Literature Review Regarding Patient Engagement in Patient Safety Initiatives

Prepared by - Monash Institute of Health Services Research

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Contributors:

Aroni, R
Beringer, K
Bernard, H
Bernath, V
Cameron, P
Cant, R
Dickson, F
Farnworth, L
Forbes, K
Green, S
Gupta, S
O'Connor, D
Page, M
Parkhill, A

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Executive Summary

Aims and Objectives

The aim of this project was to conduct a literature review regarding patient engagement in patient safety initiatives.

The specific objectives of the literature review were to answer the following key questions:

1. What are the views of patients, consumers and the public regarding their involvement in patient safety initiatives?

2. What are the different methods and processes that could be used to effectively involve patients, consumers and the public in the planning, development and implementation of patient safety initiatives and programs?
    a. Have any of these methods or processes been evaluated?
    b. What are the critical success factors for these methods and processes?
    c. What are the limitations of these methods and processes?

3. What are the outcomes of involving patients, consumers and the public in the planning, development and implementation of patient safety initiatives and/or programs?

Methodology

This literature review was conducted by a project team from the Institute of Health Services Research, Monash University, comprising personnel with expertise in qualitative and quantitative methodologies, information science, systematic review methodology and content expertise in the area of patient safety.

The literature review was undertaken in two parts:

- Firstly, a comprehensive search of the academic literature, covering nine bibliographic databases, hand searching of 11 relevant journals and a search of the grey literature was undertaken in May 2008 to identify qualitative studies, questionnaire studies or mixed methods studies that reported the views of patients, consumers and the public regarding their involvement in patient safety initiatives (Question 1).
- Secondly, a comprehensive search of the academic literature, covering 12 bibliographic databases, and the grey literature was undertaken in May 2008 to identify articles or reports that provided a description and/or evaluation of methods or processes to involve patients, consumers and/or the public in the planning, development and/or implementation of patient safety initiatives and/or programs (Questions 2 and 3).

Potentially relevant articles or reports were identified from the two respective searches (addressing question 1, and questions 2 and 3 respectively) and were screened for eligibility by at least one member of the project team. Data extraction, and where relevant, an assessment of methodological quality, was performed on all included studies. The results of included studies in Part One were synthesised using a meta-ethnographic approach. Included studies in Part Two were synthesised narratively (where they *described* methods or processes only) and quantitatively (where they *evaluated* methods or processes of engaging consumers and reported homogeneous and outcomes and experimental designs).

Key findings

- No articles or reports were found that addressed question one; reporting the views of patients, consumers and the public regarding their involvement in patient safety initiatives. However, two articles were included as they focus on consumer involvement more broadly and may offer useful insights.
- Three studies that addressed questions two and/or three were included. Two studies reported methods to involve the public in the *development* of patient safety initiatives and one study reported processes to involve consumers in the *implementation* of such initiatives. These are described in Section 4 of the report. No studies that examined the *effectiveness* of methods or processes to engage consumers in patient safety initiatives were identified; therefore no data on outcomes or critical success factors for such engagement methods is available.
- These limitations are described and considered in Section 5 of the report.

Recommendations and opportunities for future research

Evidence for consumer involvement in patient safety initiatives is limited and involvement of consumers is unlikely to occur without active recruitment programs. Given the considerable investment required to develop an active consumer voice in patient safety initiatives, it is essential that further research is undertaken. The following program of research is suggested:

- Identify patient safety initiatives in Australia (and internationally) where consumers are actively involved (conduct observational studies);
- Identify factors that have enabled this participation (studies could be undertaken by comparing organisational elements between groups involved in patient safety initiatives – qualitative and quantitative studies);
- Undertake studies to evaluate implementation of organisational elements that facilitate consumer involvement (this could be using historical control or even randomised control trial design studies – qualitative and quantitative studies);
- Evaluate the impact of consumer involvement in patient safety initiatives. This could initially involve observational and qualitative study designs to identify likely effects. Ideally a controlled study (historical, randomised control trial) would follow to demonstrate differences in outcome;
- Identify specific areas where consumer involvement appears most useful;
- Following this research program, a guideline for consumer involvement in patient safety initiatives could be developed. Prioritisation of implementation could be based on likely effect of consumer involvement.

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Abbreviations

ACQSHC	Australian Commission for Safety and Quality in Healthcare (The Commission)
AHRQ	Agency for HealthCare Research and Quality
CBPR	Community Based Participatory Research
CPG	Clinical Practice Guideline
CSF	Critical Success Factors
FMC	Flinders Medical Centre
HCC	Health and Hospital Corporation
HIV	Human immunodeficiency virus
IOM	Institute of Medicine
NHS	National Health Service
NICE	National Institute for Clinical Excellence
NTIS	National Technical Information Service
PAIS	Public Affairs Information Service
PFPS	Patients for Patient Safety
RCT	Randomised control trial
WHO	World Health Organisation

1 Introduction

The Australian Commission for Safety and Quality in Health Care (the Commission) has identified engagement with patients and consumers across all of its programs and activities as a key area of focus (Priority Program 1) for work in 2008-2009 (ACQSHC 2006). The Commission is specifically interested in how patients and consumers can be more engaged in its work, and in the patient safety work of health care providers. Part of the work plan is the development of a Consumer Engagement Strategy that will describe how the Commission will work with patients, consumers and health care advocates to best achieve its aim of achieving safer care for patients.

To support this work the Commission contracted Monash University to undertake a literature review on how patients, consumers and the public can be more effectively involved in patient safety initiatives. The Commission's focus for the literature review was not on ways in which patients can contribute to their own safer health care, but how, from an organisational perspective, patients, consumers and the public can be more effectively involved in the planning, development and implementation of patient safety initiatives and programs.

This report provides a structured evidence-based literature review on the involvement of patients and consumers in patient safety covering Australian and international published articles and reports. The review concentrates on published reports and articles within the last five to ten years.

The key questions asked by the Commission, and addressed in this review, were:

1. What are the views of patients, consumers and the public regarding their involvement in patient safety initiatives?
2. What are the different methods and processes that could be used to effectively involve patients, consumers and the public in the planning, development and implementation of patient safety initiatives and programs?
    a. Have any of these methods or processes been evaluated?
    b. What are the critical success factors for these methods and processes?
    c. What are the limitations of these methods and processes?
3. What are the outcomes of involving patients, consumers and the public in the planning, development and implementation of patient safety initiatives and programs?

In approaching the identification of literature relevant to the addressing the questions the Commission defined the terms "patient" and "consumer" as:

- individual patients who have received or are receiving care;
- consumers who have a specific interest in health, but who may not be currently receiving care;
- organisations that represent groups of consumers;
- members of the public who have an interest in broad decision making or policy regarding patient safety.

This review outlines the methodological approach used, including search methods for identification of published reports and articles, screening methods, assessment of quality and data extraction; synthesis of findings in relation to the questions of interest, followed by a discussion of specific issues of relevance in the Australian setting and recommendations for future policy and research.

This review was undertaken in two parts; Part One addressed the first question as it was likely that the majority of research on this area would be qualitative in nature and / or advocacy documents. This was undertaken by an expert in qualitative methods. Part Two incorporated questions likely to be addressed by mixed methods studies and quantitative evaluations and so was undertaken by researchers with expertise in systematic review methodology for both quantitative and qualitative research.

2 Background

Patient safety is increasingly recognised as one of the most important issues in health care around the world. Various factors have drawn attention to this issue; in particular the publication in 1999 of the Institute of Medicine (IOM) report, To Err Is Human: Building a Safer Health Care System, and a series of Australian and international studies on medical error and unsafe medical practice. In recent years improving patient safety and managing the risks associated with medical care has become a key area of focus for state and federal governments. Governments have responded to concerns over safety in the United Kingdom, Australia and Canada with patient safety initiatives in place or underway.

The importance of consumer involvement in health care is widely recognised by stakeholders (including government, the professions, healthcare administrators, industry and consumers) and the health care community. There has been considerable effort in Australia to involve consumers in health care decision-making at a national level, to support consumer bodies in a number of key policy areas, and in improving the quality of care. In contrast to consumer involvement / participation in health care, historically the majority of patient safety reform agendas have been less focused on consumer input (Vincent & Coultier 2002). More often patient safety reform agendas have been lead by committees selected for their health care delivery expertise.

Recently there has been a significant increase in awareness of the need for consumers to have a key role in the area of patient safety programs and initiatives. Subsequently there has been greater engagement of patients and consumers in talking about patient safety at an organisational level. The World Health Organisation (WHO) launched a World Alliance for Patient Safety in 2004, dedicated to “bringing the significant benefits to patients in countries, rich and poor, developed and developing” world wide (WHO 2008). Notably the WHO Alliance includes Patients for Patient Safety (PFPS) Initiative that relies on consumers to develop and lead implementation of patient safety programs.

As patient safety is addressed and discussed in many ways in the literature, one of the challenges in conducting the literature review was the lack of consensus of a universally accepted definition of patient safety. In approaching the identification and analysis of literature to address the specific questions on patient safety this review used the Agency for HealthCare Research and Quality (AHRQ) definition of patient safety which is defined as “freedom from accidental or preventable injuries or harm produced by medical care” (AHRQ 2001).

3 Part One (Addressing Question One of the Review)

3.1 Introduction

We address the first question of the literature review in response to the recognition for the need to inform more effective and appropriate engagement of consumers in patient safety intiatives drawing on evidence at the grass roots. The question in Part One is "What are the views of patients, consumers and the public regarding their involvement in patient safety initiatives?" Given the calls for the development of safer, more patient-centred health care systems it is necessary to determine how patients, consumers and the public view the possibility of involvement at the organisational and policy levels of the health care system in relation to safety initiatives and programs.

There are a number of arguments for public participation in medical and science policy formulations. It has been suggested that there are two schools of thought evident in national and international literature and that these underpin the increased interest in public involvement or citizen engagement in improving the safety of health care (Simces 2003). Simces contends that the first could be known as the consumerist approach and the second the democratic approach.

In the first approach, it is argued that consumers reap the benefits, but also bear the financial and clinical burdens of research and medical practice. Hence, it makes common sense that they should be involved at all levels of planning and decision-making. In addition, there are circumstances in which the interests of individuals or communities and the state are not in agreement; in such cases, the state should not make decisions without public input. Furthermore, while professionals have technical expertise, they are not better qualified than the lay public to make political and moral decisions (Hiller, Landenburger, & Natowicz, 1997). It is here that there is an intersection with the second or democratic approach - in which it is suggested that in a democracy, individuals should have a voice in policy decisions that have implications for the public, including those in the scientific and medical arenas. In this approach it is contended that the legitimacy of the democratic process and hence the nature of the democracy can be questioned if there is concern about a lack of effective citizen participation.

It has been assumed as axiomatic in much of the literature that participation and engagement of consumers for any and all modes of such participation is both politically and symbolically desirable as well as administratively, politically and pragmatically effective in producing improvements in health outcomes. There is some literature that is either agnostic (Contandriopoulos, 2004) or dissenting in this regard (Steckler & Herzog, 1979).

It is important to note that while there is an extensive literature that discusses patient safety and a burgeoning literature on consumer involvement and engagement in health policy, it is only in the last 10 years that there has been an interest in determining intersections between these arenas at the organisation and system levels. Nevertheless, it might be argued that much of the health consumer engagement literature is implicitly directed at optimal patient safety as an integral part of improving health outcomes. The hope is that if consumers partner with policy makers and health providers and are engaged in the patient safety initiative process (from inception to evaluation) then patient safety may improve. In order to most effectively enable such 'partnering' to occur it is necessary to ask the first question that forms the set of questions driving this review of the literature.

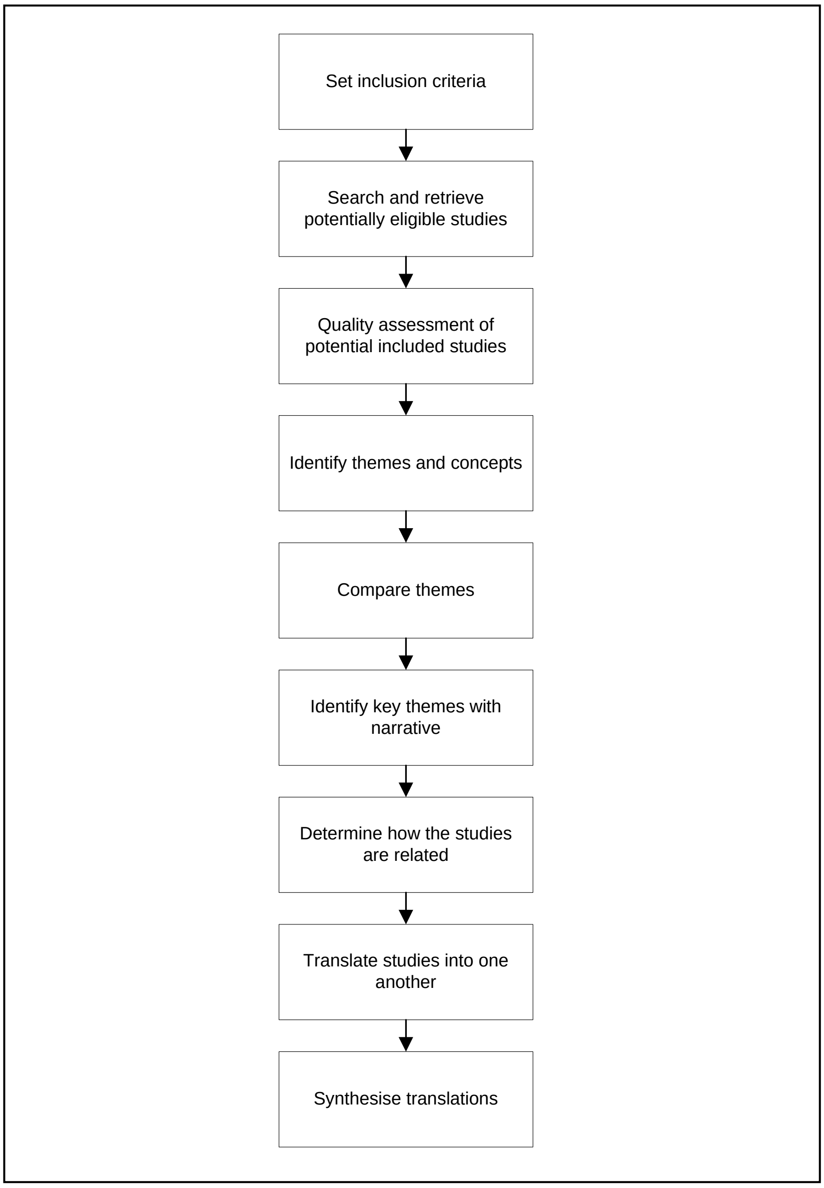
The research question that forms the basis of Part One of the literature review provides an opportunity to determine the nature of the evidence available as well as mapping the gaps.

