors reported the importance of recognising boundaries that both inhabit, and the knowledge and skills they share with one another was an important issues to confront.
Outcomes	

Limitations of study	1. Authors: NR 2. Reviewers: NR
Quality assessment	Adequate

Authors, Year, Country	**Gilbert, 2004, UK**		
Aims	Structured review to explore: • The ethics and philosophy of participatory research • The methodologies employed in the process that are designed to ensure the involvement of participants in research • Building capacity in participatory research as a pre-condition to the further development of this approach		
Methods	Structured review of the evidence for the above. Electronic searches, grey literature collected from Google searches.		
Patient and public involvement	Users not involved in the structured review process.		
Level	**No. of users**	**C & D**	**M**
1, 2, 3	NR	C=√ theory based D=NR	NR
Review identifies following theoretical conceptualisation:	Conceptualisation theory discussed: normalisation theory, social model of disability, and post-modern theory all changed the research environment. • Normalisation: based on the inter-relationship between deviance and social exclusion. Difference leads to considered deviant that leads to stigmatisation and exclusion. Reducing the stigma and deviance leads to greater inclusion (reduces exclusion). • Social model of disability is linked to exclusion from employment, poverty, and social control. The aim is for structured change in the relationship between people with disability and non-disabled people. • Post-modern theory: this focuses on social experience of impairment.		
Impact			
Outcomes	Types of research methodology to user when involving the disable public: • Narrative research methodology: This recognises that the understanding of individuals with regards to their social world are fluid and ever changing. It enables the individuals to 'tell their stories'. However, the translation by researchers of a section of speech into a narrative could contaminate the story. • Case study: Is a community based approach with a commitment to participation and change, and is committed to involvement and improvement. It involves a cyclical research process. • Action research: formation of a group of people with learning disabilities with the explicit purpose of developing participatory research. • Key points about methods employed to increase accessibility of the research process		

	• Developing an understanding of what is meant by research is fundamental to involving people with learning disabilities in the research process. It is also essential to developing and maintaining consent. • Group processes have been fundamental in success, i.e. free of jargon, produces agenda, and provides information in easy to understand format. • Non-disabled supporters to encourage participation through improving practicalities of being involved in research process. • Final reports to be in different, lay formats, ensuring that the rigour of the research is maintained.
Limitations of study	Author: NR Reviewer: Theoretical discussion, not direct reporting of literature
Quality assessment	Difficult to quality assess as not systematic review

Authors, Year, Country	**Godfrey, 2004, UK**		
Aims	To obtain the views of the users, carers, and social workers regarding their perception of change from users as participants to involving users at all stages of research, planning and evaluation of social care.		
Methods	Qualitative study. • Interviews conducted by users with users. • Training provided in interview techniques, support and reassurance provided by researchers, structured interview schedule to reduce bias in data collection, and payment given to interviewer. • Reflection of issues to set up and run research discussed		
Patient and public involvement	One user interviewed four users		
Level	**No. of users**	**C & D**	**M**
2	5	C=NR D=NR	NR
Impact	**Service users** <u>Benefits</u>: • Training in interview skills • Payment <u>Challenges:</u> • Users to not have access to the type of training and support that academic researchers have in the research process. **Research** <u>Benefits:</u> • Employing users to interview the users helps to engage users whose voice are not normally heard; i.e. users who do		

	not wish to share their views with professionals (academic researchers, clinicians), such as users who fear repercussions on future care, or users who feel alienated as a result of their experiences of social services. • A unique relationship exists between users built on their shared experience of pain, distress and suffering. • Having a shared experience means they are more likely to tease out the truth • Interviewees are more relaxed and open. • Interviewees don't feel they are being judged; 'no power' in the user interviewer/interviewee relationship • Interviewees articulate their views and talk more freely about their experiences. <u>Challenges</u>: • Training needed in confidence building, communications skills and interviewing techniques.
Outcomes	
Limitations of study	Author: NR Reviewer: Very small pilot study
Quality assessment	Partial

Authors, Year, Country	**Gooberman-Hill, Horwood, Calnan, 2008, UK**		
Aims	To examine the benefits and challenges of citizen's juries, including issues relating to process, public engagement and outcome. This jury is used as an example through which key issues in public involvement		
Methods	• Citizen's jury was set-up to identify local priorities into health and social care. • The citizen's jury had 20 members from the Bristol Councils citizen's panel, and met 11 times in a period of 16 weeks, which culminated in a written report. • All sessions were audio taped; five sessions were observed and video recorded. • All 20 members also completed written feedback forms at the end of the jury process. • The procedure was overseen by a planning team, two facilitators, and 12 expert witnesses who presented the evidence to the jury after the topics were identified.		
Patient and public involvement	Involved in the early stages of research by involving the service users in the jury to address the question: • What are the priorities of the citizens of Bristol for research into the provision of primary health and social care? Steering group of jurors and health professionals formed steering group to disseminate the findings in the final report.		
Level	**No. of users**	**C & D**	**M**

3	20	C=NR D=NR	NR
Impact	**Research community** Benefits: • Citizen juries involve the public at high levels of involvement and dialogue. **Service users (jurors)** Benefits: • Engaged and committed to the process • Believed they could make a difference • Pre-definition of role of jury helped them know what to expect in the process. • Desire to 'do something to help my fellow citizens', to improve the 'city'; 'duty' Challenges: • When involving service users early in the research process, the breadth of question was difficult, and service users found it hard to separate research from service provision. • Not able to incorporate changes in views in the final report as the production of a report for dissemination to policy makers and other appropriate audiences implies the findings are 'final' and not amenable to change after report published. Professional researchers are given more freedom to change views in this process. • Predefined role leads to less control over the process. As they do not define their own topics or questions (i.e. funders commission juries to address specific issues that match their own remit). • Context of how the recommendations from the citizen's jury would be taken forward was uncertain when funding changed from local PCT control to regional PCT control. • Tried to get diversity in jury, but possible that costs such as time, accessibility, availability of childcare and similar issues present barriers to participation. • Power imbalances were evident in the discursive process, and jurors expressed some frustration when personal presentation style of certain jurors did not match with their own expectations of appropriateness, e.g. if a juror took some time to reach a point. • More weight was put on issues expressed by those who were able to present their views more cogently than others ("*Posh articulate got more attention*"). • Challenges of deliberating and expressing views on complex issues where jurors may not have sufficient knowledge. **Researchers** Benefits: • Conducting studies that are chosen by service users who are engaged and committed to the process and believe they can make a difference		
Outcomes	**Research results:** • Research topics identified:		

	○ approaches to research in health and social care ○ older people ○ public health needs in Bristol ○ social care and mental health ○ general practice ○ patient complaints.
Limitations of study	1. Authors: NR 2. Researcher: NR
Quality assessment	Adequate

Authors, Year, Country	**Griffiths, 2004, Australia**		
Aims	To describe the contributions that consumers, and academic consumer researchers (ACRs) can make to mental health research		
Methods	Literature review		
Patient and public involvement	Patient, public and carer from mental health • Provide input into research questions • Indicate if research protocols are appropriate and likely to be accepted by other consumers. • Facilitate recruitment of other consumers to research projects • Place consumers at ease during the conduct of the project • Provide insights into interpretation of research results • Improve implementation and dissemination of research findings		
Level	**No. of users**	**C & D**	**M**
1, 2, 3	NR	C=NR D=NR	NR
Impact	**Research team** <u>Benefits:</u> • 1 (individual), 2 (research team) • PP focussed questions and methods • Improved recruitment. • Assistance with recruitment to study. • Patients more at ease during study • PP focussed interpretation, implementation and dissemination • Author and researchers who worked with consumers conducting randomised controlled trial reported that consumer input significantly improved design, conduct, and interpretation of health intervention trials.		

	Impact of ACRs (consumers who have an academic and or research background) Benefits: • Already have knowledge of scientific terminology and methodology that can often be overwhelming to consumers without formal training. • Perceived as more equal partners with academic research team (reduces problems of imbalance of power/ tokenism) • Secure paid academic positions • Better placed to obtain competitive funding. • Are familiar with procedures and supported by the infrastructure needed to disseminate their own and other consumer findings within the academic community, while being more sensitive than other consumer colleagues to the information needs of other consumers (therefore disseminate to a wider community). • Serve as a bridge between research and consumer communities as more sensitised to the value of consumer involvement (to assist other researchers to see this value). • ACRs are well placed to contribute to the design and delivery of training programmes for consumer researchers. • Influence research culture • Reduce the stigma of mental illness at the workplace and at community level. Challenges: • Stigmatised for disclosing mental illness, and therefore subjected to discriminatory behaviour (e.g. damages career prospects). • ACRs could marginalise lay consumers and create two tiers of consumers with ACRs being more superior. • ACRs may no have the objectivity of consumer researchers, leading to biased design or reporting of research, and therefore compromise their capacity to conduct research from a consumer perspective (e.g. the imperative to publish and to obtain grants might affect the questions posed and methodologies employed).
Outcomes	Impact of consumers is also outcomes of study – as review of evidence
Limitations of study	1. Author acknowledges that the ACR model is untested at this stage and although it would appear to offer potential, such potential might not be realised in practice. 2. Reviewer: paper reports non-systematic review and therefore could provide a summary of biased data.
Quality assessment	Difficult to assess as not systematic review

Authors, Year, Country	**Guarino, 2006, USA**
Aims	To compare an informed consent document adjusted by a consumer group of potential study participants to the original informed consent document developed by the study investigators.
Methods	RCT • Cluster randomised control study embedded in the 'parent' randomised controlled trial.

<table>
<tr><td></td><td colspan="3">Sample: 1092 participants with illnesses of Gulf War veterans, who underwent surgery between August 1990 and August 1991 and reported two of the following symptoms: 1) fatigue, 2) musculoskeletal pain, and 3) cognitive complaints.
Outcomes assessed were the understanding of the participants of the parent trial, and satisfaction with, rates of participation, and adherence to the parent trial.
The aim of the ‘parent’ study assessed exercise and cognitive behavioural therapy (CBT) for the treatment of Gulf War veterans’ illnesses.
Primary outcome: ICQ (Informed Consent Questionnaire) immediately after consent signed, three months, six months and 12 months into the trial.
Secondary outcomes: Client Satisfaction Questionnaire-8, impact was measured by examining the proportion that refused to participate in the trial and adherence rates of those enrolled (number of treatment sessions and follow-up visits.</td></tr>
<tr><td>Patient and public involvement</td><td colspan="3">Informed consent
Adjustments to consent form designed by researchers in the study.
Consumer panel downplayed the risks of treatment and of procedures in the clinical trial, and presented the information in a clearer way with a slightly lower reading age.</td></tr>
<tr><td>Level</td><td>No. of users</td><td>C & D</td><td>M</td></tr>
<tr><td>1</td><td>NR</td><td>C=NR
D=NR</td><td>Attempt at measuring impact of informed consent form</td></tr>
<tr><td>Impact</td><td colspan="3">Community
<u>Benefits:</u>
Trial has indirectly increased awareness of Paget’s disease amongst the general public through newspaper articles, radio interviews etc.
Service users
<u>Benefits:</u>
There is some evidence that perceived understanding was better in the group randomised to participant-developed consent document at the time of enrolment at the trial.
<u>Challenges:</u>
Consumer group made very few changes to the consent form.
Consumer group were not involved through the process of developing the consent form, and therefore were just presented with a consent form to adapt (consultation vs. collaborative working).
The consumer group may not of been representative of the study participants.</td></tr>
</table>

	Research team There is some evidence that perceived explanation of risks was better in the group randomised to investigator-developed consent document at the time of enrolment at the trial. <u>Challenges:</u> • The dialogue that occurs between the investigators and participants during the consent process was much more important than the actual information contained in the consent document, but not recognised sufficiently. • Informed consent questionnaire was not validated prior to the trial.
Outcomes	• 1092/2793 veterans enrolled for the consent study. • No significant differences between consent documents on ICQ-4 score overall or at any of the time points. Mean (95% CI) treatment differences ranged from +0.020 (-0.015, 0.055) (better understanding) at entry to -0.021 (-0.054, 0.012) (worse understanding) at 3 months for the participant versus the investigator document group. • There were no significant differences in satisfaction, adherence to the protocol, or in the proportion of patients who refused to participate in the trial.
Limitations of study	1. Author: the consumer group may not have been representative of the study participant and they did not suggest dramatic changes to the consent document. The outcome assessment questionnaire was not validated prior to the trials initiation. 2. Reviewer: differences could have been significant if used collaboration (users developed their own informed consent form, not alter an existing one) might have given significant differences.
Quality of assessment	Adequate

Authors, Year, Country	**Hailey, 2006, Canada**		
Aims	To obtain information from members of the International Network of Agencies for Health Technology Assessment (INAHTAA) on their involvement of consumers (patients, carers, and related organisations) in their programmes.		
Methods	Cross-sectional study • Questionnaire sent to all INAHAT members of agencies. • 37/40 (90%) responded.		
Patient and public involvement			
Level	**No. of users**	**C & D**	**M**
1, 2, 3	NR	C=NR D=NR	NR

Impact	
Outcomes	Also PPI: • 21/37 indicated that consumers were involved in HTA programme; 20/21 reported they involved consumer or patient organisations, 10/21 reported they involved individual consumers. • 19/21agencies contacted consumers by invitation, 14/21 accepted requests from consumers for assessment of specific topics, and 5/21 were in response to publicity on forthcoming assessments. • 4/21 provided users with some form of training. • 5/21 agencies gave details of when user involvement is avoided because there is no added value or benefit from the involvement of consumers e.g. diagnostic test, horizon scanning products. • 14/21 used consumers in the formulation of topics for assessment; 8/21 in prioritising topics for HTA, and 6/21 sought comment in refining the scope and nature of the HTA, and 6/21 involved consumers in development of the protocol. • All agencies that responded intended to involve consumers in the future process of HTAs • 12/37 prepared lay reports for consumers in the dissemination phase of the study.
Limitations of study	1. Author: NR 2. Reviewer: need careful consideration of self-reported data.
Quality assessment	Parital

Authors, Year, Country	**Hanley, 2001, UK**		
Aims	To assess the extent to which consumers are involved in the work of clinical trial co-ordinating centres in the UK, and the nature of the involvement of consumers in randomised controlled trials that are co-ordinated by these centres.		
Methods	Cross-sectional. • Questionnaire to 62 clinical trial co-ordinating centres, and investigators of 60 trials in the UK identified through a database assembled in 1997 by the National clinical trials adviser		
Patient and public involvement	Not reported in conducting this study		
Level	**No. of users**	**C & D**	**M**
1,2,3	NR	C=NR D=NR	NR
Impact	**Research** <u>Benefits</u>: • Refine research questions • Improve quality of patient information		

	• Help recruit participants • Advocates of trial • Dissemination of information • Make the trial more relevant to the needs of the patients
Outcomes	• Of the 62 eligible centres, 23 reported that consumers had already been involved in their work, and most respondents were positive about this involvement. • Seventeen centres planned to involved consumers. • Fifteen centres had no plans to involve consumers, but only four of these considered such involvement irrelevant. • Responses from investigators about the 48 individual trials were mostly positive, with respondents commenting that input from consumers had helped refine research questions, improved quality of patient information, and made the trial more relevant to the needs of the patients.
Limitations of study	1. Author: NR 2. Reviewer: need careful consideration of self-reported data
Quality assessment	Partial

Authors, Year, Country	**Hewlett et al., 2006, USA**
Aims	• To report the combined experiences of researchers and patients who have been collaborating in rheumatology research. • To develop a model of collaboration between researchers and patients in research that could be used as a practical guide. To report the benefits and challenges of such a collaboration.
Methods	Qualitative study: a reflection of the collaborative process
Patient and public involvement	• Membership of research project steering groups. • Workshop-based conferences of Outcome Measurement in Rheumatology Clinical Trials (OMERACT). • Peer reviewed grant application • Clarified research question • Extended patient cohort to include new group • Suggested reasons for low recruitment • Reviewed qualitative transcripts and categories • Raised new outcomes of importance • Re-named categories • Co-led investigator meeting

Level	No. of users	C & D	M
2	NR	C=NR D=NR	NR
Impact	**Service users** <u>Benefits</u> • Being able to contribute and give something back • Having something to offer that is valued • Creating something positive from their illness. • Gaining self-confidence • Empowerment • Sense of equal partnership • Friendship • Expressed pleasure in new partnerships • Feeling efforts have been rewarded <u>Challenges</u>: • Communication difficulties/ access: routine use of e-mail, conferences, corridor meetings by researchers, which all excluded service users. • Short time given to review documents that needed time to read because of unfamiliar material. • Difficulties of altered roles (changing from physician-patient relationship to meeting as colleagues). • Problems of confidentiality of patients (e.g. physician asking about their health during steering group meetings) • Problems of academics assuming service users lack knowledge, so their views are not taken seriously. • Anxieties of users: concern about ability to contribute; value of any contribution, unfamiliar with technical terms, lack of clarity of role, not wanting to appear foolish • Concern that close working relationship with clinician may lead other patients to assume they receive preferential clinical care. • Initial tokenism: academics collaborating with service users for political correctness (e.g. to satisfy a research funding body). **Research team** <u>Benefits:</u> • Greater understanding of rheumatoid arthritis and its impact • Respect for partners' knowledge and commitment • Beliefs and attitudes challenged • New research areas opened up • Effort rewarded • Friendship		

	Research Benefits: • Fresh insights into issues • Altered study design • Novel outcomes • Reports benefit such as research being grounded in patient relevance, being given a wider perspective, and the opening up of new research topics

Outcomes	Practical guide to involvement developed:
	• Facilitate, Identify, Respect, Support, and Train
	• Facilitate: inclusion and contribution.
	  o PI of study best person to facilitate inclusion.
	  o Best to include at early stages – to benefit goals and methods.
	  o Meetings: Timing of meeting to suit both researchers and users; payment of expenses; good chairing of meetings to enable users to contribute (especially in first meetings where confidence of users will be less)
	• Identify: projects, patients, roles:
	  o Identify research projects that service users able to contribute e.g. clinical interventions, outcomes, or service delivery issues.
	• Identify patients directly, or through patient organisations.
	  o Researchers should develop job description for potential service users to view.
	• Respect: Contribution and confidentiality
	  o PI plays important part in reassuring service users that their input is of value to the research..
	  o Users utilise training courses, e.g. presentation skills, software – to create better collaboration with researchers.
	  o Pay contribution to service users.
	  o Respect service users.
	  o Need for users to respect confidentiality of information passed to them in meeting.
	• Support: Communication and working
	  o Effective first meeting to introduce study, give a protocol, research guide, glossary of research and clinical terms.
	  o Co-researchers were given desk space, access to internet, library, training courses, given honorary contracts.
	  o Peer support, with regular contact, e-mails, and meeting up.
	  o Feedback was important.
	  o Providing users with training assists them in their contribution to the study.

