

**What strategies for consumer engagement in health and medical research have been effective for consumers and researchers?**

**A Review of the Literature.**

Dr Anne Johnson  
[anne@communityengagement.com.au](mailto:anne@communityengagement.com.au)  
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Level 1, 12 Pirie Street  
Adelaide SA 5000

GPO Box 2248  
Adelaide SA 5001

t: 08 8231 4169  
f: 08 8410 5276  
e: [info@hcasn.asn.au](mailto:info@hcasn.asn.au)  
w: [www.hcasn.asn.au](http://www.hcasn.asn.au)  
twitter: healthconsumers  
abn: 90 294 720 079



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## Executive Summary

### Introduction

This report was commissioned by SAHMRI and presents the main findings of a literature review conducted to respond to the search question 'What strategies for consumer engagement in health and medical research have been effective for consumers and researchers?'

### Review Method

A structured literature review was utilised which searched widely across different sources of published literature. An environmental scan was conducted to identify relevant information in sources not traditionally published in the biomedical bibliographic databases. The following electronic biomedical databases were searched: CINAHL, Pub-Med, Cochrane Library, OVID, and ProQuest. Medical subject heading (MESH) terms and text words were selected based on five different search concepts and adapted to common indexing practices for each database. Additional searches were conducted using Pub-Med 'related articles' feature.

Reference lists from seminal articles (systematic reviews and literature reviews) were reviewed and a search undertaken for relevant articles. Each issue of Health Expectations Journal, available online, was hand searched. This journal appeared to have more articles on the topic than any other identified in the literature search through the data bases.

The following themes emerged relevant to addressing the search question and were used to structure the discussion of the findings:

- Policy - Australia and internationally
- Contextual information - background and the current contested issues and debates about concepts and terminology
- Strategies for effective consumer and community participation in health and medical research
- Benefits and disadvantages for consumers and benefits and challenges for researchers.

A review framework was required to structure the results for Section 3 of the literature review. This was the section related to strategies that have been effective for consumers and researchers. The framework by Shippee et al. (1) was selected. The reasons being was that the framework was developed from a systematic review, was contemporary (published 2013), and presented the phases and stages of consumer participation in health and medical research in a logical and comprehensive way which encapsulated the different phases and stages of the research process. The phases identified were Preparatory, Execution and Translation. The stages identified are Agenda Setting and Funding, Study Design and Procedure, Study Recruitment, Data Collection, Data Analysis, Dissemination, Implementation and Evaluation.

## Findings

It was evident in the early stages of this review of the literature that the effectiveness of strategies used was highly context-specific, and in many instances dependent on the attitudes of, skill, and relationships between, the consumers and researchers involved in the research process.

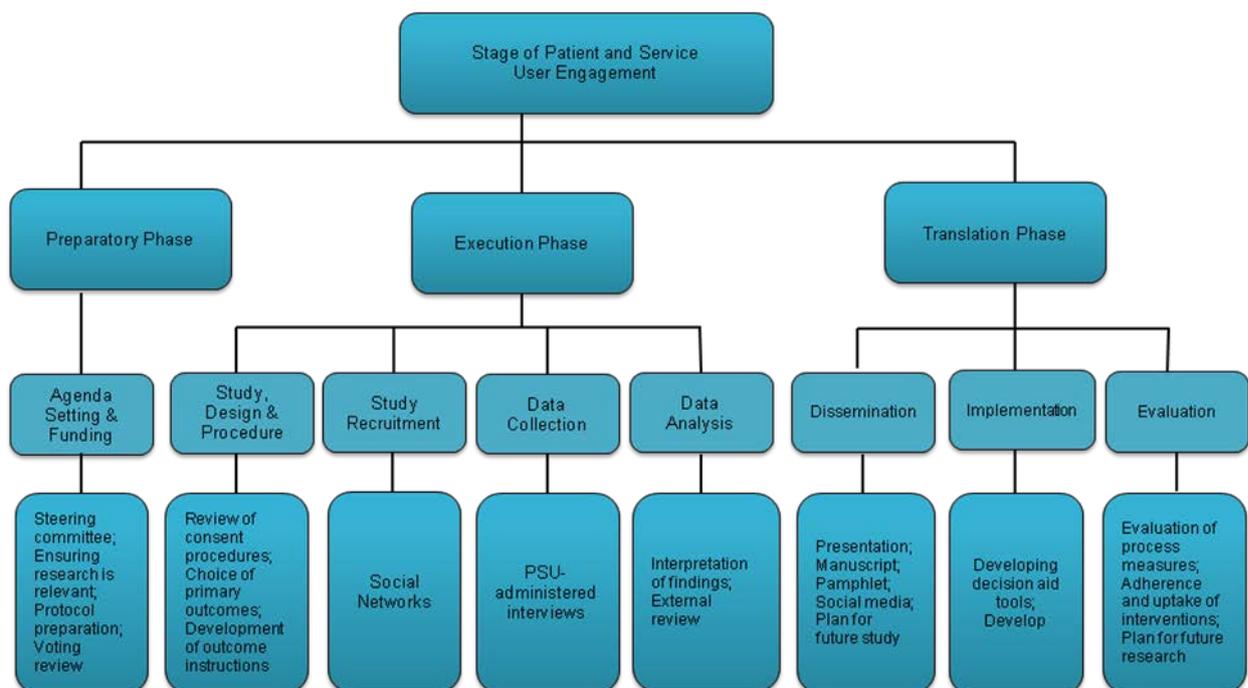
Evaluation of strategies and comparative studies were hampered by lack of evaluation frameworks due to contextual issues such as policy and variations in utilisation of terminology, ideology, models of participation and methodology. These early findings meant that there was a need to identify the contextual issues that were contested and debated in the literature to appreciate the findings in Section 3. Another challenge was to discern between impact of the research and effectiveness of the strategy used. One of the key tensions in reviewing the literature was discerning between impact of consumer participation in research and effectiveness of the strategies used. There were many papers which described the benefits and disadvantages to consumers participating in aspects of research and methods of research, but they did not necessarily come from studies related to strategies for effective participation. Similarly with the studies that identified the benefits and challenges for researchers.

Within the review of the international literature themes emerged for concepts and terminology that were contested and debated and have a significant impact on how consumer participation in research is viewed, enacted and evaluated. It is important for SAHMRI and Health Consumers Alliance SA Inc to be aware of these issues moving forward with consumer participation in research in South Australia. These included debates about terminology such as consumer and community and other terms including; patient, service user, lay, public, and citizen; and involvement, participation and engagement. In addition there were debates about concepts such as: ideologies underpinning approaches to participation; levels of participation, and representativeness and representativeness. These debates are comprehensively represented in the report.

Smith et al. (2) conclude in their review of the literature that research is undertaken for different reasons and in different contexts, as such it is not possible to say that involving consumers, will, or should, always be undertaken in the same way to achieve the same benefits. As identified by several authors (1, 3-9) there is huge variation in how the evidence of effectiveness of different strategies of consumer and community participation is evaluated and reported. Variations in terminology, concepts and design inhibited comparative effectiveness in determining effective strategies (1). In addition many of the studies are qualitative in design and may not carry the same weight of evidence within the positivist paradigm of health and medical research (10). Mockford et al. (11) stress that the absence of evidence does not indicate an absence of effectiveness of strategies, rather it indicates inadequate reporting with a lack of valid and reliable tools (11). They conclude in their systematic review that there is an urgent need to create the tools to develop the evidence base. In addition, they state that guidelines for the reporting of consumer and community participation could improve consistency and comparability of studies.

One of the main conclusions from the systematic reviews by Brett et al. (5) and Shippee et al. (1) and the literature review by Staley (3), and many other authors who have reported on evaluations of research processes and outcomes (2, 4, 6, 9, 12-20), is that effectiveness of strategies used is highly context-specific, and in many instances dependent on the attitudes of, skill, and relationships between, the consumers and researchers involved in the research process.

One key finding was that there are two levels of effectiveness of strategies for participation in research: the first level is the conditions within the research organisation to support consumer and community participation, and the second level is the strategies used within the research programs/projects. In the study by Saunders and Girgis (21) they examined a purposive sample of Australian research organisations and describes how nine Australian research organisations report they approach consumer participation at an organisational level and in research. The organisational factors, which Saunders and Girgis identified as contributing to success, were categorised as Governance, Infrastructure, Capacity and Advocacy. Literature relating to the second level utilises the following framework by Shippee et al. as the scaffolding to present and discuss the relevant publications about strategies revealed in the literature search for the three different phases and eight stages.



**Figure 1. Phases and stages of patient and service user engagement in research from Shippee et al. (1) page 7**

There were many descriptive reports on the benefits and disadvantages/challenges of consumer and community participation in health and medical research from the consumers' perspective and researchers' perspectives. A significant finding was that the reports on consumer benefits and disadvantages were mainly provided from the perspective of consumers involved in participatory and community based research projects; and the studies reporting on the researchers' perspectives were primarily from research organisations, universities, and health services and not necessarily from researchers actively involved in research with consumers. As the benefits and disadvantages for consumers, and benefits and challenges for researchers, were not often related to specific strategies or phases of the research process they have been summarised. Benefits of participation in research for consumers include: new skills and knowledge; personal development; support and friendship; enjoyment and satisfaction; increased 'research literacy'; and financial gain. Disadvantages include: tokenism; unfamiliar research language and jargon; power imbalance and conflict; emotional burden; work overload; personal exposure through the media; and frustrations at

the limitations of participation. Benefits for researchers (and the research process) include: enhanced scientific and ethical standards and outcomes of research; gave the project legitimacy and authority; ability to seek direction when tackling difficult issues; ability to get advice from people not looking at the project through a research lens; valued the benefits once they gained experience; strengthened communication; democratisation of research and fun. Challenges included: divergence from scientific methods and ethical dilemmas; turning upside down' of existing power relationships; time and cost; constraints of academic research tradition; funding consumer participation in research; lack of training and attitude.

## Conclusions

After a comprehensive and structured literature search it was ascertained that there is very little literature which reports on specific strategies for consumer engagement in health and medical research that have been effective for consumers and researchers. Much of the literature, whilst valuable and informative about consumer participation in research and impact of consumer participation in research activities did not provide the type of evidence required to conclusively and definitively answer the search question.

As identified research is undertaken for different reasons and in different contexts, as such it is not possible to say that involving consumers, will, or should, always be undertaken in the same way to achieve the same benefits. One of the major conclusions is that effectiveness of strategies used in consumer participation in research is highly context-specific, and in many instances dependent on the attitudes of, skill, and relationships between, the consumers and researchers involved in the research process.

Some key findings relating to effectiveness of strategies were that:

- More participatory strategies with consumers were more productive.
- Occasional consultations and written consultations, do not lend themselves to long-term investment, and these methods have more often failed to show the advantages of enthusiasm for involvement, or increased knowledge about consumers' priorities or constructive ways of working with consumers. In addition, these strategies were found to not be an effective use of consumers' time when comparing to influence on the research agenda.
- When collaborative methods were utilised, consumers were in a better position to influence the research.
- Consumer-researcher collaborations require planning and perseverance and these partnerships are reliant on comfortable human interaction among not necessarily like-minded people. There is no simple formula for success but allowing adequate time to establish the consumer-researcher partnership and to set realistic terms is important.

Some key factors were identified which may support consumer participation competence in organisations and contribute to success in consumer participation in research. These being governance (structures, policy, research funding), infrastructure (consumer registers, information), capacity (consumer training, researcher training), and advocacy.

There is huge variation in how the evidence of effectiveness of different strategies of consumer and community participation is evaluated and reported. Variations in terminology, concepts and design

inhibited comparative effectiveness in determining effective strategies. In addition many of the studies are qualitative in design and may not carry the same weight of evidence within the positivist paradigm of health and medical research. It was stressed that the absence of evidence does not indicate an absence of effectiveness of strategies; rather it indicates inadequate reporting with a lack of valid and reliable tools. Many academics who research in this area argue that there is an urgent need to create the tools to develop the evidence base. In addition, they state that guidelines for the reporting of consumer and community participation could improve consistency and comparability of studies.

## Introduction

Consumer and community participation in health and medical (including biomedical) research relates to an active relationship between consumers and researchers in the research process. Such participation is thought to lead to research which is of a greater quality and clinical relevance and of greater benefit to consumers due to the unique perspective that consumers can bring to the research (22). Consumer and community participation in health and medical research is underpinned by the core principle that people who are affected by research have a right to have a say in what and how research is undertaken (3).

The South Australian Health and Medical Research Institute (SAHMRI) is a newly formed research institute and is keen to increase their knowledge of the current debates and evidence underpinning strategies for effective consumer and community participation in health and medical research, with a view to developing an informed approach to consumer and community participation in health and medical research.

This report was commissioned by SAHMRI and presents the main findings of a literature review conducted to respond to the search question 'What strategies for consumer engagement in health and medical research have been effective for consumers and researchers?'

## Review Method

### Search terms and scope

The review utilised the following concepts to guide the search strategy and were developed with the input from the steering committee for this project. Combinations of concepts were used as search terms for the structured literature review.

Concept 1	Concept 2	Concept 3	Concept 4
Consumer	participate	health	research
Community	engage	medical	evaluation
Patient	involve	bio-medical	
Citizen	consult	animal	
Client	empower		
User	collaborate		
Lay	inform		
Public			

### Inclusion criteria

Relevant articles were identified by applying the following inclusion criteria:

- Relevant to search question ‘What strategies for consumer engagement in health and medical research have been effective for consumers and researchers?’
- Published in the English language
- Available in full text
- Published during the years 1988 – 2013
- From a credible source
- Journal articles reporting original research and/or theoretical frameworks/models
- Non-original or summarised literature (systematic and non- systematic literature reviews, critiques and commentaries)
- Research reports
- Evaluations of participation activities
- Books

### Environmental Scan

An environmental scan was undertaken during the second half of June 2013 to identify relevant information in sources not traditionally published in the biomedical bibliographic databases. I was interested in the key players in the area such as authors, organisations and stakeholders, key events, and documentation (statements, position papers, workshop reports, organisation’s resources). Search engines SciVerse Hub, Google, and Google Scholar were utilised. Data was extracted from relevant links such as title, source, author, URL, content description and main conclusions.