3.2 Methodology

In order to examine the literature to answer the first question addressed in the literature review it was assumed from the wording of the question itself that qualitative and/or survey questionnaire studies or mixed methods studies would be more likely to be found in our searches. In response to this view we planned to follow a meta-ethnographic approach (Noblit & Hare 1988) to synthesise findings across included studies (Figure 1).

This systematic approach enables translation of ideas, concepts and metaphors across different qualitative studies and is increasingly viewed as a favourable approach to synthesising qualitative health research (Britten et al 2002). This process was conducted by members of the team with qualitative research experience.

Figure 1 Part One - Meta ethnographic approach to synthesise findings



Criteria for considering studies

In order to enable a policy-usable commentary in response to this question the following questions were asked in sequence:

> (a) *Are there any empirical studies published in peer-reviewed journals reporting on the views or attitudes of patients, consumers and the public regarding their involvement in patient safety initiatives?*

If yes, what types of articles or reports and of what quality? Do the authors provide an adequate audit trail that enables a reviewer to determine that the design, implementation and analysis of data were performed with rigour and care? Do these articles provide indications of patterns in consumer involvement either in Australia or elsewhere that is of use to policy organisations such as the Commission to effectively engage and partner with consumers to improve patient safety outcomes?

If there are few or no such articles or reports to be found then:

> (b) *What types of publications are available which provide insight into the views or attitudes of patients, consumers and the public regarding their involvement in patient safety initiatives? What level and/or type of evidence do they provide? What useful conclusions can be drawn from them?*

Inclusion criteria

1. Articles or reports that describe/analyse/evaluate patient, consumer and/or public views or perspectives of consumer/patient/public/citizen/carer/service user/lay involvement in patient safety initiatives and programs.

Exclusion criteria

1. Patient/carer satisfaction surveys of patient safety initiatives.
2. Articles or reports describing patients’ or carers’ views of involvement in enhancing their own or family member’s safety while in hospital.
3. Articles or reports that examine development, planning, implementation or evaluation of patient safety initiatives but not consumer involvement.
4. Articles or reports that examine consumer involvement but not patient safety initiatives or programs or proxy programs.

Search methods for identification of literature

A broad approach to searching was taken in the first instance in order to determine the breadth of the field of literature. This included quantitative, qualitative and mixed method articles or reports. There were four methods of searching:

1. Electronic searches of the following bibliographic databases were undertaken on two occasions in late April and then refined in May 2008:

- ABI/Inform
- Medline
- Embase
- Cumulative Index to Nursing & Allied Health Literature (CINAHL)
- Factiva
- PsychInfo
- Scopus
- SIGLE
- Sociological Abstracts

These were conducted first by members of the project team to provide a broad inclusion of the field. The subsequent refinements and checks were conducted by three independent search specialists with extensive experience in conducting and providing expert advice on search methodologies. The reference lists of all included articles or reports were hand searched to identify further relevant articles or reports.

2. A search of the grey literature was undertaken using the following search engines and databases:

- Google Scholar
- Internet Websites using Google, Clusty and Dogpile

Broad searches were conducted and relevant material was selected and recorded.

Relevant websites are listed in Appendix 1.

3. The electronic searches were supplemented with searches of individual journals (refer Table 1 below) and citation searches of retrieved documents in May 2008.

Table 1 Part One - journals hand searched

Journals hand searched	Period searched
Health Expectations	1998 – 2008 May
Health Issues	1997 – 2008 May
Health Policy	1984 – 2008 May
Journal of Health Politics, Policy and Law	1994 – 2008 May
Milbank Quarterly	1997 – 2008 May
Patient Education and Counselling	1995 – 2008 May
Patient Safety in Surgery	
Qualitative Health Research	1999 – 2008 May
Quality and Safety in Health Care	2001 – 2008 May
Sociology of Health and Illness	1979 – 2008 May
Australian Journal of Primary Health	2001 – 2008 May

4. Finally, in order to enhance rigour and best chances of retrieving any further potentially relevant reports for review three independent experts with experience in conducting searches for systematic reviews were asked to develop their own search strategies in response to the original research questions. These data sets were combined and duplicates were removed.

Methods for screening

Members of the project team screened the titles and abstracts elicited from the search using the eligibility criteria listed above. Full-text articles were retrieved when the abstracts suggested they might meet the inclusion criteria. The full-text articles were reviewed for eligibility by two members of the project team working independently. Any disagreements were resolved by discussion and consensus.

In addressing question 1 of this review, we accepted all study types in the first instance simply to determine the breadth of the field. We also engaged in personal communication with key consumer representatives with expert knowledge in this area in the hope that they might reveal any ongoing work which was in draft form or pre-publication stage.

After conducting the electronic and hand searches as listed above, we also examined articles that commented on consumer views of consumer involvement in health policy development, planning, implementation and evaluation as a proxy tool for examining such views on patient safety initiatives as it is in these arenas that patient safety initiatives are often discussed.

As requested by the Commission, literature that focuses on patient involvement at the level of personal engagement in their own safety has not been included.

Assessment of quality and data extraction and synthesis of results

While there are a number of quality appraisal tools that have been developed for the purpose of enabling synthesis of qualitative research studies such development is still in very early stages (CASP, Public Health Research Unit, 2006.; Popay, 2006) as are the methods for synthesis themselves (Campbell R, Britten N, Pound P, & al., 2006.; Pawson, 2002). For the purposes of this review it was decided to use a meta-ethnographic approach (Britten et al., 2002; Popay, 2006) with the Critical Appraisal Skills Programmes (CASP) as the model for quality appraisal (Public Health Research Unit, 2006.).

3.3 Results

Consultation with Key Stakeholders

In order to consult with key stakeholders it was originally envisaged that focus groups would be conducted but it was found that potential participants' timetables did not match. Focus groups were replaced with telephone interviews and face-to-face contact. These included members and/or representatives of the Health Consumers Forum, Health Issues Centre, the Australian Health Ethics Committee, a number of support groups (e.g. Asthma Australia, Epilepsy Association), the Victorian Department of Human Services, Queensland Health Department and people at both public and private Australian hospitals in all states. These consultations took place in order to both determine if other literature was available that had not yet been made publicly available on organisational websites and/or if there were any other suggestions regarding search terms or strategies.

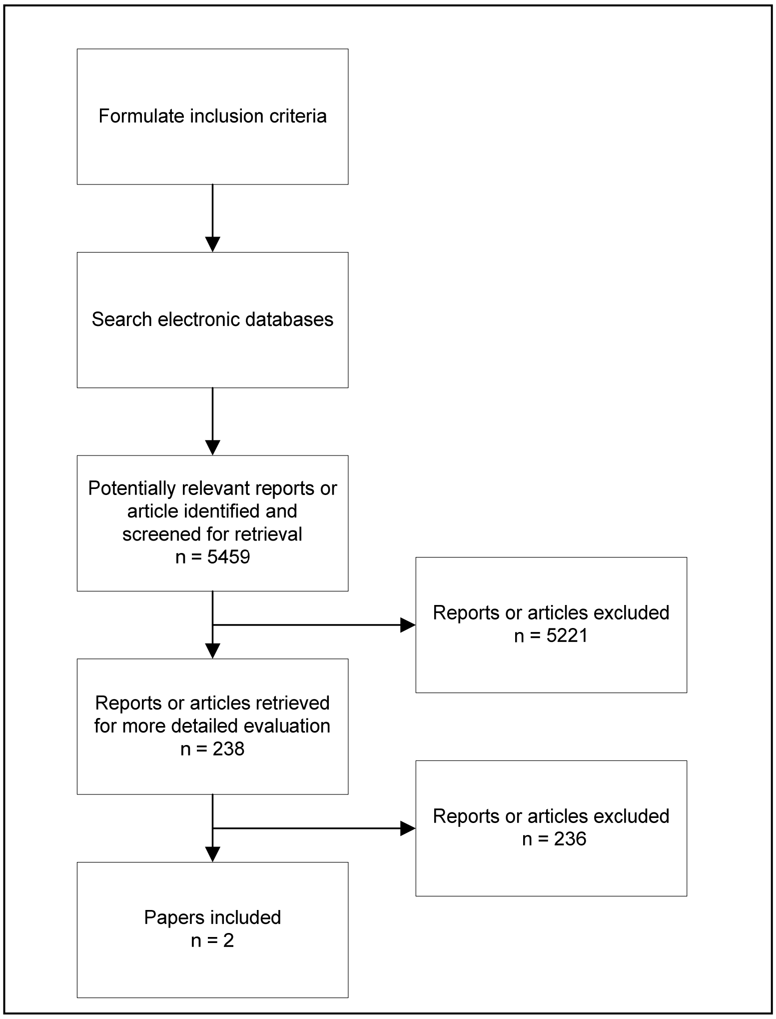
Only two documents were located using these methods, one was a draft evaluation of the Consumer Advisory Committees in Victorian Hospitals and the other was a draft report on consumer involvement at the Eye and Ear Hospital in Victoria. Both were provided for examination for review inclusion. Stakeholders contacted in all other states of Australia indicated that either conference presentations had taken place but no documents were available at the time of contact or that, whatever documents were in their possession, were not available for public release at that point in time. We also received the suggestion that certain journals would require hand searching such as *Health Expectations* and *Patient Education and Counselling*. We would like to acknowledge the assistance of Christopher Newell very early in the process regarding the very pointed focus on patient safety and consumer engagement at the policy level.

Articles and reports identified

The results of the electronic database searching are illustrated in Figure 2.

A total of 5459 potentially relevant articles or reports were identified from the search of the electronic databases, grey literature and hand searching. Five thousand two hundred and twenty one articles or reports were screened and subsequently excluded as not being relevant to the review question. Two hundred and thirty eight full-text articles were retrieved for more detailed evaluation (i.e. a decision on inclusion could not be reliably made on the basis of title and abstract information). Of these, 236 were subsequently excluded (see Figure 2 for more detail). Two articles were found that addressed questions (a) or (b) stated in 'Criteria for considering studies'.

Figure 2 **Part Two - Flowchart of the process to identify & select articles /reports & search results from electronic databases, grey literature & hand searching**



Articles and reports included

Two Australian articles (Johnson and Bament, 2002; Johnson, Beacham, Moretti & Wishart 2006) were located that addressed question (b) and provide useful insights on consumer involvement but do not directly focus on patient safety. We included them as involvement was stated as being at “policy level” and/or for the specific purpose of “improved quality of services”. While the term “patient safety initiative/s” or other patient safety terminology was not used in these articles, the alternate terms were used in a manner which could be viewed as a proxy.

There were are a number of articles and reports that were excluded as they were asking about: (a) patients involvement in their own circumstances of safety and quality of care, or (b) about potential involvement while they were in care, or (c) about specific issues of patient safety while still in the hospital setting which we felt might have an influence on responses.

Johnson and Bament (2002) investigated if, and how, consumers (users and their families), consumer /community representatives and members of the broader community, preferred to be involved in improving the quality of services in Flinders Medical Centre (FMC) (or South Australian hospitals in general for members of the broader community). They also explored issues from the perspective of consumers and representatives of consumer/community groups that may have inhibited or enhanced their participation. Finally they developed a consumer participation model for FMC drawing on their findings.

Two different participant groups participated. The first group were those people using FMC services (people using FMC, their carers, family members or friends). Face-to-face interviews were conducted with 100 people with a specifically designed questionnaire used as an interview guide. Participants included inpatients drawn form a range of medical and surgical wards (60% of sample) and outpatients from a range of outpatient areas (40% of sample) with approximately equal numbers of males and females over a range of ages.

The second group consisted of representatives from consumer/community organisations whose members had used FMC services. Two focus groups were held with 22 representatives from consumer/community groups whose members utilised FMC services. Participants were asked if they had previously participated in improving the services at FMC and if so, in what manner? The majority of participants (75%) had not had any prior involvement.

When participants were asked what their main reasons were for not wanting to participate in activities to improve FMC services their responses were as follows:

- Lack of time - 43.9%,
- Not interested - 32.7%,
- Costs involved and difficult in transport -15.3%,
- Poor health - 14.3%,
- Have no issues with FMC - 6.1%,
- Lack of confidence - 5.1%.