Limitations of study	1. Authors: NR 2. Reviewers: NR
Quality assessment	Adequate

Authors, Year, Country	**Howe et al., 2006, UK**		
Aims	• Identify good practice in involvement of the public in R& D, and to incorporate this into a locally owned project. • Aims summarised: FIRM (Find, Involve, Recruit, Maintain). • Volunteers and researchers were asked for their feedback on PPI involvement in the research projects: o In what ways do you feel the member influenced or changed the research process? o What is your general view about service users being involved? o Do you feel the professional staff present were fully aware of your role?		
Methods	• Recruitment via media adverts (radio, local papers), and by direct contact with voluntary organisations (Age Concern, Royal National Institute for the Blind). • Volunteers were invited to three information days (small group work, short keynotes, questions and discussion). • Programme of optional training offered: medical terminology, assertiveness, effective meeting skills, and communication skills. • Also offered new volunteers an induction session (introduction of NHS, beginning the research process, research methods, examples of good practice, research governance and ethics, turning research findings into practice. • Authors state use literature (Greenhaugh 2004) on diffusion of innovation (requires champions, start-up funding, policy linkage, shared values, and balanced view of the likely benefits and constraints to take it forward. • Development of a set of guidance principles was produced, by which the volunteers could expect the researcher to abide (Telford 2004). • Volunteers were mainly female and over 55 years; young people, ethnic minorities, and disabled were under-represented.		
Patient and public involvement	• Most common request was for the review of research proposals and patient information sheet/consent form. • Requests range from general enquiries to what volunteers panel can offer to requests for on-going involvement in research committees (e.g. research governance).		
Level	**No. of users**	**C & D**	**M**
1	41 (36 female, 6 male)	C=NR D=NR	NR
Impact	**Community** <u>Benefits:</u> • PPIRes has created a new interface between hosting organisations and the public by which enquiries are made (e.g. feeding through research ideas) • Funding and commitment to PPIRes project has lead to a potential for sustainable long-term impact of PPI. <u>Challenges</u>: • Recruiting volunteers from more marginalised groups are harder to reach groups (socially deprived, ethnic minorities,		

	people with disabilities). • Might involve project by project basis rather than expecting these individuals to put themselves forward by direct media and advertising. • Furthermore, need some initial confidence building of these) in order for them to perceive themselves to be effective in such a setting. **Service users** Benefits: • Able to influence research agenda • Share one's own experiences for the benefits of others. • Benefits of training: enjoyable, confidence building, gained invaluable knowledge. • Payments to volunteers were both a benefit and a limitation as regular payments may raise issues with employment legislation. However, the lack of payment was seen as a deterrent. Challenges: • Low level of perceived benefit to the volunteer (need to explain to volunteer what they might take from their involvement, and to offer something back via training. • Desire for feedback on how their involvement has helped the study, the progress of the study and the outcome of the study in terms of improving services (need for good practice guidance). **Research Team** Challenges: • Researchers expressed concerns as to the contribution that volunteers could make to the research team, but these appear to have been allayed once they engage with the volunteers. • Researchers were not convinced that the additional effort and resources required by them to work with volunteers is worthwhile, but again this improved once collaboration was underway. • Need to adapt to cultural gap between established ways researchers work and that of volunteers, which can form a barrier to full volunteer participation. • Limits to what the volunteer can do in terms of their knowledge and experience
Outcomes	
Limitations of study	1. Authors: Difficulty in trying to involve the 'hard to reach' groups 2. Reviewer: Not representative sample
Quality assessment	Partial

Authors, Year, Country	**Hubbard et al., 2007, UK**
Aims	To systematically review the literature on involving people affected by cancer in healthcare research, policy and planning and

	practice.		
Methods	Systematic search of electronic databases and grey literature		
Patient and public involvement	NR for process of systematic review		
Level	**No. of users**	**C & D**	**M**
1,2,3	NR	C=NR D=NR	NR
Impact	**Research** <u>Benefits:</u> • Knowledge and experience of service users living with cancer. <u>Challenges:</u> • Need training for both service users and researchers • Need resources – financial and time • Need right attitude from researchers and service users **Service users** <u>Benefits:</u> • Involvement led to patients being improvements in symptom management		
Outcomes	The systematic review reports the following themes from the evidence: • People affected by cancer had played five different roles in research as, advocates, strategists, advisors, reviewers and as participatory researchers. • Six examples of service users being instrumental in bringing about involvement in research, seven examples of university-based researchers initiating the involvement in research, and two examples of health professionals instigating participatory research. • Three key factors for successful involvement were reported as: training, resources, and a change in attitudes • There were only three evaluations of the impact of involving people affected by cancer on research, and one critical reflection of the experiences of researchers in involving people affected by cancer in research. • The main rationale for involving service users in research was because they had direct experience and knowledge of the disease. • 'One-off involvement exercises' where users are involved on one occasion have included involvement in education programmes, in English hospitals at health authority level, and accredited services, to develop a cancer care pathway, guidelines and a set of principles for service delivery. • Variation of patients that wanted to be involved		
Limitations of study	Authors: NR		

	Reviewers: NR
Quality assessment	Adequate

Authors, Year, Country	**Kelson, 1999, UK**		
Aims	• To identify the extent to which the Cochrane Collaboration involves service users as members of the Cochrane Review Groups (CRGs) • To explore the emphasis CRGs place on identifying and collecting information on outcomes identified by patients as being important indicators of quality and effectiveness of treatment and care (patient-defined outcomes)		
Methods	Cross-sectional study • A postal questionnaire sent in January 1998 to all CRGs registered with the Cochrane Collaboration on 1st January 1998.		
Patient and public involvement	Questionnaire was designed by The College of Health, which is a patient organisation		
Level	**No. of users**	**C & D**	**M**
1, 2	NR	C=NR D=NR	NR
Impact			
Outcomes	33/42 (79%) response rate: • 10/33 (30%) had no service user representatives • 4/33 (12%) had one service user representative • 6/33 (18%) had two service user representatives • 12/33 (36%) had three or more service user representatives. • 19 (58%) indicated that they had discussed the issue • 5 (15%) had carried out a search for literature on patient defined outcomes • 3 (9%) had produced a bibliography, summary or review • Reported contributions included informing the methodology, development and reporting of reviews, participation in working groups, suggesting outcomes and/or identifying areas of interest that patients would like thee CRG to address.		
Limitations of study	Authors: NR Researcher:NR		
Quality assessment	Adequate		

Authors, Year, Country	**Ali, 2005, UK**		
Aims	To involve stroke patients and carers in the design of a study of oxygen supplementation in acute stroke.		
Methods	Qualitative/ descriptive study • Three focus groups with individuals who had personal experience of stroke and their partners or carers. • Sample from two dysphasia support groups, and one young stroke sufferers association. • Participants of the focus group were also asked to complete a questionnaire on their views on the study. • Age range 31-86 years (mean age 64 years), 34 males, 39 females; 49 stroke patients and 24 carers.		
Patient and public involvement	Stroke patients and carers • Participated in planning stages study, inputting into aims, design and proposed outcome measures.		
Level	**No. of users**	**C & D**	**M**
1	73	C=NR D=NR	NR
Impact	2 (research team) Consumer involvement helped make the study more relevant to stroke population, but led to difficult scientific and ethical conflicts in protocol design.		
Outcomes	• 73 people attended 3 focus groups (n=34; 19; 20) • Relevance of research: general approval by participants • Outcome measures considered relevant: communication (ability of patient to speak), mood and depression, mental function, swallowing, tiredness/sleep, and 1 to 10 score of how much the patient is back to their old self. • Consent issues (to give oxygen within 24 hours of the stroke): agreed that consent from relatives or a friend would be acceptable, as stroke patient unlikely to give fully informed consent at this stage. • "The last person capable of making the decision is the stroke patient. After I had my stroke, I lost about 18 months of my life when I was incapable of making any rational decision". • "Relatives are emotionally involved and therefore it might be better for the doctor to take the lead. Therefore the doctor gives their opinion, but gives the relatives the choice. Relatives don't know the implications of recruiting or not recruiting" • "I believe doctors are best to decide on recruitment" • Follow-up arrangements: Agreed with 6 month follow-up, and agreed acceptable to contact the GP to obtain information on the health status of the patient.		

	• 1st focus group accepted follow-up method by postal questionnaire, interview or contact with GP. The second two groups (from dysphasia support groups) preferred personal contact (home visit) to a postal questionnaire. • 51/73 (70%) of focus group also responded to questionnaire. The majority of respondents agreed that the oxygen supplementation study was a worthwhile study and that the suggested outcome measures were relevant. Other outcome measures suggested were movement scores (n=9), concentration (n=8), measure of intelligence (n=6), handwriting skills (n=6), sleep (n=5) tiredness and fatigue (n=5), speech (n=6), vision (n=5), and enjoyment of hobbies (n=3). 38 (75%) thought it appropriate for the family or carer to give consent on behalf of an incompetent patient to be included in the study. 47 (92%) would allow a doctor to recruit patient to study, and seek consent later on.
Limitations of study	Authors: • 1st focus GP known to researchers, therefore may have been bias. • Sample younger and more socially active than average stroke patient. Frailer individuals who don't have access to private transportation would not have been able to attend the meetings. Researcher: • Questionnaires sent to sample that were involved in focus group. May have achieved greater representation if questionnaires sent to different sample of stroke patients. • Questionnaire answers may have been influenced by discussions in the focus group.
Quality assessment	Adequate

Authors, Year, Country	**Koops & Lindley, 2002, UK**
Aims	To determine whether consumer involvement would help to solve some of the ethical problems associated with research into thrombolysis for acute ischaemic stroke, with its inherent risk of fatal intracranial haemorrhage.
Methods	Qualitative and cross-sectional study • Consultation phase: three meetings to discuss planned research, then participants completed a questionnaire. • Two focus groups explores the responses in the consultation phase (1st focus group consisted of participants from the consultation phase, the second had new volunteers from the Bingham and District Older People's Project. • Research team developed consent procedure with supporting leaflet, and then distributed it for comment to 6 patients and carers.
Patient and public involvement	Stroke patient and carers • Consultation meetings to plan and gain knowledge of research, focus groups to discuss issues of consent, questionnaires to gain comments on the researcher developed consent form and accompanying consent form.

Level	**No. of users**	**C & D**	**M**
1	54 in consultation	C=NR D=NR	NR
Impact	**Service user** <u>Benefit:</u> • Participants valued the opportunity to discuss medical issues with the local clinician, and seemed to enjoy the meeting. **Organisation** <u>Ethics committee:</u> • Trial material was accepted after just one cycle of amendments.		
Outcomes	54 attended the consultation meetings, with 47/54 returning a completed questionnaire. • Four (9%) of participants considered the risk of thrombolysis too great, but most (89%) were prepared to accept treatment in a clinical trial. • Nearly all would accept treatment if it was shown to be effective. • Most (85%) would give their consent to enter the planned trial. • The focus group meetings and feedback from patients and carers led to significant changes in the information leaflet that supported consent procedure. <u>Focus group results</u>: • Many participants were comfortable with risk: "*Four people in 100 is a very small risk compared to living a vegetable life, I think at my age I have nothing to lose*" • Many accepted the risks due to the play of chance: "*It's like Russian Roulette, isn't it?*", "*if you got to go, you're gonna go.*" • One group discussed the maximum average risk they would be prepared to accept for a treatment that may prevent disability, and they thought a risk of up to 20% of immediate death was acceptable. • If patient is unable to communicate, participants were unanimous that the next of kin was the appropriate person to decide on treatment, although some people worried about the consequences of this: "*The implications of that though are… think of the guilt that someone signing and then the person died and they were aware they had been party to doing that".. "I would not want to put someone in that position*". • Most were happy for assent by the attending doctor: "*it's up to the doctor," "you should use your discretion, and if you think it is going to work, go for it*". • To overcome ethical dilemma, participants suggested patients who are at risk should carry cards to confirm that they would consent to emergency treatment as part of a randomised controlled trial. • The groups disliked the adjectives "large", "small", and "massive" and preferred risks to be explained in "%".		

Limitations of study	1. Author: consumers were highly selected. 2. Reviewer: lead researcher for the trial may have unduly influenced the trial.
Quality assessment	Adequate

Authors, Year, Country	**Langston, 2005, UK**		
Aims	To report on the partnership between the national association for the relief of Paget's disease (NARPD) and the PRISM (Paget's disease: a randomised trial of intensive versus symptomatic management) trial in the design, conduct and delivery of the outcomes of the PRISM trial.		
Methods	Descriptive write-up • Chief executive of NARPD sat on steering group for PRISM, reviewing the trial protocol and influencing conduct of trial. • Patient members of NARPD undertook a rigorous review of the patient information leaflets developed by the trial researchers. • NARPD assisted the researchers in recruiting collaborators by releasing their register of specialists in Paget's disease to PRISM. • NARPD update members of the charity on trial trough their quarterly newsletter, and display posters about the trial at conferences/annual patient day.		
Patient and public involvement	• Peer review • Trial steering group membership • Provision of advice to participants • Promotion of trial among patients with Paget's disease		
Level	**No. of users**	**C & D**	**M**
2	NR	C=NR D=NR	NR
Impact	**Community** <u>Benefits:</u> • Increased awareness of Paget's disease • Greater awareness and information exchange on diagnosis and treatment of Paget's disease to/from health care professionals • Increased awareness of Paget's disease leads to heightened dissemination of guidelines for Paget's disease to health professionals **Service users**		

	Benefits: • Increased access to information about Paget's disease; • Increased access to relevant health research on Paget's disease; • Increased membership to NARPD (researchers heighten awareness of organisation at recruitment). • Evolution of the 'patient' into the 'questioning customer' (Boote 2002) • Importance of involvement of user organisation from conceptual stages leading to greater feeling of power, impact and ownership of the trial (which authors report would not have been the case if not involved in the early crucial stages) Challenges: • Time-consuming and costly (answering queries, attending information meetings, dissemination of materials). **Researchers** Benefits: • Improvements in recruitment (Recruitment of participants via NARPD contacts; recruitment via NARPD newsletter [n=24, 2% of sample]); • Improved quality of information flow • Well informed participants • Unsolicited patient advocacy of the trial (nine recruited through good reports about the trial from other patients) • Interested and pro-active collaborators • Useful learning on how to communicate various aspects of the trial Challenges: • Time-consuming collaboration • Cost of collaboration • Impact is more subtle, and is mainly the achievement of a well-informed and motivated cohort of participants – having a positive impact on attrition rates to the trial and positive impact on attrition rates.
Outcomes	Outcome of user involvement: • Information leaflet changed by service users because they deemed it "too simplified" and "potentially patronising", which could have a negative impact on the recruitment of to the trial. Style and layout of the information sheet were also commented on. • Advised the research team on how to present to a lay audience. • Provision of contacts to recruit centres/participants • Advertising the trial in NARPD newsletter, and at NARPD conferences.
Limitations of study	1. Authors – NR 2. Reviewer- NR
Quality assessment	Adequate

Authors, Year, Country	**Lindenmeyer et al., 2007, UK**		
Aims	To assess the benefits of involving health care users in diabetes research. Specific questions: • What difference had consultation with users made to the research project? • Did user involvement make any difference to funding? • In what ways would the research be different without the users input?		
Methods	• Qualitative interviews with the five researchers that sat in on the diabetes • User group meetings. • Service users' views of the effectiveness of the user group during two of the groups regular meetings. • Views of the groups effectiveness were collected from external researchers who had consulted the group and from service users not attending either of the two meetings by letter or e-mail. • Minutes of the user groups minutes were analysed for content. • Eight principles and 16 indicators of user involvement were developed through a Delphi process by Telford et al. (2004).		
Patient and public involvement	• Diabetes user group comment on research proposals, study questionnaires, research participant recruitment, the focus of analysis, assisting with lay dissemination of results. • Members of the user group had different levels of involvement: 32 were willing to be consulted up to ten times a year. • Those unable to attend meetings feedback on documents.		
Level	**No. of users**	**C & D**	**M**
1	59 in user group	C=NR D=NR	NR
Impact	**Research team** <u>Benefits:</u> • A partial shift of power from researchers to users helped maintain motivation among research team (as have to answer to service users as well as other research colleagues) • The main contribution of users to research was their practical expertise of living with diabetes. • Users helped researchers to remain connected to the 'real world' in which the research would be applied: "*Working with the [research] User Group probably helped us put their hat on better than we would do if we hadn't worked with the user group. So when we're doing things, although they're not there, we can half put their hat on and*		

	think how it would be if they were there, because we know them. We know who they are. We've interacted with them" • Researchers reported that the activities of the group improved the chances of the research being funded*:* *"So many of the forms want to know upfront, not just how you are going to involve users, but how you have already involved users in designing the proposal you are submitting…And of course, for us, that's easy*". • Although one funding body criticised the researcher for giving too much power to the service users. • Minor changes by service users made a major impact on the success of the research; e.g. the order of questions in the questionnaire was changed, which was thought to be contributable to a good response rate. Challenges: • Service user group not representative of patient population – as mainly white, retired males. • Service users may become 'proto-professionals', losing the special quality of independent, experiential knowledge. **Service users** Benefits: • Long-standing nature of group enabled users to gain an insight into research • Long-standing nature of group enabled users to form constructive working relationships with researchers. • Empowered by shift of power between service users and researchers (e.g increasing understanding of research gave users confidence to ask fundamental questions). • Evaluation of the contribution of service users to research was conducted by recording a summary of changes made by a researcher as a result of the service user group. Formal minutes also assisted in recognising the value of service users. • Felt valued (e.g. pride in contributions made, being told their contribution was instrumental in gaining funding).
Outcomes	**Research**: the work of these groups fulfilled the principles of consumer involvement reported by Telford 2004.
Limitations of study	Author: NR Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Marsden & Bradburn, 2004**
Aims	To report how breast cancer patient involvement in the design of a national randomised trial of hormone replacement therapy (HRT) in symptomatic patients can increase accrual
Methods	Qualitative study • Nine focus group discussions to identify issues relevant to breast cancer patients about HRT and a national trial. • Six focus groups involved women from breast cancer support groups (n=69). • Three focus groups involved women who had previously participated in the pilot of RCT HRT study (n=14).

Patient and public involvement	• Grounded theory used to identify recommendations. • Recommendation debated at one day workshop. • Consumer's advisory group for clinical trials and patient (CAC-CT) representatives that took part in the focus groups sat on steering group to ensure that the priorities were accounted for. • Resulting trial design summaries were circulated to CAG-CT and focus group reps for comment.		
Level	**No. of users**	**C & D**	**M**
1	83	C=NR D=NR	NR
Impact	**Community** <u>Challenges:</u> • Complexities of conflicting clinical and health system goals between clinicians, researchers and service users (e.g. quality of life versus research rigor) and constant changes of health and social processes leads to uncertainty of how policy makers can take recommendations from research involving PPI forward **Research team** <u>Benefits:</u> • Focus group methodology worked well to identify issues of relevance to cancer patients. • Greater openness among patients and clinicians about side effects of breast cancer treatment and investigation of their management lead to: patients informed about different types of HRT and alternatives prior to randomisation so they can make an informed choice about which preparation they would like to receive once randomised. • Better interdisciplinary communication about the management of menopause-type symptoms so patient care is centred lead to: prompt access to breast cancer specialist if required. <u>Challenges:</u> • Patients must be in an environment conducive to expressing their views and preferences. Therefore focus groups were conducted by independent researchers • Training of researchers was important. • Consultation process prevents significant conflicts between the individual stakeholders. • Must allow sufficient time for collaborative process and subsequent feedback from service users. • Importance of offering support and keeping service users well-informed at all stages. • Misunderstanding from service users as to what is expected of them (i.e. written feedback on documents). • Review of ethical and scientific needs for a trial of HRT lead to. • No placebo arm, as patients wanted to know if they were taking HRT		

Outcomes	• Recommendations from patients participating in pilot HRT study:
	  o Key issues were ensuring informed consent and support for those in the control group who are therefore denied potentially effective treatment.
	  o Recommendations were for: adequate information about the trial (i.e. treatment side-effects, types of HRT, access to research papers), and patient support during the trial (GP and hospital based).
	• Action points:
	  o Is HRT a research priority?
	  o Is the climate right for the study?
	  o How can informed consent be ensured?
	  o Should women who are not suffering from severe symptoms be recruited to a trial where the end result is survival?
	  o Will the study give meaningful answers?

Limitations of study	Authors: time restraints prevented sufficient time for complete response about trial from users. Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Maslin-Prothero, 2003, UK**		
Aims	Reflection of the experiences of the recruitment of users to a breast cancer trial, to assist in improving recruitment to trials. Describes key issues that nurses and midwives must incorporate to have effective user participation in research and practice.		
Methods	Qualitative and review of evidence • Two-hour focus groups (n=11). Those who did not want to participate in focus groups were offered an interview (n=23). • Access to women was gained through breast care nurses or the research nurses. Women with breast cancer and women with a familial history of breast cancer were invited to participate. • Open-ended questions explored why women, why they decided to (or not to) participate.		
Patient and public involvement	• Breast cancer patients only. • Participated in focus groups to help improve recruitment to breast cancer trials		
Level	**No. of users**	**C & D**	**M**
1	NR	C=NR D=NR	NR
Impact	**Service user**		

	Benefits: • Women received remuneration for their contribution • Women received a copy of the findings from each stage of the research, and additional seminars were presented for these women. • Training that was given to users may be seen as a personal development Challenges: • Talking about their experience of breast cancer and clinical trials was an unwanted intrusion and reminder of breast cancer when all they wanted to do was forget it. **Researchers** Challenges**:** • Practical aspects of planning and managing research where there is user-involvement. Gaining access to users is a difficult and time-consuming activity • Cost implications of education and training. • Temptation by the researcher to draw on the expertise of users who are also professionals and already possess these skills; the danger here is having 'group think' where there is little challenge to commissioners and researchers because the professional users thing and act in the same way. • Need users who can debate and challenge assumptions in order to move on.
Outcomes	**Results of focus groups**: • Approaching eligible participants; how and when is important. First approached at the results clinic when they had just been told they had breast cancer. They were very anxious and found it difficult to manage their diagnosis, understand what the trial entailed and enter the trial at the same time. • Improved communication – Staff recruiting to the trial should be supportive and interested in the patient, and any explanations should be clear, positive, reassuring, honest, and focussed on the benefits and drawbacks of participation in the trial. Information should be should be provided in different ways – must be flexible and willing and able to adapt their approach to meet the needs of individual patients. This information must be supported with appropriate print-based material (or recorded) that reinforces the various treatment options and verbal explanation given. Information centres could be set up in outpatient departments, where people could access information on specific illnesses, and clinical trials, in the form of posters, leaflets, CD ROMs and access to the internet. • Avoid inconsistent information given by the clinic and then by the trial staff (e.g. one woman was told the standard treatment was local excision with radiotherapy, and then told about a clinical trial that had 4 treatment options). • Access and choice: o Patients needed to understand the commitments associated with the trial participation, which were rarely mentioned by the trial staff.