### Electronic Biomedical Databases

The following electronic biomedical databases were searched during the first two weeks of July 2013 through Flinders University Library: CINAHL, Pub-Med, Cochrane Library, OVID, and ProQuest.

Medical subject heading (MESH) terms and text words were selected based on the abovementioned range of search concepts and adapted to common indexing practices for each database. Additional searches were conducted using Pub-Med 'related articles' feature.

Reference lists from seminal articles (systematic reviews and literature reviews) were reviewed and a search undertaken for relevant articles. Each issue of Health Expectations Journal, available online, was hand searched. This journal appeared to have more articles on the topic than any other identified in the literature search through the data bases.

### **Rationale for the approach used**

A structured literature review was utilised which searched widely across different sources of published literature (as outlined above). This structured literature review differs from a systematic review in that there were no judgements made of the grade or quality of the evidence, or to assess if the results were generalisable (except where comments were made by the original authors). The reasons for taking this approach were in part due to the nature of the evidence, and to respond to the search question where there was a need to cover the breadth of literature available.

### **Identifying potentially relevant publications**

Potentially relevant articles were identified by reading the titles and abstracts of published journal articles or summaries of reports to ascertain if they contained information that would meet the inclusion criteria. A total of 268 references were downloaded, printed and reference details entered into EndNote.

Through scanning the abstracts or summaries the following broad themes emerged:

- Policy – the Australian and international context and surveys about extent of consumer participation in research
- Consumer participation in research – background about, argument for, contested issues and debates, benefits, barriers, attitudes
- Models/frameworks of consumer participation
- Original research which measured/described impact or effectiveness
- Impact on consumers and researchers
- Training in consumer participation in research and resources (how to guides)

### **Review of the Articles**

Once publications were physically organised into the above themes, all publications were read so that I could become familiar with the breadth, quality and relevance of the content to the search question. Seminal publications were identified (systematic reviews and literature reviews) and key statements and findings from original research, commentaries, and theoretical frameworks/models were highlighted for potential inclusion in the literature review.

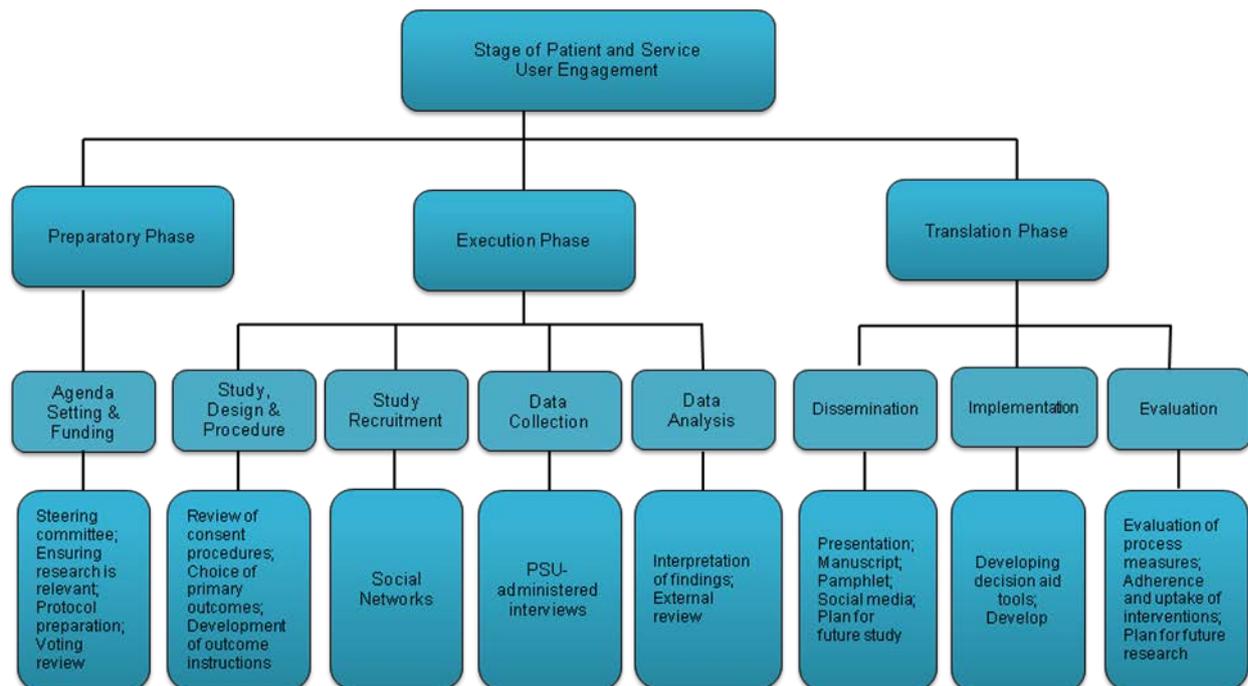
When each of the publications were read in more detail the following themes emerged relevant to addressing the search question:

- Policy - Australia and internationally
- Contextual information - background and the current contested issues and debates about concepts and terminology

- Strategies for effective consumer and community participation in health and medical research
- Benefits and disadvantages for consumers and benefits and challenges for researchers.

A review framework was required to structure the results for Section 3 of the literature review. This was the section related to strategies that have been effective for consumers and researchers.

One of the criticisms in the academic literature was the lack of an evidence-based framework for consumer and community participation in health and medical research (1). Several potential frameworks were identified in the literature review (1, 3, 10, 15, 23-25) and after discussion with the Project Managers at Health Consumers Alliance SA Inc. the framework by Shippee et al. (1) was selected. The reasons being was that the framework was developed from a systematic review, was contemporary (published 2013), and presented the phases and stages of consumer participation in health and medical research in a logical and comprehensive way which encapsulated the different phases and stages of the research process. The phases identified were Preparatory, Execution and Translation. The stages identified are Agenda Setting and Funding, Study Design and Procedure, Study Recruitment, Data Collection, Data Analysis, Dissemination, Implementation and Evaluation. See Figure 1 below.



**Figure 1. Phases and stages of patient and service user engagement in research from Shippee et al. (1) page 7.**

### Terms Used in the Findings of the Literature Review

The terms 'consumer' and 'community' will be used throughout the report on the findings of the literature review to refer to:

- People
- Patients

- Users, service users or potential service users
- Public
- Citizen
- Lay people
- Carers
- Survivors
- Clients
- Informants and key informants

In addition the term ‘participation’ will be used throughout the report on the findings of the literature review to refer to ‘active participation’, ‘involvement’ and ‘engagement’.

The use of these terms in the report is to aid the flow of the literature review and to avoid the potential of confusing the reader by using different terminology. Where direct quotes have been included, the terms used by the original authors will be used. The current debates about terminology found in the international literature will be discussed later in the literature review.

## Findings

The findings of the literature review will be structured using the following headings:

1. Policy – the Australian and international context
2. Contextual Information - background and the current contested issues and debates about concepts and terminology
3. Strategies for effective consumer and community participation in health and medical research
4. Benefits and disadvantages for consumers, and benefits and challenges for researchers.

It was evident in the early stages of this review of the literature that the effectiveness of strategies used was highly context-specific, and in many instances dependent on the attitudes of, skill, and relationships between, the consumers and researchers involved in the research process.

Evaluation of strategies and comparative studies were hampered by lack of evaluation frameworks due to contextual issues such as policy and variations in utilisation of terminology, ideology, models of participation and methodology. These early findings meant that there was a need to identify the contextual issues that were contested and debated in the literature to appreciate the findings in Section 3. Another challenge was to discern between impact of the research and effectiveness of the strategy used. One of the key tensions in reviewing the literature was discerning between impact of consumer participation in research and effectiveness of the strategies used. There were many papers which described the benefits and disadvantages to consumers participating in aspects of research and methods of research, but they did not necessarily come from studies related to strategies for effective participation. Similarly with the studies that identified the benefits and challenges for researchers.

### 1. Policy – The Australian and International Context

A survey conducted for Research Australia in 2011 found that 95% of Australian voters thought that it is important for Australia to have a strong health and medical research industry (26). The active involvement of consumers and community in health, medical and biomedical research has become central to the research policy agenda of Australia, UK, Canada and the USA, among other western countries (27-30).

In Australia, Consumers Health Forum of Australia (CHF) and the National Health and Medical Research Council (NHMRC) developed a Statement on Consumer and Community Participation in Health and Medical Research in 2001 (27), which was in response to the Willis Review in 1999. The Willis Review placed consumer and community participation in research on the national agenda for the NHMRC and Australian researchers (27). The CHF and NHMRC (27) shared vision was for 'consumers and researchers to work in partnerships based on understanding, respect and shared commitment to research that will improve the health of humankind'. The release of the statement was followed by the joint publication in 2004 of a model framework and research pack to guide consumer involvement in research practices in Australia (31, 32) to better align health and medical research with community need, and improve the impact of research. The existence of a model framework in consumer and community participation in health and medical research has been described as evidence of seminal thinking and signifies an important culture shift for research funders, research organisations and researchers in Australia (33). In addition there were several health research policy changes made by the NHMRC from 1997 to 2002 in Aboriginal and Torres Strait Islander health research which de la Barra et al. (34) state have made some progress in supporting better research models particularly in improving engagement with Indigenous communities.

A nationwide survey of research funding organisations and organisations that conduct research was undertaken during 2008-2009. The results showed that there was marked variation in consumer participation in research in Australia (35). Saunders et al. (35) identified in their study that there is, in theory, wide acceptance of the potential benefits of involving consumers in health and medical research in Australia, but there was a reluctance by some groups to test these potential benefits. The fact that there wasn't an implementation plan for the model framework developed in 2004 by CHF and NHMRC, and structures and mechanisms to support consumer and community participation in health and medical research in Australia was identified as a factor that reduced the effectiveness of the implementation of the policy direction and has led to ad hoc implementation (21). Saunders et al. (35) stated that Australia essentially lacked the range of structures and mechanisms found to be useful by other countries in supporting consumer and community participation into health and medical research, such as in the United Kingdom (UK), where the organisation INVOLVE is funded by the UK Department of Health to promote consumer participation in research and improve the way that research is prioritised, commissioned, undertaken, communicated and used. INVOLVE provides resources and training for researchers and funders on how to involve members of the public. It also supports consumers who are thinking about getting involved in research (36).

Recently the Strategic Review of Health and Medical Research (the McKeon Review) was released by the Commonwealth of Australia (37). The review states that:

Consumer engagement is also an important area which requires leadership. Consumers can and should play a prominent role in the HMR sector, particularly in setting priorities for research agendas and participating in clinical trials. By involving consumers in the initial stages of research, they are able to identify and shape research topics that are relevant to

their needs and therefore contribute in a meaningful way to improving health outcomes. Additionally, this generates a greater awareness among policy makers and researchers of pressing consumer issues and provides another avenue to continuously improve the quality of research through consumer feedback (page 53).

The review suggested that the NHMRC and Australian Institute Health and Welfare provide key leadership responsibilities for 'engaging consumers and involving consumers in priority-setting, clinical trials and patient database participation' (37)(page 54).

Currently the NHMRC is in the process of reviewing the 2001 Statement on Consumer and Community Participation in Health and Medical Research (38). This is due for release later in 2013. The CHF were funded by NHMRC to conduct a national consumer consultation workshop in late 2012 to discuss the draft revised statement (39). Since then CHF has released a future directions document to support consumer participation in health and medical research and to build on existing models of active consumer engagement (38). CHF argue in the report that there must be consideration for how the health and medical research sector can evolve so that it becomes consumer-oriented (38).

Similar policy directions to promote an agenda of consumer and community participation in health and medical research have been introduced in several other western countries, including the UK, Canada and United States of America (USA). There is a different focus in each country, with different approaches to resourcing the implementation of the policy directions. For example, in the UK The National Institute for Health Research (NIHR) states that:

Service user participation is embedded in all aspects of the programme. As part of the assessment criteria, each application the programme receives is required to demonstrate the quality and extent of PPI within the project, as well as how patients and other members of the public have been involved in the application and will be involved in the research, if successful. Patient and public involvement in research means that members of the public and / or patients are active partners in the research process by, for example, advising on a research project, assisting in the design of a project, or in carrying out the research, rather than being the subjects of research (40).

There is a range of government initiatives to stimulate the growing interest in promoting and supporting patient and public involvement in research in the UK. As early as 1996 the Standing Advisory Group for Consumer Involvement in R&D was formed in recognition of the need for consumer involvement in influencing the research agenda. This group evolved to become an advisory organisation in 2001 called INVOLVE. INVOLVE is funded to support public involvement in the National Health Service (NHS), public health and social care research (36). An additional model of support for consumer and community participation in research is the James Lind Alliance. This is a not for profit making initiative and was formed in 2004 to facilitate priority setting partnerships (41). It is primarily funded by the National Institute for Health Research and the Medical Research Council. There are over 300 organisations and individuals affiliated with the James Lind Alliance and input comes from a mix of lay people, healthcare and clinical research professionals, and experts in patient and public involvement.

The Canadian Institutes of Health Research (CIHR) is the Canadian Government's agency responsible for funding health research. CIHR has established a Framework for Citizen Engagement, recognising that, 'there is a desire to communicate research findings to the public in a more effective manner and to develop tools that will assist all of the funding agencies to engage the public effectively' (42). The CIHR consists of 13 virtual institutes, which support a broad spectrum of health research. The Canadian Government also has a strategy for patient-oriented research which states that patient-oriented research is the cornerstone of evidence-informed health care (29). The vision of Canada's Strategy for Patient-Oriented Research is 'to demonstrably improve health outcomes and enhance patients' health care experience through integration of evidence at all levels in the health care system' (p iii).