Further analysis of the data showed that participants in the youngest age group (18 to 40 years) were most likely to give ‘lack of time’ as their reason for not participating (63.6% of participants in this age group). This compares with 40% of participants in the 66+ age group and 29.3% of participants in the 41 to 65 age group who gave ‘lack of time’ as their reason for not participating. Neither age nor gender affected the likelihood of participants giving ‘lack of interest’ as their reason for not participating, however, a trend was observed between age groups and the likelihood of a participant giving the reason of ‘poor health’. For example, no one in the 18 to 40 year age group identified ‘poor health’ as a barrier to participation, but 12.2% of participants in the 41 to 65 year age group and 36% in the 66+ age group did. This is obviously an area that deserves further research.

The majority of participants (60%) felt there was not anything FMC could do to make it easier for them to participate. Among those who felt there was something that could be done, responses included covering the costs of parking and travel to attend activities (31%), providing training (10%), general remuneration (5%), holding meetings/forums in local areas (3%) and holding meetings at flexible times (3%). When representatives of consumer/community groups were asked if they had ever previously participated in improving the services at FMC, the majority indicated that their group had not been invited to be involved and had not had any prior involvement. Most representatives were involved in fairly well-established groups. These groups met on a regular basis and had processes in place to consult with their members. A small number of representatives commented on the technical support needed for their group to be involved with FMC. This included access to computers, phone, fax and the Internet.

All consumer and community representatives felt that it would be crucial for their group to have a hospital contact person whom they were familiar with, and who was familiar with the issues faced by their group's members. Most consumer/community representatives also felt that provisions needed to be made to cover the cost of parking if they were to be involved in activities based at FMC. Some also identified a need for training on the procedures and systems that operate at FMC so their group members would have a better understanding of how FMC works and were thus better able to comment on how change could be implemented. Both groups of participants in this study had little previous involvement in improving the quality of services at FMC in the past.

To ensure more active participation of consumer/community representatives in hospital safety and quality activities, the authors suggested that FMC formalise relationships with these consumer/community groups and develop mechanisms to enable more consistent ways for these groups to participate (e.g. appointing a contact person). They also concluded that FMC needed to develop organisational supports such as policy direction, allocation of resources and appropriate training and support for staff.

The second study (Johnson et al, 2006) reports on one aspect of a larger study identifying the concerns, skill areas and support and training needs for consumer representatives to effectively participate in health services and at a policy level. In the publication their focus is on participants' identifying their concerns about participating as health consumer representatives who will be representing health consumers on various health system and health services committees (including committees potentially dealing with patient safety issues, initiatives and programs).

They used an exploratory qualitative research design, conducting a series of eight focus group interviews with 48 health consumers (35 women and 13 men) in metropolitan Adelaide and regional South Australia during August 2004. The authors provide a good audit trail for their sampling, data collection and analysis processes. Participants were health consumers who had been or were at the time of the study participating as consumer representatives with health services or at a policy level in the health system or were wishing to be involved in the future. They were provided with a series of questions and scenarios to which they were asked respond. Content and thematic analyses were performed. The key themes that were reported as of concern to the participants are listed below:

- Inaction or no outcomes achieved while being a consumer representative;
- Dealing with conflict: viewed as inherent in the role;
- Intimidation, discrimination, rejection or humiliation: behaviours of health professionals as not respectful;
- Feeling uncertain about how to undertake the role and their capacity to fulfil expectations;
- Resource Issues;
- Feeling obliged to participate.

The two retrieved articles were heterogeneous in participants, data collection and analysis methods notwithstanding that they included participants who were members of the public and others who had experience of being consumer representatives.

A key finding was that people who were members of the public may differ considerably from those who have acted as consumer representatives in their attitudes to the nature and level of involvement sought.

3.4 Synthesis of findings

We have synthesised the themes drawn from the two papers but have also included a subsequent brief commentary on other issues found in the excluded literature that suggest future arenas for review. The themes that are evident in these two papers are as follows:

1. Concerns with the specific role of consumer representative

There was a concern about the capacity to undertake the role and fulfil other’s expectations of them. This included both those they might be representing as well as health professionals. Participants indicated four major areas of concern areas of concern; representation, resources, micro-politics, and effectiveness.

2. Representation and degree of involvement

The issue of adequate representation of others was a pervasive theme. Tokenism was raised and was described in terms of the politics of selection of representatives. The focus of the comments indicated that participants were concerned about top-down structuring of selection of representatives where organisations may choose individuals to fit their own agendas and interests rather than those of the community. They may “seek only to involve majority groups, rather than also including minority groups”. These issues of inclusiveness and equity were well understood and were matters of significant concern. Participants also raised concerns about being required to consult with other consumers. They were concerned about adequately representing the views of others rather than their own. Underpinning this was determining how they were to appropriately identify a constituency, how to then conduct community consultation effectively and how to subsequently provide feedback.

An alternate facet of this theme was tied to those who did not wish to be involved at all or others who felt obliged. In the latter case this was either construed as being pressured into involvement or only choosing to be involved in a passive form such as responding to surveys. Consumers who had not been consumer representatives were more likely to prefer passive modes of involvement particularly given the perceived costs. This raised the concern that there was the potential for some groups to be excluded from having input into improving the safety and quality of health services. There was also an indication that whether one had previously been involved or not that interest in participation decreased with an increase in the level of involvement required. This may be tied to the theme of resource impact

3. Resource impacts

A clear theme emerged that indicated that participants were well aware of the “costs” associated with involvement in improving the quality of care as they recognised that involvement would need to be prolonged and that this would have a financial impact There was a clear recognition that these resource needs were not only financial (travel communication, time away form income earning activities) but also technological (requiring computing and internet access) and material (training). There was a concern that involvement may influence other financial matters such as pensions or other benefits and this was viewed as a deterrent. The choice not to become involved may be tied to the assumption that there would be a lack of requisite resources to sustain involvement beyond a passive or ineffective manner.

4. Power and micro-politics

The theme that emerged here was that of role value and status. The issue of tokenism underpinned the concern about the actual working on committees. That is, there was disquiet about what the perceived value and credibility of consumers might be when participating in organisational settings. Timing of involvement was used as the focal point to underscore this issue. Participants understood that authentic involvement meant that involvement needed to occur in the early stages of planning of initiatives. The question that underpinned this was whether consumers were genuinely wanted and valued on committees.

The social context of being a “committee member” was raised in terms of four key facets of tacit knowledge; the first was in operating as an outsider while other committee members were insiders by virtue of working together regularly. The second was concern about the procedural requirements in a meeting. Lack of familiarity with the meeting rules, boundaries and processes suggested to participants a lack of acceptance of real involvement. Past experience of non-respectful management of such meetings was identified as a factor influencing consumers’ lack of desire to become involved or maintain involvement. The third facet was conflict. This was recognised as being inherent in the role of being a consumer representative and there was fear of “getting caught in the middle if consumers want one thing and an organisation wants something different”. How to contend with conflict in an effective and positive manner was a matter of concern. The fourth facet was concern about being unequal in power and vulnerable in the context of a “the world of professionals”. The use of expert language and non-respectful management of meetings confirmed this understanding. Further, this was expressed as a fear of “being criticised, ridiculed, rejected or humiliated if others did not agree with their position”.

5. Effectiveness

The theme of effectiveness emerged in two distinct ways. The first manner in which the issue of effectiveness was expressed was as a “lack of confidence” about fulfilling the role of consumer representative. There was uncertainty expressed about the ability to meet others’ expectations of them and the ability to advocate effectively for an authentic consumer perspective. This concern about being effective was expressed as anxiety about personal ability to not be “too nervous or embarrassed to speak up” or “being too sensitive and defensive and hurt when conflict occurred rather than staying focussed on the key issues and not taking things personally.” Nevertheless, there was also recognition that personal capacity was not the only factor involved. The organisational context into which the individual came as a representative was particularly influential and could affect capacity for effectiveness. Effectiveness was also viewed as teaching staff from a “carer’s point of view” or providing staff with an understanding of different ethnic and religious backgrounds and thus influencing quality of care.

There was clearly an awareness amongst participants (irrespective of whether they have previously acted as consumer representatives or not) of the complexity of the role and the tasks associated with it.

Synthesis of the themes drawn from these papers indicates that consumers recognise that involvement can occur at different levels and that in the most overtly engaged level, involvement requires support, training in conjunction with a context that values such involvement.

While there is a paucity of articles or reports that directly examined consumers’ views regarding involvement in patient safety initiatives, it is important to recognise that this is an emerging field. We did locate publications in journals such as *Health Issues* where there were a number of articles that reported interviews that were conducted with consumer representatives. However, these publications were not able to be appraised as they did not provide details of the methodologies used. It is of note that the issues raised in the quotations drawn from some of these publications (refer Table 2) provides insight into the views some consumer representatives have about their experience of involvement at a level other than that of their own or family member’s safety (Please note these quotes are indicative of the rest of the interview from which they were drawn).

Qualitative articles or reports of consumer experiences of consumer involvement at the policy or organisational

The other commentaries that were found were publications of individual interviews with people about their experiences of being a consumer representative from an unpublished study carried out by Pilcher and others (Pilcher, 2007) in which there was no information about sampling or modes of analysis. In addition, we also located conference presentations by representatives of consumer organisations that commented on key issues about consumer experience of involvement but these were not publications of empirical research but rather viewpoints of the authors. Some of these authors were well placed to provide such comment as they were clearly involved in consumer groups but with others it was more difficult to discern what value to place on the commentary. We also located editorials, review style articles and newsletters of various organisations (hospitals, consumer groups and research organisations) that referred to issues of concern about consumer experience of involvement, and conference presentations which reported on consumer advisory committees or equivalents in the arena of quality improvement or boards of acute care organisations. While we would normally not include discussion of such literature given that it does not constitute empirical research (either quantitative or qualitative) and hence cannot be appraised using standard or even emerging appraisal tools we have in our discussion below provided some of the key insights using a both content and thematic analyses (Minichiello, Aroni, & Hays, 2008) in order to suggest areas for future research in this arena. The discussion below is couched in a narrative framework.

Even though these documents do not meet the inclusion criteria for the review they provide some guidance of what the key issues and concerns are about maintaining consumer involvement at the level of decision making. The issue of tokenism versus authentic or empowered involvement is repeated over and over both nationally and internationally in the grey literature. It is also evident that the mechanisms which are suggested as potential solutions are pragmatic and oriented to dealing with the administrative environment of committees, boards and panels. Hence, the proliferation of training sessions being offered to potential and current consumer representatives as a means of assisting improved skills in the settings where they are involved at the organisational and policy levels. Most of these training workshops and manuals include discussion of payment and the association with worth and status within the context of the involvement/representation process. Payment is also a means of ensuring continuity of involvement otherwise economic circumstances can prevent individuals from being able to engage over a longer period of time. They also indicate that acceptance and engagement is often dependent on individual health providers, or other organisationally powerful individuals are often needed to champion valuing of consumer input and the process of engagement. Safety and quality initiatives in acute care and other health care settings are often dealt with in such settings and consumers are more often to be found on such committees.

Articles or reports that examine clinician views of consumer participation indicate a split between those who welcome it and those who do not or are equivocal. These confirm consumer views in the grey literature where there is recognition of the culture that has already been discussed in the more general patient safety literature.

Table 2 Part One – concerns about tokenism

Theme	Quotation as Evidence	Reference
Professionals concentrate on planning, rather than equity of access.	*"I have to say that the professionals are great at planning things but they don't always appreciate the effects that this can have on the consumer. I feel professional representatives on committees can often be very focused on detail but as a consumer representative I try to focus on the basic principles of equity of access".*	Lowther, D., and Pilcher, J., (Winter 2008) Interview with Eleanor Sumner, *Health Issues,* 95:11
Doctors now involve health consumers in decision-making about their own treatment.	*"I think health consumer participation is almost the 'in thing' these days. I spoke to a social workers' group at [university] recently and I reminded them that once upon a time you went to the doctor and you told him what you thought was wrong—got an ache here or there—he examined you, wrote a prescription and said 'come back in a month or so when you've finished this'. Whereas now they will talk about the options or the side effects of treatment, increasingly so, and also take into account the consumers' wishes instead of telling them this is what you'll do. I think it [health consumer participation] is a growing force in health care"*	Lowther, D., and Pilcher, J., (Winter 2008) Interview with Eleanor Sumner, *Health Issues,* 95:11
Financial considerations constrain ideal operation of hospitals	*"It's given me a better understanding of how hospitals function and helped me to realise that as a consumer, there will be an ideal standard that I would like to see operating in all hospitals but I accept that finances are limited"*	Lowther, D., and Scott, S., (Winter 2008) Interview with Reg Shelley, *Health Issues,* 95:13