	○ Costs of participating include side-effects of treatment, travelling for treatments and appointments. ○ Patients could carry out treatments or check-ups at a centre close to home or place of work. ○ Incentives of financial assistance for travel and/or cover for care costs. • Where possible, women would like to choose their treatment option.
Limitations of study	1. Authors: NR

Authors, Year, Country	**McCormick et al, 2004, USA**
Aims	To understand the obstacles, processes, and benefits of public involvement in breast cancer research, and to develop a model of lay involvement in research based on the analysis of three empirical cases.
Methods	Qualitative • Research projects were stimulated by local concern that mandated lay participation. • The three projects were: ○ Long Island Breast Cancer Study Project (LIBCSP) ○ Silent Spring Institute study (SSI) ○ Marin County Breast Cancer Watch study (MCBSW). • Aims of studies: to assess environmental factors associated with breast cancer. • Twenty-nine interviews with advocates (of public) and researchers. • Ten ethnographic observations of public meetings, scientific review panel meetings, and conferences. • Interviews with Government officials who overseas programs that fund the public involvement.
Patient and public involvement	LIBCSP: • Advocate representation on advisory panel • Community hearings for creation of GIS (Geographic Information System: map of diagnosed women mapped next to environmental data) study, which was described as sporadic involvement. SSI: • Separate Science and community advisory boards to advise researchers on the project (described as well developed involvement) • Advocates assisted in selecting research questions, and prioritising research topics. MCBSW: • Advocate inputs into study design and construction (described as involvement at beginning of development), e.g. of

	changes to research. • GIS was to be county by county, but lay people pointed out that there is too much differentiation within counties – so changed to using zip codes.		
Level	**No. of users**	**C & D**	**M**
1, 2	NR	C=? D=?	NR
Impact	**Community** Benefits: • After initial distrust between scientists and advocates of public involvement, but mutual respect developed. • Makes science more accountable to the public • Relates research more directly to the illness experience. Challenges: • Need for support from universities and funding institutions to improve their support of such research in order to counter this institutionalised system. • Most challenging compromise is creating research that answers community concerns and is also scientifically valid For success: • Researchers and lay people need to: o develop mutual trust o make a commitment to a time investment for the project o establish its goals o define the community being served o engage a funder who is committed to public involvement • Mutual co-operation, the quality of the leadership, processes of evaluation, and goals of research can be developed only through effort on the part of both partners. **Service user** Benefits: • After initial distrust of scientists, advocates developed a sense of being respected and feeling that their work was worthwhile and transformative: *"…most surprising was how much the scientists and the M.D.s have come to value the advocate perspective on these panels and not only just putting a face on the statistic, but also that they appreciate when you ask the questions 'why is this relevant, who cares?"* • Feeling of empowerment • Creation of project LEAD to train advocates to understand the science of breast cancer Challenges: • Lack of scientific expertise of advocates • Time spent learning scientific information		

	• LEAD training concentrated on reviewing and not on environmental research.
	• Reading of large amounts of scientific documents
	• Differences in research agenda:
	  o Scientists = genetic and lifestyle factors.
	  o Lay people = interest in environmental causation.
	
	Research team
	<u>Benefits:</u>
	• Scientists greatly appreciated input from advocates, in addition to the advocates efforts that brought research projects into existence
	<u>Challenges</u>:
	• Self-selected, non-representative sample of scientists who were previously open to advocate involvement.
	• Have to make language more accessible to service users with improved user understanding.
	• Difficulty giving up control or share of power.
	• Worry over threat to their credibility and professional status (as breaking notions of objectivity in research, which introduces bias and unconstructive methodologies.
	• Felt they had to work harder than others (e.g. university researchers) to establish the validity of their work.

Outcomes	**Research lessons**:
	• Types of involvement from these studies:
	  o Peer review: has the most pro-active effects by determining what kind of research will take place, limited as only a small number of lay people involved in the reviewing process.
	  o Advising board: can advise research processes, but must enter the research during the planning stages.
	  o Lay involvement in research methods: fosters more accuracy and educates the public about scientific methods, but alone has little power to affect anything other than this.

Limitations of study	1. Authors: NR 2. Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Menon, Stafinski, 2008, Canada**
Aims	• To assess the feasibility of using a citizen's jury to elicit public values on health technologies and to develop criteria for setting priorities for health technologies. • To develop criteria for setting priorities for health technology assessment (HTA)
Methods	Qualitative and cross-sectional

	• Sixteen service users participated in a 2.5 day jury which comprised of presentations of by 'expert witnesses', who represented innovators, patients, health-care policymakers and clinicians. • They also participated in a series of small and large group priority setting exercises based on actual examples of technologies that had recently been considered for assessment by local and national HTA bodies. • The sessions were audio-taped and analysed qualitatively • Questionnaire completed by Jurors to evaluate the process		
Patient and public involvement	Sixteen service users sat on jury panel, which was aimed at collecting public values on health technologies.		
Level	**No. of users**	**C & D**	**M**
1	NR	D=NR	NR
Impact	**Service users** <u>Benefits</u>: • Information presented in a balanced, clear way • Felt welcomed • After 2.5 day jury, they felt informed • Felt able to contribute		
Outcomes	Criteria were identified by the jury for setting priorities for HTA (in ranked order): • Potential to benefit a number of people • Potential to extend life with quality • Potential to improve quality of life • Potential clinical benefit over existing treatments • Lack of alternative • Potential to detect a condition which, if treated early, averts costs in the future • Potential for additional applications • Potential to extend life • Completeness of data on adverse events Criteria not used: • Cost		
Limitations of study	Author: NR Reviewer: NR		
Quality assessment	Partial		

Authors, Year, Country	**Meyer et al., 2003**		
Aims	• To explore how lay Hispanic health promotion (LHP) with participatory research (PR) methods work. • To explore the benefits and challenges of this participatory research. • To describe opportunities to use this approach. • To discuss how this approach can create personal growth and empowerment.		
Methods	• Three-month training course to become a LHPs or PRs for unemployed • In-depth interviews and a survey of 240 Hispanic Spanish-speaking women. • Reflection of events. • In-depth interviews with LHPs and PRs to reflect experiences of becoming PRs, conducting interviews, collecting survey data, and combining that role with those of LHPs and community members. • Iterative analysis with collective writing.		
Patient and public involvement	• Constructing interview schedule. • Recruitment and informed consent. • Interviews • Surveys • Reflection diaries/documentation. • Initial analysis of data.		
Level	**No. of users**	**C & D**	**M**
2	11	C=NR D=NR	NR
Impact	**Community** <u>Benefits:</u> • Established links formed between community and health care system: *"The LHP/PRs come from the community, belong to the community, and go back to the community to strengthen the links that they had previously established."* • Greater intercultural understanding of issues • Science more accountable to community • Received diagnosis and treatment which may not have received without the research project. • Better targeted health promotion in community **Service users**		

	Benefits: • Learned to work better cross-culturally: *"…you are not only 'the friend' but also 'the researcher', who comes not only to ask you questions but also to give you information."* • Validated in the community – able to develop closer contacts with those in the community who had little contact with before: *"… they open the doors to us and talk to us as professionals."* • Built up trust in the community, particularly around confidentiality. • Became bridges to the mainstream health system for many isolated Hispanic women. • Became credible leaders in the community. • Learnt about research methods and health promotion • Sense of personal satisfaction • Went from fear/ reluctance of doing research to the desire to have more time to engage in research. • Paid part-time, although commitment from these LHPs and PRs meant many were working full time in their roles. • Challenge of completing an academic programme: *"…this gave us more confidence in the learning process and in being in contact with the teachers as guides."* Challenges: • Difficulty of duel role (LHPs and PR); e.g. as researchers they had to wait until the end of the interview to discuss inaccuracies and access to health services. • Increased demands on their time. • Sense of duty to their community • Burden of responsibility of being the 'bridge' to health care systems in the community. **Research team** Benefits: • As women in the community, the LHPs and PRs opened doors to obtain interviews or survey data. • LHPs and PR gained greater understand of community health needs and identified barriers to health services for this population.
Outcomes	**Research results**: • Isolation of Hispanic women, and therefore not able to talk about their health needs, from dealing with cancer in the family to broader issues of dealing with immigration and the school system. • 90% of women saw the project as very beneficial and with great future for the community.
Limitations of study	1. Authors: NR 2. Reviewers NR
Quality assessment	Adequate

Authors, Year, Country	**Minkler et al., 2002**		
Aims	To explore the issue: death and dignity or physician assisted suicide legislation for severely disabled people led by a Community Advisory Group		
Methods	Qualitative study • Forty-five people with substantial disabilities were interviewed by the CAG members. • CAG members included five natural helpers, informal leaders in the community and one trained researcher.		
Patient and public involvement	Members of CAG led on all stages of the research the support of a research team from Berkeley University: • protocol development • development of interview schedule • recruitment • data collection, analysis and write-up		
Level	**No. of users**	**C & D**	**M**
3	NR	C=NR D=NR	NR
Impact	**Research** <u>Benefits</u>: • Provide more patient relevant research instrument • Gain access to a highly diverse sample • Interpret study findings with new community insights • Report those findings back to the community in ways that engendered further rich dialogue and plans for subsequent education and action. <u>Challenge</u>: • Selection of physical disability disempowered other types of disability (mental, sensory, or as a result of aids and other conditions) • Tension in team; e.g. the researcher wanted to recruit from the older population of disabled people, because they had the opinion that they were more interested in DWD. Community members disagreed and said if someone lives with disability long-term, they confront the issue of DWD at numerous times throughout their life. • Difficulty disseminating controversial results to the community involved. **Service users** <u>Benefits</u>:		

	• Developed skills in research methods including sampling, questionnaire construction, data analysis, compiling report, dissemination or report Limitations: • Time demands of research • Conflicting time frames
Outcomes	Seven key findings or themes emerged from the study: • The existence of great breadth of opinion with respect to attitudes towards death with dignity (DWD) legislation: "*There seems to be one public position on behalf of people with disabilities about DWD legislation put forward by disability community spokespersons and groups, but when you go deeper into the community there are many different opinions. And individual's opinion seems to depend on their own character, personal experience [of self or loved one] with near-death or death , among other things.*" • The importance attributed to self-determination and autonomy in the way people with disabilities live and die. Regardless of their opinions on DWD, all respondents reported wanting their independence and autonomy in life choices to be respected. All but one reported that, if they were close to death or experiencing intractable pain or loss of cognition, they would want to have their own opinion about ending or continuing their life respected. • The pervasiveness of discrimination based on disability: 90% had experienced discrimination based on their disability "*I have heard people say to disabled people, 'why don't you die?'*"; "(legislators)*…still see it as we'll take care of you*." • Contradictions between personal experiences and abstract or political beliefs shaping attitudes towards DWD legislation. That is participants reported having personal experiences or anticipated changes in their own life that would cause them to have opinions at odds with their abstract or political beliefs regarding DWD • Misinformation about the law on DWD (passed in one state in the USA): *"…could be used to hasten death in people with disabilities*"; "*once suicide was legalised, an expensive drug for pain was not covered by the insurance company*." • Fear of criticism from other disable people in relation to the expression of attitudes towards DWD legislation is common. Twenty four out of 45 participants had experienced, knew someone who had experienced, or feared they would experience criticism if they spoke out in favour of DWD legislation. • Lack of association between attitudes towards DWD legislation and a host of factors, including disability identification, religion, race, class, social support, and relationship with one's own physician.
Limitations of study	Authors: NR Reviewer: Very descriptive, lacks formal reporting of data.
Quality of assessment	Partial

Authors, Year, Country	**Minogue et al., 2005, UK**
Aims	To examine the development of one service user and carer research group in a mental health trust.

<table>
<tr><td>Methods</td><td colspan="3">Cross-sectional

Survey of 10 consumers and carers involved in research in SW Yorkshire Mental Health NHS Trust
Skills audit and training needs analysis of consumers</td></tr>
<tr><td>Patient and public involvement</td><td colspan="3">Service users from 18 service evaluation or research projects. Involvement ranged from sitting on project boards, members of project team, advising on questionnaire design, interviewing, analysis of data, contributing to approval of projects (consultation or collaboration, but not user control)</td></tr>
<tr><td>Level</td><td>No. of users</td><td>C & D</td><td>M</td></tr>
<tr><td>1, 2, 3</td><td>1-3 on most projects.
5 on one project, one involved
6 or more.</td><td>C=NR
D=NR</td><td>NR</td></tr>
<tr><td>Impact</td><td colspan="3">Community
<u>Benefits:</u>
• Changes in information given to service users
• Continuation of services
• Continuing to the next stage of evaluation

Service users:
<u>Benefits:</u>
• Sharing knowledge
• Personal experience enabling others to represent others with mental health problems and make relevant and valued changes to the service.
• Putting something worthwhile back into the services
• Being able to give informed views and opinions
• Promote the carer’s perspective
• Service users working alongside researchers
• Support (preparation/briefing/debriefing, information sharing, training and mentoring, one to one support, explaining and checking understanding, transport and refreshments)
• Being treated equally by Trust staff.
• Benefits they identified were categorised into: knowledge (treatment, services, jargon, research skill), experience (Talking to other service users, attending and presenting at conferences, training, visiting new places), emotional (interest, support, helping others) development (confidence, self esteem, listening skills)
<u>Challenges:</u>
• One project didn’t involve users from the beginning of the project had resulted in it having lack of focus on service user perspectives
• Lack of clarity about their involvement</td></tr>
</table>

	• Lack of feedback about their input meant they could not determine how useful their input had been. **Research team (from Trust)** <u>Benefits:</u> • Bring different perspective that might not have been considered by staff • Direct experience of services • A broader or more critical view as well as helping iron out the softer issues • Specific expertise in a particular area • Ensure researchers stay focused on service user involvement • Changes in research process rather than just a service change <u>Challenges:</u> • Can often be seen as a statutory requirement and can therefore often be tokenistic.
Outcomes	N/A
Limitations of study	1. Authors: NR 2. Reviewer: very small pilot study
Quality of assessment	Partial

Authors, Year, Country	**Morgan et al., 2004, UK**		
Aims	To involve and enable lay people to identify and direct a research study as co-researchers consulting members of the general public about their awareness and knowledge of stroke and stroke risk		
Methods	• Questionnaire designed by two consumers trained in research skills at a year long training programme. • The questionnaire was sent to 250 stroke patients who were selected randomly aged 40 to 65 years from one general practice in North Staffordshire.		
Patient and public involvement	• Identified and directed study • Conducted literature review. • Developed questionnaire and conducted survey. • Dissemination of results. **NB.** Was part of the year long skills programme, so were assisted by researchers from Staffordshire University.		
Level	**No. of users**	**C & D**	**M**
1	2 lay researchers (142/ 250, 57% service users	C=NR D=NR	NR

	responding to survey)		

Impact	**Community**
	Benefits:
	• Linked two national priorities:
	  o 1) Vision of user involvement in the processes of health service research
	  o 2) National Service Framework for Older People which identifies service developments to improve stroke services in UK.
	• Improved relevance of enquiry to community.
	• Engaging patients and users in identifying and researching local issues to raise awareness of the issue in the community
	
	Service users
	Benefits:
	• Consumers were able to select a topic that would be of local public concern and could angle the enquiry so that the specific questions posed were likely to be relevant to the community (theory of inclusive research as being essential to ensure both the relevance and benefit of the research to the research participants).
	• Felt their efforts were taken seriously, which improved their motivation to be involved in the research.
	• Training and gaining first hand knowledge of research in health care e.g. assistance from researchers enabled service users to search the literature on stroke, revealing major gaps in the publics knowledge of potential risk factors and warning signs of stroke.
	
	Research team
	Benefits:
	• Dissemination by users is beneficial as will do this in a more 'user-friendly way'
	• Researchers would have targeted a wider population and made the questionnaire more scientific (balance between scientific integrity and level of consumer direction).
	• Reduce imbalance of power between researchers and the researched
	• With service users conducting research, lightens the workload of the researchers.
	Challenges:
	• Problems of gaining balance between enthusiasm of consumers, the NHS, and the constraints of ethics and scientific principles of research
	• Lack of experience of consumers involved academic support without providing undue direction of research		

Outcomes	**Research results**: • 57% response rate (142/250). • Knowledge of stroke and stroke risk was good. • 90% knew stroke occurs in the brain and most correctly identified the causes as related to impaired blood supply to the		

	brain. • 96% said it was extremely important to get immediate treatment for someone who may have suffered a stroke. • 78% stated they would like further information about stroke. • Most popular sources of information identified were: general practice (51%), TV and radio (36%), and friends and family (33%).
Limitations of study	1. Authors: Future research should seek more in depth information about what patients understand by a healthy diet and lifestyle, moderate exercise, and other preventative measures. Measures of health belief and behavioural change could be included. 2. Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Morris et al., 2004, USA**		
Aims	To determine the applicability of exception from informed consent to a randomised, controlled trial of emergency interventions after resuscitation from inpatient paediatric cardiac arrest.		
Methods	Qualitative and cross-sectional study • Eight focus groups (23 parents and 33 hospital staff). • Written and e-mail responses (seven parents, 42 staff) • Telephone responses (20 parents of children previously resuscitated). Analysed in NVivo		
Patient and public involvement	Parents (carers) and public (hospital staff) of children entering PICU. Service users participated in consultation process (focus groups, e-mail, telephone, and written responses) to consider their opinions on exclusion from informed consent.		
Level	**No. of users**	**C & D**	**M**
1	50 parents 75 staff	D=NR	NR
Impact	**Community** <u>Benefits:</u> • Broad range of users selected from multitude of ethnic, socioeconomic and religious backgrounds • Ample opportunity for community to respond with various methods of input provided (focus group, written, e-mail, and telephone)		

	Service user Challenges: • Lack of understanding of controlled trials led to concern about use of randomisation in trial (none selection of child for treatment). **Research team** Benefits: • Involving user community in decision-making about informed consent led to understanding and acceptance of research, which led to less risk of legal liability and public repercussions.
Outcomes	Written responses: • 7/7 parents and 21/42 hospital staff endorsed exception from informed consent; 5/42 staff were against this. Telephone conversations: • 14/20 (70%) of parents agreed with endorsed exception to informed consent, while 3/20 (15%) opposed this. Parents and health professionals state the emotional state of the parents and the volume of information to absorb as reasons inappropriate informed consent at this time. An alternative is to seek informed consent from all parents at the time of hospital admission, although this would add to the anxiety of parents at an already anxious time, be time-consuming process for staff, and give added paperwork for parents. Also, the validity of this informed consent is questionable, if a parent does not expect their child to be eligible for this study. The importance of the timing of the intervention was discussed, and agreed it should be initiated within 30 minutes of after cardiac arrest.
Limitations of study	1. Author – NR 2. Reviewer - NR
Quality assessment	Adequate

Authors, Year, Country	**O'Donnell and Entwistle, 2004, Scotland**
Aims	To explore whether, why, and how UK funders promote consumer involvement in research projects
Methods	Cross-sectional, qualitative study • Postal questionnaire survey and in-depth interviews with UK funders
Patient and public involvement	• Not reported in this cross-sectional study. • Reports on outcomes of survey on how and why UK funders involve consumers.

Level NR	No. of users	C & D	M
NR	NR	C=NR D=NR	NR
Impact	**Funders** <u>Benefits:</u> • Helps ensure that research funded is of relevance and importance to the community (n=1) • Makes allocation of funds more transparent (n=1) • Makes funding organisations more accountable (n=1) <u>Challenges:</u> • Need to motivate funders to support PPI in research in order to overcome institutionalised system • Funders look for scientific integrity, whereas user-led research focussed on making research 'real' • Research bodies/funders take user-involvement less seriously than academic research • Funders want to fund specific projects to fit their own remit, and therefore little room for user involvement in agenda setting for research		
Outcomes	• 81% (68/84) public and voluntary organisations responded to the postal survey. • 42 (62%) involves consumers in their work. • 32/42 encouraged researchers applying for funding to include consumers in research. • Types of activities that UK funders encourage researchers to involve consumers: o Managing research - 25/42, 60% o Carrying out research (e.g. carrying out interviews) – 15/42, 36% o Interpreting the results – 15/42, 36% o Other (e.g. dissemination) – 9/42, 21% • Ten respondents reported providing information about involving consumers in the guidance notes that they gave to researchers. • Eleven respondents asked researchers to explain how they had involved consumers in the development of the grant application. • Twelve respondents said they asked researchers to explain how they would involve consumers in their proposed research. • Seventeen funding organisations were interviewed. • Reasons given for importance of encouraging consumer involvement: o Matter of principle, o Government/NHS policy (public sector funding bodies) o Ethical requirement in the Research Governance Framework document. o Funding bodies perceive consumers as useful sources of information and advice to researchers (e.g what it is		

	like to live with the particular health condition, how relevant particular research outcomes are to consumers, whether particular research methods would be acceptable to consumers, how to gain access to study populations, how to go about recruiting participants to a study, the content of information materials for research participants, and where to disseminate research results. o Improve consumers understanding of research o Raise awareness of and legitimise research in consumer communities. o Comments by individual funders: o As researchers become more in tune with consumer perspectives, consumer involvement may diminish over time of study. o Bringing researchers into contact with consumers on a research project could help motivate researchers. • Possible negative effects: o Consumers might 'hijack' projects to satisfy their own personal or political agendas o Cost considerations o Organisational capacity o Types of research project not appropriate to include consumers in. • Perceptions of consumers' roles in research: o 'Early' involvement had more potential to improve the quality of research o Inclusion of consumers on advisory or steering groups (need for more than on consumer to ensure a range of consumer interests and to ensure consumers have peer support). o Dissemination activities (consumers who had been assigned to individual projects from the start of a project were seen as particularly well placed to contribute to dissemination activities because of their "excellent inside knowledge of what the project has been all about". o Others included conducting interviews, writing up research findings, and contributing to interpretation and policy implications. • Steps to facilitate consumer involvement prior to submission of research applications: o Describe what they mean by consumer involvement and why they consider it important, the appropriateness of different types of consumers and consumer involvement activities, suggestions about how to identify appropriate consumers, and potential barriers to consumer involvement and how to overcome them. Also to consider time and cost implications. o Try to avoid being prescriptive because recognise that there are differing appropriateness of particular forms of consumer involvement depending on the study. • Approaches used to address consumer issues: o Explain relevance and importance of the research to consumers o Describe how consumers have been involved during the development of the project o Describe how consumers will be involved once the project has begun o Provide a lay summary of the research proposal • Perceived indicators of 'good' descriptions of consumer involvement: o Types and numbers of consumers involved o Proposed descriptions of consumer involvement were 'credible' or 'feasible'

	○ Whether consumers were named as co-applicants on the research proposals ○ Demonstration that made initial contact with consumers ○ Details of training, personal and financial support for consumers ○ Costing of activities associated with consumer involvement. • Approaches to monitoring consumer involvement in research projects: ○ Funders sought feedback from consumers, or discuss consumer involvement activities in interim reports or during progress meetings.
Limitations of study	1.Author: NR 2. Reviewer: difficulty in assessing whether funders do what they say they do.
Quality assessment	Adequate

Authors, Year, Country	**Oliver et al., 2008, UK**		
Aims	To describe the development of a multidimensional conceptual framework capable of drawing out the implication for policy and practice of what is known about public involvement in research agenda setting.		
Methods	• Systematic review of the literature using electronic databases, and policy and lay networks. • Framework analysis, previously described in primary research, was used to develop the framework, which was then applied to reports of public involvement in order to analyse and compare these.		
Patient and public involvement	In literature: patients, publics and carers. Mixed population		
Level	**No. of users**	**C & D**	**M**
1, 2, 3	NR	C=√ D=√	NR
Impact	**Policy** <u>Benefits</u>: • Framework has been used since in a systematic review of involvement in a broader range of activities: developing health care policy, clinical practice guidelines, and patient information (Nilsen et al., Cochrane, 2006). **Reported in literature (Hanley and Involve, 2003)** **Consultation process** <u>Benefits</u>: • Obtain the views of lay people quickly, but without necessary commitment to acting on them (regarded as 'safe' option by researchers).		