In the USA, service user involvement in research is more likely to be described as public participation. Public participation is based on the belief that those who are affected by a decision have a right to be involved in the decision-making process. Most recent US federal laws authorising or establishing federal programs contain requirements that government agencies consult with the public during the design and implementation. If funding is awarded to a state, then the public participation requirements are also passed on to the state authorities. The National Institute of Health (NIH) has established a Council of Public Representatives which advises the NIH Director on issues related to public participation in NIH activities, outreach efforts, and other matters of public interest (43). The Patient-Centred Outcomes Research Institute (PCORI) has been authorised by Congress to conduct research to provide information about the best available evidence to help patients and their health care providers make more informed decisions. PCORI's research is intended to give patients a better understanding of the prevention, treatment and care options available, and the science that supports those options (44). PCORI was formed as a result of the Patient Protection and Affordable Care Act, which was signed into law in 2010 to develop methodological standards that can help ensure that comparative effectiveness research produces information that is meaningful, unbiased, timely, actionable and applicable to patients' needs (30). PCORI has a mandate under the Affordable Care Act to seek meaningful ways to integrate the patient's voice into the research process (45). PCORI joins several federal agencies, including the Agency for Healthcare Research and Quality, the National Institutes of Health, and the Food and Drug Administration, that have begun to involve patients and stakeholders in a generating and reviewing research questions (45).

It is evident from the brief examples provided above that there is an international movement towards government legislation and policy positions supporting, and approaches to implementing, consumer and community participation in health and medical research which are government driven and implemented using different strategies with different outcomes. The significant issue identified by Saunders et al. (35) is that consumer and community participation in research is a significant culture change that is evolving for governments, research funders, research organisations, researchers and consumers.

## 2. Contextual Information

### Background

Health and medical (including biomedical research) has been traditionally driven by researchers/investigators, whereby they generate research questions, design the research

methodology, conduct the research, analyse the results and release the study results. The traditional role of consumers has been as passive participants in research, known as 'subjects' or 'potential 'users' of the end product (29, 46, 47). This is described as doing research 'to', 'about' or 'for' consumers (28) and 'experimenting on' consumers (48). There is substantial evidence that there are considerable mismatches between the research that gets done and the research that consumers would like to see done. This has led to the call for greater involvement of consumers in the research process (49).

There is now an emerging trend in health and medical research to actively involve patients and the public in different aspects of the research process and in different roles where they can act as a research partner in a team of professionals (27, 36, 47, 50). For several decades there has been an emphasis on the importance of better connecting health and medical research with society (35). In addition, it has been argued that health and medical research is a social process, and as such it should be informed by the interactions of researchers and potential end beneficiaries, where both groups exchange expectations, views, and ideas, and combine this knowledge to enhance the quality of the research (35).

In addition, communities have been seen as 'hosts' of research trials and were largely absent from the research process and decision-making (46). The practice of involving communities and community groups in health and medical research has evolved to be more participatory over recent years in response to mistrust between communities and researchers, where communities or community groups have felt 'used' as laboratories, 'stung' by researchers insensitivities, 'betrayed by parasitic researchers', or suffered from 'consultation fatigue' and not seen any changes made (51-54). This has led to an effort by policy makers, research funders, and researchers to enhance research by improving the quality, relevance, and impact of research in the community (52, 53). In Australia there is now an acknowledgement that Aboriginal and Torres Strait Islander communities are no longer prepared to be research 'objects' for external, mostly non-Indigenous researchers, and that they now demand a role in decisions about what is researched and how it will be researched (55).

The history of consumer and community participation in health and medical research beyond being 'passive subjects', has its roots in the 1970's with the emergence of the women's health movement. Women began to protest about the inadequate inclusion of women in biomedical research and to demand a role in decision-making regarding research on women's health issues such as contraception, pregnancy and hormone replacement therapy. In the 1980's the traditional health and medical research landscape was changed forever through the efforts of HIV/AIDS activists in North America and Europe, where they called for a 'seat at the table' and challenged researchers' approaches to conducting trials which overlooked patients' preferred outcomes (48). The work of HIV/AIDS activists has had a significant impact on the research agenda, reform of clinical trials, and has demonstrated the value of lay expertise (29, 46, 48, 56).

Wright et al. state that there are three principal drivers for consumer and community participation in research (57). These being:

- The political imperative for the engagement of consumers in research.
- The growth of consumer and carer advocacy, where the influence of consumer advocacy has been effective in ensuring that consumers are involved extensively in research, especially in the areas of breast cancer, Alzheimers, disability, mental health, and multiple sclerosis.

- The academic community who involve consumers in research are promoting the benefits of such engagement. Boote et al. state that the Cochrane Collaboration have been influential in this respect (58).

Oliver et al. (23) suggests that in addition to a political mandate, the pursuit of ‘better’ research is an additional main reason.

Within the review of the international literature themes emerged for concepts and terminology that were contested and debated and have a significant impact on how consumer participation in research is viewed, enacted and evaluated. It is important for SAHMRI and Health Consumers Alliance SA Inc to be aware of these issues moving forward with consumer participation in research in South Australia. The following section will cover these key contentious issues and debates.

### **Debates about Terminology: Consumer and Community and Many Other Terms**

Issues of terminology are important for understanding how consumer and community participation is understood in the academic literature and research practice. One of the most hotly contested debates in the health and medical research academic literature is about the terms used to represent consumers and community.

In Australian academic literature and policy documents there appears to be a fairly consistent use of the terms consumer and community participation in health and medical research (27, 31-33, 38, 39, 59, 60). This term has consistently been used in the health service policy documents and academic literature since the Consumer Focus Collaboration program implemented by the Commonwealth Government in late 1990’s and early 2000 (61). This health service oriented program, linked to the safety and quality in health care agenda, appears to have influenced the use of terminology in Australia regarding consumer and community participation in health and medical research. In addition, it was stated that the Cochrane Collaboration has used the term ‘consumer’ since their inception (16). This international organisation has had significant involvement of, and influence on, Australian researchers, academics and consumer advocates.

However, within the international literature there are many different terms used which can be confusing. Bastian (62) states that there is no universal agreement about the words used to specify people who use, or are meant to be served by health services or involved in research. She states that it is more than just an argument about words; it is about ways of seeing and portraying people and their relationships with the health care system. Boote et al. (22) state that the terminology applied to receivers of health care may be influenced by the agenda of the person or organisation using the term. Oliver (23) states that terminology varies with geography, between disciplines, and over time. In the USA the term ‘consumer’ suited the commercial insurance-based US health system and was adopted more widely in health policy circles in the mid-1990s to encompass people using health services, even those services that received public funding (23). More recently the term ‘patient and service user’ in health and medical research has been used in academic literature from the USA (1) and service user is more likely to be described as public participation (63). In the Canadian health and medical research strategy document (42) the term ‘citizens’ is widely used, a term Oliver (23) states invokes rights and democracy. However, she is critical of the term being used as it excludes refugees and asylum seekers who do not have citizen status. More recently in the health sector in the UK, the preferred term ‘patients and public’ is commonly used in UK based policy and academic literature (36, 64). Sociologists refer to ‘lay people’ or ‘lay publics’ to emphasise

the diversity of people and groups within the public and to distinguish them from professionals (23). In addition, some people prefer to be called 'people', 'service users', 'users', 'survivors', 'carers', 'resident', 'informant', or 'client' (23).

Telford et al. (16) reports on the findings of a scoping study where there were diverse opinions expressed about the terms used to describe people who receive health care, where it was concluded that although far from perfect, the term 'consumer' was preferred. Oliver (23) argues that 'whatever the terminology, the aim of a participative approach is to support the participation of those people, individually or collectively, who are most intimately affected by any efforts to improve health on a population-wide basis'.

### **Debates about Terminology: Involvement, Participation or Engagement?**

The concepts of involvement, participation and engagement have been hotly debated in the research literature. There is variation in the use and interpretation of the terms 'participation', 'involvement' and 'engagement'. In the UK, INVOLVE differentiate between 'involvement' and 'participation' in health and medical research, with 'involvement' defined as being of a higher order in health and medical research. INVOLVE define 'involvement' as being where members of the public are actively involved in research projects and in research organisations. 'Participation' is where people take part in research (65). The reasoning behind this differentiation is that despite 'participation' being a term that is widely used within health services in Australia, in the field of health and medical research the term 'participation' can be confused with 'participant', which is often interpreted as having a passive role in research. In a recent consultation by CHF there was discussion about using the term involvement in preference to participation in research (39). Williamson distinguishes between 'overt' and 'covert' involvement: 'overt consumers' get involved because they are motivated through personal experience or health problems, where 'covert consumers' bring particular skills as part of their role (66).

However, this is challenged by Ward et al. (67) who argue that 'participation' invokes some level of power sharing or empowerment where consumers are engaged, rather than solely being 'involved'. Other authors are also critical of the term 'involvement' because it implies a situation where consumers are brought into professional research worlds and overlooks that fact that consumers may lead, control or undertake research themselves (68). Involvement also implies that consumers are being invited in to be an active participant in the research, whereas in reality, the involvement may be tokenistic or a low level of interaction may be experienced. The example Beresford (51) provides is where minimal consultation is done about a minor aspect of the research and it is still labelled 'involvement'.

The term 'engagement' is also used in the international health and medical research literature, but not as frequently as 'involvement'. The term 'engagement' invokes images of an active and power sharing relationship between researchers and consumers and the community, which can become a partnership.

Morrow et al. (63) suggest that a way to address this conceptual uncertainty is for researchers to describe in detail what type of involvement is planned and to describe it according to level of participation.

### Debates about Concepts: Ideologies Underpinning Approaches to Participation

Boote et al. (28) and Beresford (54) provide perspectives on ideologies, or systems of beliefs and values, that underpin approaches to consumer and community participation in health and medical research. These are 'Managerialist/Consumerist', 'Democratic', 'Epistemological', 'Moral' and 'Consequentialist'. Whilst some of these ideological approaches may seem similar, they do not necessarily sit comfortably together (69). They do however; provide insight into the ideological debates that persist within the academic literature and the way researchers may approach consumer and community participation in health and medical research. Beresford (69) argues that consumer participation in research is ultimately an ideological and ethical issue, not a technical one. However, Wright et al. (57) argue that sustaining a purely ideological approach can lead to tokenism, which whether inadvertent or deliberate can undermine the real value and impact of consumer participation. There is a need to consider pragmatic issues, as well as ideological approaches, in order to ensure that effective participation practice, and quality research, is achieved.

The different ideologies are defined as:

- **Managerialist/consumerist approach**, which is framed mainly in market research terms of 'improving the product', where 'customer' intelligence-gathering can improve research. There is no commitment to the redistribution of power or control (69).
- **Democratic approach**, which is concerned with people having more say in research that impacts upon them and enables them to exert more control over their own lives. There is a commitment to the redistribution of power and control in this approach and the logic is for 'user-led' and 'user controlled' approaches to research (69).
- **The epistemological approach**, which is underpinned by the belief that patients and service users have direct knowledge about their own health condition that can benefit researchers and the research outcomes. Beresford's epistemological argument is that "the shorter the distance between direct experience and interpretation, then the less distorted, inaccurate and damaging resulting knowledge can be"(51). Boote et al. (28) state that the epistemological argument is best encapsulated by the phrase 'nothing about us without us' (70).
- **The moral, ethical and rights approach**, which is underpinned by the belief that the public have the right to be involved in any publicly funded research that may impact on their health status or services they receive. In addition public involvement is also a means of empowering minority or disadvantaged groups in society and the appropriateness of methodologies need to be carefully considered (28, 71).
- **The consequentialist approach, or effectiveness approach**, which is where public involvement has the potential to improve the quality, relevance and impact of health and medical research, whilst also improving transparency of the research process and accountability to the wider community (including the researcher community) (28).

### Debates about Concepts: Levels of Participation

There are several models debated in the international literature which depict levels of involvement. Ward et al. (67) state that although there are different levels of consumer participation, with the aim of current policy to move consumer participation in health and medical research from non participation (other than as subjects) towards creating and maintaining partnerships with researchers, the level best suited to individual research programs and projects (or within research projects) will be socially, culturally and politically contingent. Oliver et al. (12) state that while the

levels of participation provide a conceptual framework to articulate consumer and community participation in health and medical research, it should be remembered that consumer and community participation is a complex and complicated phenomenon. In reality, consumer and community participation may range from none, to some, of full participation as a research project develops.

The most influential, and frequently referred to in the international medical and research academic literature is Sheri Arnstein's ladder of citizen participation (72). Arnstein argues that 'there is a critical difference between going through the empty ritual of participation and having the real power needed to affect the outcome of the process'. Arnstein's ladder depicts 9 different levels of participation:

- **manipulation** and **therapy** (non-participation);
- **informing, consultation** and **placation** (consultation);
- **partnership, delegated power** and **control** (degrees of control).

The International Association for Public Participation (IAP2) spectrum of levels of participation is also referred to in some of the debates about levels of participation. The IAP2 spectrum goes from lowest to highest level of impact (73):

- **Inform** – to provide the public with balanced and objective information to assist them in understanding the problem, alternatives, opportunities and/or structures.
- **Consult** – to obtain public feedback on analysis, alternatives and/or decisions.
- **Involve** – working directly with the public throughout the process to ensure that public concerns and aspirations are consistently understood and considered.
- **Collaborate** – to partner with the public in each aspect of the decision including the development of alternatives and the identification of the preferred solution.
- **Empower** – to place final decision-making in the hands of the public.

In the UK academic literature the levels of participation described by Boote et al. (28) and INVOLVE (36) are the most frequently cited. Both Boote et al. and INVOLVE describe three main levels of participation in research, albeit with slightly different terminology in the third level.

- **Consultation** - where researchers seek the views of the public on key aspects of the research;
- **Collaboration** – where there is an ongoing partnership between researchers and the public throughout the research process;
- **Publicly Led Research** (36) - where the public designs and undertakes the research and where researchers are only invited to participate at the invitation of the public; or **Consumer Controlled Research** (28) where the consumer designs, undertakes and disseminates the results of a research project and the researchers are only involved at the request of consumers themselves, or consumer organisations commission research into a topic of particular interest to them.

An Australian model developed by Hider & Farjou (74) identifies four levels of consumer participation that may be considered during the different stages of consumer participation, ranging from lowest to highest. These are:

- **None**
- **Restricted scope**

- **Open involvement**
- **Active participation**

Happell and Roper (75) propose a model to guide consumer participation in mental health research with four levels of consumer involvement in research.