Theme	Quotation as Evidence	Reference
Numbers of consumers versus department heads	*"There were two consumers on their panel, and I really don't think we made a difference there [Melbourne hospital]. The first year I think I was out of my depth because it wasn't an ordinary consumer group, it was heads of departments. [The hospital] decided they needed some consumer input, but they didn't really know how to take it"*	Lowther, D., and Scott, S., (Autumn 2008) Interview with Iva Steinke, *Health Issues,* 94:7
Small changes make a difference. Learning is a two-way street.	*"At the [metropolitan health service], I think yes we made quite a few changes, they're minor but they make a difference to the consumer. We don't do a lot because we only meet every six weeks, but we do give opinions and I've learnt a lot which is good too"*	Lowther, D., and Scott, S., (Autumn 2008) Interview with Iva Steinke, *Health Issues,* 94:7
Poor treatment and concerns about safety and quality motivates involvement in Consumer Advisory Committees	*"[What got me involved] was personal, it was [the] treatment [that some people I knew received] and hearing horror stories from practically everybody that used these services, and I thought something needs to be done"*	Lowther, D., and Scott, S., (Autumn 2008) Interview with Iva Steinke, *Health Issues,* 94:7
Individual advocacy does not result in systemic change	*"You can advocate for that individual and you might get the outcome you want for that individual, but it doesn't give you systemic change. That's when I decided I need to move into systemic change because these things should no longer be happening"*	Lowther, D., and Pilcher, J., (Summer 2007) Interview with Sophy Athan, *Health Issues,* 93:7
Recognition of the key elements evident in patient safety literature about systems approaches and hospital culture but clear understanding that systems fixes may not alter cultures	*"I really think it's systemic, you've got system issues and culture, change the system, change the culture, because they're two separate things, you can have systems working, you can still have culture which is inappropriate culture. We're talking about health care and they're critical life threatening, life quality situations, they're not [like], go to this coffee shop, the coffee's lousy, move to the next one, it's not quite exactly the same"*	Lowther, D., and Pilcher, J., (Summer 2007) Interview with Sophy Athan, *Health Issues,* 93:8
Experience of being valued by provider groups	*"We sat with a lot of academics, a lot of doctors, medical doctors as well as administrator doctors, and the view of the ordinary man/woman, so to speak, was greatly appreciated by them because [you are] looking at a large committee made up of 90% of academics"*	Lowther, D., and Pilcher, J., (Summer 2007) Interview with Graeme Roberts, *Health Issues,* 93:9

Theme	Quotation as Evidence	Reference
Consistent concern found in much of the consumer literature about the need to provide financial support to maintain involvement over time and to provide status recognition	*"One of the things that it is important as a consumer rep is that you are paid as well. This is only just because all those professionals are paid for being there, for their time, even if they take an hour off work, they are still being paid for that time so why should a community representative have to pay out of [pocket expenses] or not get remunerated, because I know what I give—my contribution—is just as important as everyone else's"*	Pilcher, J., (Spring 2007) Veronica Gribble: Consumer Representative for Osteoarthritis, *Health Issues,* 92:7
Being a consumer representative restores the self-esteem that illness takes away	Being a consumer representative has been an empowering experience for Veronica, giving her opportunity to speak about her experiences with osteoarthritis in public and helping her regain some of the confidence that having a chronic condition has taken from her. *"Being a consumer rep has given me the confidence to speak about how I feel and it has empowered me to know that my osteoarthritis doesn't define me. I am not my osteoarthritis. I am a someone who just happens to have osteoarthritis. On the committee I wasn't treated like the 'poor thing with osteoarthritis' I felt I was given respect for who I was as an individual"*	Pilcher, J., (Spring 2007) Veronica Gribble: Consumer Representative for Osteoarthritis, *Health Issues,* 92:8
Recognition that consumer representatives require support in negotiating valuing of self and their own expert knowledge and status	*"Take confidence from your own experience and don't be cowed by other people because they are professionals. They might have the words [jargon] but they don't necessarily have the understanding that you have—your personal point of view. Don't be afraid to ask questions or put your contribution forward"*	Pilcher, J., (Spring 2007) Veronica Gribble: Consumer Representative for Osteoarthritis, *Health Issues,* 92:8

While it was not possible to engage in a formal synthesis of these interviews given the degree of editing that obviously took place for the purposes of their publication in the journal, it is possible to gain an inkling of the experience and perception of those experiences. The issues mentioned are not dissimilar to those found in the proxy articles or reports included.

It is also useful to note that there are other arenas in which consumer engagement takes place that could be regarded as having an impact on patient safety. We have provided a brief summary of a few of these with a view to including the insights that they may provide for policy development.

Guideline articles or reports and consumer involvement

Guideline development is an activity which can be construed as having a strong influence on improving patient safety through potentially improving clinical practice by providing clear clinical advice to clinicians.

We have included discussion of a study which was electronically published as a report on the National Institute for Clinical Excellence (NICE) website as one of the few articles or reports which did elicit views of consumers about involvement in policy development in the arena of guideline development. This was a qualitative article, conducted by Linda Jarrett and the Patient Involvement Unit of NICE in the UK (Jarrett, 2004) published on the Web in 2004 on the NICE website. Jarret et al conducted interviews with 36 patient/carer members of Guideline Development Groups of NICE as well as 19 Chairs of such groups (of 20 groups possible in total). Content analysis of responses was conducted and while themes were mentioned there were insufficient methodological details provided in the publication to determine the form of thematic analysis used. Nevertheless, the findings and discussion were produced sufficiently clearly to provide some understandings of the conclusions drawn by the authors regarding the views of consumers about their involvement.

The conclusions drawn by the authors indicated that while consumers found their experience overall to be a good one there were areas in which there were concerns about the ability to participate fully. They found that patient/carer members wanted more training and information to enable competent participation, as well as support throughout the process. Participants indicated that while meetings were in the main well run, Chairs of such groups needed to be selected on the basis of their chairing skills or otherwise be adequately trained. More significantly, they indicated that guideline development groups did sometimes dismiss patient and carer experiences and that one means of preventing this was to ensure a dedicated item on the agenda to discuss patient /carer issues. There was also a consistent view that there was a need to draw on other patient views and this required funding. In addition there were participants who indicated that they wanted systematic reviewers to have better training in the use of qualitative research data and that this was currently lacking and hence was not used adequately. Interviews with the Chairs produced similar results. Variability of patient carer members in understanding of complex scientific issues was also raised by the Chairs interviewed and their response was similar in requesting training and information to be provided but there was uncertainty as to what was possible without altering the parameters of involvement. Another central concern was determining the acceptability of patient/carer members using their parent organisation as a source of information to inform their contributions.

Consumer involvement in the training and education of health professionals

If we accept that there is a significant portion of the patient safety literature is concerned with the issue of culture change, then it would be important to examine the views of consumers about being involved in altering that culture. Repper and Breeze (Repper, 2006) conducted a literature review which examined user and carer involvement in training and educating health professionals. Three of the articles they reviewed (Mansfield et al, 1982; Rudman, 1996) and (Forrest et al, 2000) reported on consumers' views about what healthcare workers should be taught. In each case the consumers were pleased to be involved in the process and hoped that they would have an impact. Consumers chose to become involved in an effort to improve services or through 'a wish to give something back'. However, there were no detailed reports specifically mentioning patient safety. Repper and Breeze indicate that several of the articles included in their review emanate from the field of mental health. We might hypothesise that given the stigma and discrimination that have been evident in the field for over a decade that consumer perception may be that they are engaged in preventing iatrogenic illness occurring through their involvement in training and education of budding health professionals.

Key messages

1. The capacity building process for consumer representatives' optimal participation in committees and advisory groups that deal with patient safety initiatives should be viewed as a joint partnership with three partners – the health system and health services personnel, health consumer organisations, and the individual health consumer representative rather than the sole responsibility of the individual consumer representative.

2. In order to maximise the capacity for consumer involvement consumers need to be supported to feel able to engage confidently and effectively. This would require training, material and financial support and access to mechanisms to enable adequate representation strategies to be used.

Key recommendations

1. Close the gap in the literature by conducting a national study of consumer representatives' views on nature, level and effectiveness of involvement in patient safety initiatives at both organisational and health system level.

2. Ensure that engagement strategies use knowledge from such a study to enable maximisation of consumer involvement and effectiveness.

4 Part Two (Addressing Questions Two and Three of the Review)

4.1 Introduction

As stated previously this review was undertaken in two parts; Part One addressed the first question as it was likely that the majority of research on this area would be qualitative in nature and /or advocacy documents. This was undertaken by an expert in qualitative methods.

This section, Part Two incorporated questions likely to be addressed by mixed methods studies and quantitative evaluations and was undertaken by researchers with expertise in systematic review methodology for both quantitative and qualitative research.

The questions answered in Part Two are:

2. What are the different methods and processes that could be used to effectively involve patients, consumers and the public in the planning, development and implementation of patient safety initiatives and programs?
    a. Have any of these methods or processes been evaluated?
    b. What are the critical success factors for these methods and processes?
    c. What are the limitations of these methods and processes?
3. What are the outcomes of involving patients, consumers and the public in the planning, development and implementation of patient safety initiatives and programs?

4.2 Methodology

Criteria for considering potentially relevant articles or reports

Types of Participants

Articles or reports that described inclusion of patients, consumers or the public were considered for inclusion in the review. The terms ‘patient’, ‘consumer’ and ‘the public’ were operationalised using definitions from the Commission:

- Individual patients who have received or are receiving care;
- Consumers who have a specific interest in health, but who may not be currently receiving care;
- Organisations that represent groups of consumers;
- Members of the public who have an interest in broad decision making or policy regarding patient safety.

Types of Interventions

Articles or reports that described or reported a method or process of involving patients, consumers and/or the public in the planning, development and/or implementation of patient safety initiatives or programs were considered for inclusion in the review.

Articles or reports that described methods or processes of patients improving the safety of their own care were excluded (as requested by the Commission).

Types of Outcome Measures and Data Extracted

For all articles and reports meeting ‘Participant’ and ‘Intervention’ selection criteria, the following information was extracted for the review:

- participant details
- description of interventions (i.e. methods and processes of consumer engagement) and any comparisons where available.

For those articles and reports reporting an *evaluation* of the method or process of participation, the following outcome measures were extracted (where reported by individual studies):

- participation or response rates of consumers
- consumer influence on decisions
- healthcare outcomes or resource utilisation
- consumers’ or professionals’ satisfaction with the involvement process or resulting products
- cost
- critical factors for success
- limitations of methods or processes.

Types or Articles or Reports

No restriction on study design was applied to descriptive reports of methods or processes of involving patients, consumers or the public in the planning, development and/or implementation of patient safety initiatives or programs (answering Question 2).

Articles or reports involving an *evaluation* of methods or processes (answering Question 2a-c and 3) were considered for inclusion if they were randomised or quasi-randomised controlled trials, interrupted time–series analyses, or controlled before and after studies.

Articles or reports were only considered for inclusion if they were published in English over the past 10 years (1998 to 2008).

Search methods for identification of articles or reports

Electronic searches of the following bibliographic databases were undertaken in May 2008;

- ABI / Inform
- Medline
- Embase
- Cumulative Index to Nursing & Allied Health Literature (CINAHL)
- PsychInfo
- Cochrane Central Register of Controlled Trials
- Cochrane Database of Systematic Reviews
- Database of Abstracts of Reviews of Effects (DARE)
- Health Technology Assessment Database
- Factiva
- SIGLE
- Sociological Abstracts.

The search was undertaken by an independent search specialist with extensive experience in conducting and providing expert advice on search methodologies. The reference lists of all included studies were hand searched to identify further relevant studies.

The search strategies for each database are presented in Appendix 1.

In addition, a search of the grey literature was undertaken using the following databases:

- Google Scholar
- Internet websites using Google and Clusty.

Broad searches were conducted and any relevant material was selected and recorded.

Relevant websites are listed in Appendix 1.

The broad search strategy is outlined in Appendix 1.

Methods for screening articles and reports

Members of the project team selected the articles and reports for inclusion in the review by applying the eligibility criteria (as listed above) to all retrieved citations or material.

Firstly, the titles and abstracts (where available) of all citations retrieved from the search were reviewed for eligibility by at least one member of the project team, at which point citations were either excluded as not relevant or identified as possibly relevant. The full-text of all citations considered to be possibly relevant were retrieved and reviewed for eligibility.

In instances where the decision to include an article or report was unclear, a second member of the project team independently assessed the article or report for eligibility and any disagreement was resolved by consensus.

Assessment of quality, data extraction, and synthesis of results

Members of the project team extracted data from included articles or reports using a standardised data extraction form. Information was collected on study purpose, methods (including participant details and a description of methods or processes of involvement), findings (including outcome measures where reported), limitations and comments. Extracted data was checked for accuracy by a second member of the project team. Any discrepancies were resolved by discussion and consensus.

The project team undertook an assessment of methodological quality of included articles, where they were evaluative in nature (i.e. constituted one of the following study designs: randomised or quasi-randomised controlled trial, interrupted time–series analysis, or controlled before and after study). A descriptive approach to quality assessment was planned, taking into consideration the following risk of bias domains, depending on study design:

- For randomised or quasi-randomised controlled trials the following domains were assessed: sequence generation, allocation concealment, blinding of outcome assessors, incomplete outcome data, selective outcome reporting, other sources of bias.
- For interrupted time–series analyses and controlled before and after studies the following domains were assessed: protection against secular changes (the intervention was independent of other changes, there were sufficient data points to enable reliable statistical inference, formal test for trend conducted), protection against detection bias (intervention unlikely to affect data collection, blinded assessment of primary outcome), completeness of data set, reliable primary outcome measures.

A narrative, descriptive synthesis was conducted to summarise the information identified from descriptive articles and reports of methods or processes of involving patients, consumers or the public in the planning, development and implementation of patient safety initiatives or programs (answering Question Two).

A quantitative synthesis (meta-analysis) was conducted where studies involving an *evaluation* of methods or processes (with homogeneous methods and outcomes) were found.