	Challenges: • Patients and public find it frustrating process to be asked their views, without commitment to acting on them **Collaboration** Benefits: • Increased access to research participants (involving lay people in recruitment and informed consent). • Increased relevance of interpretation and understanding of data. • Greater relevance of outcomes measures and assessment criteria to lay public. • Patient and public feel more ownership of results, and therefore greater dissemination. Challenges: • Additional time and results • Loss over control of over research by research team. **Lay-controlled** Benefits: • More likely to reach marginalised groups • Addresses research questions that researchers may not consider relevant. • Development of research skills for patient and public • Greater commitment to disseminate findings Challenges: • Researchers find it difficult to hand over control to patient and public

Outcomes	• Evidence from the systematic review drew on differing priorities, conceptual frameworks, community equipoise, power, democratic practice and advocacy.
	• The health topics covered in the literature were different:
	  ○ Health conditions (asthma, breastfeeding, cancer, cystic fibrosis, dental health, diabetes, disfigurement, HIV, hyperactivity, learning difficulties, mental health, physical and complexities disabilities).
	  ○ Populations (older people, younger people); interventions (physiotherapy, organ transplants, wheelchair and other assistive devices).
	  ○ Settings (homelessness, occupational health, school health, urban health).
	
	Report research results only:
	Framework was based on three critical dimensions:
	• Whether lay people are involved as individuals or as members of organised groups.
	• Whether public involvement was at invitation of the research programme or as a response to action by the lay public (‘reactive’ or ‘pro-active’).
	• The degree to which public was involved (consultation, collaborative or lay control).

	Eight dimensional framework developed: • **Degree of public engagement (P)**: o 1) Lay control o 2) Collaboration o 3) Consultation o 4) Minimal • **Researcher degree of engagement with public (R):** o 1) Inviting lay groups o 2) Inviting individual lay people o 3) Responding to lay action o 4) Minor partner or absent. (**NB**: In grid P2, R1= A; P3, R1=B; P2, R2=C; P3, R2=D; P2, R3=E; P3,R3=F; P4, R3=G; P1, R4=H) • The conceptual framework takes into account: o the people involved o the people initiating the involvement o the degree of public involvement o the forum for exchange o methods used for decision-making o context (in terms of the research focus and historical, geographical, or institutional setting) o theoretical basis • The framework draws together examples of public involvement that share fundamental principles, but that have developed in very different contexts. It distinguishes between variables operating at different levels: o at initiation o subsequent choice of participants, forum, and decision making processes • Using the categories in the framework, (A-H). o The "A" method (commonly used in large scale research programmes in committee membership) alone achieved little o Bottom-up type C achieved a lot, but only for small scale research. o The most effective way of involving the public in setting large-scale research agenda appeared to be a combination of collaboration and consultation, with lay people taking leading roles in consulting their peers. • A key barrier to public involvement being effective was not the inability of lay people to identify or prioritise research topics, but the tendency of professional organisations not to grasp them.

	• The framework highlighted the abstract concept of empowerment in practical terms:
	  ○ the number of people involved
	  ○ whether they were individuals or networked group members
	  ○ whether there were one-off or repeated opportunities for involvement
	  ○ whether members of the public had leading roles or played a part in decision-making
	  ○ whether there were any training processes or other resources to support their involvement
	
	• Two measures of impact were chosen that related directly to the review question (records of lay priorities, and records of reflection and lessons learned), and aligned the work with participatory approaches for mutual learning, reflection and change.
	
	• Applying the framework: with consultation more was learnt by involving patient and public in debate (Delphi study, focus groups, face to face) rather than written consultation. Lack of thought into how to involve the public led to the loss of opportunities for shared learning. Importance of involving public in the agenda setting exercise. Working with community groups gauged local opinion, but could be time consuming, and faced difficulties of lack of attendance, lack of understanding and lack of commitment.
	
	• Little known about how lay people view consultation, as mainly evidence on the research perspective. Investing time and money into user-involvement led to better learning from user-involvement. Opinion surveys gave a shallow picture of attitudes, perceptions of benefit and harm of research, and little data on research priorities due to close questions.
	
	• Interviewing in clinical settings led to greater identifications of interventions and outcomes to frame evaluation agenda. Patients or public with personal experience of problems added more emotive and persuading language and ideas.
	
	• Collaboration: when it worked well, this facilitated democratic processes, openness, appropriate choice of members, and support and training for all involved. Careful management needed to avoid tensions. More 'successful' when programmes were required to reflect on methods for incorporating their perspectives, and when users seen as 'partners' in research.
	
	• If individuals were involved (rather than organised groups), more input was needed in training, education and 'knowledge transfer', but more meaningful input was put into research.
	
	• Lay controlled research: least formally developed.
	
	• Collaborative strategies with individual consumers achieved more than consultation through committee membership. Most successful method of user involvement appeared to be when using collaboration and consultation, with lay collaborators consulting their peers.

	Challenges: • The literature was replete with enthusiastic reports and reflections but with little or no detail about public involvement, and often little attempt at objectivity • The framework exposed important gaps in the existing literature, most notably about methods for collective decision-making, which are rarely reported in detail.
Limitations of study	1. Author: NR 2. Reviewer:NR.
Quality of assessment	Adequate

Authors, Year, Country	**Oliver et al., 2001, UK**
Aims	To describe the methods used for involving consumers in a needs-led research programme (Health Technology Assessment programme), and to discuss facilitators, barriers and goals.
Methods	Qualitative study • Interviews: face-to-face, telephone, post or e-mail with service users who had been involved in the Health Technology Assessment (HTA) programme. • Recruited consumers who had an understanding of the topic area, and were willing to give time and effort to undertake a specific task and discuss the process afterwards. • Analysis: the action researcher trawled through policy and procedural documents of the NCCHTA, agenda and minutes of meetings of the HTA and NCCHTA, documents produced for the pilot, such as letters to consumers and training materials, documents produced for the pilot, such as observations of panel meetings, staff meetings, the meeting convening to reflect on the pilot, feedback about the pilot from consumer observers, consumer panel members, other panel members, other consumer contributors, NCCHTA, and panel chairs (on one to one basis). Also, telephone calls, e-mail messages, letters, questionnaires, and group discussions with the NCCHTA staff. • Facilitators, barriers and tensions of consumer involvement were identified. • Consumers: campaigning, self-help, and patient representative groups; national charities, health information services and journalists.
Patient and public involvement	• Identifying important research questions (topics sent out to consumers, discussions about research needs with consumers, reviewing qualitative research undertaken by consumers). • Prioritising research, which was normally achieved by the Standing Group on Health. Two consumers joined each of

	the three panels (and given appropriate training). • Commissioning research: the selection of one topic out of four by charities, health service users and campaigners. • Reporting research: two final HTA reports given to consumers for review. • Increased awareness of HTA reports through availability of summaries at conferences, sending to consumer organisations and asking them to comment. • Registering the HTA programme with the Centre for Health Information Quality database.		
Level	**No. of users**	**C & D**	**M**
2	NR	C=NR D=NR	NR
Impact	**Service users** <u>Benefits:</u> • Learning from others (learning from more experienced colleagues). • Training, e.g. turning health needs into questions, introduction to critical appraisal. • Appreciated induction day, but highlighted need for on-going support throughout the process, perhaps through mentorship (e.g. practice peer-review sessions, someone to phone when perplexed, and opportunities to meet others every 6-12 months. <u>Challenges</u>: • Unfamiliar processes, acronyms and technical language, including the suggestion for a glossary of terms. • Need for defining roles of people involved in the panel meetings. • Avoid marginalising people (e.g. only one women in group, only one ethnic minority in group). **Research team** <u>Benefits:</u> • Helpful and timely contributions to clarifying and prioritising the knowledge gaps. • When seeking research topics, face to face discussion with a consumer group was more productive than scanning consumer research reports or contacting consumer health information services. <u>Challenges:</u> • Increased workload & cost (e.g. recruitment), but not fundamentally challenging an open working culture that was already receptive to listening to the views of others. • Professionals often felt wary on new processes involving consumers, which impeded communication at times.		
Outcomes			
Limitations of study	1. Author: small pilot study 2. Reviewer: NR		
Quality of assessment	Adequate		

<table>
<tr><td>Authors, Year, Country</td><td colspan="3">Ong and Hooper, 2003, UK</td></tr>
<tr><td>Aims</td><td colspan="3">• To involve users in the design of a research project to assess a 12-month course of lower back pain (quantitative)

• To determine patient and professional perceptions of low back pain and its treatment relate to the use of health care and subsequent outcome (qualitative)</td></tr>
<tr><td>Methods</td><td colspan="3">• Consumers recruited from hospital back pain clinic (n=5: two new patients and three chronic patients), and by searching GP computerised consultation records (n=10: five male and five female selected from two age bands (30-44 years and 45-59 years).

• Three focus groups prior to study, one involving patients with lower back pain, one involving GPs, and another involving health professionals (HPs).

• Discussed experiences of living with low back pain, and research questions for consideration within the study were identified.</td></tr>
<tr><td>Patient and public involvement</td><td colspan="3">Assisted in identifying themes (in focus group forum) from which to develop study questions.</td></tr>
<tr><td>Level</td><td>No. of users</td><td>C & D</td><td>M</td></tr>
<tr><td>1</td><td>6 in focus group.
(15 recruited)</td><td>D=NR</td><td>NR</td></tr>
<tr><td>Impact</td><td colspan="3">Service users
<u>Benefits:</u>
• Patients judged discussions positively:
“Listening to other people talking about their experiences[…] and have people listen to me, has made me feel more positive’; and ‘it’s so nice that someone ‘cares’ enough to find out about the indications and effects of pain […]”
<u>Challenges:</u>
• Exploration of conflicting viewpoints between patients and doctors, e.g. the criticisms of service users of not being listened to were contrasted with the sometimes rigid and rather limited beliefs of some health professionals.

Research Team
<u>Benefits:</u>
• Focus group optimal method of eliciting views of user groups.
• Benefits of input ‘from personal experience, the subject of the research’.
• More equal power between health professionals and service users.</td></tr>
</table>

	• Able to explore the attitudes, feelings, beliefs, reactions and experiences of respondents. Challenges: • Focus groups dominated by personal experiences of personal narratives (participants did not make a distinction between personal experiences, perceptions, and the research potential for each issue). • Therefore, participants offered their experiences as material for analysis. • Focus groups were seen as a forum to get other parties to accept their understanding of low back pain at the expense of formulating questions. • Need to gear focus group towards identifying themes that can be translated into research topics (not aiming to develop research topics immediately in the focus groups). • Need for training of users on how to question the appropriateness of the research design and methods, which service users in this study failed to do. • Allowed focus groups to become more about the process (talking about experiences) than the outcomes (formulating questions).
Outcomes	Summary of key themes from focus groups: • Diagnosis and causality: o GP able to work better with person with obvious trauma. o In absence of identifiable signs of physical damage, GP relies solely on patients account, which they feel uncomfortable with. o Patients with vague symptoms want their pain to be recognised and legitimised. o Almost all participants of the patient focus group mentioned they had difficulty in gaining recognition of the nature and degree of pain: "*I've got a full face of make-up on. I've done my hair – I look great…but I have had to get up at 6.30 this morning, have a couple of baths, have loads of drugs. Fiddle about with myself so that I look wonderful- because I look bloody awful when I get up in the morning because I've had no sleep. People look at you and there is no plaster on it […]"* • Proving the pain: o Changing cultural acceptance of minor back pain. o Need for diagnosis in terms of fitness to work. o Need for a more detailed understanding of what was wrong with them and the challenges that this may place on their activities. o The experience of not knowing was disempowering: "*If you haven't got a cause, I think your own mind plays havoc and you think all sorts is going on. So, if you have a cause, and something to read about it and understand, then it does make you cope better…"* • Need for a search for knowledge as to causality, effective treatments, and boundaries to their activities. • Quality of life: problems of differing expectations of quality of life between the patient and doctor; e.g. balance between pain relief and side effects, self help and professional treatments • The inflexible application of medical categories by GPs/ HPs ("*…you are working, and therefore your back pain is not serious enough for pain management offered on the NHS*"). Therefore, not recognising the variation and complexity of

	their experiences. • Need for direct access to professional help when needed, rather than waiting months for an appointment.
Limitations of study	**Authors** <u>Challenges:</u> • Users may have benefited from training in research agenda setting before focus groups to help develop more explicit research questions • Issues of resolving tensions and contradictions between users, GPs and other health professionals. Reviewer: NR
Quality of assessment	**Adequate**

Authors, Year, Country	**Owens, Ley, Aitken, 2008 , UK**		
Aims	To identify the research priorities of different stakeholder groups within the mental health care service and examine the extent and nature of agreement between them.		
Methods	Delphi technique with four different stakeholder groups • 34 mental health service users • 26 carers • 35 mental health practitioners • 23 service managers		
Patient and public involvement	60 service users (patients and carers) were involved in a Delphi group to identify research agenda for mental health care service		
Level	**No. of users**	**C & D**	**M**
1	60	D=NR	NR
Impact			
Outcomes	**Important research topic agendas** **Carers:** • Impact of mental illness of the health and lives of carers • Respite and practical support for carers • Residential care/ supported living: effectiveness and adequacy of provision • Access to crisis services, especially out of hours • Alternative to hospital: safe environments of sanctuaries for people to recover in • How to improve communication between carers and health professionals • Factor affecting the motivation and effectiveness of carers and professionals • The understanding of diagnosis of service users and carers; access to information		

	• Aftercare following acute episodes • Putting care plans into practice • Effective methods of preventing crisis • Helping service users to recognise onset crises and seek help early • Early detection of mental disorders (e.g. at school) • Length of time between first onset of symptoms and diagnosis • Public education about mental health • Causes and triggers of serious mental disorders • Implementing available research evidence and cost of doing so **Service users:** • How to find the meaning and purpose in everyday life; battling hopelessness • Alternative places to go when ill or recovering: sanctuaries • Crisis prevention • Challenging stigma; changing public attitudes towards mental illness • Which aspects of services do service users perceive as enhancing or undermining their personal autonomy and dignity • **Health professionals:** • Quality of life of in-patient environment and care • Brief psychological interventions: what components are helpful **Managers**: • Admissions to hospital: how are decisions taken • What do patients see as central to their recovery? • Effective self-management packages for chronic mental illness • Good customer service skills: impact on service users, staff and visitors • Performance monitoring: impact on service delivery and patient experience All groups identified and attached high importance to issues that related to the promotion of independence, self-esteem, and recovery. The quality of in-patient care, the place of psychological therapies and relationship between physical and mental health also emerged across the board
Limitations of study	Author: NR Reviewer: NR
Quality of assessment	Partial

Authors, Year, Country	**Paterson et al., 2004, UK**

Aims	To pilot adequacy of outcome measures, assessing therapeutic massage for people with Parkinson's disease		
Methods	• Service users (n=7) recruited co-researchers from Parkinson's Disease Society (PDS) were given a course of eight one-hour sessions of deep body (therapeutic) massage over eight weeks. • They completed the Parkinson's Disease Questionnaire (PDQ-39), the Measure Yourself Medical Outcome Profile (MYMOP), and the Medication Change Questionnaire (MCQ) four weeks before and three days before treatment, the start of treatment, and then monthly for five more months. • Semi-structured interviews just before and just after treatment to examine whether relevant quality of life measures adequately reflect the experience and perceptions of patients receiving massage. • The sample was aged between 60-78 years and had been affected by PD for between two and 19 years.		
Patient and public involvement	• Recruited participants • Administered the funding • Administered questionnaires		
Level	**No. of users**	**C & D**	**M**
2	NR	C=NR D=NR	NR
Impact	**Research team** <u>Benefits:</u> • Consumer involvement assisted in design of study; for example, the time of day of the massage is important because symptoms can be variable throughout the day due to timing of medication.		
Outcomes	• Multi-disciplinary team including lay members came to following conclusions: o Intervention at best described as 'visiting the massage therapist o Participants have potential for improvement (PDQ-39) o The time of day of massage is important o Attention is needed with regards to the administration of questionnaire to those with disabilities (e.g. poor eye sight, speech problems) or those for whom the questions would cause distress. o PDQ-39 is a suitable Q of L measure to use in the study o An objective assessment of change should be added in (e.g. video of them conducting certain tasks) rather than a reliance on subject reports from participants (using a 'blinded' researcher). o Baseline data should be collected on several occasions to overcome changes due to anticipation of intervention itself. o No. of massages given o Consideration of additional funding for participants to continue massages after study has finished.		

	○ Cluster randomised trial for actual study ○ Well-being outcome can be 'not getting worse', rather than always 'getting better'.
Limitations of study	1. Author: Small sample size and loss of two participants during the treatment programme. 2. Reviewer: small pilot study
Quality assessment	Partial

Authors, Year, Country	**Philpot et al., 2004, UK**		
Aims	To elicit users' views of electroconvulsive therapy (ECT) in two mental health trusts with a user-designed questionnaire		
Methods	Survey – 20 item questionnaire constructed by members of Communicate (the users' group at the Maudsley Mental Hospital. The questionnaire was divided into two parts: The Care Satisfaction Scale, and the Adverse Effects Scale. Response rate: 44/108 (41%)people who had completed courses in bilateral ECT		
Patient and public involvement	Users ran this study – from idea for study, design of study, conducting study (questionnaire came from 'Communicate', not doctors or researchers). Support given by researchers at South London and Maudsley NHS Trust.		
Level	**No. of users**	**C & D**	**M**
3	3 user researchers 44 users of ECT	C=NR D=NR	NR
Impact	**Research** Benefits: • Patients were more honest about their satisfaction levels with bilateral ECT because they were interviewed by fellow users. • Evidence shows that patients who had been interviewed on the ward by the treating doctor reported higher satisfaction scores (Clark et al., 1999, Polowycz et al., 1992)		
Outcomes	• Users reporting they would 'never have ECT again' had significantly lower satisfaction scores and higher adverse effect scores (p=0.024, p=0.033, respectively), than those who had had ECT before and were more prepared to have it again. • Those respondents who had had ECT before went on to say they would agree to it again (α^2=4.91, df=1, p<0.05). • Those receiving care at Maudsley Hospital had significantly lower satisfaction scores (p=0.007). • Those who said they would have ECT again were significantly younger than the remainder (54.8±16.1 years vs. 66.4±13.2 years; F=5.26, df=1, 42, p=.0286). Qualitative responses: • Feeling compulsion (no choice): patients reported '*not given another alternative by staff*', or '*felt for themselves that there was no alternative*', either because ECT had worked before or because they were at the end of their tether, or were prepared to try anything.		