- **Consumer advisory**
- **Consumer consultation**
- **Consumer collaboration**
- **Consumer led**

Shippee et al. (1) identified two levels of engagement in research: **Passive** and **Engaged**.

Stewart & Liabo (76) contest the abovementioned models which present consumer participation in the form of a ladder, from a low rung where research is led by researchers with no consumer participation, to a high rung where studies are consumer-led. They argue that these types of hierarchical models over simplify participation in terms of the power relationship held between two parties, researchers and consumers. They go on to state that a hierarchy may be helpful when considering the amount of influence desired in a study, but it obscures the goal of improving the quality of the research. Moreover, they state a hierarchical model does not sit well with many clinicians and academics whose expertise appears to be downgraded.

A model developed by Shirk et al. (77) is based on five levels or degrees of participation in scientific research. This model has not been referred to in health and medical research literature to date, but provides an interesting perspective about the different levels of relationships that can occur between consumers and community and researchers.

- **Contractual projects** are where communities ask professional researchers to conduct a specific scientific investigation and report on the results.
- **Contributory projects** are generally designed by scientists and for which members of the public primarily, contribute data.
- **Collaborative projects** are generally designed by scientists and members of the public contribute data, but also help to refine project design, analyse data, and/or disseminate findings.
- **Co-created projects** are designed by scientists and members of the public working together. Some of the public participants are actively involved in most or all aspects of the research process; and
- **Collegial contributions** are where non-credentialed individuals conduct research independently with varying degrees of expected recognition by institutionalised science and/or professionals.

Stewart & Liabo argue that research quality and relevance can be optimised when consumer expertise is integrated with researcher expertise and each role acknowledged and valued. Stewart & Liabo (76) propose an alternative model for consumer and community participation, which places research and expertise at the centre of the participation enterprise.

### Debates about Concepts: Representatives and Representativeness

The issue of representativeness of consumers in health and medical research is a frequently debated and contested issue within the health and medical research literature (63). It has been suggested that the tensions surrounding 'representation' have contributed to the delay in the evolution of consumer participation in health and medical research (10).

Consumers and community members are often referred to as 'consumer representatives' or 'community representatives' in the research process. The issue of 'representativeness' is commonly raised as an argument against consumer participation (78). It is argued that it is not possible to engage all perspectives, and is thought to be discriminatory, or alternatively, consumers have no real mandate and their participation becomes questionable (79).

'Representativeness' has been criticised on the grounds that the consumer who takes part in the research cannot, and will not, be representative of all consumers in the research area. In addition there is a concern commonly expressed that the more a consumer takes part in research, the more the consumer will become 'professionalised' and not be able to represent the views of consumers. This is where consumers see research issues from the view of researchers and not the consumer perspective (22). Hogg and Williamson (80) observational study of 'lay people' involved in health service committees supports these assertions. They state that it is generally assumed that 'lay members' on committees are working for patients' interests, but their observations led them to think that some lay people tend to support professionals' or managers' interests rather than patients' interests. Hogg and Williamson (80) observed three broad categories of lay person's representation:

- supporters of dominant (professional) interests
- supporters of challenging (managerial) interests
- supporters of repressed (patient) interests.

They argue that the different roles that 'lay people' play need to be explicitly defined in order for their contributions to be realised.

Beresford (78) states that the issue of 'representativeness' is commonly confused with the need to address diversity in consumer participation. He argues that other stakeholders are not expected to be 'representative' and generally they have no special mandate, so he questions why raise this particular argument in relation to the constituency that is most liable to exclusion (78). Consumer perspectives, rather than consumer representatives is advocated as a more suitable approach (81). Beresford argues for the importance of researchers seeking to be inclusive and address diversity in consumer participation (79). Boote et al. (22) also argue that 'representativeness' is not a one-sided issue and that a researcher is not necessarily representative of other researchers in their field. Hanley et al. (82) argue that 'it might be helpful to think about seeking consumer perspectives rather than consumer representatives'.

Boote et al. (28) state that concerns about representativeness betrays to some extent the researcher's epistemological, quantitative learnings; a viewpoint whereby consumers taking part in research ought to share similar characteristics to the 'average' demographic makeup of potential participants.

Robinson et al. (10) state that providing a statistically representative sample of a target research population is a concept traditionally associated with the positivist paradigm. They argue that such methods do not necessarily guarantee accurate representation.

Robinson et al. (10) suggest one of the most successful ways to involve consumers in health research is through relationships that already exist and are well established. However, Robinson et al. (10) also state that such approaches have been criticised in the academic literature for their associations with selectivity and elitism and a reliance on self-selection or the selection of acquiescent or financially better-off individuals. Some others claim that this results in only a few voices being heard, often at the expense of socially marginalised groups (79).

Morrow et al. (63) suggest that statements about representation are very common in the academic literature, but the meaning of the term is rarely considered. Morrow et al. describe different forms of representation and stress that it is important to understand that representation and representativeness have different meanings. Morrow et al. (63) stress the importance of clarity the different terminology used to depict the different forms of representation and have provided the following description of the different forms of representation (see Box 1).

**Box 1 Forms of Representation (63) page 23**

- **Democratic representation** – ‘One person one vote’, equally weighted voting
- **Proportional representation** – The use of shared or weighted votes to represent different groups
- **Statistical representation** – Could include selection, randomisation or controlled samples.
- **Representational membership** – Nominated or elected individuals represent the views of their candidacy
- **Representation by someone who is ‘typical’ of others** – An individual is nominated or identified because they are thought to share similar experiences or characteristics as others
- **Dispositional representation** – Individuals become or adopt representative roles by virtue of their job/organisational membership
- **Representation of shared interests** – Self-nominated representatives from groups on the basis of their shared interests
- **Representation of self** – Personal image, interests and decisions

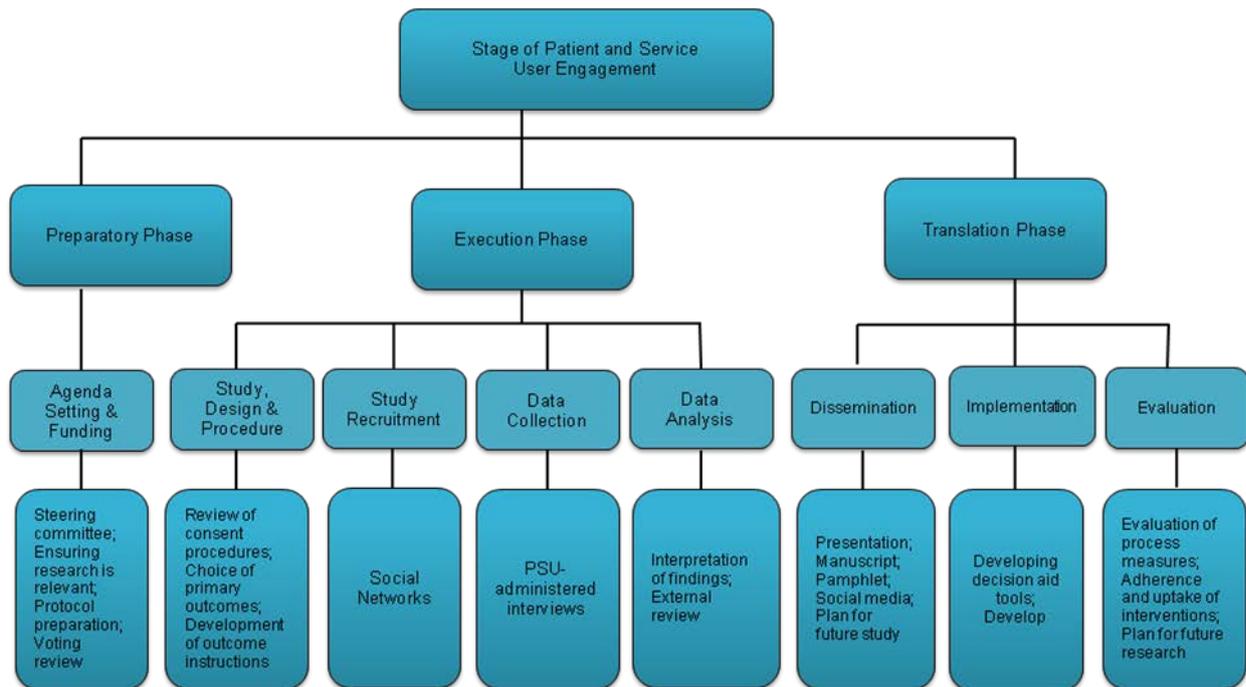
### 3. Strategies for effective consumer and community participation in health and medical research

The search question has determined that the focus be on strategies that are effective for consumers and researchers. This has proven challenging as there was limited literature located through this search that was specifically about the effectiveness of strategies. Much of the literature identified describes the evaluation of impact of consumer participation, and does not necessarily address the effectiveness of the strategies used to achieve that impact. Throughout the analysis and writing of the literature review there were tensions about which articles to include, as many articles reported on evaluation of impact without any mention of effectiveness of the strategies used, or only made an inference that the strategy may be effective. Also many articles were descriptive of the strategies used, but did not include a critique or evaluation of those strategies.

Smith et al. (2) conclude in their review of the literature that research is undertaken for different reasons and in different contexts, as such it is not possible to say that involving consumers, will, or should, always be undertaken in the same way to achieve the same benefits. As identified by several authors (1, 3-9) there is huge variation in how the evidence of effectiveness of different strategies of consumer and community participation is evaluated and reported. Variations in terminology, concepts and design inhibited comparative effectiveness in determining effective strategies (1). In addition many of the studies are qualitative in design and may not carry the same weight of evidence within the positivist paradigm of health and medical research (10). Mockford et al. (11) stress that the absence of evidence does not indicate an absence of effectiveness of strategies, rather it indicates inadequate reporting with a lack of valid and reliable tools (11). They conclude in their systematic review that there is an urgent need to create the tools to develop the evidence base. In addition, they state that guidelines for the reporting of consumer and community participation could improve consistency and comparability of studies.

One of the main conclusions from the systematic reviews by Brett et al. (5) and Shippee et al. (1) and the literature review by Staley (3), and many other authors who have reported on evaluations of research processes and outcomes (2, 4, 6, 9, 12-20), is that effectiveness of strategies used is highly context-specific, and in many instances dependent on the attitudes of, skill, and relationships between, the consumers and researchers involved in the research process.

As mentioned in the Review Methods section the framework developed by Shippee et al. (1) (see Figure 2) will provide the scaffolding for the presentation of the findings for the effectiveness of strategies for this section. The terms consumer and community participation will be used throughout this section, except where direct quotes are provided from authors and they use different terminology.



**Figure 1. Phases and stages of patient and service user engagement in research from Shippee et al. (1) page 7**

In an Australian study by Saunders and Girgis (35) they surveyed research funding organisations and organisations that conducted health and medical research during 2008-2009. The results provide insight into how consumers were reported to be involved in research in Australia at that time. It appears as though membership on committees was the most common strategy used. Consumers were least likely to be involved in research policy development, research data collection and research grant review (35). No data was collected in this study about the perceived efficacy of these strategies. The following table has been organised into the three phases of the framework by Shippee et al. (1); preparatory, execution and translation.

**Table 1 Results of Australian study of research organisations by Saunders and Girgis (35)organised into the framework by Shippee et al. (1)**

<b>Current Involvement included:</b>	<b>Total %</b>
<b><i>Preparatory Phase</i></b>	
Input into organisational governance (organisation wide committee member)	65%
Fundraising	44%
Contribute to the formulation of research policy such as funding guidelines	4%
Identify research needs	24%
Prioritise research	24%
Assist the development of research funding applications	7%
Member of research grant review panel	5%
<b><i>Execution Phase</i></b>	
Individual research project committee member	29%
Input into acceptability of proposed research and likelihood of participation	22%
Recruit participants	19%
Other (ethics committee member)	16%
Assist in the development of research tools e.g. participant surveys or information sheets	6%
Gather/facilitate research data collection	6%
<b><i>Translation Phase</i></b>	
Other – provide community talks	1%
Disseminate research information	44%

Of interest in the above reorganisation of Saunders and Girgis's (35) findings is that the main areas of consumer participation activity in health and medical research in Australia appears to be in the Preparatory Phase. However, there were very few Australian literature found in this search which has evaluated the effectiveness of these strategies for consumer participation health and medical research.

In an additional study by Saunders and Girgis (21) they examined a purposive sample of Australian research organisations and describe how each has applied consumer participation approaches across a range of purposes and contexts. They in turn highlighted a broad range of examples of involving consumers in research and hints and hurdles to involving consumers in research. This study is illuminating in that it describes how nine Australian research organisations report they approach consumer participation at an organisational level and in research. This clearly identifies two levels – organisational level to support consumer participation and research program/project level. The factors, which Saunders and Girgis identified as contributing to organisational success, were categorised as Governance, Infrastructure, Capacity and Advocacy. These are summarised below.

**Governance:**

- **Structures:** concerted efforts for consumer participation through the establishment of shared supportive structures.
- **Policy:** comprehensive organisation-wide policy concerning consumer participation. Research reflects the requirements of the organisational policies which require consumers and researchers working together to add value to research; acknowledgement of consumers a key

stakeholders in all research; partnership roles decided through consultation between consumers, community and researchers which are based on mutual respect for one another's different knowledge and experience; and resources including a practice guide to support policy implementation.

- **Research funding:** ensuring that consumers have an influential and sustained voice in research funding decisions. Examples provided include, research conducted with consumers to assess their views on aspects they value as important in selecting research for funding and as a result a set of values and associated guidelines were developed for use by a purpose convened Consumer Review Panel to assess and rate research funding applications. Training and information in the understanding and use of the consumer review criteria is provided to support consumers and researchers. This process is supported by a range of staff in the development of formal terms of reference, coordination, training and management of the consumer panel members and communicating processes, program and problems to the Board and management.

#### **Infrastructure:**

- **Consumer Registers:** some established and maintained state-wide registers of consumers with experience working in research, advocacy, policy development and other field requiring consumer participation, and who are interested in being involved in research decision making and support.
- **Information:** recognising the importance of formal and informal support networks and resources and providing opportunity for consumers involved to share information and advice with others. One additional strategy used was to provide information via a web-based library to support knowledge-sharing.