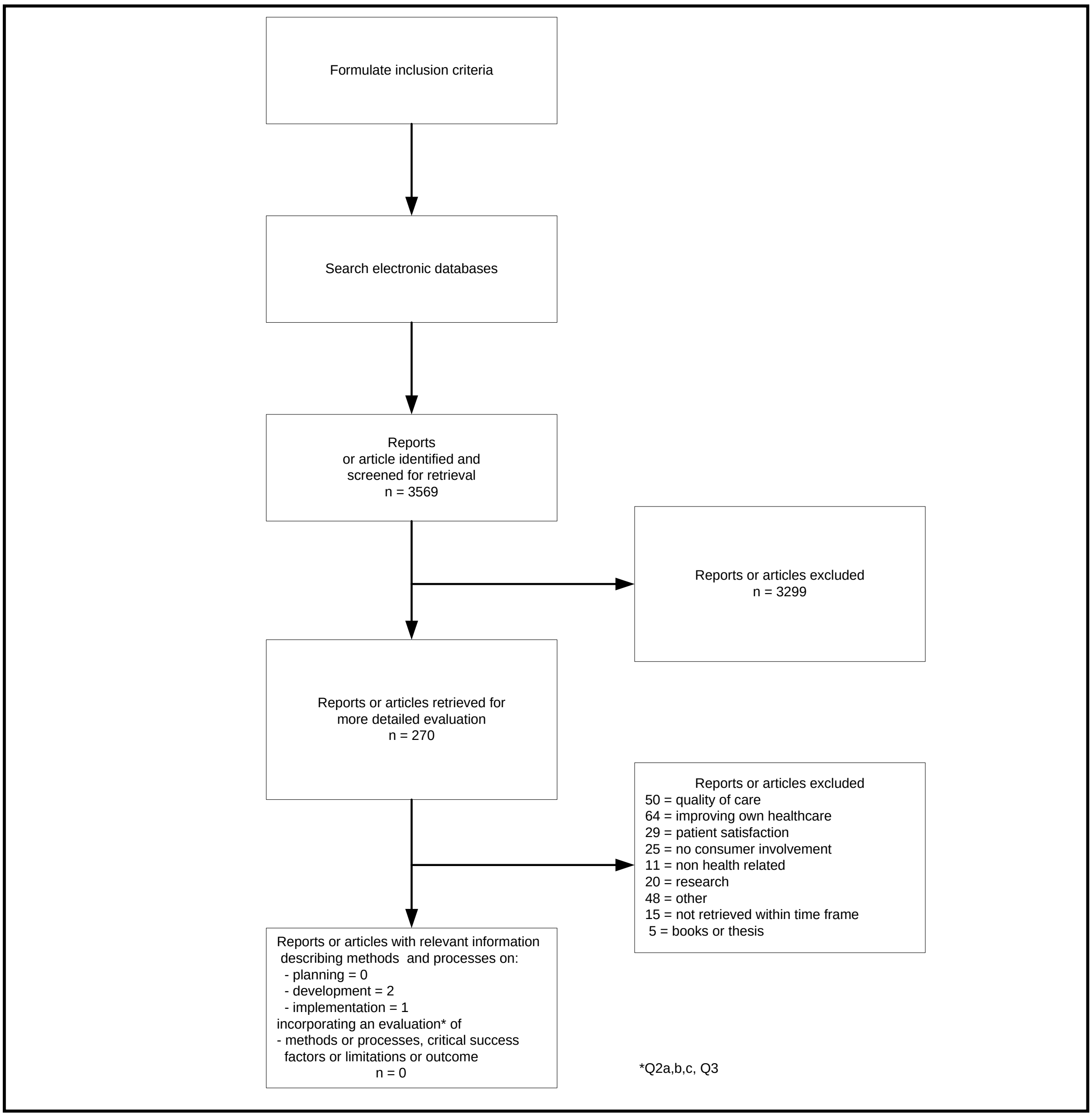
4.3 Results

Articles and reports identified

The results of the electronic database searching are illustrated in Figure 3 below.

A total of 3569 potentially relevant articles or reports were identified from the search of the electronic bibliographic databases. Three thousand two hundred and ninety nine articles or reports of the 3569 were screened and subsequently excluded as not being relevant to the review question. Two hundred and seventy full-text papers were retrieved for more detailed evaluation (i.e. a decision on inclusion could not be reliably made on the basis of title and abstract information). Of these, 267 were subsequently excluded for reasons including: not reporting consumer involvement (n=25), focusing on consumer involvement in quality of care generally (n=50), and focusing on consumer involvement for improving their own healthcare (n=64) (see Figure 3 and Appendix 1 for more detail). Three articles were found to explicitly meet the selection criteria of this review.

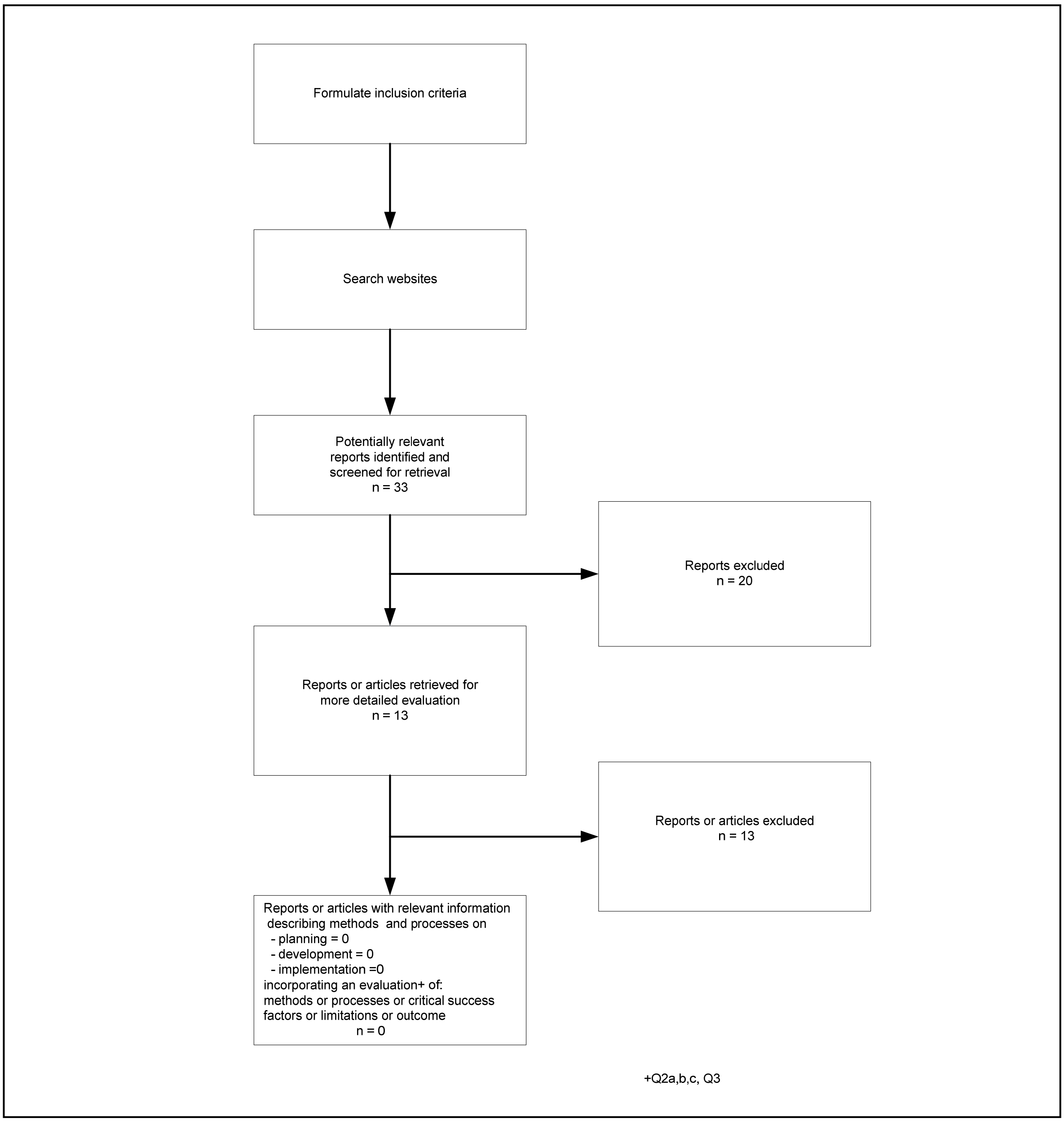
Figure 3 Part Two - Flowchart of the process to identify & select articles or reports from electronic databases



The results of the website searching are illustrated in Figure 4 below.

A total of 33 potentially relevant reports were identified from the search of the grey literature. Twenty reports were screened and excluded as not being relevant to the review question. Thirteen reports were retrieved for more detailed evaluation, all of which were subsequently excluded as they did not meet the selection criteria of this review.

Figure 4 Part Two - Flowchart of the process to identify & select grey literature & search results from Google Scholar



Articles and reports included

This section presents and discusses the major findings from the included articles and reports pertaining to the engagement of patients, consumers and the public in patient safety initiatives and/or programs.

Three articles that satisfy the eligibility criteria for this review were included from the search of bibliographic databases (Figure 3). Two of these (Evans, 2006; Long, 2008) reported methods to involve the public in the development of patient safety initiatives and one (Wale & Moon, 2005) reported processes to involve consumers in the implementation of patient safety initiatives. No studies examined the effectiveness of methods or processes to engage consumers in patient safety initiatives, therefore no data on outcomes or critical success factors is available.

A substantial proportion of the citations retrieved from the search of bibliographic databases, and for which we obtained the full text publication for more detailed evaluation, focused on individual patients' involvement in improving the safety of their *own* health care (i.e. 64/270; see Figure 3). These articles did not meet the eligibility criteria for this review (i.e. they did not address patient safety initiatives at an *organisational* level). They may provide some useful insights and strategies for engaging consumers in health care generally and thus some relevant articles have been summarised and are included in Appendix 3 for general information.

We did not identify any reports or documents in our search of the grey literature which satisfied the eligibility criteria for this review. Many of the documents relate to methods of consumer participation generally and may provide some useful insights; therefore some relevant documents have been summarised and are included in Appendix 3.

Description of included articles

Evans et al (2006) examined interview data from almost 3000 members of the South Australian public to seek opinion on the rate and severity of adverse events experienced in hospital and the public perception of safety in public hospitals. They undertook their analysis to identify predictors of lack of safety in hospitals and to identify possible strategies to address safety concerns. Their descriptive analysis of interview data uncovered that (i) consumer self- reported adverse event rate in hospitals (7%) was similar to that identified using medial record review (3-16%), (ii) individual experiences of, or knowledge about, adverse events have negative impacts on consumer confidence in public hospital safety, and (iii) a significant proportion of included participants felt unsafe in hospital. Strategies, such as pre-admission hospital orientation and early discharge with hospital-in-the-home services, are suggested by the authors to specifically address the needs of patients requiring hospitalisation who may feel unsafe prior to admission. No strategies are suggested to redress the public perception of hospital safety.

Long et al (2007) conducted in-depth discovery interviews with 15 consumers who had experienced an adverse event in hospital (e.g. a fall, hospital-acquired infection or medication error), to elicit their perspectives on the barriers to, and enablers of, safe, high quality care. This data was synthesised and results validated by the participants and the hospital's Consumer Advisory Committee. Following validation clinicians and hospital quality managers discussed the results and recommendations for practice were made with a view to improving consumer care and reducing the incidence of adverse events in hospital with the ultimate aim of improving patient safety outcomes and reducing adverse events. The recommendations for practice were summarised as (i) the assessment and prevention of risk should be undertaken for all aspects of care to minimise the occurrence of an adverse event on an individual basis; (ii) education and communication strategies should be in place to ensure consumers are a) adequately informed of the occurrence and the following processes should they experience an adverse event, b) provided with evidence-based consumer information pamphlets, c) aware of the risk of adverse events and safe practices in hospital, and d) provided with a holistic approach to care by adequate communication between departments involved in their care; and (iii) the hospital environment should be such that it reduces the risk of adverse events e.g. equipment placed appropriately to minimise falls risk, regular audit and assessment of patient areas to reduce the incidence of adverse events, signage designed with consideration of consumer requirements. These recommendations highlight the significant contribution consumers' bring to the identification and development of patient safety initiatives at an organisational level.

Wale et al (2005) present a series of case studies describing various methods to involve patients and family members in patient safety initiatives in a mental health service in the US with the aim of promoting the safest and most successful treatment. Approaches discussed include (i) the establishment of a Consumer Representative to facilitate the involvement of patients and their families in improving service delivery; (ii) the implementation of a communication training program for patients and families to facilitate dialogue on their perspective of care with staff and the identification of what could be done differently; (iii) the introduction of patient and consumer counsellors and a consumer case manager in an inpatient mental health rehabilitation unit; and (iv) a parent advocate to facilitate the engagement of parents at all points of entry into mental health services for adolescents.

Additional detail on the included articles is provided in the summary tables.

Summary tables

The tables below provide a summary of the retrieved articles and reports.