	• Informed choice: a patient reported that even though she had tried to make an informed choice, she felt that the information was wrong because the treatment did not work and she had memory loss afterwards. • The most severe side effect was memory loss.
Limitations of study	Author: NR Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Pivik, Rode, Ward, 2003, Canada**		
Aims	To identify what health consumer orgs consider meaningful involvement, examine current international practices, and develop a model for involvement based on identified priorities and needs.		
Methods	Literature review of existing models or methods searching electronic databases: • Information from the review was used to identify criteria for the assessment of working models • These criteria were then applied to existing working models of consumer involvement to identify strengths and weaknesses, and gaps. • A questionnaire was designed for consumer groups to ask if CI is a priority, how consumers could be involved, what resources are needed.		
Patient and public involvement	NR		
Level	**No. of users**	**C & D**	**M**
NR	NR	C=NR D= Development of consumer involve. Model for HTA	NR
Impact	NR		
Outcomes	<u>Literature review</u>: Three main themes were identified • consumer involvement is more meaningful if focus is on involvement versus consultative strategies • 2) the most feasible type of involvement based on current practices involved consumer participation on a decision-making committee • 3) the views of both health professionals and consumer perspectives should be represented. This led to two sources for evaluation: • The elements of Fairness Framework (Martin et al., 2002), which was based on priority-setting for decision makers and includes: o external transparency		

	o multiple perspectives o external consultation o consensus o honesty o identifying potential conflicts of interest and appeal mechanisms o leadership o internal transparency, o Understanding o opportunity to express views o agenda setting opportunities • The conceptual Framework for Citizen Involvement in Health Planning (Pivik et al., 1997) was based on four categories: o i) nurturing a climate conducive for citizen participation (mobilising the community, fostering respect and trust, developing an attitude shift for professional and utilising a partnership approach) o ii) process issues (defining partners, developing a common vision, clarifying roles and responsibilities, defining decision-making process, and assessing participation o iii) knowledge requirements (information, education and training) o iv) support requirements (financial, organisational, and political). • Two models of consumer involvement were identified: o National Institute for Clinical Excellence (NICE) citizen's council, UK o Breast Cancer Network Australia Consumer Representative Project, Australia o These 2 models were assessed using the evaluation criteria described above. Strengths and weakness of these models are reported in paper. • Based on these strengths and weaknesses, the following factors were identified in relation to CI in HTAs: o type of involvement needed informational resources o best methods to provide this information o other resources to facilitate involvement o accessibility issues o feedback mechanisms o level of interest in database that would list the skills, knowledge, and level of expertise of members o importance of consumer involvement in HTA o timelines required for consumer involvement. • Forty-nine consumer groups completed the questionnaire (25 national and 24 provincial organisations): o 89% reported very important for consumers to be involved in treatment and therapy assessment; o 98% reported consumers have important information to add to HTA decision-making. • When asked how they were involved:

	○ 82% reported that they used questionnaires ○ 80% used focus groups ○ 74% took part in key informant interviews ○ 71% participated in community forums ○ 71% were willing to send representatives to take part in the decision-making committee • When asked what type of information was required: ○ 92% reported that information was needed on the specific treatment or therapy being reviewed ○ 89% wanted information on health issues, health policies and programmes ○ 78% wanted information that would help them understand the scientific research process • The best way of imparting such information was: workshops, easy to read manuals and guidelines over the internet. Consumers stressed the importance of ensuring the information is presented in lay language. • Consumers reported that the resources required to be involved were: educational materials, re-imbursement of expenses, and access to experts for advice. • 63% said accessibility issues would have to be taken into account, with the main issues being physical accommodations (wheelchair access, opportunities for breaks in longer meetings, and accommodation related to illness or disability (e.g. a scent-free room for asthmatics). • 83% supported the idea of a database listing the skills, knowledge, and level of expertise of members. • 88% of national orgs and 71% of provincial orgs were happy to participate in Decision-making Committees that lasted 12 to 18 months. • 58% said there should be at least two consumer representatives on the committee, while 21% said there should be three. • Consumer involvement model developed (see paper for more detail): ○ A fair and transparent process involves an independent, nationally-based consumer organisation that works in tandem with, but is not governed by the centralised review committee. ○ Federal Government needs to provide funding ○ Development of a HTA network ○ Development of formal consumer stakeholder involvement process (selection, feedback mechanisms, timelines, accommodation needs, training and educational support, access to expert advice) ○ The development of consumer national database providing details of their knowledge, skills and expertise. ○ Provision of training and education support for consumers (health issues, health policies, treatment or therapy, scientific and research processes, and information on the practical side of meetings, including planning, evaluating, procedures of meeting, and communication. ○ Development of web-pages and organisation of educational workshops. ○ Evaluation of programmes and the effectiveness of the process.
Limitations of study	1. Author: NR 2. Reviewer: needs to be evaluated and validated during HTA process. No formal measurement offered
Quality assessment	Not possible to report as not systematic review

Authors, Year, Country	**Plumb et al., 2004, USA**		
Aims	To assess the success of the program Community Research Collaboration (CRC) intended to foster community-researcher collaboration on all aspects of the research process, and to identify areas for improvement.		
Methods	Qualitative study • 11 question open-ended telephone interviews. • 15 confidential interviews conducted with 15 community and academic researchers. • Secondary data = reviewing all nine grant applications and the progress reports from the 15 researchers that were interviewed. • Review of CRC materials including application packets and the application process.		
Patient and public involvement	• Four studies reported intensive involvement (i.e. community collaboration beyond use of community members on the research team). • They held community meetings, meetings with core groups of community members over an extended period of time, and let clients review the proposal, research methods and tools in order to provide feedback.		
Level	**No. of users**	**C & D**	**M**
1, 2, 3	Nine CRC funded studies N not reported	C=NR D=NR	NR
Impact	Six grants were initiated in the community: two were community-researcher collaborations that had worked together before, and one was initiated by an academic researcher. **Community** **Service users** <u>Benefits:</u> • Developed knowledge of research skills • Increased understanding • Academic researcher		
Outcomes			

Limitations of study	Author: NR Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Reed, Weinder, Cook, 2004, UK**		
Aims	Reflection of issues that have arisen in three projects where older people were involved in research at different levels (from sources of data to independent researchers)		
Methods	Case series. • Study 1: Quality improvement in care homes by promoting the voice of older residents. o Focus groups and interviews with older people aimed to identify and improve aspects of life in a care home. • Study 2: Looking at going home from hospital. o Firstly, had "whole systems" event with older people and service providers. o Then used appreciative enquiry to assess what successes and failures within the organisation discharging the old people. o This was conducted by old people interviewing individuals in these organisations, analysing the data to develop models of why the successful interventions for discharge worked, which led to the development of action plans. • Study 3: Pre-retirement courses. o Older person approached the university for help in research he wanted to conduct to examine the issues that older people felt most affected their quality of life in retirement so he could offer post-retirement courses more appropriate to the post-retirement period. o Conducted all aspects of study with help of university (protocol design, interviews with older people, analysis, write-up etc)		
Patient and public involvement	• Elderly patients, carers, and public. • All three levels of involvement reported		
Level	**No. of users**	**C & D**	**M**
Study 1=1 **Study 2=2** **Study 3=3**	NR	C=NR D=NR	NR
Impact	**Service users (user conducting study 3)** <u>Benefits:</u>		

	• Training in research given by university. Challenges: • Normal channels of finance were not open to older people, so study was entirely self-financed. • Had to provide own transport (car) to get to interviews. • Time taken to conduct study. • Level of education (had good education, but higher education is not so wide spread in this generation. • Training given, but training in research methodology may just reinforce the traditional view of research. **Research team** Benefits: • Drew on their interpersonal skills and sensitivity towards older people. Challenges: • Difficulty of researching in partnership because it means '*turning upside down existing power relationships'* Academic researchers and health professionals have traditionally had control over what is researched in health, and user-involvement involves sharing out this power. **Group (users vs. researchers)** Challenges: • Tension between views of what constituted a good research study (academic criteria vs. extensive experience of users). • When interviewing, older people felt restricted by the interview schedule, and departed from it when they felt it was appropriate, leading to inconsistencies. This challenged the traditional academic criteria about reliability.

Outcomes	• Author reported difficulty of researching in partnership because it means '*turning upside down existing power relationships*'. Academic researchers and health professionals have traditionally had control over what is researched in health, and user-involvement involves sharing out this power.
	• Putting user involvement into practice:
	  o Developing research questions: research questions have to be formulated and expressed for funders and reviewers, yet these questions may not make sense or have low priority to users.
	  o Therefore need to listen to older people and reflect their experiences in research questions asked.
	• Developing methodology:
	  o Issues of validity and reliability of design may have great importance to researchers, but for service users hey can seen like technical fussiness.
	  o Suggest researchers educate users in methodology, and let it be challenged by users.
	  o As a result the researchers became less rigid about methodology and began to see diversity as a strength of the study, while the service users became more aware of issues of reliability.
	• Data collection:
	  o If users to interview in study need support and training.

	○ However, the advantage is the improved rapport that the interviewer has with the interviewee. ○ Training should involve critical reflection, rather than become tied up with technicalities. • Analysis and interpretation of findings: ○ If frameworks for analysing data have been developed in partnership, the outcome of the analysis is more likely to reflect joint thinking. ○ Need to use interactive process where ideas are taken to service users and debated, or in which service users can put forward their ideas for discussion. • Project management: ○ Lead researcher (project manager) has responsibilities and accountability to the funders, but such a hierarchical model does not facilitate user-involvement in project management. ○ If one person has to give an account of the study to funders, then it becomes difficult for this person to approve a decision which they do not support and do not feel that they can defend. ○ Furthermore, if the older people are to be partners in managing the project, they need access to IT equipment, able to type and post letter etc, which the university may be reluctant to set up. • Writing up and reporting: ○ Academic researchers need to follow a range of rules and conventions in order to get their papers published in peer reviewed journals, which is important for academic recognition. ○ This makes it difficult to get users involved in the writing up phase of the study. ○ Furthermore, convention often diminishes user-perspective; e.g. prefacing the discussion with a summary of the literature can serve to diminish the user perspective as here the world of service user has historically been given little priority. ○ One strategy would be to incorporate the view of the user by preparing a special report summary for users, although this would be unlikely to get accorded the same status as, for example, a published journal article.
Limitations of study	1. Authors: NR 2. Reviewer: NR
Quality assessment	Partial

Authors, Year, Country	**Rhodes et al., 2002, UK**
Aims	To report on an advisory group of service users set up to support and advise a project to evaluate diabetes services in Bradford, UK
Methods	Case study • Recruitment of members of the user advisory group (n=8: six users and two researchers) through contacts in health service and community organisations. • Service users: four men and two women. (Originally four women and five men). Two women that did not speak

<table>
<tr><td></td><td colspan="3">English dropped out, and one man dropped out because of time limitations.
• The advisory group met every two – three months over two years.</td></tr>
<tr><td>Patient and public involvement</td><td colspan="3">Service users gave:
• Information about networks and contacts for recruitment to study
• Direction in appropriate issues and line of enquiry for study
• Advice on the design of interview schedules and questionnaire
• Assess validity of the initial interpretations of the data
• Links to improve dissemination</td></tr>
<tr><td>Level</td><td>No. of users</td><td>C & D</td><td>M</td></tr>
<tr><td>1, 2</td><td>6</td><td>C=NR
D=NR</td><td>NR</td></tr>
<tr><td>Impact</td><td colspan="3">Community
<u>Benefits:</u>
• Gain greater intercultural understanding about issues of diabetes
• Well informed patient population

Service users
<u>Benefits:</u>
• Gained confidence in speaking in groups
• Opportunity to exchange information with others about diabetes (reflecting feeling of paucity of information available and isolation felt)
• Mutual support group for members
• Motivation to be involved through personal contact from researchers, continuity of membership, and integration into the management structure of the study.
• Confidence in numbers (group of consumers brought confidence, rather than being an individual consumer on an advisory group).
• Opportunity to meet and discuss issues away from the formal and often intimidating atmosphere of the steering group of the project, where it was difficult to understand terminology, and often felt like a token gesture
• Personal and social value
• Awareness of other groups issues with diabetes in the community (e.g. Asian)
• Provided pool of ‘expert’ patients for future projects in the diabetes field
• £20 expenses for each meeting attended

Research team
<u>Benefits:</u>
• Gained experience from users to give background knowledge to the project</td></tr>
</table>

	• Help in best recruitment methods • Provided forum in which to assess the appropriateness and effectiveness of research instruments (interviews and questionnaires) • Provide suggestions of topics and lines of enquiry that had not previously been considered by the research team. • Improved quality of research outcomes • Give researchers and project credibility locally • Access to community networks and contacts • Enhance dissemination of findings • Steering group members: • Helped in adapting the language to lay audience. <u>Challenges:</u> • Time-consuming to run group • Temptation to see the group as another focus group. • Reflected on issues of scientific integrity vs. consumer-led research. • Funders and ethics committees looking for scientific integrity
Outcomes	NR
Limitations of study	1. Author – NR 2. Reviewer - NR
Quality assessment	Partial

Authors, Year, Country	**Rose et al., 2005, UK**		
Aims	• To review patients views on issues of information, consent and perceived coercion • To assess where there is a difference between service users gaining patient views and clinicians gaining patient views		
Methods	Review • 17 papers and reports were identified that dealt with the views of patients on information and consent. • 134 testimonies or first-hand accounts were identified.		
Patient and public involvement	• A service user was involved in the study throughout, and is the main author of the paper. • In evidence: service users assessed views of patients on informed consent		
Level	**No. of users**	**C & D**	**M**
3	NR	C=NR D=NR	NR

Impact	
Outcomes	• Approximately half of the patients reported that they had received sufficient information about ECT and side effects. • Approximately a third did not feel they had freely consented to ECT even when they had signed a consent form. • Clinician-led research evaluates these findings to mean that patients trust their doctors, whereas user-led work evaluates similar findings as showing inadequacies in informed consent*:* *"I was given no information and had to sign for it after all my medication at night so I was very drugged when I signed the form for my consent"; "I want you to have an ECT. You're not sectioned at the moment, but I will section you, under section 3 of the Mental Health Act, I will get a second opinion doctor to come and….assess you"* (woman who had nine ECT treatments between 1993 – 1994)
Limitations of study	Author: NR Reviewer: NR
Quality assessment	Not possible to report as not systematic review

Authors, Year, Country	**Ross et al., 2005, UK**
Aims	• To explore the expectations, priorities, and need for information in relation to fall of an older population • To compare the views of older people on risk factor and risk reduction with their carers; to inform local implementation of Standard Six of the National Service Framework (NSF) for older people using the consumer involvement model. • Study: PROP • Insights into professional and consumer perceptions of involvement were gained from the responses to open-ended questions in a self-administered questionnaire that was distributed at the 12-month time point.
Methods	Qualitative and participatory action research • Interviews with older people and with health professionals, focus groups with carers. • Consumer panel (n=29) was recruited by awareness through local community health council and by approaching networks known by the researchers • 1st meeting: mapping of consumer networks, establishing the consumer panel, and developing the terms of reference and methods of working, was a vital precursor to building relationships and carrying out the research. • Research nurse maintained personal contact with panel members, who communicated between panel meetings and ensuring clarity around roles, responsibilities and processes.

<table>
<tr><td>Patient and public involvement</td><td colspan="3">Project design
Management
Analysis
Dissemination
Consumer panel worked alongside research team and met every three months</td></tr>
<tr><td>Level</td><td>No. of users</td><td>C & D</td><td>M</td></tr>
<tr><td>1, 2</td><td>NR</td><td>C=NR
D=NR</td><td>NR</td></tr>
<tr><td>Impact</td><td colspan="3">Community
<u>Study influenced</u>:
Policy drivers for the NSF for older people and patient and public involvement strategies.
Commissioners brief, which focussed on funding innovative primary care research
Service users
<u>Benefits:</u>
Positive about involvement
High level of engagement in this project, as indicated by the low rate of attrition within the consumer panel, and the commitment and willingness of members to take on additional responsibilities outside of the scheduled meetings (such as reviewing project information sheets, piloting interviews, developing a vignette used in the interviews with professionals and disseminating the work of the project through their own community networks).
Support for effective dissemination
Provided guidance and validated methods; e.g., one member acted as an independent observer of two focus groups, taking notes and providing feedback to the panel and the researchers on issues relating to the appropriateness and consistency of method, facilitation approach, and equity of participation of focus group members.
Training (for their role on the panel)
Payment of honorarium and expenses
Personal benefit (for example an opportunity to learn about falls prevention)
<u>Challenges (suggested by service users):</u>
Lack of recruitment of older people for in-depth interviews with ethnic minority groups
Need access a wider network of consumer groups at an earlier stage using new methods, such as television and radio broadcasts
Responsibility to the wider community
Making more use of the panel
Communication issues
Avoiding being overprotective
Wanted reassurance that it would be a worthwhile endeavour and that PROP wasn't 'just another talking shop'</td></tr>
</table>

	Research team Benefits: • Committed to consumer involvement • Felt the project had gained from deeper and more personal insights, which were embedded in the lived experience of ageing, health and fall panel • Produced a 'cohort of advocates' to support the implementation • Adding another layer of insight to interpretation of the data (e.g. panel worked with the researchers on preliminary analysis of the interview data to develop a vignette to be used in the interviews with health and social care professionals. Anonymised extracts from interview transcripts were presented on colour coded index cards to illustrate key themes such as: o views on self and ageing o independence o perceived threats to independence o personal falls prevention strategies • Small groups worked with these cards to construct a story that was discussed with the whole group and refined later by a few members of the panel who volunteered to continue the work outside the panel meeting Challenges *(suggested by research team):* • Need for consumers to ask questions, be clear about the support required for full participation and to ask for clarification if explanations were inadequate. • Time-consuming to develop relationships and involve consumers from onset of study • Avoid being overambitious, take advantage of existing networks and secure sustainability • Process may be unpredictable and non-linear
Outcomes	
Limitations of study	1. Authors: limited and bounded by the research brief, time available and funding expectations 2. Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Rowe , 2006, UK**
Aims	To evaluate the experiences of a group of lay (parent) researchers undertaking a community survey in the Sure Start programme (to improve health and well-being of families and children before school age) in Derbyshire.
Methods	Qualitative study • All lay researchers were mothers of pre-school or primary school age children.

<table>
<tr><td></td><td colspan="3">• Education and work experience was diverse among the group; 7/16 researchers had previous experience of surveys.
• Initial postal questionnaire (prior to training)
• Final postal questionnaire (after project finished)
• Researcher diary to record experiences of the data collection phase of the work (during data collection phase)
• Focus group (immediately following data collection phase)</td></tr>
<tr><td>Patient and public involvement</td><td colspan="3">• Development of the questionnaire
• Collection, analysis and presentation of data</td></tr>
<tr><td>Level</td><td>No. of users</td><td>C & D</td><td>M</td></tr>
<tr><td>1</td><td>16</td><td>C=NR
D=NR</td><td>NR</td></tr>
<tr><td>Impact</td><td colspan="3">Community
<u>Benefits:</u>
• Local lay knowledge informed the research
• Increased acceptability of research to participants

Service users
<u>Benefits:</u>
• Initial expectations – contact with new people, giving something to others, new opportunities for self, finding out about the views of others, supporting Sure Start.
• Training (ten week Open College Network accredited course ‘ A Community Survey’)
• Felt quite or very involved in development of questionnaire
• Improved listening skills, which improved confidence
• Improved communication skill, which improved confidence
• Learnt or improved research skills
• Learnt or improved telephone skills
• Interviewing lead to reflection, learning and re-evaluation of own assumptions
• Became advocacy for interviewees
• Provided information about local services
• Felt involved and interested in analysis
• Good sense of ownership throughout project.</td></tr>
</table>

	• Ongoing learning and links with Sure Start • Expenses and childcare costs were paid • Success of consumer involvement (by consumers): group activities, shared experiences, support from researchers Challenges: • Initial anxieties: not having the necessary skills, not being able to gain the co-operation of interviewees, dogs, driving, home visiting, returning to employment. • Not enough time given between completing training and developing and piloting the survey questionnaire. • Felt thrown in at the deep end when it came to making appointments and interviewing people. • Frustration at non-attendance of interviewees • Taking on emotional burden of interviewees • Decision-making within team of parents often difficult, and consensus was not always reached. • Temptation to take action (frustrations of having to go through formal procedures of research when want to help parents directly) • Frustration that they had no input into the direction and nature of the study (not involved in initial stages) **Research team** Benefits: • Opportunity to have a number of partners in the research • Opportunity to share knowledge and learning • Witness the impact on the survey findings • Ensure the questions being asked were acceptable to the local community. Challenges: • If involved parents at scoping phase of study, may have been different scope. • Difficulty of gaining patience and respect for what parents could bring to the study
Outcomes	NR
Limitations of study	1. Authors: relative inflexibility of survey design decided upon by research funding body. 2. Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Royle, Oliver, 2004, UK**
Aims	To describe a cycle of development leading to sustainable methods for involving service users in the management of a program commissioning health technology assessment (HTA)
Methods	Case study • Reflection of process to develop methods for involving service users

Patient and public involvement	• Service users recruited o as lay members of the advisory panels that decide which, of many suggestions received from the NHS and its users, should become research priorities o to comment on summaries of research need o as peer reviewers of research proposals		
Level	**No. of users**	**C & D**	**M**
1	NR	C=NR D=NR	NR
Impact	**Service users** <u>Benefits (introduced further into the process):</u> • Support through mentor system • Guidelines given to explain role of peer reviewing and suggest how consumers may approach the task <u>Challenges (initially):</u> • Initially found panel meetings difficult because of the speed at which discussion took place • Unfamiliarity with the process in the panel meetings • Peer reviewing research was found to be technically demanding • Found reviewing forms inadequate and irrelevant to the main thrust of their contributions • Unsure of their role		
Outcomes			
Limitations of study	Author: NR Reviewer: Small study		
Quality assessment	Partial		