#### **Capacity:**

- **Consumer training:** ensuring consumers are adequately supported through the provision of training, education and resources appropriate to their expected role.
- **Researcher training:** developing a training program for researchers to better understand the contribution that the community can make to the research when they are involved as active partners. The training program covered content such as: identifying and addressing barriers to consumer participation; exploring and developing ways to start involving consumers as partners in their research work, and encouraging and supporting other researchers who may have an interest in consumer participation in research.

#### **Advocacy**

Actively promoting and advocating for greater community understanding of, and consumer participation in, health and medical research. Acting as ambassadors they help to build an understanding of the valuable role of the consumer in health and medical research and drive important initiatives that may not be addressed.

The study did not include insights into how effective the different strategies were for consumers and researchers. However, they did state that:

Common input from participants was that consumer-researcher collaborations require planning and perseverance and that these partnerships are reliant on comfortable human interaction among not necessarily like-minded people. There is no simple formula for success but allowing adequate time to establish the consumer-researcher partnership and to set realistic terms is important. The findings suggest that partnerships are likely to work best when all parties are clear about their intentions, assumptions, and limitations from the start. Trust is essential, as is quelling any anxieties with regard to roles and other aspects of the partnership such as formal acknowledgements and other expectations.(21) (p 200)

## Preparatory Phase

### ***Agenda setting***

Previous studies have suggested that research agendas can be biased and there is a mismatch between the current research base and the agenda of consumers of that research, which challenges the notion of evidence-based medicine representing consumers needs (83). Research agenda setting processes, which are more democratic and involve consumers amongst other stakeholders, have been evolving over the past 15 years or more (83).

The agenda setting phase of the research process yielded a sizable literature, primarily from the UK. There were two literature reviews which incorporated the majority of the literature yielded. These will be summarised along with key findings from two recent studies from Australia and the Netherlands (60, 84-87) which provide examples of different methodology.

The literature review by Oliver et al. (85) examined the processes and outcomes of involving consumers for identification and prioritisation of research agenda setting in UK national and regional R&D programs, with the aim of developing an evidence-based approach to agenda setting for the NHS. They concluded that in the absence of comparative studies they could not determine what methods were more or less advantageous than others. In addition they concluded that the approach to consumer participation, and methods for interaction, will depend on the researchers, the consumers, the research task, the funding body and the social context and values informing the agenda setting process. They identified that some methods, such as occasional consultations and written consultations, do not lend themselves to long-term investment, and these methods have more often failed to show the advantages of enthusiasm for involvement, or increased knowledge about consumers' priorities or constructive ways of working with consumers. In addition, these strategies were found to not be an effective use of consumers' time when comparing to influence on the research agenda. When collaborative methods were utilised, consumers were in a better position to influence the research agenda. Oliver et al. recommend that research programs embarking on working with consumers to set research agendas, do so within an ethos of reflexive research so that the evidence base is developed for how consumers influence the agenda setting process and outcomes. In their discussion of the results, they distinguish between purposeful research agenda setting from opportunistic agenda setting (where research priorities were identified in the course of planning services). Purposeful research agenda setting approaches could also be distinguished between researchers listening to consumers, and then making decisions informed by their view (consultation), and researchers and consumers making decisions between them about priorities (collaboration).

Stewart et al. (84) built on this earlier literature review by Oliver et al. (85) by conducting another literature review to ascertain whether there was research literature to inform how consumers and clinicians can work in partnership to identify and prioritise research suggestions. They found a sizable research literature, and identified in this review that the literature on this topic has grown since the earlier review by Oliver et al. (85). Most agenda setting strategies that involved consumers as part of a mixed group of stakeholders employed formal methods for reaching decisions about priorities. Strategies such as a Delphi exercise, focus groups, nominal group technique, individual rating and applying of criteria, voting, scoring, citizen's juries, or a consensus conference were

commonly used. Of the studies analysed in greater detail, only three considered the influence of different groups of participants on the research questions prioritised. Consumer contributions were noted as valuable and constructive, but did not necessarily change the substance of the prioritised research agenda. Stewart et al. questioned whether the processes of eliciting consumers and clinicians priorities were largely an academic exercise and as such unlikely to lead to the desired improvement in health care and policy. Staley and Hanley (88) identified in their earlier study that research priorities for the public and charitable sector in the UK are often set by the research community and rarely restrict what research is funded. Due to the significant number of publications about different disease groups' research priorities (e.g. cancer, mental health, asthma, rheumatoid arthritis). Stewart et al. (84) recommend that funders ensure that researchers state in their research applications how their research questions support these published priorities.

Taking into consideration the gaps identified in the evidence from earlier literature reviews, Oliver et al. (86) undertook a study to identify the input and influence of consumer participation in setting the agenda for a national research program. The nature and influence of contributions from consumers were compared with those of other experts. They found that consumers provided unique contributions both as external experts and as panel members, which were valued and influential and resulted in some important changes in the focus of the research, adding new outcomes, making patient and carer perspectives explicit, refuting the need for the planned research, providing up-to-date prevalence data and providing plain English background text. This resulted in outcomes research that incorporated patient and public preferences and values and resulted in influencing decision making for research commissioning. The strategy used for the agenda setting process was a collaborative approach to agenda setting using advisory panel meetings and vignettes. Consumers were involved in developing the vignettes and had the greatest influence in the preparation of these.

In another study by Oliver et al. (89) they conclude that involving consumers in a needs-led research program, that when seeking research topics, face-to-face discussions with consumers were more productive than scanning consumer research reports or contacting consumer health information services.

A more recent Australian study by Saunders and Crossing (60) used the 'Global Cafe' process for harnessing group experiences and views as part of the agenda setting process. Participants in the workshop were cancer consumers. The study sought to harvest diverse input from cancer consumers on the issues they need addressed through research. The most pressing needs of cancer consumers were identified and offered a workable process for identifying the research needs of health consumers. Similar needs of cancer consumers were identified by Corner et al. (90) in a study using modified nominal group technique with cancer consumers in the UK. Both strategies were collaborative and required active participation and decision making by consumers.

In a study by Elberse et al. (87) of consumer participation in a scientific advisory process for setting the research agenda for medical products in the Netherlands, they found the more democratised process did not compromise the scientific authority of the advisory committee. They stated that tokenism can be averted and a balance can be found whereby the advisory committee can predefine the focus, set criteria, and keep the mandate for decision-making, while consumers are able to provide input from their own perspective. The consumers provided new perspectives and complementary insights from a bottom-up approach. Consumer participation created legitimacy

and support for decisions made, and raised enthusiasm for consumer participation in setting the research agenda.

### **Funding**

Four articles were identified which related to consumer participation strategies and research funding.

The article by Petit-Zeman et al. (91) stated that consumer participation in the various research organisations had changed the direction of what research was funded, and in one instance the direction of the research. The examples provided by Petit-Zeman provide an appreciation of the different levels of responsibility and power that consumers have within these four different research funding processes. They found that peer review of grant applications involved consumer reviewers using a range of different strategies, though these strategies were not evaluated for effectiveness, only if consumer participation had made a difference.

For example:

- The Alzheimer Society's Quality Research in Dementia program used a strategy of 'Triage by users of research' which they found extremely effective, where only research deemed relevant to carers and people with dementia was funded by the charity. Members of the society's consumer network comment on each application and score it for importance and relevance to the research priorities of the society, with only those applications that quality at this stage being sent for scientific peer review. This process gave power to consumers to triage the initial applications, but the ultimate decision appeared to rest with the professionals who completed the scientific peer review.
- The Arthritis Research Campaign has a USER committee that looks at the practicality of doing research, and questions the assumptions of researchers. Concrete examples were provided where the USER committee's comments had identified issues that the researchers had not and consequently changed the direction of the research. This is an example of a partnership approach to funding where there appears to be joint decision making and agreement on funding.
- The Stroke Association uses lay member reviews in parallel to scientific reviews. Applicants to the Stroke Association are required to complete a plain English form, alongside a traditional research application form. The plain English summary is sent to the service user review panel for comments. The panel is made up of 22 consumers with experience of stroke. The Stroke Association value both lay and scientific reviews and decisions about funding appear to be a joint decision making process.
- In another model, Ataxia UK has consumers on its scientific advisory committee receiving recommendations from peer reviewers. It is not clear how this process worked, but it has the potential to be tokenistic if the perspectives of consumers are not valued by the professionals. In committee situations consumers are often disadvantaged in the decision-making process, due to the ratio of consumers to other stakeholders, the assertiveness of the consumers, and the willingness of other stakeholders to listen seriously to consumer views. These factors can impact on the influence consumers have (92).

In a study by O'Donnell and Entwistle (92) it was identified that research funding organisations employ a variety of strategies to involve consumers in research funding. These include strategic decision-making about the focus of research, and decision making about the funding of specific

research proposals. They identified that varying methods that funding organisations used to engage with consumers permitted different degrees of consumer influence. For example, some consultation strategies give consumers a voice but there is no guarantee of influence over the selection of research topics for funding. They conclude that the extent of consumer influence on research funding is likely to be moderated by a number of factors, including the types of consumers involved, the particular structures and processes in which they are involved, the timing of their input and the different ways in which they are asked to contribute in relation to others. The appropriateness of particular approaches to consumer participation need to be considered in the broader context of the whole research funding system, including the roles that other stakeholders play and the values implicit within the funding organisations.

In another study by O'Donnell and Entwistle (93) they focused on identifying how research funders promote consumer participation in research projects. They identified that many UK funders of health-related research are adopting a policy of promoting consumer participation in research projects. However, they identified that the funding organisations vary in the ways they encourage and support researchers to involve consumers. There was no measure of effectiveness of the various ways. Stewart et al. (84) advocate for funders to ensure that research applicants describe in detail the consumer participation process, rather than a 'tick a box' approach.

A study by Andejeski et al. (94) evaluated the benefits and drawbacks to involving consumers in the review process to determine what projects were funded. In this study, scientific and consumer reviewers took part in a survey before and after a review panel meeting, to explore their views on the process. It focused on expectations, concerns and experiences of the scientific and consumer reviewers. The overall scoring of proposals was also analysed. The researchers found there was little difference between the average consumer score and the average scientist score for the reviews. The consumers' votes had minimal impact, because there were only two consumers on each panel (with 11-17 scientists), and their scores were similar to those of the scientists. Scientists had been worried that consumers would have a 'hidden agenda', that they would want to alter the direction of the research and that their involvement would adversely affect the scoring process. The findings from this study alleviated their concerns. Most of the scientific reviewers reported that consumers had added an important perspective to the review processes. The consumer reviewers had informed the scientists about the concerns and interests of breast cancer survivors. One of the scientific reviewers commented that 'just having consumers at the table led him to consider more carefully the potential impact of each proposed research project on breast cancer' (p. 385).

## Execution Phase

### ***Study Design and Procedures***

There was limited literature found on the evaluation of the effectiveness of the strategies used for study design and procedures.

In a study by Wyatt et al. (95) they identified that traditional ways of involving consumers in the execution phase of research were mostly used, such as advisory groups. However, there were no mechanisms in place to conduct formative evaluation to evaluate effectiveness of advisory groups. However, there was a strong consensus from the participants in the study that consumer participation through the advisory groups in the various research projects had brought tangible benefits to the research, on both the processes and outcomes. Wyatt et al. (95) cautioned that the

presence of consumers on advisory groups was not in itself a sufficient condition to ensure active and meaningful participation. Some participants described their relationship with researchers on advisory groups as being a partnership, others described tokenistic involvement. Those consumers that described a partnership relationship with researchers on the advisory group had the greatest impacts on the research design process. These new ways of conducting research through involving consumers on advisory groups did have resource implications, particularly additional time for meetings, which also affected funding for the research project.

In addition to the lack of focus on evaluating the strategies used, an additional complexity was identified where there were many different approaches to consumer and community participation in the execution phase of research. For example, in addition to consumers participating in different ways in specific stages of the research process, or across stages, there were community-engaged research practices that used approaches such as community-based participation research (CBPR) and participatory action research (PAR) approaches which engaged community members in different parts of, or throughout, the whole research process. Moreover, there are different levels of participation within these, such as advisory, consultation, collaboration, consumer-led, and consumer researchers which result in different strategies being utilised at different stages of the research process.

In a review by Hubbard et al. (96) they concluded that three key factors that need to be implemented in order to successfully involve consumers in research are: training, resources, and a change of attitudes by researchers. These factors transcended the strategies used and stage of the research process.

Researchers have reported that involving consumers right from the beginning of a project helped to reshape and clarify the research question. It also changed the focus of the design and also challenged the researchers' assumptions and aims (97-99). However, they did not evaluate the strategies used.

In 1995, Iain Chalmers, a UK clinician and health researcher, stated he had witnessed more than two decades of consumer participation in research into pregnancy and childbirth which had led him to believe that greater lay involvement in health research would promote reliable, relevant research of importance to patients and those caring for them(100). He provided several examples of consumers who had made significant contributions to the study design, research process and outcomes. One example was where the mother of a young woman with vaginal adenocarcinoma was the first to suggest that her daughter's cancer might have been caused by the drug (diethylstilbestrol) which she had been prescribed during pregnancy. He also gave the example about a mother of a child with trisomy 18 who was the first to suggest that a low level of maternal serum alpha fetoprotein might be a prenatal marker for the chromosomal abnormality (100). Chalmers states that no-one – and certainly not researchers – can claim a monopoly of relevant wisdom in discussions about what deserves attention in health research. He argues that consumers can draw upon different kinds of knowledge and perspectives that differ from those of professional researchers. Today Sir Iain Chalmers remains a strong advocate for consumer participation in health research and will only work with a consumer partner when a member of any research committee (101). This requirement of a consumer partner is an attempt to change the balance of power from resting with researchers, to ensure more equal numbers of consumers and researchers are on committees and to avoid

tokenism that is so commonly seen when there are one or two consumers amongst 10-20 researchers on committees.