Table 3 **Part Two - included article by Evans et al 2006**

Title: Consumer perceptions of safety in hospital

Author: Evans SM, Berry JG, Smith BJ, Esterman AJ

Research Purpose	Methods	Findings	Limitations of study	Comment
To identify predictors of lack of safety by seeking public opinion on: • the rate and severity of adverse events experienced in hospital, • the perception of safety in public hospitals.	A multi stage clustered survey. People > 18 years of age in metropolitan Adelaide and country towns in South Australia. Interviews = 2, 945 Face to face survey (interviews) over a three month period in 2001. Data on the following was obtained from participants: • occurrence and severity of adverse events; experienced in hospital either by the participant or a member of their current household; • their perception of the safety of public hospitals. A descriptive analysis was undertaken to determine the adverse event rate and severity. This was limited to interviewees aged over 40 years.	The experience of adverse events has a negative impact on public confidence in hospitals. Consumer-reported adverse event rate in hospitals (7.0%) is similar to that identified using medical record review (2.9% - 16.6%). The study also highlights that: • Individual experience of an adverse event or knowledge of an adverse event has a negative impact on consumer confidence in public hospital safety. • A significant proportion of the participants felt unsafe in hospital. • The true incidence of adverse events in hospitals is underestimated, given that many adverse events are not recoded in medical records. The authors conclude that consumers who feel unsafe visiting hospitals and who are required to be hospitalised, could benefit from strategies such as pre-admission hospital orientation and early discharge with hospital in the home services in allaying their fear. These and other strategies need to be considered when developing ways to best meet the patient’s needs.	The authors noted the following limitations: 1. There was no defined interpretation of an adverse event; this was subjective to participant interpretation of a lay person definition. Respondents may not have construed this definition in the same way as medical reviewers, who used strict criteria. 2. There were inherent risks when using data based on a person's recall; namely limitation of the amount and type of information retained by people over time (recall bias). 3. The respondents were only asked to rate one adverse event. For those who had experienced more they may have reported only the most severe adverse event, resulting in an overestimate of severity and an underestimate of the adverse event rate. 4. Adverse event rates may have been underestimated by respondents being unfamiliar with household members' medical history or because errors may have been concealed from them.	When interviewing patients language can make a significant difference to the responses given. The use of plain jargon-free language is critical in conducting in-depth interviews.

Table 4 **Part Two - included article by Long et al 2007**

Title: Engaging consumers in safety and quality at Royal Adelaide Hospital

Author: Long L, Pearson A, Page T, Jordan Z

Research Purpose	Methods	Findings	Limitations	Comments
To develop recommendations, and strategies, for consumer input into a large tertiary hospital's safety and quality initiatives based on their experiences. To evaluate the degree to which capturing narrative accounts of consumer's experiences of compromised safety and quality can contribute to patient safety and quality initiatives in a large tertiary teaching hospital.	In-depth discovery interviews were conducted with 15 consumers who had experienced an adverse event (such as a fall, occurrence of a pressure-related ulcer, a hospital acquired infection or medication error) in hospital to identify strategies that could contribute to the improved safety outcomes in hospital and a reduction in adverse events. Results from the consumer interviews were thematically analysed and validated by participants and the hospital's Consumer Advisory Committee. The validated results were discussed with health professionals and recommendations presented to the hospital Safety and Quality Unit.	Many of the causes for adverse events identified by consumers in this study are congruent with the literature. The use of consumer in-depth discovery interviews facilitated the identification of a number of strategies that could contribute to improved safety outcomes in hospital and reduce the incidence of adverse events: • Assessment of risk undertaken and strategies devised to prevent adverse events on an individual basis. • Education and communication strategies e.g. consumers adequately informed following an adverse event, in the development of consumer information pamphlets, raising consumer awareness of risk of adverse events, safe practices in hospital. • The hospital environment should be such that it reduces the risk of adverse events e.g. equipment placed appropriately to minimize falls risk, regular audit and assessment reduce incidence of adverse events, consumer requirements for signage etc.	No evaluation of the use of in-depth discovery interviews as a method of involving patients was undertaken. There is no discussion on the limitations on the use of in-depth discovery interviews by the authors. Limitations discussed by the authors refer to the recruitment of participants and terminology used in the in-depth discovery interviews. A factor (but not identified as a critical success factor by the authors) to consider if using in-depth discovery interviews is language. When interviewing patients language can make a significant difference to the responses given. The use of plain jargon free language is critical in conducting in-depth interviews.	This article provides a useful insight on the use of patient interviews and perspectives of adverse events to identify potential patient safety initiatives from the patient's perspective. Consumer perspectives on adverse events have significant potential to inform the development of safety initiatives. This publication identifies some recommendations for possible future safety and quality initiatives. The identification of barriers and enablers of safe care as identified by the consumers positions consumers as possessors of valuable knowledge related to systems and practices rather then receivers of knowledge and information. This study provides a foundation upon which future research may be conducted.

Table 5 **Part Two - included article by Wale & Moon 2005**

Title: Engaging patients and family members in patient safety – the experience of the New York City Health and Hospitals Corporation

Author: Wale JB, & Moon CSW

Purpose	Method of involvement	Findings	Limitations	Comments
To describe, using case studies, the approaches undertaken by New York City Health and Hospitals Corporation (HCC) to involve patients and their family members in patient safety initiatives in a mental health service.	The following methods of involvement are described: 1. Involvement of a consumer advocate in the development of a training curriculum on self management strategies and communication skills for staff-patient and consumer-consumer interactions.	All findings reported are anecdotal. 97% of participants rated the experience as good to excellent.	This is a qualitative article describing case studies so there is no discussion of an evaluation, limitations or success factors of the methods described. Similarly outcomes are not discussed. Other case studies are described within this article but refer to the involvement of patients and their family members in improving the safety of their own care rather than in patient safety initiatives or programs from an organisational perspective.	The article describes a number of case studies using innovative and interesting approaches to involve patients and consumers in the planning, development and implementation of patient safety initiatives.
	2. Implementation of ‘patient providers’ (peer counsellors) as members of the clinical team on an inpatient mental health unit.	Inpatient units with peer counsellors reported the atmosphere to be calmer and fewer patient conflicts.		
	3. Implementation of a parent advocate at a children and adolescent psychiatry outpatient service once a week. The parent advocate offered services such as support groups and training for parents, and helped in the communication between parents and clinicians.	No findings are discussed regarding the implementation of a parent advocate.		
	4. Implementation of a Consumer Case Manager who worked with patients and their families on issues related to transition from inpatient to community care and provided outreach to improve treatment compliance.	No findings are discussed regarding the implementation of a parent advocate.		
	5. Patients and families were engaged in improving patient safety during the planning for development and /or renovation of buildings. Families had an opportunity to review architectural drawings and models, attend focus groups to discuss how to design more modern facilities and enhance the environment.	No findings are discussed regarding the implementation of a providing patients and families a safe and therapeutic environment.		

4.4 Synthesis of findings

This section presents the themes and issues identified in the literature answering the specific questions:

- *What are the different methods and processes that can be effectively used to involve patients, consumers and the public in the planning, development and/or implementation of patient safety initiatives and programs at an organisational level?*
- *Have any of these methods or processes been evaluated? What are the critical success factors, and what are the limitations for these methods and processes?*

We identified no articles or reports that conducted an evaluation of the methods or process of participation i.e. no outcome measures were reported.

The key themes drawn from the three articles described in the previous section are summarised below:

- Consumers are significant contributors to patient safety. Because of their experiences, consumers bring a different perspective to patient safety initiatives.
- Consumer self-reported estimates of adverse events are similar to medical record review. Claims of past adverse events by consumers appear to be credible.
- Studies investigating adverse events have principally been undertaken from the medical perspective. The involvement of consumers of health care on how systems and practices of care can be changed to improve safety is a significant addition to the area of patient safety.
- Consumer insights into the identification of adverse events can be used to inform the development of potential strategies to improve safety. Interviews with consumers to elicit barriers and enablers of safe, high quality care, as identified and viewed as important to them, should be considered in the development of safety initiatives targeting adverse events. This will result in meaningful outcomes from the perspective of the consumer.
- Consumers feel strongly that the hospital environment should be such that it reduces the risk of an adverse event and they are able to identify possible strategies to improve safety.
- Involving consumers and service providers in the process of identifying safety and quality issues can strengthen the relevance of the changes being introduced and identify priorities for patient safety initiatives.

5 Discussion

5.1 Discussion of gaps in the literature

This comprehensive literature review of both academic journals and the grey literature has identified a large number of articles and reports (n = 9028) referring to patient engagement in health care, with very few identified as directly relevant to the engagement of patients, consumers and the public in patient safety initiatives or programs.

We found very few primary research articles involving robust research methodologies. Even fewer articles relate to situations where consumer input and engagement does not describe the way patients contribute to improving the safety and quality of their own health care. The scant literature available suggests there is currently little direct involvement by consumers in patient safety initiatives or programs, little information on what factors might change this and that even if involvement were to increase, it is not certain that consequent patient safety initiatives would improve outcomes.

The qualitative information relating to consumer attitudes to involvement in safety and quality initiatives, suggests that practical barriers such as parking, transport, payment for lost time and poor health, may be less important than attitudinal factors such as interest, time prioritisation and lack of confidence in their ability to participate with health professionals on committees and planning groups. Some consumers rightly perceive a degree of “tokenism” in the recruitment of patients on committees. Certainly, involvement where a “token” consumer is appointed to a committee with no clearly defined role or voice is unlikely to influence outcome. There have been no studies examining the impact of educational programs to improve consumer involvement, either general programs aimed at all patients or those targeted at individuals beginning participation in safety initiatives. In addition, there have been no articles examining the impact of training health professionals on how to involve consumers in groups to improve patient safety. It is important that initiatives to improve participation are evaluated to demonstrate effectiveness.

Although many commentators have supported the involvement of consumers to assist with the development, planning and implementation of patient safety initiatives (Alvarez 2006, WHO 2008), this review has shown that there are no robust studies that have demonstrated that such involvement has resulted in better patient outcomes or patient perception of improvements in patient safety. A number of articles suggest that some clinicians may feel uncomfortable with participation by consumers on committees, especially when technical information is being discussed (Boote 2002, Perkins 2002). If there is to be a significant investment directed at increasing consumer involvement, then evidence of benefit and the circumstances where consumer involvement is most beneficial, must be provided.

There is a considerable body of literature relating to involvement in improving personal patient safety and this is generally positive and provides some insight into the more common methods of consumer engagement such as changing the culture of health care professionals and empowering consumers’ (Davis 2007, Entwistle 2007). However, even in this domain there is a lack of robust evidence (beyond case studies) to demonstrate improvements in patient outcomes and the effectiveness of different methods and processes of consumer involvement due to the scarcity of outcome evaluation. This important topic was specifically excluded from this review, as requested by the Commission. Similarly development of policies, guidelines and patient information leaflets with consumer involvement has been reported and associated with positive outcomes (see

Appendix 3). Generally the consumer involvement in these studies was seen as positive because of the different perspective and understanding of patient concerns that were not apparent to health professionals.

Most of the literature does not clearly articulate what a “consumer” is. Older or sick patients are often not in a physical or mental condition to participate actively in health care planning or implementation. Equally, the relatives may not represent the view of the patient concerned, and in some cases, the views might be contrary to the views expressed by the patient. The most vulnerable consumers – those who are older, indigent, or from a culturally diverse background - may not feel confident or may be unable to participate in health care activities. Therefore the most vocal, educated groups will tend to get priority, thus potentially perpetuating inequality in healthcare. In addition, many consumer lobby groups have “professional” consumers who will attend meetings to “represent” consumers. There is nothing to suggest that these consumers would have additional insights for specific patient groups. Some patient groups, especially those relating to chronic disease, have well organised and representative lobbyists who are able to articulate the major concerns of patients (e.g. cystic fibrosis or HIV); however this approach is more challenging when dealing with trauma victims or other acute illnesses.

This review confirms the findings by Grol, Berwick and Wensing (2008). In their recent analysis of the imperatives for the quality and safety research agenda they describe ‘a poverty of research’ to inform decisions about how to improve the delivery of health care. These international experts argue for further research on the needs of specific groups of patients, and their role in improving the quality and safety of health care. To achieve this they recommend partnerships be created with patient groups and organisations to support research and development into the quality and safety of health care.

As with any review of the literature the articles and reports identified are dependant on the search terms used. While a rigorous search of the literature has been conducted, the articles and reports identified are a reflection of the search terms used.

In conclusion there is a substantial gap in the evidence about methods and processes of effective engagement of patients, consumers and the public in patient safety initiatives at an *organisational* level. This is despite the fact that patient safety has always been a goal of health care delivery. Based on the findings from the literature reviewed, we are unable to draw any conclusions about the relative effectiveness of methods of consumer involvement in patient safety initiatives at an *organisational* level.

5.2 Recommendations for future policy/research and /or practice

Evidence for consumer involvement in patient safety initiatives is limited and involvement of consumers is unlikely to occur without active recruitment programs. Given the considerable investment required to develop an active consumer voice on committees involved in patient safety initiatives, it is essential that further research is undertaken. In addition, consumer involvement in personal safety was not specifically evaluated by this systematic review; this is an important area that requires evaluation. The following program of research is suggested:

- Identify patient safety initiatives in Australia (and internationally) where consumers are actively involved (observational and survey studies).
- Identify factors that have enabled this participation (studies could be undertaken by comparing organisational elements between groups involved in patient safety initiatives – qualitative and quantitative).
- Undertake studies to evaluate implementation of organisational elements that facilitate consumer involvement (This could be using historical control or even randomised control trial design – qualitative and quantitative studies)
- Evaluate the impact of consumer involvement in patient safety initiatives. This could initially involve observational and qualitative study designs to identify likely effects, such as identifying how consumers influence the process and what safety initiatives are important from their perspective. Ideally a controlled study (historical, randomised control trial design) would follow to demonstrate differences in outcome.
- Identify specific areas where consumer involvement appears most useful.
- Following this research program, a guideline for consumer involvement in patient safety initiatives could be developed. Prioritisation of implementation could be based on likely effect of consumer involvement.

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Appendix 1 - Detailed search strategies

A. Part One

Grey literature websites

Grey literature was gathered from the websites listed in Table 6 below.