Authors, Year, Country	**Savage et al., 2006, USA**
Aims	To review four basic principles of community based participatory research (CBPR) in public health nursing using an ethnographic study related to the culture of African-American infant health
Methods	Qualitative and discussion • Ethnographic study: two semi-structured interviews with each participant. N not reported. • Discussion around benefits and challenges of CBPR
Patient and public involvement	• Researchers contacted two community nurses, who helped approach and invite participation to study • Stakeholders of larger community concerned with infant health were asked to become members of the partnership • Meetings held every four to six weeks in the community church • Helped develop interview schedule and assisted with the identification of themes and coding of interviews

	• Helped agree findings • Helped identify next steps to be taken		
Level	**No. of users**	**C & D**	**M**
3	3 stakeholders 4 community members.	C=NR D=NR	NR
Impact	**Community** Benefits: • Building trust helps establish a good relationship between researchers and community members, which improved recruitment to study • Gives understanding of cultural differences Challenges: • Community members did not have access to e-mail, so were communicated with by written reports, telephone calls, or visits. • Building trust was time-consuming (although vital to the success of the study). **Research** Benefits: • Evaluation of research methods for cultural relevance (e.g. community in fact divided into 3 different neighbourhoods, so researchers recruited from all three sub-communities • Assisted in gaining entrance into the community • Cultural interpretation of research results (e.g. community partners explained that in one neighbourhood black wrought iron fences had been built between buildings to discourage criminal activity. So when a participant referred to the "black bars", the researchers knew they were not referring to liquor establishments. • Initially the members of the partnership came from 3 distinct viewpoints – researcher, stakeholder, or community member. As the partnership progressed, these distinctions became less obvious, especially during the data collection phase **Researchers** Challenges: • Shift in approach of researchers to allow equal say for all members of the partnership		
Outcomes			
Limitations of study	Author: NR Reviewer: NR		
Quality assessment	Partial		

Authors, Year, Country	**Schneider et al., 2004, Canada**		
Aims	To assess schizophrenic people's experiences with medical professionals (MPs), particularly in relation to communication.		
Methods	Qualitative (participatory research) In-depth interviews with people with schizophrenia conducted by schizophrenic patients. Demographics not reported They developed and performed a readers' theatre presentation of the results and their recommendation for of how they would like t o be treated by MPs		
Patient and public involvement	Schizophrenic patients only Grant proposal submitted by both researcher (Dr Schneider) and consumer lead at the schizophrenic support group 'Unsung Heroes' Interviews conducted by people with schizophrenia with people with schizophrenia. Input into analysis of transcripts Script for the theatre performance of results was written by the academic researcher based on consumer group suggestions for content and includes quotes from the interviews. Presentation of theatre performance paper Co-authors on academic		
Level	**No. of users**	**C & D**	**M**
2	NR	C=NR D=NR	NR
Impact	**Community** <u>Benefits:</u> • Building of relationships with a population of patients with schizophrenia **Service user** <u>Benefits:</u> • Learnt interview techniques and developed confidence in their interviewing, articulate problems, and public speaking skills. • Created an environment in where members of the group could talk freely about aspects of their lives that they didn't		

	normally have an opportunity to talk about. • Reported a transformation in their sense of self – "*we feel like we have a real voice*" • Motivated them to continue assisting in another study. • Through interviewing, the group became a more caring and supportive community of friends, as barriers were broken down between people. **Research team** <u>Challenges:</u> • Difficulty in collaborating with people with schizophrenia in the analysis as they often had limited concentration, and difficulty reading and writing **Policy** <u>Benefit:</u> • Research has offered an understanding of the importance of communication in developing the therapeutic relationship, which has contributed to a change in the practice of healthcare for people with severe mental illnesses
Outcomes	Eleven interviews and one focus group. Themes identified: • Diagnosis: often takes years, which is frustrating for the people with schizophrenia. Lack of clear communication about their illness is frustrating and makes it harder for people to deal with the situation: "*For cancer or heart attacks or anything they always tell you, "you've had a heart attack, you've got cancer, you've got leukaemia. Only with mental illnesses they won't tell us*." • Medications: lack of communication of medication. Severe side effects include weight gain, lethargy, vision problems, elevated blood sugar, increased risk of diabetes, constipation, dizziness, loss of sexual drive, headaches, and hair loss. For MPs it is better for the patients to take the medication and put up with the severe side effects in order to reduce the risk of psychotic symptoms. This was not always the view of the patient. Patients found the unwillingness of their doctors to discuss their treatment option difficult to deal with: "*you have your choice…do I want to walk around crazy, or do I take the weight gain and stiffness and blurred vision and dry mouth and all the other things…?*" • Information and support: participants rarely recall doctors as being helpful to them in understanding their illness, saying they got more information from nurses and support groups. Some participants had to seek info themselves from internet and television. Participants emphasised the need to communicate information on the illness to family and friends too. • Treatment: participants recalled painful stories about their past treatment, when they were not listened to, or when they were not treated with respect or dignity. • Institutions e.g. psychiatric hospitals: they were looked down upon, treated harshly, regarded as '*less than human'*. • Doctors: not listened to, lack of communication, lack of respect *"…it's like hitting a brick wall. It's very frustrating and I'm tired of felling that way. I just want to be heard …"*

	• Positive experiences with MPs: when the people with schizophrenia get a definitive diagnosis, get information about medications, get information about the illness and the support they need, and are treated with dignity and respect, they begin to feel much more accepting of their situation. They start to understand their need to take their medications and to look after themselves, and they start to see ways to deal with their situation. Good communication enables them to move away from denial to acceptance, to adapt their lives to the illness, and to cope with their difficulties. **NB.** Recommendations that resulted from this data are reported in the paper.
Limitations of study	1. Author: NR 2. Reviewer: bias of interviewers influencing participants
Quality assessment	Adequate

Authors, Year, Country	**Shah (Ghulum) and Robinson, 2007, UK**		
Aims	To investigate the benefits and barriers to users involvement in medical device technology device and evaluation		
Methods	Structured review of published literature in peer-reviewed journals, 1980-2005, English only		
Patient and public involvement	• This review process did not include user involvement. • Selected studies reported involvement of users in the development and evaluation of medical device technology.		
Level	**No. of users**	**C & D**	**M**
1, 2, 3	NR	C=NR D=NR	NR
Impact	**Research** Benefits: • Beneficial access to user ideas and perspectives • Improvement in design, user interface, functionality, usability, and quality of medical devices • Beneficial if involved in the early stages for conceptualisation and idea generation • Important to involve 'lead users' (first users), who provide information about major user needs • Important to have direct engagement and communication with users, as enhances quality, functionality, usability, design, effectiveness and better adaptation of product • Reduces cost and time of development process • Increase value of new product • Helps implementation phase of product. Challenges: • Lack of resources (time, money and labour) for involving users • Lack of user availability		

	• Lack of training, support of users • Lack of co-operation of users • Character clashes between users and researchers • Lack of technological knowledge and understanding about products **Community** <u>Challenges:</u> • The attitudes of manufacturers to user-involvement in research into medical device design may be negative, as the idea of user-involvement may be seen as less valuable and therefore unnecessary.
Outcomes	
Limitations of study	1. Author: NR 2. Reviewer: NR
Quality assessment	Not possible to report as not systematic review

Authors, Year, Country	**Shea et al., 2005, Canada**
Aims	To assess the benefits of the development of a Cochrane network of consumers to guide research priorities, peer review systematic reviews and promote and facilitate consumer appropriate knowledge dissemination for people with musculoskeletal diseases (CMSG – Cochrane Musculoskeletal group)
Methods	Systematic review methodology used with service users • Consumers were recruited through links with other arthritis organisations. • Training in systematic review and evidence based health care provided on one to one basis initially, then in workshop format.
Patient and public involvement	Three main areas of involvement: • Setting research priorities • Peer reviewing • Translating the results of systematic reviews. Have been involved in all activities involved in producing a systematic review (canvas consumers for research priorities, assist with editing of systematic reviews, writing systematic reviews, raise awareness of CMSG, participate in national and international conferences, recruit new consumers to the group, translate reviews into consumer-friendly format, assist in the development of consumer-friendly formats, write and edit consumer summaries, publish consumer-friendly research results for

	newsletters, provide input into research for consumer-related knowledge translation, and assist with seeking funds.		
Level	**No. of users**	**C & D**	**M**
2	NR	C=NR D=NR	NR
Impact	**Community** <u>Benefits:</u> • Effectiveness of involvement is determined by the characteristics of both the consumer characteristics and the work environment • More timely, relevant reviews • Builds co-operative spirit between Cochrane and consumers. • Ensures information from reviews is reaching consumers. **Service user** <u>Benefits:</u> • Feel part of a team • Personal benefit • Opportunity to keep abreast of current evidence about treatments that affect them individually and collectively. • Benefit from seeing concrete products: published reviews, consumer summaries • Sense of fulfilment and satisfaction gained from positive feedback. **Research team** <u>Challenges</u>: • Challenge to maintain consumer membership as interests change, time and work commitments change over time, and the disease affects participation. • Need to offer training, clear expectations, acknowledgement and frequent communication to achieve greater consumer participation and engagement.		
Outcomes	Consumers identified research needs: • More drug to drug comparison rather then drug to placebo comparison. • Provide valuable feedback on clarity of review; e.g. concerns about generalisability of review • Identify research gaps • Identify what information is most important to tell the consumer (identified that consumers need different amounts of information to make health care decisions, so now formatted with a short consumer summary, long summary, and decision aid). • Consumers identified need for more information about complementary and alternative therapies. • Development of the format for consumer summaries		

Limitations of study	1. Authors: NR 2. Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Smith et al., 2006, UK**		
Aims	To report theoretical limitations to current understanding of service user involvement and to provide some suggestions for theory and methods of development in nursing, midwifery and health visiting research.		
Methods	Systematic review		
Patient and public involvement	Recruitment of 26 members from service user organisation. • Meeting 1: Service user reference group met to discuss expectations, purpose and objectives, and discuss terms of reference and ground rules. Discussion focused on what makes user involvement successful and what are the important issues. • Meeting 2: Service user reference group met to discuss main findings from literature and use Review framework to identify issues that are important to the group. Also discussed ideas for dissemination • Meeting 3: Dissemination planning meeting with stakeholders from NHS, R&D, DH Commissioning, user groups, and networks to discuss key messages and dissemination		
Level	**No. of users**	**C & D**	**M**
1, 2, 3	26	C=√ D=√	NR
Impact	**Service users** <u>Benefits</u>: • Supportive (Moore 2001) • Form of empowerment <u>Challenges</u>: • Form of disempowerment **Researchers** <u>Challenges</u>: • The rationale of researchers for including service users in their research does not reflect their actual motivation for involving service users (Alabaster et al., 2000). They could only be fulfilling a policy requirement or a condition of research funding (tokenistic involvement). • Difficult to meet the expectations of service users as to whether the research would be funded or not funded. • Insufficient time to involve service users **Research** <u>Benefits</u>:		

	• Ensures that research is more relevant to the groups that it intends to inform. • Ensure that research processes or methods are acceptable to participants e.g. sensitive to cultures or beliefs of participants (Meyer et al., 2003; Reeve et al., 2002; Ramon, 2000). • Helps identify ethical issues before they arrive in ethical approval process (Entwistle et al., 2002). • Help in design of study (e.g. highlight differences between professional and patient views of quality of care and quality of life that were fed back into the design of assessment practices (Brown et al., 2004). • Helped to validate questionnaire in terms of language being used, the appropriateness of the questions being asked, and the method of collection, leading to improved response rates (Nicolson et al., 2001). • Naming or creating categories with which to analyse data, providing perspective on the categories chosen, identifying issues or themes within the data, and checking a researcher's application of categories to an interview transcript. • Assisted in the dissemination of results. • Co-presenting a paper at a conference can have a powerful impact and make findings more accessible (Liberty et al., 1999; Flaserud and Anderson, 1999) <u>Challenges</u>: • Not possible to know what the outcomes of the research might have been without the involvement of service users, and therefore difficult to assess the benefit. • Involving service users in the writing of publications raises issues about ownership and validity of different interpretations. • Impacts are affected by the unique qualities of different research contexts, different approaches to involvement and the complexity of research relationships. However, general factors affecting success of service user involvement depend on: o Strategic planning e.g. building greater flexibility into projects, particularly in relation to timescales and the provision of additional support. Also affected will be pattern of working, economic implications – which should be taken into account in developing proposals and funding costs. o Working in new ways: redefining roles and responsibilities/ power balance. Processes of negotiation, mutuality, and respect. o Education and training: o Ethical issues: e.g. confidentiality, anonymity, informed consent and protection from harm o Diversity: which service users are involved needs to be considered in context of any proposed research; this includes ways of approaching different service users, raising awareness, generating interest and keeping people involved. o Communicating with service users before and during the research process.
Outcomes	<u>Contextual factors reported:</u> • Consumerism and participation: consumers have more choice about how their care is provided (Segal, 1998; Almond, 2001). Consumerism has stimulated service wide, strategies of participation and community involvement (Croft and Beresford, 1996; Higgins, 1993). • Changes in patient-professional relations: move towards involving people in healthcare, and shifts towards promotion

	of health and prevention of illness led to greater informed patients and patient-centred care (Coulter, 1999; Cody, 2003). • Growing concern and expectations about research due to the work of Sir Ian Chalmers, high profile inquiries into incidents of research and clinical practice, and the setting up of the Research Governance Framework for Health and Social Care (DH, 2001) have led to movements to involve service users in the process of research. • Changes in the way research is undertaken: in some fields of health research there have been long traditions of user-led movements and user controlled research (Beresford, 2005; Mercer, 2002; Oliver, 1999). This has led to patients and public taking a more active role in community and practice development activities. <u>Conceptualisation and approaches (reports):</u> • Arnstein's Ladder of Citizen Participation (Arnstein, 1969) – with different levels of control • Hierarchical levels of consumer involvement – from consultation, through to collaboration, and consumer control (Boote, 2002). • Empowerment – involvement hierarchy/continuum as corresponding with progressive levels of power (Barnes and Walker, 1996; Poulton, 1999; Rodwell, 1996) • Consumerist and democratic concepts of involvement (Hickey and Kipping, 1998) • Alternative classifications of involvement that have positioned service users according to their possible contributions to the research process (Dixon 1999) and in relation to different stages of the process (Hanley, 2000). <u>Concerns:</u> • Under-representation of marginalised groups; people's motives for wanting to be involved; different meanings associated with the term 'community'; different service users' viewpoints may not be in consensus; healthy people may not be represented; and concerns that the more an individual is involved the more they become 'professionalized' and less representative. <u>Examples:</u> • Setting up advisory groups in diabetes care (Rhodes, 2001); involving older people as research advisors (Ross et al., 2005); creating user groups in midwifery (Wray, 2003) involving people with learning disabilities or intellectual disability (Kiernan 1999, Cambridge and Forrester-Jones, 2003, and people with HIV infection (Yates et al., 1997, and people near the end of life, or receiving palliative care (Karim, 2000). • These examples show that service users might be involved for different reasons at different stages and that research methods and approaches need to be tailored to suit different research questions and different groups of service users. • Therefore the current conceptualisation of service user involvement as a hierarchy/continuum is limited. • They do not reflect that involvement might be going on simultaneously at multiple levels of decision-making (for example, a service user is undertaking part of the research and there is also a service user advisory group), shift between levels (for example, service users have more involvement in a particular aspect of the study than in another), or graduate from one level to another (for example, service users contribute to more important decision as the study progresses, or vice versa).
Limitations of study	1. Author: NR

	2. Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Staniszewska et al., 2007**		
Aims	To involve service users in the development of a research bid to examine parents' experiences of having a pre-term baby		
Methods	Case study • Reflection of involving service users on a panel to develop the bid. • Meetings occurred once a month for 14 months to discuss the wide range of issues relating to pre-term babies and to discuss their experience of having a pre-term baby. o 0-7 months: a study focussing on the general experiences by parents that were identified by the group o 7-12 months: a more specific study focussing on information, communication and support. o 12-14 months: a more specific study focussing on the identification of effective interventions to help parents with pre-term babies, in relation to information, communication and support. • Both support group and research advisory group helped refine the bid at each stage of development.		
Patient and public involvement	The parent support group provided: • Advice on methods and ethical issues • Advice on timing of interview and focus groups		
Level	**No. of users**	**C & D**	**M**
2	Variable	C=NR D=NR	NR
Impact	**Research** <u>Limitations:</u> • Support group and advisory group were not able to meet due to the conflicting time demands of both the researchers, health professionals and service users. • The support group did not become involved in writing the bid because of the requirement of funding bodies for research bids to be written in an academic style.		
Outcomes	<u>Motivation of service users:</u> • Hoped that their involvement would result in more parent-orientated services • Use of research as a tool to change service provision and make things better for future parents of pre-term babies • Dissemination: to raise the profile of pre-term babies among national charities and Government agencies		

	<u>The parent support group provided:</u> • Advice on methods and ethical issues; interview and focus groups were agreed the best method to collect the data. • Advice on timing of interview and focus groups. • The support group felt very strongly that the parents should not be interviewed or participate in a focus group while their baby was in hospital, as this is a difficult time for parents and the group also felt that researchers might not glean as much information from parents about their experiences soon after birth compared with later participation.
Limitations of study	Author: NR Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Stevens et al., 2003 , UK**		
Aims	To report novel ways of identifying and recruiting service users that have been adopted by one cancer network in the UK		
Methods	Case study, reflective narrative study		
Patient and public involvement	Involvement of service users in cancer networks at all levels of research		
Level	**No. of users**	**C & D**	**M**
1	NR	C=NR D=NR	NR
Impact	**Service users** <u>Benefits</u>: • Increased knowledge of research • Training leads to new skills • Reimbursement for expenses and time		
Outcomes	Three innovative ways of involving service users were reported: • Three open consumer conferences have increased awareness of research among service users • Recruitment of service users to sit on a project steering group and a committee to provide a strategic overview of current research • Establishment of a consumer panel for research to provide a considered consumer perspective in a range of settings; training service users		
Limitations of study	1.Author: NR 2.Reviewer: No clear study methods.		
Quality of assessment	Partial		

Authors, Year, Country	**Sutton J, Weiss M, 2008, UK**		
Aims	To reflect on the benefits and difficulties of involving the service users with a chronic condition as advisors in research project exploring pharmacist supplementary prescribing.		
Methods	• Ethnographic approach to accounts from service users. • Recruited from two clinical areas: a diabetes support group and a chronic lung disease group. • Six meetings held over one year (also attended by two researchers) at the University of Bath.		
Patient and public involvement	Focus group meetings to: • Gain users opinions of concept of supplementary prescribing • Identify qualities and attributes of the prescriber that would be valued by them as patients • Assist in development and refinement of interview schedule • To gain the perspective of the patient group on a range of ethical and professional issues • Discuss communication and accountability issues • Discuss final report and define dissemination approaches		
Level	**No. of users**	**C & D**	**M**
1, 2	10	C=NR D=NR	NR
Impact	**Service users** <u>Benefits:</u> • By the final meeting, users were able to identify problems and come up with solutions due to their increased knowledge and confidence they had developed over the project. • There was full attendance at focus group meetings, which showed that service users felt happy and confident in their roles. <u>Challenges:</u> • There was scepticism about the ability of pharmacists to make prescribing decisions, but this was due to a misunderstanding of how well-qualified a pharmacist is. • Concern on shop environment confidentiality, including the access of pharmacists to medical notes. • Concern over the introduction of yet another health professional made life even more confusing for the patient. **Research team** <u>Challenges</u>: • Difficulty making the shift from researcher to a more participative role and the relinquishing of control.		