In a study by Ali et al. (102) they evaluated the effectiveness of consumer input into the design of a clinical trial that aimed to test the effects of oxygen supplementation following an acute stroke. The consumers were asked to comment on consent issues, the relevance and acceptability of the outcome measures and the preferred method of follow-up. One of the main changes to the design process was to introduce new outcome measures, where they pointed out that quality of life after stroke is determined more by cognitive and emotional problems than by the level of disability. The consumers therefore wanted the trial to assess the impact of treatment on communication, mood, cognitive function, tiredness and sleep. The researchers changed the assessment tools to reflect the consumers' requests; however they were concerned because they were not using a validated tool that the scientific rigor of their trial would be compromised.

Boote et al. (28) reviewed published examples of consumer participation in research design and found that group meetings, such as focus groups or consultation meetings, were the most common strategies used. Other methods identified were in-depth interviews, home observations and taste trials, telephone conversations and questionnaires, and a stakeholder event to reach consensus. However, the strategies were not evaluated for effectiveness.

The article by Dear et al. (103) describes consumer involvement in the design and development of the Australian Cancer Trials website (ACTO) which was a collaboration between consumers with cancer, doctors, and policy makers. The website was developed to disseminate information about cancer research, improve the access of consumers to information about clinical trials and assist with doctor-patient communication about trials. Dear et al. state that the development of the ACTO was an exemplar of a partnership between consumers, clinical researchers, and policy makers to create an informative national resource about cancer clinical trials for people affected by cancer, doctors and researchers. Consumers helped set the agenda for the initiative, helped obtain research grant funding for the evaluation of the ACTO, contributed to the website's development and design, and developed an effective dissemination strategy to promote awareness of the website and research. The evaluation identified that the critical success factors for this project were:

- The research team worked with well-recognised consumer groups with extensive networks.
- It was determined that a consumer friendly cancer clinical trials website was a priority for consumer groups and their members, and this was supported by the research team.
- The research team listened to the needs of consumers' and responded to their needs.
- The research team assisted consumer groups to provide input when necessary.

In a study of UK investigators by Hanley et al. (49) they identified one strategy for involving consumers in research was through Community Health Councils. These Councils were established to act as watchdogs for patients' interests and were active in some areas of health research. In the research centres or specific research trials where Community Health Councils were involved Hanley et al. identified that consumers were effective in influencing the design of trials. However, the researchers questioned why the Councils were not involved in more research centres and trials. In following up on the internet to gain an understanding of how effective these Councils are, it was ascertained that the Councils were abolished by the UK government in 2003.

### ***Research Ethics***

Research into consumer participation in the research ethics process has identified that when consumers are actively involved in the development of the consent information sheets for participants, that the information is clearer and more accessible to consumers considering taking part in the research (2, 13, 17, 81). A study by Guarino et al. (104) assessed impact of involving consumers in writing patient information sheets via a randomised controlled trial. These researchers found that participation made little difference to consumers understanding of the information. However, the researchers stated that there were limitations to their research which may reduce the significance of their findings.

Nilsen et al. (13) found in their Cochrane review that there was low quality evidence that an informed consent document developed with consumer input (potential trial participants) may have little, if any, impact on understanding compared to a consent document developed by trial investigators only.

There were some studies which examined if consumer participation improved the ethical acceptability of research. In a number of studies, it was found that consumer involvement in the early stages of a project helped to identify potential ethical issues and ways to improve the ethical acceptability of the research, which led to more ethically sound research (2, 49, 105). Some specific benefits identified were:

- Defining the acceptable limits of controversial research.
- Ensuring the results of research projects are more relevant to consumers needs and more likely to be used, making participation in health and medical research more valuable and respectful use of consumers time.
- Ensuring the way the research is conducted better meets the needs of participants by contributing to research design and management.
- Ensuring due respect is shown to participants by providing them with feedback and disseminating the finding to a wider group of their peers.

However, specific strategies were not discussed.

Hull et al. (106) state from their experience a Patient and Public Involvement (PPI) panel in the design of documentation for patients taking part in clinical trials, reduced the likelihood that ethics committees and national review bodies would require rewriting of information in plain English. They conclude that the strategy of having a PPI panel to work with researchers is an effective approach. Uhm et al. (107) explored in detail the role of PPI panels for shaping health research in detail. They concluded that panels with all-patient or public membership provide a forum for valuable debate but are distanced from the decision-making forum. Panels with a mix of patients or public and researchers, if not managed well, risk marginalising patient or public members, either because of their structures (minimum patient or public numbers) or because patient or public members lack support for working in an alien research culture.

Stewart et al. (108) conducted a study to identify Aboriginal and Torres Strait Islander participation in the ethical review process. Ethics committees are the key processes used for health researchers to have ethics proposals reviewed. Their results suggest that the level of involvement of Indigenous people on Health Research Ethics Committees across Australia at the time of the study (2006) did not meet the NHMRC's Values and Ethics Guidelines that equal participation of Indigenous people is recommended in all stages of research and this includes the process of ethical review. This study highlights the issue of membership of ethics committees to meet research industry and government

guidelines. Some alternative strategies to having Indigenous representatives on an Ethics committee identified by respondents to the survey were: (1) referred proposals to a specified Indigenous person outside the committee process, and (2) co-opting an Indigenous person on the committee for a particular meeting.

Staniszewska et al. (109) evaluated whether consumer participation in an advisory group had any impact on the research design. They found that through careful collaboration a research bid was produced which was rooted in users' experiences, whilst also addressing key research questions. The key enablers were good working relationships and funding for the lead researchers time. Barriers included lack of financial support for consumers, the time-consuming nature of participation and the research language (jargon). One area where the advisory group influenced the design was in the timing of the focus groups which proved helpful in developing the methods section and considering the ethical implications of when parents should be contacted.

### ***Study Recruitment***

Stevens et al. (110) state that in many cases, consumer participation in research is a one-off, short-term consultation. It offers poor value to the researcher and limited opportunity for the consumer. They state that a primary objective of their work with consumers is to maximise inclusion. In order to achieve a broad-based strategy to recruitment was adopted. This meant establishing relationships with existing consumer groups and going beyond existing networks to 'reach the hard to reach'. They describe the extensive strategies they employed, such as local radio and newspapers, posters and leaflets in clinics, GP surgeries, Citizens Advice Bureau, law centres, libraries and supermarkets, utilising cancer Research Centre clinical trials databases to publicise initiatives, community centres and feedback reports sent to clinical trial participants. In addition clinicians were approached to request that they approached patients and carers attending their clinics. However, they did not include information about the effectiveness of these different strategies. An interesting strategic initiative, which came out of this process was to include a performance indicator 'evidence of appropriate involvement in planning and delivery of research' in the centre's strategic plan. This has proven effective in keeping the team focused and needing to measure their achievement against that performance indicator each year.

Fouad et al. (111) describe what strategies their research group used to enhance the accrual and retention of minority participants in current and future cancer prevention and control trials. They conducted focus groups and interviewed key informants to ascertain the community's perception of participating in clinical trials. From this process a coalition was formed and a formal Statewide Tuskegee Alliance for Clinical Trials was formed and a conference held to serve as a forum for discussion between researchers and community members. They conclude that the partnerships that developed between researchers and the community through this process provided an infrastructure that supported the interests of both groups.

Happell et al. (75) state they identified in a review of the literature that consumer involvement may increase recruitment of participants into, and reduce the number of drop-outs from, research projects. However, there was no indication of the strategies used to enable this to occur.

Hull et al. (106) report on the development of a Patient and Public Involvement (PPI) panel for the National Institute for Health Research Birmingham Liver Biomedical Research Unit (NIHR BRU). Areas where the PPI panel thought changes were required included; the information provided was

too complex for them to understand, making scientific principles about a study comprehensible and, in some studies, showing where information was missing. A review of the impact of the panel eight months after establishment indicated that there had been an improvement to the recruitment and participation in trials. They state that developing relationships with consumer and community members, providing training and support, and authentic opportunities to participate through the panel method, has been integral to the effectiveness of the PPI panel.

Mackenzie et al. (112) evaluated a media campaign that they conducted to increase public awareness and understanding of clinical research in Scotland. They identified that there had been an increase in public awareness of clinical research, but further efforts are required to influence individuals' decisions to take part in clinical research.

The study of UK investigators conducted by Hanley et al. (49) identified that involving consumers in clinical trials, mostly through membership on committees, provided insight into issues important to the community and patients. Their participation led to improved recruitment, and provided 'front line' intelligence on how the trial was being received during its development and execution. Whereas the strategy wasn't evaluated per se, the outcome of their involvement on the committees was evident.

Dear et al. (113) conducted research to ascertain if a consumer-friendly cancer clinical trials web site increased the proportion of patients participating in a clinical trial. They concluded that albeit weak evidence, a web site such as the Australian Cancer Trials may be an important tool to encourage discussion about clinical trial participation.

In a study by Corneli et al. (114) community members were involved to inform the design of a clinical trial on the safety and efficacy of antiretroviral and nutrition interventions to reduce postnatal transmission of HIV. The women consulted raised concerns about the amount of blood that was planned to be taken from mothers and their babies as detailed in the draft protocol. After the consultation, the protocol was amended. This made the research more acceptable to the community and was suggested to have increased recruitment to the trial.

Abma (115) states that consumer involvement has been particularly effective in improving recruitment to research where the demands of a project are high. He suggests this is because community members know how best to motivate and encourage their peers. This was supported in a study by Burrus et al. (116) of diabetes within a black community in the US, where involvement of a well known and respected black health educator proved essential to developing a successful recruitment strategy.

### ***Data Collection***

McCormick et al. (117) commented that consumer involvement in data collection may foster more accuracy and educate the consumer about scientific methods, but alone it has little power to affect anything other than this.

Nilsen et al. (13) in their Cochrane review found evidence from two trials that provided low quality evidence that using consumers interviewers instead of staff interviewers might result in small differences in satisfaction surveys. Nilsen et al. (13) state that there needs to be consideration of

the distinction between consumer and staff that could influence the responses; for example, the personality of the interviewer, or how well the interviewer and the interviewed know each other.

Kelly et al. (55) report on the meaningful participation of eight Aboriginal and Torres Strait Islander community members employed as community researchers investigating the impact of pandemic influenza in rural and remote Indigenous communities in Australia. Participatory Action Research (PAR) was used. A key feature of the research was the employment, training and strengthening the capacity of local community members in the role of community researchers. They documented the participation process and the building of research capacity. Through their evaluation of the process they concluded that there are considerable benefits for Indigenous people researching in their own communities. Most important for the community researchers was the sense that they were doing important health work, not just conducting research. They state that whilst research outcomes are important, in many cases the process used is of greater importance for the community.

Shippee et al. (1) identify in their systematic review that consumer participation in developing self-report questionnaires/indices can be helpful and may produce evidence more consistent with consumers' concerns and minimise bias towards researchers' perspectives.

Kelson (118) showed that one in three respondents in a survey undertaken by Cochrane research groups did not include consumers' perspectives in determining the data to be collected in systematic reviews.

Shippee et al. (1) conclude in their systematic review that there is a need for more attention to consumer participation in data collection.

### **Data Analysis**

Shippee et al. (1) conclude in their systematic review that consumer participation in data analysis mainly occurred by researchers presenting their findings and conclusions to participants prior to publication. This process resulted in an improved ability of the researchers to contextualise conclusions to consumers' environments and beliefs, added language and cultural insights and highlighted consumers priorities for a more focused analysis. Consumers abilities to analyse data should not be undervalued: challenges such as serious mental illness (119), or lack of resources in developing countries (120) have not prevented consumers from understanding research foundations, giving feedback and strengthening research. Information should be understandable to consumers while avoiding oversimplification (121). Shippee et al. (1) conclude that in analysis, perhaps more than any other stage in the research process, consumers require sufficient education and training.

### **Translation Phase**

The description of translational research by Callard et al. (122) has a different interpretation than translation phase used by Shippee et al. (1), which describes the translation phase of research as post-analysis activities such as dissemination, implementation and evaluation. Descriptions from both Callard et al. and Shippee et al. will be addressed in this section.

Translational research aims to translate findings from basic research more quickly and efficiently into clinical and health-care practices. Callard et al. (122) state that this is frequently given the name 'from bench to bedside' and they describes four translational phases.

- The T1 phase encompasses the movement from basic science to clinical research.
- T2 phase is research that seeks to move T1 research into an actual health application, and research that develops evidence-based guidelines.
- T3 phase is research that seeks to move evidence-based guidelines into health practice through dissemination, implementation and diffusion research.
- T4 phase is research that seeks to move health practice into population health impact through outcomes research.

Callard et al. (122) state that there is a small but growing body of evidence regarding the scientific benefits of consumer participation and other stakeholders throughout the translational conduit. The following table summarises their findings on reasons to embed involvement, and methods and strategies for embedding participation for the four translational phases. Callard et al. (122) state that the methods and strategies recommended in Table 2 include methods and strategies that are evidence based, as well as suggested on theoretical grounds.

**Table 2 – Embedding consumer involvement in translational research adapted from Callard et al. (122) p 394 Table 2**

<b>Reason to embed involvement</b>	<b>Relevant translational phase</b>	<b>Methods and strategies for embedding involvement</b>
Consumers knowledge and experiences of use in agenda setting, problem definition and hypothesis construction	T1	Creation of 'small innovation networks' devoted to the transition to involvement, and comprising biomedical researchers, service users and other stakeholders, experts in participation and representatives from research funding agencies and government organisations.  Collaboration with consumer organisations.  Dialogue Model: democratic interaction between all stakeholders in the service of an integration of different knowledge sources.
Consumers knowledge and experiences of use in defining treatment targets and developing outcomes measures	T1-T2	Participatory research (e.g. service user-led focus groups to generate outcome measures).  Priority setting partnerships (that join clinician organisations and consumer organisations).
Service users' knowledge and experiences of use in the design of medical devices/technologies	T1-T2	Direct and active collaboration and interaction between users and producers in early stages (concept and idea generation) rather than only or mainly in

		late stage of product lifecycle.
Service users' knowledge and experiences of use in trial design and consent processes	T1-T2	Stakeholder representation on trial steering committees.  Combination of quantitative and qualitative methods (e.g. through consultation, focus groups and questionnaires with consumers).
Service users' knowledge and experiences of use in development of health services research/implementation science/ dissemination	T2 – T4	Principles of successful service user involvement in health research outlined in Telford et al. (123)
Assistance with recruitment into trials	T1-T2	Involvement of consumers in trial governance so that they can provide advice to trial participants, and promote trial to prospective participants.
Translational research that uses biomarkers for potential diagnostics, therapeutics and genetic testing raises ethical issues related to risk, susceptibility and stigma / discrimination.	T1 – T4	Interdisciplinary collaborations between scientists, clinicians, social scientists, ethicists, legal scholars, policy makers, service users and those involved with industry / commercialisation of biomarkers.
Public / civic engagement with biomedicine.	T1-T4	Citizen's juries. Town hall meetings.
Involvement can empower consumers (which can in turn improve health)	T1-T4	Shared decision making (reduction of power differentials.