Table 6 Part One - grey literature websites searched & search results

Website	Website address	Date Searched	Yield/Results Returned
Department of Health UK	http://www.dh.gov.uk/en/index.htm	16/05/08	22
UK Clinical Research Collaboration	http://www.ukcrc.org/default.aspx?page=0	16/05/08 20/06/08	2
Activity Log UKCRC	http://www.ukcrc.org/PDF/PPI%20Activities%20Log%20-%20March%2008.pdf http://www.ukcrc.org/patientsandpublic/currentppiprojects.aspx	16/05/08	1
People in Research UK	http://www.peopleinresearch.org/	16/05/08	0
Community Health Involvement & Empowerment Forum	http://www.chiefcic.com	16/05/08	0
National Institute for Health Research	http://www.nihr.ac.uk/Default.aspx	16/05/08	1
National Cancer Research Centre UK	http://www.ncrn.org.uk/	16/05/08	4
NHS Centre for Involvement	http://www.nhscentreforinvolvement.nhs.uk/	16/05/08	15
Picker Institute	http://www.pickerinstitute.org/	16/05/08	1
Picker Institute Europe	http://www.pickereurope.org/page.php?id=59	9/05/08	29
Action Against Medical Accidents	http://www.avma.org.uk/	16/05/08	1
Connecticut Center For	http://www.ctcps.org/resources.cfm	16/05/08	0

Website	Website address	Date Searched	Yield/Results Returned
Patient Safety			
Consumers Advancing Patient Safety	http://www.patientsafety.org/	25/5/08	9
PULSE	http://www.pulseamerica.org/	16/05/08	0
Institute for Clinical Evaluative Studies	http://www.ices.on.ca/webpage.cfm?site_id=1&org_id=26	16/05/08	2
Ottawa Health Research Institute	www.ohri.ca/DecisionAid	6/5/08	5
Finding Consumers and Carers	http://svc244.wic005v.server-web.com/consumers/	16/05/08	0
Australian Government Websites			
ACT Health	http://www.health.act.gov.au/c/health	6/5/08	3
Australian Commission on Quality and Safety in Health Care	http://www.safetyandquality.gov.au/	16/04/08	24
Department of Health and Ageing	http://www.health.gov.au/	7/05/08	4
Department of Health WA	http://www.health.wa.gov.au/home/	16/05/08	4
Health Care Complaints Commission	http://www.hccc.nsw.gov.au/	16/05/08	1
Health Consumers of Rural and Remote Australia	http://www.agric.nsw.gov.au	16/05/08	2
Mental Health Unit, S.A Department of Health	http://www.dh.sa.gov.au/mental-health-unit/	16/05/08	2
New South Wales Department of Health	http://www.health.nsw.gov.au/	14/05/08	6
Northern Territory Department of Health and Families	http://www.health.nt.gov.au/index.aspx	14/05/08	3
Queensland Health	http://www.health.qld.gov.au/	14/05/08	8

Website	Website address	Date Searched	Yield/Results Returned
Queensland Health - Multicultural Health	http://www.health.qld.gov.au/multicultural	13/05/08	0
Safety and Quality in Health	http://www.safetyandquality.sa.gov.au	13/05/08	3
South Australian Community Health Research Unit	www.sachru.sa.gov.au/	13/05/08	0
South Australian Department of Health	http://www.health.sa.gov.au/	13/05/08	2
Tasmanian Department of Health and Human Services	http://www.dhhs.tas.gov.au/	13/05/08	2
The Cancer Council of SA	http://www.cancersa.org.au/	13/05/08	3
Victorian Department of Human Services	http://hnp.dhs.vic.gov.au/wps/portal	13/05/08	6
Victorian Department of Human Services	www.health.vic.gov.au/consumer	13/05/08	0
Women's Health Statewide	http://www.whs.sa.gov.au/	13/05/08	0
Women's Health Victoria	www.whv.org.au	13/05/08	0
Australian Organisational Websites			
Aboriginal Health Council of South Australia	http://www.ahcsa.org.au/	16/05/08	1
ACSA: The AIDS Council of South Australia	http://www.acsa.org.au/	13/05/08	0
Alzheimer's Australia (SA)	http://www.alzheimers.org.au/	16/05/08	
Asthma SA	http://www.asthmasa.org.au/	16/05/08	
Asylum Seeker Resource Centre	http://www.asrc.org.au	16/05/08	
Australian Council on Health Care Standards	http://www.achs.org.au/	9/05/08	0
Australian Health Care Alliance	www.healthreform.org.au	9/05/08	0

Website	Website address	Date Searched	Yield/Results Returned
Australian Health Policy Institute (AHPI)	www.ahpi.health.usyd.edu.au.	9/05/08	0
Australian Indigenous Health Promotion Network	www.indigenoushealth.med.usyd.edu.au	13/05/08	0
Australian Institute of Health Policy Studies	www.aihps.org	13/05/08	9
Australian Mental Health Consumer Network	http://www.amhcn.com.au/	13/05/08	4
Australian Policy Online	www.apo.org.au	13/05/08	
Australian Refugee Association	http://www.ausref.net/	13/05/08	
Breast Cancer Network Australia	www.bcna.org.au	9/05/08	11
Brisbane Refugee and Asylum Seeker Health Network	http://www.brashn.org.au	9/05/08	0
Carers Association of SA	http://www.carers-sa.asn.au/	13/05/08	0
Carers Australia	www.carersaustralia.com.au	13/05/08	
Carers Victoria	www.carersvic.org.au	13/05/08	
Centre for Cultural Diversity in Ageing	www.culturaldiversity.com.au/Home/tabid/181/Default/aspx	20/05/08	4
Chronic Illness Alliance	http://www.chronicillness.org.au/	9/05/08	4
Cochrane Collaboration Consumer Network	http://www.cochrane.org/consumers/homepage.htm	9/05/08	4
Commonwealth Fund	www.cmwf.org/publications/	13/05/08	
Consumers' Health Forum	www.chf.org.au	9/05/08	23
Cooperative Research Centre for Aboriginal Health	www.crcah.org.au/index.cfm	9/05/08	3
Council on the Ageing SA	http://www.cota.org.au/states.htm	9/05/08	0

Website	Website address	Date Searched	Yield/Results Returned
Council on the Ageing (Victoria)	www.cotavic.org.au/	9/05/08	0
Deaf SA	http://www.deafsa.org.au/main/	9/05/08	1
Diabetes Australia (Vic)	www.dav.org.au	9/05/08	0
Diabetes South Australia	http://www.diabetessa.com.au/	9/05/08	0
Disability Information Resource Centre	http://www.dircsa.org.au/	13/05/08	2
Epilepsy Foundation of Victoria	www.epinet.org.au	13/05/08	0
Federation of Ethnic Communities' Councils of Australia (FECCA)	http://www.fecca.org.au	9/05/08	3
Genetic Support Network Victoria	www.gsnv.org.au	13/05/08	1
Headroom: Mental Health for Young People	http://www.headroom.net.au/	13/05/08	0
Health Care Consumers' Association ACT	www.hcca.org.au	16/04/08	3
Health Consumers Alliance of South Australia	www.hcasa.asn.au/	16/04/08	7
Health Consumers' Council of WA	www.hcc-wa.global.net.au	16/04/08	5
Health Consumers of Rural and Remote Australia	www.ruralhealth.org.au/hcrra/index.html	13/5/08	2
Health Issues Centre	http://www.healthissuescentre.org.au/	16/05/08	48
Maternity Coalition	http://www.maternitycoalition.org.au/	13/5/08	0
Mental Illness Fellowship Victoria	www.mifellowship.org	13/5/08	0
Migrant Resource Centre	http://www.users.bigpond.com/mrcsa/	9/05/08	0
Multiple Sclerosis Australia	www.msaustralia.org.au	9/05/08	0

Website	Website address	Date Searched	Yield/Results Returned
National Association of People Living with AIDS	http://www.napwa.org.au/	9/05/08	0
National Mental Health Consumers Self-Help Clearinghouse	http://www.mhselfhelp.org/	9/05/08	0
National Rural Health Alliance	http://nrha.ruralhealth.org.au	9/05/08	0
Onemda VicHealth Koori Health Unit	www.chs.unimelb.edu.au/koori	13/5/08	2
Palliative Care Council of SA	http://www.pallcare.asn.au/	13/5/08	0
Palliative Care Victoria	www.pallcarevic.asn.au	13/5/08	0
Panic Anxiety Disorder Association SA	http://www.panicanxietydisorder.org.au/	13/5/08	0
Participate in Health	http://www.participateinhealth.org.au/clearinghouse/	9/05/08	19
People Living With HIV/AIDS Vic	www.plwhavictoria.org.au	9/05/08	0
Primary Health Care Research & Information Service	http://www.phcris.org.au/	13/5/08	0
Public Health Association of Australia	www.phaa.net.au	14/05/08	3
Refugee Health Research Centre	www.latrobe.edu.au/rhrc/index.html	14/05/08	0
Research Australia	http://www.researchaustralia.com.au	14/05/08	0
Research Bites	http://www.phcris.org.au/resources		0
Rural and Remote Mental Health Service of South Australia	http://www.users.bigpond.com/telemed/	14/05/08	0
SA Ambulance Service	http://www.saambulance.com.au/	16/05/08	0
SANE Australia	http://www.sane.org/	16/05/08	0
Self Help Queensland Inc	http://www.selfhelpqld.org.au/	16/05/08	0

Website	Website address	Date Searched	Yield/Results Returned
The Health Consumers Alliance Inc of South Australia (HCA)	http://www.hcasa.asn.au/index.php	16/05/08	3
Victorian Mental Illness Awareness Council	www.vmiac.com.au	16/05/08	12
		Total	339

B. Part Two

Electronic database choices

The project data was gathered from nine electronic databases (Table 7) chosen to cover health and medical as well as sociological and general interest topic areas.

Table 7 Part Two - electronic databases searched & search results

Database name *	Dates covered	Date searched	References 2nd "Titles only" search numbers in brackets
ABI / Inform	1998 -	29052008	39 (146)
CINAHL	1982 to May Week 4 2008	29052008	285 (192)
Cochrane	1950 to Present with Daily Update	29052008	1
Embase	1806 to May Week 3 2008	29052008	894 (297)
Factiva	Last 3 months	29052008	365 (not easy to alter strategy)
Medline	1950 to Present with Daily Update	29052008	1, 980
PsycInfo	1806 to May Week 3 2008	29052008	93 (108)
SIGLE		29052008	10 of 38
Sociological Abstracts		29052008	180 (58)
			TOTAL **4,085** (**3,569** after duplicates removed)

A recent Cochrane review (Nilsen 2006) also mentions the following five databases but recorded that they retrieved no relevant records.

- CSA Worldwide Political Science Abstracts
- ERIC
- International Political Science Abstracts
- NTIS (the USA government's National Technical Information Service)
- PAIS (Public Affairs Information Service)

Search strings draft

For this literature review four term sets were investigated; those for

1. *Health facilities, health issues.*

   (Initially collected from the Cochrane review Methods of consumer involvement in developing healthcare policy and research, clinical practice guidelines and patient information material 2006. ES Nilsen, HT Myrhaug, M Johansen, S Oliver, AD Oxman and reading of the tender proposal)
2. *Consumer/patient involvement* (collected as above)
3. *Safety and quality* terms
4. *Evidence filters.* Compiled from the Cochrane handbook and saved Monash University Expert Searches

In the initial, highly sensitive searches, there was little relevant information retrieved. More specificity was achieved by reducing the search term numbers and limiting the search fields as indicated in the search strategies below.

Search strings

ABI/INFORM Global

(((health* OR Medic*) AND (Safety OR quality))) AND ((((consumer* or stakeholder* or patient* or user* or lay or disab* or citizen* or communit* or public or advoca* or carer* or caregiver* or parent* or relative* or client*))) W/3 ((particip* or involv* or represent* or collaborat* or consult* or contribut* or governance* or empower*))) AND ((random* or trial*))

TITLE(((consumer* or stakeholder* or patient* or user* or lay or disab* or citizen* or communit* or public or advoca* or carer* or caregiver* or parent* or relative* or client*) W/3 (particip* or involv* or represent* or collaborat* or consult* or contribut* or governance* or empower*))) AND ((safety or quality))

Cinahl

1. exp Consumer Participation/
2. Patient Participation/
3. Consumer Advocacy/
4. ((consumer* or stakeholder* or patient* or citizen* or public or lay or users* or carer* or client*) adj2 (particip* or involv* or represent* or collaborat* or consult* or contribut* or governance* or empower* or engag*)).mp.
5. or/1-4
6. (safe* or quality).mp.
7. evaluat*.mp.
8. ((outcome* or process*) adj2 (measure* or assess*)).mp.
9. or/7-8
10. and/5-6,9
11. Meta Analysis/
12. Literature Review/
13. systematic review.tw.
14. exp Literature Searching/
15. practice guidelines.tw.
16. nursing interventions.tw.
17. (care plan or critical path or protocol).tw.
18. (metaanaly$ or meta analy$).tw.
19. ((systematic or quantitative or methdologic$) adj (overview$ or review$)).tw.
20. integrative research review$.tw.
21. research integration.tw.
22. (handsearch$ or ((hand or manual) adj search$)).tw.
23. (medline or cinahl or psych$info or psyc$lit or embase).tw.
24. (scisearch or science citation or isi citation or web of science).tw.
25. CROSSOVER DESIGN/
26. Double-Blind Studies/
27. Clinical Trials/
28. Single-Blind Studies/
29. or/1-18
30. and/10,29
31. ((consumer* or stakeholder* or patient* or citizen* or public or lay or users* or carer* or client*) adj2 (particip* or involv* or represent* or collaborat* or consult* or contribut* or governance* or empower* or engag*)).ti.
32. and/6,29
33. 28 not 32
34. limit 32 to yr="1998 - 2008"
35. limit 33 to yr="1998 - 2008"
36. 34 and 35