	• Difficulty biting tongue when views of patients did not match the researchers. • Needed to allow a long time for service users to understand supplementary prescribing by pharmacists.
Outcomes	<u>Benefits to the research project:</u> • Queries and concerns about supplementary prescribing such as views on pharmacy shop environment/confidentiality not suitable for discussing private medical issues. These issues were included in the Phase 1 of the interview topic guide. • Further refinement of Phase 1 topic guide; e.g. concerns were raised about combined dispensing and prescribing in the role of the pharmacists (associated pharmacists working in a chemist's shop). • Queries of adequate training for the new role of pharmacists. • Queries over whether supplementary prescribing a good thing for patient care, the pharmacy profession and the NHS. • Queries over who does the pharmacist go to for support, should they need it. • Query over whether pharmacists have ever got prescriptions wrong? • Is the time allowed for patient consultations sufficient? • Do pharmacists feel comfortable conducting patient consultations? Key themes were identified and methods of sampling (to ensure diversity) were discussed. <u>Issues raised from final report</u>: • Is the supplementary training too intensive and, in reality, will it meet the needs of the individual prescriber? • Transcripts reflected the desire of pharmacist prescribers to move towards independent prescribing, which worried patients. • Fear that the patient might lose contact with GP. • Accountability of pharmacist: should they be able to prescribe without guidance from the doctor? • Would pharmacists have sufficient knowledge to make judgements about patient care in all cases • Would they still refer to the GP if necessary? This led researchers to develop Phase 2 of the study, which included interviews with GPs, hospital consultants, and other HPs. <u>Questions from patient input:</u> • How do you share the responsibility for patient care? • Do you feel there are clear lines of responsibility? • How do you decide which patients will be given to the pharmacist supplementary prescriber? • Do you meet regularly with the supplementary prescriber? • Need clear guidelines regarding the relationships of pharmacists with other HPs, especially GPs. Management structures and care pathways should be in place. • Sensitivity towards other HPs (nurse practitioners, GPs), who may feel threatened by the new role of the pharmacist.
Limitations of study	1. Authors: NR

	2. Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Taylor, 2006, UK**		
Aims	To explore the barriers that prevent older people from assisting in research and measures that may encourage increased involvement.		
Methods	Qualitative data was collected by semi structured interviews that involved: • Older People's Forums (people 50 years and over) • Thematic analysis of data.		
Patient and public involvement	Desire to be involved in all aspects of research		
Level	**No. of users**	**C & D**	**M**
1, 2	10 Older People's forums	C=NR D=NR	NR
Impact	**Service users** <u>Challenges:</u> • Length and commitment to training courses difficult because of often committed to caring for others, child-minding, attending clubs, doing other courses. • Lack of funding for training. • Information Needs and Access acknowledged, but this was not related to research.		
Outcomes	• Seven out of ten forums reported a need to access to appropriate research support and guidance in order to engage in future research activity or undertake their own projects. Training was thought to facilitate independence and 'inclusivity'. • Reported need to be involved in questionnaire design: *"…we do not want to be presented with a questionnaire [from external agencies]..if say we get a questionnaire from say a local authority, we are answering their questions. We are not answering the questions that older people want to put forward. We are answering….[questions} that they have set for us and do they know …the questions we want to ask";"We would look more professional as a group, if we can produce a good survey, with proactive findings…I think we would …raise our profile as well".* • Commonality was not recognised: *"…face to face older people probably come over better, older people being interviewed by older people. I think there is more affinity there…"; "the Government really does not [see that] we are such a rich resource… it's not recognises"*		
Limitations of study	1.Author: NR		

	2. Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Telford, Boote, Cooper, 2005, UK**		
Aims	To obtain consensus on the principles and indicators of successful consumer involvement in NHS research.		
Methods	Purposeful sampling strategy was used to identify people who had experience/or knowledge of consumer involvement in NHS research: • Expert workshop employing nominal group technique was used to generate potential principles and indicators n=13, seven were service users). • Two round postal Delphi process was used to obtain consensus on the principles and indicators (n=96/131 completed both rounds: 29 were consumers, 26 were consumer researchers). Respondents were asked to rate the principles on two nine-point scales (clarity, validity), and each indicator on three 9-point scales (Clarity, Validity and Feasibility) • Each principle and indicator had to achieve 85% or more in range 7-9 on each scale to be retained.		
Patient and public involvement	Service users participated in the expert workshop and in the two rounds of postal Delphi process. • Mostly 36-55 years old; mostly white (n=85), consumer (n=29), researchers (n=33), consumer and researcher (n=26). • Activist/advocate and consumer reps (n=21), patient/ long-term service user (n=15), employee of consumer org/charity (n=12). • Three users who participated in the in expert workshop agreed to join the advisory group for the study.		
Level	**No. of users**	**C & D**	**M**
1,2, 3	Expert work group=7 (+ six researchers) Q=96 Three in advance group.	C=√ D=√	NR
Impact			
Outcomes	**Reported results only** Eight principles were identified, with 16 indicators to assess those principles: **Principle 1**: • The role of the consumers was agreed between the researchers and the consumers involved in the research. <u>Indicator of Principle 1:</u> • The roles of the consumers in the research were documented.		

	Principle 2: • Researchers budget appropriately for the costs of the consumer involvement in research. Indicators of Principle 2: • Researchers applied for funding to involve consumers in the research; • Consumers reimbursed for their travel costs • Consumers were reimbursed for their indirect costs (e.g. carer costs) **Principle 3**: • Researchers respect the differing skills, knowledge and experience of consumers Indicators of Principle 3: • The contribution of the skills, knowledge and experience of consumers were included in research reports and papers **Principle 4**: • Consumers were offered training and personal support, to enable them to be involved in research Indicators for Principle 4: • The training needs of consumers that were related to their involvement in the research were agreed between consumers and researchers. • Consumers had access to training to facilitate their involvement in the research. • Mentors were available to provide personal and technical support to consumers. **Principle 5**: • Researchers ensure that they have the necessary skills to involve consumers in the research process. Indicator for Principle 5: • Researchers ensured that their own training needs were met in relation to involving consumers in research. **Principle 6**: • Consumers are involved in decisions about how participants are both recruited and kept informed about the progress of the research. Indicator for Principle 6: • Consumers gave advice to researcher on how to keep participants informed about the progress of the research. **Principle 7:** • Consumer involvement is described in research reports. Indicators for Principle 7: • The involvement of consumers in research reports and publications was acknowledged • Details were given in research reports and publications of how consumers were involved in the research process. **Principle 8**: • Research findings are available to consumers, in formats and in language that they can easily understand. Indicators for Principle 8: • Research findings were disseminated to consumers involved in the research in appropriate formats (e.g. large print, translations, audio, Braille). • The distribution of the research findings to relevant consumer groups was in appropriate formats and easily understandable language

	• Consumers involved in the research gave their advice on choice of methods used to distribute the research findings.
Limitations of study	1. Author – Lack of ethnic diversity, disabled, and other hard to reach groups influencing work. 2. Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Telford et al , 2002, UK**		
Aims	To investigate the extent to which user involvement is incorporated into NHS Research projects in one NHS region.		
Methods	Cross-sectional study. • A survey of Trust R&D contacts, scrutiny of ongoing and recently completed regional research initiatives via the National Research Register, the York University database of examples of consumer involvement in research, key internet sites, and personal contacts. • Response rate=55/66		
Patient and public involvement			
Level	**No. of users**	**C & D**	**M**
1	NR	D=NR	NR
Impact	**Researchers/ NHS research teams** <u>Challenges</u>: • Difficult for researchers to understand the concept of consumer involvement in the research process. • They saw consumers as passive subjects with no influence on the design or the course of the research. • Unsure about how experienced the consumers should be. • Unsure how differences in priorities between consumers and professionals can be addressed.		
Outcomes	• Also PPI. • Only seven research teams (13%), representing just five trusts (less than ¼ of trusts) were actively involving consumers in the research process. • These projects addressed maternity care issues, cancer, disabilities, the respite needs of people with dementia and their carers, Cochrane Collaboration research activities. • Consumers were involved in research at all three levels: user-controlled, collaboration, and consultation.		
Limitations of study	1. Author: NR 2. Reviewer: NR		

Quality assessment	Adequate

Authors, Year, Country	**Lloyd et al., 1996, UK**		
Aims	To survey the needs of physically disabled people in a metropolitan borough in order to address deficits in service provision and inform community care and health service planning. • Initial stage of research: to develop, with service users, a postal questionnaire for gathering data for this main aim.		
Methods	Qualitative and cross-sectional study (for initial aim only) • Small groups of between eight and ten disabled people met for two two-hour meetings. • Questionnaire material and approaches from other studies were introduced to the groups in order to test their effectiveness as instruments for expressing the experiences and issues raised by the group members. • The questionnaire was piloted with eight disabled users drawn from the group to test content, clarity and presentation of the questionnaire.		
Patient and public involvement	Disable patients only Development of content of questionnaire, piloting questionnaire, disseminating results from study.		
Level	**No. of users**	**C & D**	**M**
1	73	C-yes Theories: • Objectivity • Social construct theory • Positivist/ foundationalist • See impact section D=NR	NR
Impact	**Research team (consumer group)** <u>Challenges:</u> • The short time given to set up group (one month) gave no opportunity for establishing contact with non-users, isolated disabled people, and ethnic minorities. • The consumer group was therefore made up of known consumers. • It is possible that different needs and perspectives might have been addressed had other people been included in the groups. • Therefore setting up of consumer group is lengthy process, but forms a central plank in the definition of need that is ultimately used.		

	Steering group Challenges: • Not satisfied with questionnaire because not using the 'correct' measure of disability, and not asking the 'correct' questions. • Author argues the dangers of using objectivity theory (follows scientific method to gather data independently of their position in the social world; therefore we have the view that disability is a problem experienced by individuals, which can be medically defined and its effects measured scientifically). • Author refers to this as the 'personal tragedy theory' of disability (Oliver 1993, p64). The other reported theory is the social construct theory, which views all knowledge as socially constructed, viewing disability where the experiences and knowledge of the disabled people are central; '*they are not the problem, the experts are'*. • Authors report that the questionnaire was developed using the latter theory. • The commissioning research unit (support unit for the funders) in this project had a major role in influencing, and at points changing, what went into the questionnaire. • They had a role in weighting the analysis towards the tick box quantitative data (even though the qualitative data was more representative of the experiences of disabled peoples). • They also wrote up the recommendations from the project and therefore introduced a potential bias.
Outcomes	• After observation of other questionnaire used in previous studies, a new questionnaire was developed using the observations of the group members. • The following issues were addressed: o accommodation o environment (including access to buildings) o needs assessment o met and unmet needs o lifestyle o services o information provision o employment o costs and income • Some members of the groups participated in workshops of service users, carers and providers which were held to disseminate the findings and to use these as a basis for the service planning.
Limitations of study	1. Authors: • Limited time to set up group and conduct research. • Influence of objectivity theory (scientific methods) on questionnaire development.

	• Not enough reflection on qualitative responses to questionnaire, which they argue were more reflective of the 'real' situation for disabled people. (Author challenges positivist theory that both quantitative and qualitative data should compliment each other e.g. comments of a 23 year old man who ticked to say the needs of others (family/carers) were fully met, went on to comment that he only spend half an hour on his own each week due to the efforts of his mother, stating that they were in the process of trying to set up day service for him). • Managing research unit were a support unit for the funders – who wrote the final recommendations (and therefore potential bias) 3. Reviewer: Time limitations
Quality assessment	Partial

Authors, Year, Country	**Thompson et al., 2009 , UK**		
Aims	To investigate the attitudes of health research teams to involving the public in research		
Methods	Qualitative study • Semi-structured interviews with 15 purposefully sampled UK-based University Health researchers • Sampled to reflect diversity in geographical location and the type of health research, comprising biomedical and laboratory-based research.		
Patient and public involvement			
Level	**No. of users**	**C & D**	**M**
1, 2	NR	C=NR D=NR	NR
Impact	**Research team** <u>Benefits:</u> • Advantage of multi-faceted nature of public involvement in research (from partnership in research to offering the public information about research): *'…key purpose is to take the viewpoint of the people you are researching, and not to use them as subjects but as equal partners in research, as far as you can, because I think there's far too many times when research is done to people and they haven't been able to inform it…it's about respecting the people that you're researching because I don't think you can just come at it from one angle when you are not in the shoes of the people you are researching.'* • Gave research a seal of approval or a 'validation effect'. • Made research 'more real' and 'more sensitive to public need'.		

	• Brings a '*unique point of view*' to the research process by improving the documentation, question formulation, and data collection processes. • Public can get information from people easier than researchers • Better public acceptance of research. • Attitudinal barrier to involvement. • Move away from the positivist paradigm and towards research more grounded in experience <u>Challenges:</u> • Resistance to transferring or sharing power: *'…we the researchers have to lead it…there can be a danger if we go too far overboard…the research agenda…becomes unworkable.'* • Confusion between public involvement and public engagement (the latter is when professionals work with local communities to inform them of research) • Public involvement mistaken as '*having patients as participants on a clinical trial and keeping them informed about progress (which made them 'more compliant')'*. • GP researcher believed involving the public in research was less relevant to him as he engages with his parents on a daily basis: *'…I'm a GP and I am sitting listening to what patients are telling me every day. So it is less relevant to the non-clinical researchers.'* • Involving public is seen as a political imperative (by funders, research governance, ethics committees). However, this leads to tick box mentality of researchers in order to obtain funding so they can begin their research with often only one individual being involved: *'…I suspect there is a lot of lip service paid to it rather than genuine attempts to involve the public'* • Fear of the unknown – changing their working ways: *"it's a different way of working, it's uncomfortable to move out of your set way"* (which reflects the need for clearer and more accessible information for researchers). • Increasing public involvement could undermine professional skills and academic knowledge (boundaries between what is know as 'expert knowledge' and what is 'lay knowledge'): '*…she spent years training and studying to be a researcher…and these people have been bobbing around taking pills and whatever for, and claiming incapacity benefit for five years and they are coming in and suddenly they are the experts and they have done no studying, no qualifications…their experience cannot outweigh my academic qualifications…*'
Outcomes	**Research results**: • Researchers need training and education to help them understand PPI • Researchers need time to adjust • Researchers need greater institutional support structures • Researchers who use PPI at a tick box may then have a greater appreciation of the benefits of involving the public.

Limitations of study	Author: • Small sample of researchers. • Team conducting the research were known as pro-public involvement, which may have influenced the responses in interviews. • It could be that those who agreed to be interviewed were enthusiastic about public involvement in research, and it was therefore a biased sample. Reviewer: Small study
Quality assessment	Partial

Authors, Year, Country	**Trevedi and Wykes, 2002, UK**		
Aims	To report the challenges in joint research projects		
Methods	Case study Amalgamation of user and clinical researcher consideration for study around improving education and knowledge about medication on in-patients in our local psychiatric intensive care unit (PICU).		
Patient and public involvement			
Level	**No. of users**	**C & D**	**M**
2	User group – communicate. One user-researcher involved in research design and write-up	C=NR D=NR	NR
Impact	**Research** <u>Benefits</u>: • Influence the content of the research and make it more relevant to clinical practice • Set out an explicit agreement about how researchers and users work together addressing issues of when and how researchers will be involved in the research, payment of users, acknowledgement of users contribution, and issues of confidentiality. This established clearly how the interests of the users could be protected. • Working with different interpretations of the same data (those of researchers and service users) may provide new and exciting lines of enquiry that were been obvious at the beginning of the study. **Researchers** <u>Challenges</u>: • Researchers did not fully appreciate before they embarked on it just how time-consuming and challenging this study would be.		
Outcomes	• This project arose directly in response to requests from patients on the PICU about medication. • This led to a decision to provide group medication education to sessions.		

	• The proposal was developed in collaboration with users. The researchers received a very firm initial negative response to it – as they did not like the outcome measures for insight and compliance. Users thought insight as '*agreeing with the health professionals*', and being compliant as '*doing what you are told to do by the health professionals*'. • Unfortunately, there were no standard measures for assessing these, so outcome insight and compliance had to remain the major outcomes. However, hoped that more work with service users will enable the development of appropriate methods for assessing patient empowerment. • The proposal was submitted to the support group in writing for their consideration. • The ward staff feared that providing education on medication would only make their work more difficult if patients, through becoming more knowledgeable and empowered, became less compliant and more questioning about their medication. These fears proved to be unfounded. • The single user-researcher highlighted her concern that if the educational intervention was seen to 'fail', patients might be blamed for not engaging with the sessions, rather than looking at whether the delivery of the sessions was appropriate. • Factors such as the physical environment where the sessions would be delivered, the skill of the teacher, and the ethos and attitudes of the clinical staff towards the patients who took part in the sessions might influence the success or failure of the intervention. • Service users also pointed out that since clinical teams in the hospital were known to have very different attitudes to information about medication, this could markedly affect how the patients responded to the medication education sessions, which led the researchers to use specific use of matching procedure to improve the scientific method of the investigation. • Two papers were written, one on actual medication education study, and one on user involvement in the study. • Dissemination: Centre for Recovery in Severe Psychosis (CRiSP), South London policy of using newsletters and web-pages to disseminate to service users.
Limitations of study	Author: NR Reviewer: NR
Quality assessment	Partial

Authors, Year, Country	**Truman and Raine, 2001, UK**
Aims	To examine the role of user involvement in evaluative research within the provision of evidence base related to practice development in mental health services.
Methods	Qualitative study • Eight focus groups over 12 months. • Poor attendance at these led to a consultative process with users to find a better method. Need to make users active partners in research and use one to one interviews to fit in with the individual needs and constraints. • Method therefore changed to users and researchers working in co-learning partnership (Cornwall, 1996).

<table>
<tr><td></td><td colspan="3">Authors suggest involvement of users from the outset might have been better, but concerned that the funding body would only favour proposals with minimal interaction of users.
Used model developed by Cornwall 1996, that looks at the levels of involvement:
Co-option: representatives chosen, but no real action. Tokenistic.
Compliance: tasks assigned with incentives; researchers decide on a course of action.
Consultation: opinions of users asked; researchers analyse these and decide on a course of action.
Cooperation: users work together with researchers to determine priorities; responsibilities remain with researchers for directing the process
Co-learning: users and researchers share their knowledge to create new understanding and work together to form action plans with researcher facilitation
Collective action: users set their own agenda and mobilise to carry it out, in the absence of outside researchers or facilitators.</td></tr>
<tr><td>Patient and public involvement</td><td colspan="3">Users evaluation group recruited:
Project design
Data collection (pilot of evaluation questionnaire)
Comments to help with development of tool
Ongoing implementation of evaluation tool.</td></tr>
<tr><td>Level</td><td>No. of users</td><td>C & D</td><td>M</td></tr>
<tr><td>1, 2</td><td>NR</td><td>C=NR
D=NR</td><td>NR</td></tr>
<tr><td>Impact</td><td colspan="3">Service users
<u>Benefits:</u>
Getting involved in the design helped them feel they were ‘making a difference’ or ‘giving something back to the service’.
Training in administering questionnaires so the users conducted a pilot study.
Physical, mental and social benefits of attending the research facility during the research.
Therapeutic value associated with active participation in the research process:
“…it’s me doing it for myself…I’m actually pushing myself a bit, see how I cope with it…”
Because users were central to the process of developing the evaluation tool, anticipated that ongoing evaluation of the facility would be carried out by users
<u>Challenges:</u>
Failure to attend initial focus groups (co-option phase) due to anxiety concerning group situations, feeling they had little to contribute and variation in mental health symptoms.
Research team
<u>Benefits:</u></td></tr>
</table>

	• Identified importance of spending time in the field with the service users to help build up confidence and trust. • Discovered that users were the best pragmatic critics of any research protocol and will vote with their feet if they do not perceive research to be relevant or appropriate to their circumstances. • Researchers had less workload as their role became more of one of technical support, ensuring that questions were worded in a way that would ensure validity. <u>Challenges:</u> • Although payment of expenses was offered to participants, recruitment proved difficult. Reasons given for this: o Variation in mental health symptoms could preclude attendance. o Users felt they had little to contribute. o Anxiety concerning group situations. • One-to-one interviews could be used instead of focus groups. • Learned that even though their proposal went through the peer-review process and was deemed by 'experts' to be worthy and viable, the reception of users suggested otherwise. • Discovered users were the best pragmatic critics of any research protocol and will vote with their feet if they do not perceive research to be relevant or appropriate to their circumstances.
Outcomes	• Only the results of experience with user involvement were reported. • Researchers found that service user involvement became more effective by building up a rapport with the service users and increasing their level of involvement.
Limitations of study	1. Author :NR 2. Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Welfare et al., 2006, UK**		
Aims	To identify topics for research that are important to people with ulcerative colitis, and provide a framework by which their research priorities can be analysed		
Methods	Qualitative study • Focus groups and interviews with 40 service users with ulcerative colitis.		
Patient and public involvement	Forty service users to identify research agenda for ulcerative colitis		
Level	**No. of users**	**C & D**	**M**
1	40	C=NR D=NR	NR
Impact			

Outcomes	Topics identified were grouped into main categories: • Finding the cause of colitis • Cure of colitis • Prevention of colitis • Living with colitis • Treatment (conventional, complementary and surgical) and complications • Control over particular symptoms • Information provision • Communicating with health professionals • Methods of service delivery The study reported the potential to utilise service users to generate research topics that are rarely researched and to involve them in agenda setting.
Limitations of study	Author: NR Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Wright et al., 2005, UK**
Aims	To explore how effective is a collaborative participation of patients and carers in the design and conduct of a cancer research study. Main study aim: • Exploring the views of people affected by cancer have about cancer research and identifying their research priorities ('Listening to the Views of People Affected by Cancer about Cancer Research").
Methods	Exploratory, qualitative approach. • All patient forums in each of the 40 Cancer Networks were contacted to ask for volunteers for the reference group. • Phase 1: Ten focus groups with purposively sampled participants over the age of 18 recruited from 7 cancer networks in UK. • Phase 2: A series of six focus groups with purposively selected population groups providing a exploration of views of participants with specific characteristics often under-represented (South Asian, Black), specific age groups (13-19 years), and over 75 years old, and patients in the palliative phase of illness.