### **Dissemination**

Shippee et al. (1) conclude in their systematic review that peer-reviewed publication is the most common dissemination strategies for academics. However, it is not the most direct way to disseminate findings to consumers and the community who tend to access health information through different sources that are more publicly and socially available. It is argued that there needs to be a dissemination approach that is jointly agreed upon by researchers and consumers involved in the research process, and that the process needs to be personalised and accessible for people with different abilities and preferences within the community (124, 125). Accessibility includes language and terminology according to the target audience. Consumer participation may assist in the development of creative dissemination methods, which are more efficient and which may not have been considered by researchers (125, 126). However, literature about what constitutes an effective dissemination strategy developed collaboratively by consumers and researchers was not identified in the literature.

Aspects of a dissemination strategy can be consumer information and written materials. The Cochrane review by Nilsen et al. (13) identified there was moderate quality evidence that involving consumers in the development of patient information material resulted in material that was more relevant, readable and understandable to patients, without affecting their anxiety.

Another aspect of a dissemination strategy can be presentations. Smith et al. (127) found that consumers involved in the research process were able to relate the findings of the research to their own experiences, which made the message more poignant when presenting findings of research.

Shippee et al. (1) state that effective dissemination of research results to consumers and the community is important, as it has been proven to be helpful to facilitate obtaining resources and funding for implementation of findings from the research.

### **Implementation**

This aspect of the translation phase refers to activities involved in implementation of findings, such as participating in the development of clinical practice guidelines (1). It has been suggested that clinical practice guidelines may have the greatest impact on health care and services. Boivin et al. (128) state that it is recommended that consumers are involved in developing clinical practice guidelines as a way for guidelines to be more responsive to consumer expectations and needs, and to improve the quality and implementation of clinical practice guidelines. They conclude after conducting an international consultation workshop that current approaches favour involvement of consumers on guideline development groups, consultation of draft clinical guidelines and the development of patient versions of clinical practice guidelines. Boivin et al. (128) state that other potential methods reported in the literature were not used. These methods included systematic reviews of published evidence on consumers' views and preferences, the integration of patient decision aids, the use of decision analysis to integrate consumers' utilities in clinical practice guideline recommendations and consumer participation in strategic aspects of clinical practice guideline development, including clinical practice evaluation. Boivin et al. (128) conclude that there is a lack of process and impact evaluation, which limits the current understanding of the conditions under which consumer participation in clinical practice guidelines is most likely to be effective.

Boote et al. (58) identified through an analysis of case examples of public involvement in the systematic review process that there were five main contributions that consumers could make to the systematic review process. These were:

- Refining the scope of the review.
- Suggesting and locating relevant literature.
- Appraising the literature.
- Interpreting the findings.
- Writing up the review.

However, there were various strategies used in the review process including consultation workshops, membership of Review Advisory Groups, membership of the review team, email discussion lists, and the Delphi process. It was concluded that there is a lack of process and impact evaluation which limits the current understanding of the conditions under which consumer participation in systematic review process is most likely to be effective. Boote et al. (58) recommend that a section of a systematic review's abstract and main body of text should be devoted to detailing

the contribution(s) of consumers to the review process, together with the stage(s) at which, and the method(s) by which consumers were involved.

Kreis et al. (7) state that consumer participation has been placed high on the comparative effectiveness research (CER) agenda in the US. They conducted a study of US-based and international organisations commissioning or engaged in systematic reviews regarding current practices of consumer participation. Kreis et al. conclude that consumers were currently involved in systematic reviews in a variety of ways and for various reasons. However, there was little formal evaluation of the effects of consumer participation being undertaken or published, with the exception of the Cochrane Collaboration which conducted an external review of CCNet in 2009. This review reported that just over half of the 36 review group respondents felt that involving consumers was beneficial (e.g. increased readability and quality of reviews, usefulness of summaries in a consumer-friendly language). All six consumers interviewed found it 'very hard to comment on whether their involvement had had any impact' (129)(p.3).

Kreis et al. (7) recommend that it is important to evaluate which strategies are most effective in achieving the different aims of consumer participation to inform future recommendations on consumer participation in comparative effectiveness research.

Smith et al. (17) established a Consumer Reference Group for a review of user involvement in nursing, midwifery and health visiting research. The consumer reference group helped to access information locate findings in issues that were important to consumers, and to disseminate findings. However, there was no evaluation conducted to ascertain how effective this strategy was.

### ***Evaluation***

Despite the benefits of evaluation, this is an area which does not appear to be routinely or effectively undertaken.

As mentioned in the beginning of Section 3 many commentators, who have reported on evaluations of research processes and outcomes (2, 4, 6, 9, 12-20), state that effectiveness of strategies used is highly context-specific. Nilsen et al. (13) found in their Cochrane review that consumer participation varies according to its purpose, the consumers involved, the degree of involvement, the methods employed to support participation, and the context. No literature could be found which provided sufficient details of effective strategies. This finding was also supported by Shippee et al. (1), but they did identify some key findings within the literature which stated that the evaluation process should be constant, that a continuous flow of information was valuable, as was having clear, pre-defined assessment tools.

Barber et al. (8) state that it is feasible to evaluate consumer participation in research, but it is complex. The reason being is that it is a process that is subjective and socially constructed. Oliver et al. (85) recommend that research programs embarking on working with consumers do so within an ethos of reflexive research so that the evidence base is developed.

Elberse et al. (87) state that the evaluation of the participatory process in their research was assessed retrospectively against the following criteria: (1) representativeness of participants, (2) neutral facilitation, (3) early involvement, (4) influence on policy (5) transparency in process, (6) resource accessibility, (7) task definition, (8) structured decision-making and (9) cost effectiveness.

Morrow et al. (15) provide a model and measure for quality consumer participation in health research for researchers and consumers to be more reflective about the constraints and possibilities of participation. The tools they developed could help research teams to examine personal factors and the research contexts that influence the nature and quality of consumer participation in research. They also suggest that the tools can help to identify reoccurring issues about quality which could inform future policy, practice and research.

#### **4. Benefits and Disadvantages/Challenges Reported by Consumers and Researchers**

There were many descriptive reports on the benefits and disadvantages/challenges of consumer and community participation in health and medical research from the consumers' perspective and researchers' perspectives. A significant finding was that the reports on consumer benefits and disadvantages were mainly provided from the perspective of consumers involved in participatory and community based research projects; and the studies reporting on the researchers' perspectives were primarily from research organisations, universities, and health services and not necessarily from researchers actively involved in research with consumers. As the benefits and disadvantages for consumers, and benefits and challenges for researchers, were not often related to specific strategies or phases of the research process they have been summarised in the following section.

##### **The benefits for consumers and community participants included:**

###### **a) New skills and knowledge**

- Thompson et al. (130) state it was common to hear that participants believed they had developed an understanding of their condition and its treatment, or of caring for another person.
- Learning from others and more experienced peers and colleagues (89).
- Some identified a better appreciation of current issues and services in their community and becoming aware of different opinions and viewpoints (11, 131-133).
- Putting learning and training into practice (133)
- In the study by Kelly et al.(55) the benefits of learning new skills and knowledge and 'on the job training' led to employment opportunities for the Aboriginal researchers through developing research capacity.
- Faulkner (134) identified that consumers involved in forensic mental health research had found involvement to be a valuable 'stepping stone to work'.
- Some parent researchers went on to further education (55, 135, 136).
- Some consumers acquired more general skills that were transferable to other areas of life, for example computer skills, listening and communication skills, and the ability to work as a member of a team (133, 135, 137, 138).

###### **b) Personal Development**

- Consumers frequently reported benefiting personally from participation, most often through a general increase in their self confidence and self-esteem (133, 135-137, 139) and feeling more confident about speaking up in groups and giving presentations (133).

- Some consumers identified that they felt more valued, respected and had a voice (133, 138, 140).
- Mongeau et al. (141) reported that using a participatory research approach resulted in the consumers feeling empowered.

**c) Support and Friendship**

- Consumers frequently reported that they greatly benefited from working within a team, made new friends, and met people with different experiences and backgrounds. For some participation in research enabled them to gain additional social support (133, 139, 142, 143).
- There was respect for opinions and expertise, and an understanding was gained about how people's different situations can affect their ability to contribute. This meant that the representatives always felt valued and supported. There was also a feeling of acceptance by all persons involved and it wasn't a token activity to satisfy the project requirement (144).

**d) Enjoyment and satisfaction**

- Many consumers reported that they enjoyed being part of a team, being able to concentrate on someone else and forget about themselves, having regular employment, meeting and talking to different kinds of people, and being involved in something meaningful and personally stimulating (95, 133, 143-145).
- Many reported a sense of achievement from being able to offer different perspectives on research, contributing to the creative elements of the research, making a difference to the project, investigating what they thought were important issues, helping to produce a significant and influential research report, being rewarded for their efforts and recognised for their contribution, and rising to the mental and intellectual challenges (133, 139, 145-147).

**e) Increased 'research literacy'**

Ward (67) identified 'research literacy' as facilitating consumers to develop a better understanding of the research process and to engage in a meaningful and empowered relationship with researchers. The knowledge and experience gained by consumers was identified in other studies as a benefit of consumer participation in research, but was not specifically described as 'research literacy'. This included a better appreciation of research and the process involved (55, 117, 133, 136, 146), also learning new skills such as questionnaire design, interviewing skills and data analysis (137, 146).

**f) Financial gain**

For consumers who were paid for their participation, they reported that they valued the opportunity to earn some money and felt it appropriate that they received a fair payment for their contribution (137, 139).

**The disadvantages reported by consumer and community participants in health and medical research included:**

**a) Tokenism**

Brett et al. (5) identified in the systematic review they conducted that some consumers felt devalued and had a bad experience through tokenistic involvement in the research process. This had resulted when researchers involved consumers to comply with policy, and didn't

really understand the contribution that consumers and community participation could bring to the research process.

In another study consumer participants stated that lack of feedback concerning results was a contributor to them having a negative attitude towards participation in research (148).

**b) Unfamiliar research language and jargon**

Consumers stated that lack of knowledge about research was a disadvantage, as they did not understand the language and jargon used by researchers. Lack of training in this prior to participation was a significant disadvantage and barrier to being able to actively participate (149).

**c) Power imbalance and conflict**

- Academic researchers have traditionally had control over the research agenda and often struggle to relinquish control over the study. This can lead to conflict between consumers and researchers, due to power imbalance (5).
- In addition lack of training and not understanding research language and jargon can contribute to the power imbalance between consumers and researchers (149).
- Some researchers, who were unresponsive to involving consumers, maintained their 'professional paternalism' (149).

**d) Emotional burden**

- Some consumers who have been involved as interviewers, peer interviewers, or as co-researchers reported that hearing about the hardships of people was emotionally difficult, sometimes causing them to relive their own life situations and memories (143, 145).
- Some consumers have reported feeling burdened by the confidential knowledge to which they were privy during the research interviews (55, 139, 143). For some, who worked as co-researchers in their own community, they felt anxious about how the community would perceive them due to distrust about previous research conducted in the community (55).
- For some people researching within their community they can potentially face penalties if the community see that they 'get it wrong or do it wrong' (150).
- Some young people, who were doing peer interviews, found it very distressing to hear some of the interviewees report about having been abused in care without having the training to deal with the issue beforehand (143).
- Some consumers found it difficult to ask people about their problems and then 'just leave them'. They felt responsible for making people upset as well as frustrated at not knowing what to say, and not being able to offer help immediately (135, 143).
- Some people affected by cancer have reported other emotional burdens. Some have been upset by the loss of their fellow team members through a re-occurrence of cancer. Others found it difficult to cope with the insensitive views and opinions expressed by professionals (145).
- Training, capacity building, and more formal supports were identified as being imperative to support consumers conduct interviews and be co-researchers (55, 143, 150). It was also integral to being ethically responsible research (3). People with cancer commented on the importance of preparing and equipping people before they get involved, so that they are better able to protect themselves from these kinds of emotional experiences, or at least be prepared (145). Kelly et al (55) argue that:

building research capacity means not simply equipping local people to undertake research on a particular project, but to have the knowledge and skills to undertake research in other areas. It should also provide people with a critical understanding of the difference between empowering and disempowering research (p. 7).

**e) Work overload**

There was a report of a mental health user researcher who was so overloaded with work that they experienced a relapse (151). The academic researchers recognised they were to blame for the situation as they had only recruited one user researcher and had not made arrangements for adequate support or followed best practice in consumer participation in health and medical research (151).

**f) Personal exposure through the media**

Some user researchers reported being personally exposed through inappropriate media coverage for the research project they were involved in. For example:

- Following a study of teenage pregnancy, two of the user researchers received a lot of negative media attention, which was personally distressing. The results of the research were inaccurately reported (152).
- During a study of acute mental health services, a draft report was leaked to the press which caused a 'media frenzy'. One of the user researchers was harassed by the media at this home and this caused significant distress (153).

**g) Frustrations at the limitations of participation**

- There were various reports about feeling frustrated with participating in health and medical research. Some consumers felt restricted by either financial or health considerations, and some felt anxious about how much the research costs (81, 154). However, most commonly people have felt frustrated at being powerless and unable to change the direction of the research. This has usually been because they had not been involved early in the process, and had been locked in to how the academic researchers had designed the research project (135, 142). However, in one study the researchers also commented that they felt similar frustrations when they had to deliver research to a pre-determined brief (135).
- As mentioned in the previous section on emotional burden, some felt frustrated at not being able to do more for the participants in the study, particularly when the ultimate goal of the research was to improve people's lives (145).
- One other frustration reported was that once the research project comes to an end, so does their research role. Some felt that their newly developed skills had been wasted and their experience underutilised (134, 155).

**The benefits for researchers (and the research process) included:**

In the literature it was often difficult to discern between what researchers stated were the benefits for them as researchers and the benefits for the research process. These often appeared to be inextricably linked for many researchers.

**a) Enhanced scientific and ethical standards and outcomes of research**

- Researchers thought that the scientific and ethical standards of the project were enhanced, and that consumer participation increased credibility of the project and they acknowledged a good rounding of consumer input with scientific/research fact (144).
- In addition, Smith et al. (17) identified that decisions made at the conceptual level, and in the early stages of research design, can impact on users and researchers in complex and personal ways, and stated that researchers need to involve consumers in the embryonic stages.
- Wilson (156) stated that participation of consumers throughout the research process ensured the findings were relevant for end users.

- Brett et al. (5) identified in the systematic review they conducted that participation of consumers helped to ensure that emerging themes and trends were interpreted from the different lay perspective, as well as from the academic and clinical perspective, and assisted in identifying research gaps. Consumers and community participants helped to define the scope and questions being posed, and supported the retrieval and analysis of sources of data, contributing to the formulation of recommendations and informing guidelines, and enable dissemination beyond academic communities (17).
- In a study by Nierse et al. (157) they conclude that collaboration of consumers in the research team contributed to the quality of the substantial findings. Consumers noted the diversity within the patient population, related to the lives of patients in the interviews, and used their experiential knowledge to probe during interviewing.
- Lindenmeyer et al. (140) found in their assessment of the benefits of consumer participation in health research, that it was generally seen as contributing to effective and meaningful research. The important contributor to this was the longstanding nature of the diabetes group involved, enabling consumers to gain more insight into the research and form constructive working relationships with researchers.
- Wyatt et al. (95) state that their study of consumer involvement in research provided evidence about the impact that consumers had not only on the research process but also on the outcomes of the research.
- Staniszewska et al. (109) state that consumer participation in their study had a clear impact on the research aims, methods, ethical issues, and dissemination plans. This led them to conclude that as a result their research was more firmly rooted in the reality of the consumers, had more relevant research questions, used appropriate and sensitive methods and had a strong dissemination strategy to reach out to health-care professionals.
- Happell and Roper (75) identified in a review of consumer involvement in mental health research that participation 'allows for a more inclusive approach to the design, conduct and interpretation of research, thus enhancing the relevance of research results to positive outcomes for consumers, as judged by the consumers themselves' (page 238).
- Happell and Roper (75) state that by virtue of the experience of service usage, consumers have a unique perspective which makes an invaluable contribution to the articulation of research questions and the identification of appropriate methodologies.

**b) Gave the project legitimacy and authority**

- The involvement of community had a significant influence on the success of the project and provided project legitimacy and authority. Researchers thought that obtaining realistic viewpoints from consumers and community participants made the project more meaningful (144), as well as culturally relevant (5).
- Other studies found that involving consumers in the research process improved recruitment to, and participation in research, and reduce the number of drop-outs from research projects (75, 106).
- Consumer and community participation was identified by Watermeyer (158) as positively affecting the public image and reputation of the medical researchers and induced greater willingness on the part of community groups to participate as research subjects.

**c) Ability to seek direction when tackling difficult issues**

Researchers appreciated being able to seek direction when tackling difficult issues and directly approaching the community with messages, especially with messages that could stigmatise consumers or were contentious (144).

**d) Ability to get advice from people not looking at the project through a research lens**

- Researchers were able to obtain advice from consumer and community participants and thought it was important to get advice from people who were not looking at the project through a research lens and to learn directly from them (5, 144).
- A study by Farrow (159) showed that asking participants about the perceptions and experiences provided a wealth of information that researchers might not usually consider. Lay researchers can function as successful translators between the different social worlds of communities and organisations.
- Lindenmeyer et al. (140) found that consumer participation helped researchers to remain connected to the 'real world' in which research would be applied.

**e) Valued the benefits once they gained experience**

- In several studies it was identified that when researchers went through the experience of working with consumers and/or community members on a research project, they usually valued and enjoyed the experience and could see the benefits (11, 149, 160).
- Initial anxiety and negative attitudes diminished once researchers had experienced working with consumers (149, 160).
- Some studies built in reflection of the participation process to explore what worked well and what didn't work well so that processes could be improved in the future (54, 69, 95, 144, 161).

**f) Strengthened communication**

It was identified in a Cochrane Systematic Review (13) that content and wording was more meaningful to consumers if consumers were involved in the writing process. Communication was strengthened for the development of information to disseminate findings to the community in a more lay user-friendly way (5, 161). Consumer participation was found to improve the quality and relevance of consent forms and information sheets for participants (5, 106). Consumer participation was found to strengthen lines of communication with non-expert audiences (158). Community participation was also found to steer researchers clear of potential public relations disasters and improve communication with communities (158).

**g) Democratisation of research**

Consumer and community participation in health and medical research creates a new value structure to science that democratically relates research interests to the public that is funding it and is affected by it (117). Consumer and community participation is often seen as the ideal solution for the growing gaps between health and medical science and society; it fits into the idea of 'upstream engagement' – engaging consumers and the community in research issues from the stage of agenda-setting onwards. It is also a way of democratising health and medical research (19, 141, 158, 162, 163). Mutual learning was identified as a strength of consumer participation in the research process (157), as was more reciprocal and supportive relationships (164).

**h) Fun**

McLaughlin (139) stated that working with consumers can be great fun, which is not a term he commonly associated with research. He also states that in addition to being fun, it is stimulating when working with the energy and enthusiasm that consumers bring to the process. This frees up ideas, creates new synergies and leads to new solutions to old problems.

**The challenges of consumer and community participation in research for researchers included:**

**a) Divergence from scientific methods and ethical dilemmas**

During the initial stages of setting up a research program, studies reported more challenging impacts of consumer participation (5). This included divergence from scientific methods and ethical dilemmas during the protocol design. This can provide tensions between academic criteria of good quality research compared with consumer perspective of what constitutes appropriate research. There were concerns raised by some researchers that consumer and community participants may not be able to be as objective as academic researchers and this may impact on the scientific merit of the research (164). Traditional research approaches advocate that reliable and valid knowledge is generated by 'keeping a distance' between the researchers and those being researched or those that have the experience. Dewar (165) suggests that this raises the questions about whether knowledge generated by reducing the distance between the user and the professional can indeed be more authentic.

**b) 'Turning upside down' of existing power relationships**

Academic researchers and health professionals have traditionally had control over what is researched and consumer and community participation can change this balance (5). This can be quite challenging to researchers, especially if they do not fully appreciate the contribution that consumers and community participation can make to the research process. Consumers sometimes challenged the methods used by researchers, which for some caused conflict (5). The participation of consumers in research as partners, rather than as subjects, radically alters power differentials and may be challenging for researchers (75). Some researchers raised concerns about consumers losing their objectivity and becoming 'professionalised' as the boundaries between lay researchers and academic researchers become more blurred over the lifetime of the research (5).

**c) Time and cost**

- Practical aspects of planning, collaborating with consumers and managing consumer participation in research can be timely and costly (75, 139). This can be difficult within the time and funding limitations of a research project and must be planned for (5, 164). If these aren't factored in to the research proposal then there can be increased workload for the researchers to meet time schedules within budget, and there is the risk of tokenistic approaches being used (5).
- Establishing trusting relationships, maintaining good communication and negotiating are all activities that require a substantial time commitment in order to succeed (141). It can take considerable time and cost to recruit consumers to the research process and can be a difficult process. Consumers also need training and support which is also time consuming and costly (139).
- Staniszewska et al. (109) state that researchers need to recognise the resource implications of involvement and factor these in.
- Ward (18) identified factors such as short and often immovable deadlines, lack of time, limited budgets that do not have in-built finances for consumer participation, and lack of researcher training were the barriers and challenges most often cited in the study he undertook.

**d) Constraints of academic research tradition**

- Nyden (166) argues that there is a strong undercurrent of tradition in most universities. University-based research is aimed at furthering the knowledge base of the researcher's discipline, which is traditionally seen as the 'highest standard' of research. Consumer and community participation challenges these traditions. He argues that academic researchers are often protective of their self-interests.

- Nyden (166) and Thompson et al. (149) identified in their studies that the culture of universities, where many academics and researchers are on short term-contracts and not tenured, can be a challenge to engaging consumers and community in research activities, especially from the beginning of the process. Most research needs to be funded before research staff are employed and funding becomes available to engage with consumers and community in the research. This left researchers querying their ability to involve consumers in a meaningful way (149).
- Several researchers reported challenges regarding publishing about consumer and community involvement in their research in academic journals. Issues reported include: limited word counts prevented documentation of consumer and community participation in journal articles; results of participation were not perceived as important; and concern by publishers that the consumers involved may disseminate the results before they had been written up and published in academic journals (167).
- Most university promotional processes tend to count peer-reviewed articles, not impact, as the measure of its success. Few university decision-makers seriously count impact on the local community or the region or publication in non-peer reviewed journal, which may be more important to reach a lay audience in a culturally appropriate way as part of the dissemination strategy designed with consumers who participated in the research (166, 168). Funding may not be provided for the development and distribution of culturally appropriate materials that can assist in the dissemination of research findings to specific consumers and communities (168).
- Some researchers thought consumer participation was an additional pressure in a highly competitive environment (149).

**e) Funding consumer participation in research**

- Structural barriers have been identified that prevented collaborations to support funding research. CHF (38) argue that consumer driven research networks cannot apply as a lead applicant for NHMRC or ARC research funds because they do not fit the definition of an Administering Institution or Eligible Organisation.
- Robinson et al. (10) identified in their research that many funding bodies now request that researchers provide evidence of consumer participation when submitting research proposals. However, they state that it is difficult to involve consumers in a meaningful way in the initial formulation stages of research. Academic research culture is fundamentally project-driven and researchers are frequently employed on short-term contracts within tightly defined deadlines. For many researchers the research begins when the project begins and this means that there is no funding available for consumer participation or for staff to involve consumers. In addition some organisations require ethics approval before commencing any work with consumers. These issues can lead to consumers not being involved in the early developmental stages of the research. These findings were also identified in a study by Caron-Flinterman et al. (19), where funding agencies did not provide support in terms of money or time for the involvement of consumers.
- CHF (39) identified that some public research funding bodies don't recognise the costs associated with consumer and community participation as legitimate research expenditure when assessing funding applications. CHF (38) have also identified the need for greater flexibility within existing funding structures to promote community partnerships without the need for additional investment. This was supported by O'Donnell and Entwistle's findings in a study in the UK (92).

**f) Lack of training**

Lack of researcher skills in involving consumers in research was identified as a major barrier for consumer participation. Researchers highlighted the need for more training in this area (35, 149).

**g) Attitude**

- Some researchers felt very strongly that whilst involving consumers in research may be of benefit, the way in which consumers are involved and the overall control of the research should remain in the researcher's hands (149).
- Some researchers believed that because they engaged with patients on a daily basis, involving consumers in research was less relevant to them – after all they know what their patients experience and need. They saw consumer participation playing a greater role for those researchers who have little or no contact with patients (149). Thompson et al. (149) state that this attitude suggests a construction of consumer participation based on the impact it will have on the researcher, and perhaps on the research, rather than accounting for redistribution of power and a greater voice for consumers in research.
- These findings are also supported by Ward (18) where in the study he did, he identified that researchers were defending their 'professional boundaries'. He also found that whilst comments were not necessarily dismissive of consumer participation, there was a lack of appreciation of the reflexivity about the potential for researchers to learn something from consumers or to share in new forms of knowledge construction (18).
- Thornton et al. (160) identified in their study that the main requirement for successfully incorporating consumer input into research is researchers who believe that the validity of the work is enhanced by ensuring that the voice of the consumer has an equal opportunity to be heard from inception through to dissemination (160).

## Conclusions

After a comprehensive and structured literature search it was ascertained that there is very little literature which reports on specific strategies for consumer engagement in health and medical research that have been effective for consumers and researchers. Much of the literature, whilst valuable and informative about consumer participation in research and impact of consumer participation in research activities did not provide the type of evidence required to conclusively and definitively answer the search question.

As identified research is undertaken for different reasons and in different contexts, as such it is not possible to say that involving consumers, will, or should, always be undertaken in the same way to achieve the same benefits. One of the major conclusions is that effectiveness of strategies used in consumer participation in research is highly context-specific, and in many instances dependent on the attitudes of, skill, and relationships between, the consumers and researchers involved in the research process.

Some key findings relating to effectiveness of strategies were that:

- More participatory strategies with consumers were more productive.
- Occasional consultations and written consultations, do not lend themselves to long-term investment, and these methods have more often failed to show the advantages of enthusiasm for involvement, or increased knowledge about consumers' priorities or constructive ways of working with consumers. In addition, these strategies were found to not be an effective use of consumers' time when comparing to influence on the research agenda.
- When collaborative methods were utilised, consumers were in a better position to influence the research.
- Consumer-researcher collaborations require planning and perseverance and these partnerships are reliant on comfortable human interaction among not necessarily like-minded people. There is no simple formula for success but allowing adequate time to establish the consumer-researcher partnership and to set realistic terms is important.

Some key factors were identified which may support consumer participation competence in organisations and contribute to success in consumer participation in research. These being governance (structures, policy, research funding), infrastructure (consumer registers, information), capacity (consumer training, researcher training), and advocacy.

There is huge variation in how the evidence of effectiveness of different strategies of consumer and community participation is evaluated and reported. Variations in terminology, concepts and design inhibited comparative effectiveness in determining effective strategies. In addition many of the studies are qualitative in design and may not carry the same weight of evidence within the positivist paradigm of health and medical research. It was stressed that the absence of evidence does not indicate an absence of effectiveness of strategies; rather it indicates inadequate reporting with a lack of valid and reliable tools. Many academics who research in this area argue that there is an urgent need to create the tools to develop the evidence base. In addition, they state that guidelines

for the reporting of consumer and community participation could improve consistency and comparability of studies.

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