<table>
<tr><td></td><td colspan="3">• Formation of the ‘Reference group’ to collate opinions and views of consumers and assist with the development and process of research.</td></tr>
<tr><td>Patient and public involvement</td><td colspan="3">• Reference group met to discuss the study
• Research design
• Recruitment process, the study question schedule
• Patient-related materials such as the Patient Information Sheet
• Reference group continued to meet throughout the study to discuss various aspects of the study, and met at the end of the study to have an input in the interpretation of the data and in the dissemination of the results using their links with their own cancer research and support groups</td></tr>
<tr><td>Level</td><td>No. of users</td><td>C & D</td><td>M</td></tr>
<tr><td>2</td><td>25 in reference group, 15 co-researchers</td><td>C=NR
D=NR</td><td>NR</td></tr>
<tr><td>Impact</td><td colspan="3">Service users
<u>Benefits:</u>
• Benefited from training
• Benefited from increased knowledge in research methods
• Benefited from increased knowledge in field of cancer

Research team
<u>Benefits</u>:
• Effective in enhancing the conduct of the study.
• Effective enhancement of the overall design, with use of focus groups, but stress importance of capturing individual responses e.g through use of follow-up questionnaires.
• Assisted in the clarification of the ‘post-treatment’ category of user to be recruited
• Emphasised the need not to select participants who were perceived to be “research positive” or experienced.
• Re-worded section of the patient information sheet and changed the font to make it more legible
• Re-phrased some of the questions for the focus group to make them clearer.
<u>Challenges</u>:
• Time and cost of involving patients and carers.
• COREC had confusion over the aims of study, which led them initially to say that ethics approval was needed. When it was realised that the patients were co-researchers, this was rejected.
• Issues of maintaining confidentiality.
• Time was needed to gain honorary contracts for patients and carers to co-moderate or observe in focus groups.
• Lay researchers became ‘professionalised’.</td></tr>
</table>

Outcomes	• Consumers identified need for more drug to drug comparison rather then drug to placebo comparison. • Provide valuable feedback on clarity of review. • Identify research gaps. • Concerns about whether the review could be generalised. • Most important points to tell the consumer were identified.
Limitations of study	1. Authors :NR 2. Reviewer: NR
Quality assessment	Adequate

Authors, Year, Country	**Wyatt et al., 2008, UK**		
Aims	To evaluate consumer involvement in the London Primary Care Studies Programme (LPCSP) and understand what impact consumers had on the research process and outcomes.		
Methods	Qualitative and cross-sectional study • Multi-method study approach using survey techniques (61/163 questionnaires), interviews (n=44), focus groups (n=2), observation (15 hours) and scrutiny of written documents. • Eleven primary care-based research projects were reported on. • Users and consumers were recruited through community groups, consumer groups, and local relevant support groups.		
Patient and public involvement	Eleven projects had service users or carers as co-applicants. • Six projects used consumers within the research process, two recruited consumers to advisory groups, and two recruited consumers for both. • One project altered its research question, and five altered their recruitment processes in response to the comments of consumers. Six used consumers to help them develop the research tool, six used consumers to run interviews and focus groups, five involved consumers in the analysis, and three involved consumers in the dissemination of the study. • Most projects did not involve consumers in establishing the research question or design. • The majority of studies were qualitative in design, with some using a mixture of quantitative and qualitative.		
Level	**No. of users**	**C & D**	**M**

1, 2, 3	NR	C=NR D=NR	NR
Impact	**Service users** <u>Benefits:</u> • Feeling useful • Able to offer unexpected contributions • Training in research methods • Financial reward (eight projects gave token payments or employed users; one project offered travel expenses) **Research team** <u>Benefits:</u> • Commented on value of having the consumer perspective, and on how much they had learnt from having consumers involved. • Processes of development and delivery of research benefited directly from the involvement of consumers. <u>Challenge:</u> • Difficulty of measuring impact because no comparison group without involvement to allow associations between outcomes and involvement to be made.		
Outcomes	• Eight studies reported impacts on: o The initial design of study o Recruitment of the research subjects o Developing data collecting tools o Collecting data o Analysis and dissemination of the findings • Some projects achieved 'partnership' style consumer involvement, while the involvement felt tokenistic for some service users and carers. • Greatest impacts were where the projects achieved 'partnership' style consumer involvement.		
Limitations of study	1. Authors: NR 2. Reviewer: NR		
Quality assessment	Adequate		

B: Unpublished papers (grey literature)

Authors, Year, Country	**Barnard et al, 2005, UK**
Aims	To evaluate consumer involvement in the London Primary Care Studies Programme
Methods	• Collected commissioning documents, project applications, and other background documents.

	• Collected project progress reports, minutes of meetings and other relevant documents • Interviews with commissioners • Questionnaire survey (61/163) • 44 one to one interviews • 2 focus groups (n=16) • Feedback day		
Patient and public involvement	Service users were included throughout the study		
Level	**No. of users**	**C & D**	**M**
1	NR	C=NR D=NR	NR
Impact	**Service users**: Benefits: • Felt empowered • Felt support through empathy, sensitivity and individual contact Challenges: • Communication problems • Lack of resources (time, money, and skills) • Motivation **Research:** Benefits: • Changes to research questions were made because users/carers were able to say what the important questions were for improving services • New or revised questionnaires, interview designs etc (research tools) were created by service users/carers • Found new ways of collecting data and were able to include many more people to provide data • Explanation of data related directly to how people experience the delivery of services • Users/carers used their own networks to tell other people about their findings • Users/carers were successful in finding ways to change services, based on the research findings, and in measuring those changes • Their involvement increased the number of service users/carers in research		
Outcomes	User involvement had the following effect:		
Limitations of study	Author: NR Reviewer: NR		
Quality assessment	4		

Authors, Year, Country	**Faulkner 2008 UK**
Aims	To review 4 case studies in forensic mental health services, and summarise lessons learnt
Methods	Case study Project 1: focus groups for development of questionnaire, survey to pilot questionnaire Project 2: Action research: interviews, focus groups and non-participant observation

<table>
<tr><td></td><td colspan="3">Project 3: Informal discussions to develop and evaluate a framework for engaging residents of a medium secure unit for people with learning disability with the nature of research, consent, and ethics in participatory research.
Project 4: Focus group meetings to discuss experiences of forensic mental health services.</td></tr>
<tr><td>Patient and public involvement</td><td colspan="3">Project 1: Assisted in the development of questionnaire to measure user satisfaction with forensic inpatient services
Project 2: User-led project to assess concerns of users of forensic services
Project 3: Discussions (focus groups?)with residents to find ways of understanding research.
Project 4: user led research, using focus group meetings</td></tr>
<tr><td>Level</td><td>No. of users</td><td>C & D</td><td>M</td></tr>
<tr><td>1,2,3</td><td>NR</td><td>C=NR
D=NR</td><td>NR</td></tr>
<tr><td>Impact</td><td colspan="3">Community:
Benefits:
• Raising awareness of research in forensic mental health services

Service users:
<u>Benefits</u>:
• Learning research skills & team working skill
• Developed knowledge of research
• Improved confidence
• Stepping stone to work
• Challenges:
• Lack of support and supervision

Research:
<u>Benefits</u>:
• PPI resulted in better quality data
• PPI provides the opportunity to engage more or different people in research
• PPI helped produce richer and more insightful data
• PPI helped identify more patient related themes in the analysis of data
• PPI helped improve the terminology used in information and outcomes measures
• Challenges the stigma of using residents in research

<u>Challenges:</u>
• Time needed to involve users
• Shortage of funding for PPI
• Bureaucracy of payment e.g. residents often didn’t have access to bank accounts, and slowness of payment process
• Literacy levels among users was low
• Gender – all users involved were men
• Access and communication difficulties with residents
• Attitude of staff towards residents being involved in research

Researchers:
<u>Benefits</u>:
• Learnt to share power and control
• Gained insight into issues that wouldn’t have otherwise gained.</td></tr>
</table>

	Challenges: • Time needed to involve users
Outcomes	Project 1: Produced seven main themes for the questionnaire: staff interaction, rehabilitation, milieu, communication, finance, safety, gender. 95 item scale (Forensic Satisfaction Scale). After validation, 60 item questionnaire reported. Project 2: 8 main themes for concerns for men: the quality of the nursing, boredom, psychiatric medication, illicit drug use within the unit, food, peer support, and desire for freedom. Project 3: Project 4: Negative experiences were mainly reported, including relationships with staff – lack of trust and honesty, racism, concerns about psychiatric medication, lack of hope for the future.
Limitations of study	Author: NR Reviewer: Reflection of case studies reported
Quality assessment	4

Authors, Year, Country	**Nilson et al, 2006, UK**		
Aims	To assess the effects of consumer involvement and compare different methods of involvement in developing healthcare policy and research, clinical practice guidelines, and patient information material.		
Methods	Systematic review Searched electronic databases for randomised and quasi-randomised trials, interrupted time series analyses, and controlled before and after studies.		
Patient and public involvement	Consumer panel (e-mail discussion list) of members of the Cochrane Consumer Network assisted in following tasks: Make authors aware of unpublished studies that could be considered for inclusion and commenting on drafts of the protocol and review.		
Level	**No. of users**	**C & D**	**M**
1, 2,3	NR	C=NR D=NR	NR
Impact	NR		
Outcomes	• There is moderate quality RCT evidence that involving consumers in the development of patient information material results in material that is more relevant, readable and understandable to patients, and may improve the patients' knowledge without affecting their anxiety. • There is low level quality evidence of telephone discussions and face to face group meetings engaging consumers better that mailed surveys in order to set priorities for community health goals, and resulting in different priorities being set for these goals. • Little evidence from comparative studies of the effects of consumer involvement in healthcare decision		
Limitations of study	Author: NR Reviewer: NR		
Quality assessment	5		

Authors, Year, Country	**Oliver, Armes, Gyte 2006, UK**

Aims	To assess whether public involvment has influenced research commissioned by the NHS Health Technology Assessment programme		
Methods	Qualitative Action research – based on successive cycles of planning, action and critical reflection		
Patient and public involvement	Non-reported in this study, but reflects on PPI in studies		
Level	**No. of users**	**C & D**	**M**
1,2,3	NR	D=NR	NR
Impact	**Research:** Benefits: • Fills in the gaps for suggestions of reviews • Makes user perspectives explicit • Changed focus of reviews • Refuted the need for planned research • Provided pain English background to text • Endorsed plans to research in a certain area • High profile of research done by HTA Challenges: • Difficulty of identifying and quickly recruiting users • Intimidating attending meetings if you are the only user participating • Difficulty in contributing to commissioning board where scientific merit is considered **Service users:** Benefits: • Increased information/knowledge about research • Financial support		
Outcomes	Better ways of working with users suggested: • Briefing users • More public involvement in developing individual proposals		
Limitations of study	Author: NR Reviewer: NR		
Quality assessment	4		

Authors, Year, Country	**Rees & Oliver, 2004, UK**
Aims	To assess a variety of user perspectives on the issue of sexual health for men who have sex with men (MSM) in the context of HIV, in order to help scope a review of this subject
Methods	Qualitative

	Advisory group made up of user members was established. Two focus group meetings: Meeting 1: research team presented its ideas for the review and asked group members to discuss whether they thought important aspects would be covered. Meeting 2: Research team presented the systematic review map. This map described the range and the number of studies found, but not study findings. The group was then asked to identify which interventions, and which sub groups of men who have sex with men seen on the map, should be a priority for the review's synthesis, using a formal consensus development exercise.		
Patient and public involvement	Advisory group of user members advised researchers on type of intervention, sub group of MSM, and relevant outcomes to search for. Advisory group met a second time to comment on initial findings of review, give advice on communicating reports of the review, and to comment on the draft report of the review.		
Level	**No. of users**	**C & D**	**M**
1	NR	C=NR D=NR	NR
Impact	**Research**: <u>Challenges</u>: Lack of budget for PPI – could have affected participation in advisory group Lack of staff time allocated to manage the advisory group may have affected participation rates in the group Limited time in meetings to address meaning of terminology used to describe the different research designs and methods		
Outcomes	1st meeting: • Users Changed emphasis away from risky sexual behaviours to idea of men taking control over their own health • Changed review date to include studies after 1996, as there was widespread introduction of of `highly active Antiretroviral Treatment (HAART) which changed attitudes to HIV and sexual behaviour 2nd meeting: • Users suggested the review prioritise sub groups of men that have sex with men (e.g. HIV positive men who have sex with men, young men who have sex with men, working class men who have sex with men, balck and ethnic minority men who have sex with men, and disabled men who have sex with men. • Users prioritised outcomes for the review.		
Limitations of study	Authors: NR Reviewers: NR		
Quality assessment	4		

Authors, Year, Country	**Sainsburys centre for mental health, 2008, UK**
Aims	To review the evidence on service user involvement (SUI) in health research and service user engagement programmes in prisons to see how these models might be applied to research in prison mental health care.
Methods	Structured review and survey Structured review of the evidence of service user involvement in prison mental health research Survey consultation with patients, public, and professionals on their views of SUI in prison mental health research
Patient and public	Not reported for review or delivery of survey

involvement			
Level	**No. of users**	**C & D**	**M**
1, 2, 3	NR	C=NR D=NR	NR
Impact	**Service users**: Benefits: Opportunity to have their voices heard Valuable skills gained from being involved in research Greater awareness of key issues Opens up communication even if issues can not be resolved immediately Challenges Need additional time and support planned into project Don't feel valued, therefore reluctant to get involved No payment for their work as a lay researcher Power imbalances are amplified for service users and become apparent when considering the status of prisoners and offenders in society, in view of their compromised rights on receipt of a custodial sentence **Research**: Challenges: User researcher may not be representative of all service users Issues of confidentiality Distrust of research Attitudes of prison staff/attitude of gatekeepers Administrative and bureaucratic barriers are time consuming **Researchers** Benefits: Development of skills to resolve differences of opinion Challenges: Difficulty getting ethics approval to involved prisoners in research Difficulty in ensuring secure setting for research to be conducted		
Outcomes	Reported areas where SUI is used: Prisoner councils: agenda setting – e.g. including drug treatment, food, diet Expert patient programme (EPP) – explored prisoners' perception of the barriers and opportunities for managing long-term conditions in prison (e.g. diabetes, high blood pressure, arthritis, and back problems Peer- mentoring training and user-led services – Mentor2work delivered peer mentoring training to prisoners with mental health problems in order to help them gain employment on release.		
Limitations of study	Author: NR Reviewer: Very little description of methods used		
Quality assessment	4		

Authors, Year, Country	**TwoCan Associates, 2009, UK**		
Aims	To evaluate the impact of PPI in the advisory groups of the UK Clinical Research Collaboration		
Methods	Qualitative Review of relevant papers Interviews with patient and public members of the UK CRC advisory groups, UKCRC group chairs and UKCRC staff Workshop patient and public members of the UKCRC advisory groups to review initial findings Interview with key stakeholders to test out findings		
Patient and public involvement	Involved in interviews to evaluate impact		
Level	**No. of users**	**C & D**	**M**
2	NR	C=NR D=NR	NR
Impact	**Research (advisory group contributions):** <u>Benefits</u>: • Users asked questions that may have appeared simple questions, but which are actually questions fundamental to the debate • Users keep the discussion grounded • Users monitor performance and recognise good performance • Users promote issues or questions that they believe would be important to patients and/ or the public • Users act as a remainder of patient/public accountability • Users bring knowledge of patient/public accountability • Users contribute to practical decisions • Users promote the use of plain English • Users lobby for more PPI within particular activities. • Users often involved for brief periods, making it difficult to involve them in decision making. Challenges: Creating a good context for PPI to happen The complexity of the environment (fast moving, changing environment) **Service users:** <u>Benefits</u>: • Felt valued • Felt experience had been recognised • Learn more about the UKCRC • Intellectual challenge • Doing something important <u>Challenges:</u> • Time burden (time for meetings, speed at which decisions are made) • Lack of clarity of their role		
Outcomes	<u>Recommendations</u>: • Continue the involvement of patient/public members in UKCRC advisory groups, and maintain the level of support provided for PPI • Capitalise on the expertise and knowledge that have been gained within the UKCRC advisory groups and use the learning plan for the future		

	• Review and define the purpose of PPI and the role of PPI members within the UKCRC • Explore and clarify how support for PPI will be provided beyond Dec 2009 • Review how PPI is put into practice at Board level, and explore how this can be done more effectively • Bring together patient/public members who are involved in strategic decision making in health research at a national level, to share experience and promote learning, identify opportunities for collaboration and shared goals, and /or identify any common needs for training and development • Support patient/public members to access networks of patients or the public to enable them to access the views of others, if patient and public members feel this would help them to fulfil their role • Offer informal debriefing and support to patients/ public members after all UKCRC group meetings to help them to review their performance • Ensure greater diversity amongst new patient and public members • Explore how technical expertise might be made available to patient/ public members, when they are dealing with complex issues and are ncertain about how best to consider specific questions or concerns • Continue to develop methods to capture and where possible measure the impact of pPI across UKCRC.
Limitations of study	Authors: NR Reviewers: NR
Quality assessment	4

Authors, Year, Country	**Viswanathan et al, 2004**		
Aims	To evaluate consumer involvement in the research process within the Agency for Healthcare Research and Quality (AHRQ)		
Methods	Systematic review Searches of electronic databases Use analytic framework to report evidence 60 studies were examined		
Patient and public involvement	NR for review process		
Level	**No. of users**	**C & D**	**M**
1,2 3	NR	C=NR D=NR	NR
Impact	**Research**: Benefits: • Helped set priorities and generate hypotheses for research • Made measurement instruments more culturally relevant • Strong involvement of users in advisory groups • Raised recruitment and participation rates in the study. • Users fluent in language of target group helped administer surveys and conduct interviews with this population • Helped translate research results into policy change Challenges: • Lengthy process of building partnerships between institutions and communities		
Outcomes			

Limitations of study	Authors: NR Reviewer: Brief summary of evidence
Quality assessment	5

Appendix 4 Excluded papers

PPI & Children:

1. Broad B, Saunders L. Involving young people leaving care as peer researchers in a health research project: A learning experience. *Research Policy and Planning*, 1998, vol. 16, no. 1, pp. 1-9.

2. Byas A, Hills D, Meech C, Read L, Stacey K, Thompson E, Wood A. Co-researching consumer experiences of child and adolescent mental health services: Reflections and implications. Families, Systems, & Health, March 2002, 20/1(75-89).

3. Dona G. Children as research advisers: Contributions to a 'methodology of participation' in researching children in difficult circumstances. *International Journal of Migration, Health and Social Care*, 2006, vol. 2, no. 2, pp. 22-34.

4. Holmes W, Stewart P, Garrow A, Anderson I, Thorpe L. Researching Aboriginal health: Experience from a study of urban young people's health and well-being. *Social Science & Medicine,* 2002, vol. 54, no. 8, pp. 1267-1279

5. Kellett M, Forrest R, Dent N, Ward S. 'Just teach us the skills please, we'll do the rest': Empowering ten-year-olds as active researchers. *Children & Society*, 2004, vol. 18, no. 5, pp. 329-343.

6. Kellett M. Children as researchers: Exploring the impact on education and empowerment. *childRight*, 2006, vol. 226, no. May, pp. 11-13.

7. McLaughlin H. Involving young service users as co-researchers: Possibilities, benefits and costs. *British Journal of Social Work*, 2006, vol. 36, no. 8, pp. 1395-1410.

8. Petrie S, Fiorelli L, O'Donnell K. 'If we help you what will change?' Participatory research and young people. *Journal of Social Welfare and Family Law*, 2006, vol. 28, no. 1, pp. 31-45.

Other excludes:

1. Alderete E. The formulation of a health research agenda by and for indigenous peoples: contesting the Western scientific paradigm. Journal of Alternative & Complementary Medicine, 1996, 2/3(377-85).

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5. Chalmers I. What do I want from health research and researchers when I am a patient? BMJ, 310, 1315-1318

6. Coats AJ. Consumer involvement in cardiovascular research: ways to combat bias and secrecy. International Journal of Cardiology, 2000, 75/1(1-3).

7. Collier A, Johnson K, Heilig L, Leonard T, Williams H, Dellavalle RP. A win-win proposition: fostering US health care consumer involvement in the Cochrane Collaboration Skin Group. Journal of the American Academy of Dermatology, 2005, 53/5, (920-1).

8. Culyer AJ. Involving stakeholders in healthcare decisions - the experience of the National Institute for Health and Clinical Excellence (NICE) in England and Wales. Healthcare Quarterly, 2005, 8/3(56-60).

9. Davies S, Nolan M. Editorial: Nurturing research partnerships with older people and their carers: Learning from experience. Quality in Ageing - Policy, practice and research 2006, 4(4), 2-5.

10. Denis J, Lomas J. Convergent evolution: the academic and policy roots of collaborative research. Journal of Health Services Research and Policy, 2003, 8 (supplement 2), S2:1-S2:6

11. Entwistle VA, Renfrew MJ, Yearley S, Forrester J, Lamont T. Lay perspectives: advantages for health research. BMJ, 1998, 316/7129(463-6).

12. Faulkner A, Gillespie S, Imlack S, Dhillon K, Crawford M. Learning the lessons together. Mental Health Today, 2008, (24-26).

13. Faulkner A. Involving clients in counselling and psychotherapy research. Healthcare Counselling & Psychotherapy Journal, 2008, 8/3(16-18).

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22. Richardson A, Sitzia J, Cotterell P. 'Working the system'. Achieving change through partnership working: an evaluation of cancer partnership groups. Health Expectations, 2005, 8, p210-220

23. Rose D. Collaborative research between users and professionals: peaks and pitfalls. Psychiatric Bulletin, 2003, 27, 404-406.

24. Smith L. How ethical is ethical research? Recruiting marginalised, vulnerable groups into health service research. Journal of Advanced Nursing, 2007.

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