Embase

1. exp Consumer Participation/
2. Patient Participation/
3. Consumer Advocacy/

4. ((consumer* or stakeholder* or patient* or citizen* or public or lay or users* or carer* or client*) adj2 (particip* or involv* or represent* or collaborat* or consult* or contribut* or governance* or empower* or engag*)).mp.
5. or/1-4
6. (safe* or quality).mp.
7. evaluat*.mp.
8. ((outcome* or process*) adj2 (measure* or assess*)).mp.
9. or/7-8
10. and/5-6,9
11. random*.mp.
12. factorial*.mp.
13. crossover*.mp.
14. cross over*.mp.
15. placebo*.mp.
16. (doubl* adj blind*).mp.
17. (singl* adj blind*).mp.
18. assign*.mp.
19. allocat*.mp.
20. volunteer*.mp.
21. Crossover Procedure/
22. Double Blind Procedure/
23. Randomized Controlled Trial/
24. Single Blind Procedure/
25. or/1-14
26. 15 and Human/
27. and/10,26
28. ((consumer* or stakeholder* or patient* or citizen* or public or lay or users* or carer* or client*) adj2 (particip* or involv* or represent* or collaborat* or consult* or contribut* or governance* or empower* or engag*)).ti.
29. and/6,28
30. 27 not 29
31. limit 30 to yr="1998 - 2008"
32. limit 29 to yr="1998 - 2008"
33. 31 and 32

Factiva

Group: Major Austn Papers

health* AND (consumer* or patient* or user* or lay or disab* or citizen* or communit* or public or advoca* or carer* or caregiver* or parent* or relative* or client*) AND (particip* or involv* or represent* or collaborat* or consult* or contribut* or governance* or empower*) AND (Safety OR quality)

Medline

1. exp Consumer Participation/
2. Patient Participation/
3. Consumer Advocacy/

4. ((consumer* or stakeholder* or patient* or citizen* or public or lay or users* or carer* or client*) adj2 (particip* or involv* or represent* or collaborat* or consult* or contribut* or governance* or empower* or engag*)).mp.

5. or/1-4

6. (safe* or quality).mp.

7. evaluat*.mp.

8. ((outcome* or process*) adj2 (measure* or assess*)).mp.

9. or/7-8

10. and/5-6,9

11. randomized controlled trial.pt.

12. meta-analysis.pt.

13. controlled clinical trial.pt.

14. clinical trial.pt.

15. random$.tw.

16. (meta-anal$ or metaanaly$ or meta analy$).tw.

17. ((doubl$ or singl$) and blind$).tw.

18. exp clinical trials/

19. crossover.tw.

20. or/11-19

21. clin$ trial.tw.

22. (control$ and (trial$ or stud$)).tw.

23. ((singl$ or doubl$ or tripl$ or trebl$) and (blind$ or mask$)).tw.

24. placebo.tw.

25. research design/

26. comparative study/

27. or/20-26

28. and/10,27

29. ((consumer* or stakeholder* or patient* or citizen* or public or lay or users* or carer* or client*) adj2 (particip* or involv* or represent* or collaborat* or consult* or contribut* or governance* or empower* or engag*)).ti.

30. and/6,29

31. 28 not 30

32. limit 30 to yr="1998 - 2008"

33. limit 31 to yr="1998 - 2008"

34. 32 and 33

PsychInfo

1. Patient Participation/

2. ((consumer* or stakeholder* or patient* or citizen* or public or lay or users* or carer* or client*) adj2 (particip* or involv* or represent* or collaborat* or consult* or contribut* or governance* or empower* or engag*)).mp.

3. (safe* or quality).mp.

4. evaluat*.mp.

5. ((outcome* or process*) adj2 (measure* or assess*)).mp.

6. ((consumer* or stakeholder* or patient* or citizen* or public or lay or users* or carer* or client*) adj2 (particip* or involv* or represent* or collaborat* or consult* or contribut* or governance* or empower* or engag*)).ti.

7. random$.tw.

8. (meta-anal$ or metaanaly$ or meta analy$).tw.

9. ((doubl$ or singl$) and blind$).tw.
10. exp clinical trials/
11. crossover.tw.
12. or/1-2
13. or/4-5
14. or/7-11
15. 3 and 12 and 13 and 14
16. 3 and 6
17. 15 not 16

SIGLE

((title:(consumer* title:or title:patient* title:or title:user* title:or title:lay title:or title:disab* title:or title:citizen* title:or title:communit* title:or title:public title:or title:advoca* title:or title:carer* title:or title:caregiver* title:or title:parent* title:or title:relative* title:or title:client*)) AND ((Safety OR quality)) AND (title:(particip* title:or title:involv* title:or title:represent* title:or title:collaborat* title:or title:consult* title:or title:contribut* title:or title:governance* title:or title:empower*)))

Sociological AbstractsS

Search Query #6 KW=((consumer* or stakeholder* or patient* or user* or lay or disab* or citizen* or communit* or public or advoca* or carer* or caregiver* or parent* or relative* or client*) within 3 (particip* or involv* or represent* or collaborat* or consult* or contribut* or governance* or empower*)) and KW=(safety or quality) and KW=(health* or medic*)

Date Range: 1998 to 2008

TI=((consumer* or stakeholder* or patient* or user* or lay or disab* or citizen* or communit* or public or advoca* or carer* or caregiver* or parent* or relative* or client*) within 3 (particip* or involv* or represent* or collaborat* or consult* or contribut* or governance* or empower*)) and KW=(safety or quality)

Date Range: 1998 to 2008

Grey literature broad search terms

Find articles with all of the words: patient safety initiative

With the exact phrase: consumer participation

Where words occur: anywhere in the article

Grey literature website choices

Grey literature was gathered from two search engines (Table 8).

Table 8 Part Two - grey literature website search engines & results

Website	Website address	Date searched	Yield	Reviewed for more detailed evaluation
Clusty	http://clusty.com/	29 May 2008	484	11
Google Scholar	http://scholar.google.com/	29 May 2008	327	13

From the above results on Clusty the following websites links were identified by the expert searcher for further review

Table 9 Part Two – Clusty search engine results

Website Link	Reason for Exclusion
http://www.participateinhealth.org.au/ClearingHouse/	No hits returned on consumer involvement in patient safety initiatives
http://www.research.deakin.edu.au/custom/fac_arts/member_pubs.php?person_code=lanexka	Does not examine patient safety initiatives
http://www.nyam.org/library/pages/grey_literature_report	No hits returned on patient safety initiatives
http://www.anzhealthpolicy.com/content/4/1/13	Focuses on consumer participation in research and health policy
http://www.rand.org/pubs/technical_reports/2007/RAND_TR463.pdf	Focuses on patients role in improving their own health care
http://www.moh.govt.nz/moh.nsf/0/5da5ed919301cd21cc256d4a0009c17a/$FILE/TCEToolkitconsumers.pdf	Does not examine patient safety initiatives- a tool kit on involving consumers in credentialing
http://www.patientsafety.org/page/94874/	Focuses on patients role in improving their own health care
http://www.participateinhealth.org.au/ClearingHouse/Docs/cappsbuildingconsumersinmanualweb.doc	Focuses on patients role in improving their own health care
http://www.who.int/patientsafety/en/brochure_final.pdf	Background overview document on WHO progress on the World Alliance for Patient Safety Programme

Website Link	Reason for Exclusion
http://www.rpsgb.org.uk/pdfs/exptpatsemrept.pdf	Focuses on patients' role in improving their own health care. Summary report on presentations from a seminar on perspectives of 'expert patients'.
http://www.crd.york.ac.uk/crdweb/ShowRecord.asp?View=Full&ID=32006000023	Consumer involvement in Health Technology Assessment

From the Google scholar search of 327 potentially relevant hits the following reports were retrieved for further evaluation and then excluded.

Table 10 Part Two - grey literature excluded reports (Google Scholar)

Report	Reason for Exclusion
Barraclough 2004	Does not examine consumer involvement in patient safety initiatives. Provides an overview of the efforts to improve patient safety in Australia.
Clark 2001	Does not examine consumer involvement in patient safety initiatives. Survey results of Australian attitudes and preferences to participation in health care and perception of patient safety.
Comden 2002	Does not examine consumer involvement in patient safety initiatives.
Consumer Focus Collaboration 2001	Does not examine consumer involvement in patient safety initiatives. Summary of the evidence that supports active consumer participation at in health.
Coulter 2006	Does not examine consumer involvement in patient safety initiatives. Review of the evidence of involving patients in improving their own health care.
Farley 2004	Does not examine consumer involvement. Annual evaluation on AHRQ's activities, progress and issues.
Health Issues Centre 2006	Does not examine consumer involvement in patient safety initiatives. A guide for consumer members of public health services Community Advisory Committee..
Jeffs 2005	Does not examine consumer involvement. A summary of research priority areas and future research areas for patient safety initiatives.
Johnson 2001	Does not examine consumer involvement in patient safety initiatives. Literature review on the dimensions and definitions of consumer participation.
Johnson 2002	Does not examine consumer involvement in patient safety initiatives. A very good report on the different definitions and methods of consumer participation.
NHMRC 2005	Does not examine consumer involvement in patient safety initiatives. Guide on involving consumers in health and medical research.

Report	Reason for Exclusion
Oliver 2004	Does not examine consumer involvement in patient safety initiatives. Literature review on consumer involvement in research and development.
Wadhwa 2002	Does not examine consumer involvement in patient safety initiatives. Commentary on methods of consumer participation in health care generally.

Appendix 2 - Excluded articles

Part Two

Table 11 Part Two - excluded articles

Author and Year	Reason for Exclusion
Aaen Geest 2006	Does not examine patient safety initiatives. Uncontrolled before-after study to detect and evaluate changes in perceived quality of care of GPs after implementation of a programme (GP education and introduction of leaflet to assist patients in preparing for the consultation) to enhance patient involvement in consultations with their GP. Outcomes – GPs and patient questionnaires.
Abbasi 2004	Does not examine patient safety initiatives. Observational study of patients in a general practice participating in a model of diabetes management to increase self management of diabetes in a supported environment.
Abma 2005	Does not examine patient safety initiatives. Discusses the patient's perspective of their role in health research, key issues to consider when involving patients in research and uses a case study to illustrate some of the barriers and enablers for patient participation in healthcare research.
Agha 2006	Does not examine patient safety initiatives. Qualitative report on results of a pre and post survey of client perceptions of access to and quality of services provided by private providers of reproductive health services in Nepal.
Akl 2007	Does not examine patient safety initiatives. Questionnaire study examining consumers' understanding and preference for different methods of representing clinical practice guidelines.
Albert 2005	Does not examine patient safety initiatives. Telephone interviews of patient caregivers on their experiences of the transition following cessation of formal home support services to managing the patients care on their own. Telephone surveys were conducted.
Altus 2002	No consumer involvement and does not examine patient safety initiatives. Qualitative report – use of nursing assistants in a residential care facility to report on the involvement of residents with dementia in activity programs.
Alvarez 2006	Does not examine patient safety initiatives. Editorial on the importance of patient involvement in patient safety, and discusses various strategies to boost involvement.
American Society of Clinical Oncology 2008	Does not examine patient safety initiatives. Narrative report on the effect of health insurance on access to quality care for prostrate cancer in the USA.
Amtmann 1998	No consumer involvement in developing patient safety initiatives. Describes benefits of the internet and IT for disabled healthcare consumers.

Author and Year	Reason for Exclusion
Anderson 2000	Does not examine patient safety initiatives. Editorial focusing on ways to best consult the English general public about how to improve the National Health Service.
Anonymous 1995	Does not examine patient safety initiatives. Press release: the benefits of involving patients with prostrate cancer in choice of treatments.
Anonymous 2003	Does not examine patient safety initiatives. Editorial on the benefits of using patient representatives to improve patient safety in a hospital setting.
Anonymous 2004	Does not examine patient safety initiatives. Editorial on patient involvement in NHS cancer services.
Anonymous 2006	No consumer involvement. Brief report on the 2007 Patient Safety Goals, does not discuss methods of implementation.
Anonymous 2006	Does not examine patient safety initiatives. Press release for the recruitment of public participation on amendments to blood safety regulation.
Anonymous 2007	Editorial – briefly describes the SPEAK UP initiative, but does not discuss ways of implementing it.
Anonymous 2007	Does not involve patients in the planning, development, or implementation of patient safety initiatives. Report on the involvement of patients in their own health care.
Anonymous 2008	Report/Letter – Does not examine patient safety initiatives. Reports briefly on a new initiative to enable patients and carers to report safety concerns at a great of hospitals in Indianapolis.
Anonymous 1994	Does not examine patient safety initiatives. Commentary on empowering consumers to participate in healthcare reform debate.
Anonymous 1995	Does not examine patient safety initiatives. Commentary on a five year study of prostate disease treatment comprising patient involvement.
Anthony 2005	Does not examine patient safety initiatives. Report describing one hospital’s efforts to engage patients and families in care decisions, results, and planning.
Anton 2007	Does not examine patient safety initiatives. Report on potential methods to assess public involvement in the planning and delivery of health services policy in the NHS.
Attree 2001	Does not examine patient safety initiatives. Descriptive study on what quality care means to health professionals, patients and relatives, and identification of criteria to evaluate the quality of care.
Ayana 2001	Does not examine patient safety initiatives. Patient satisfaction survey on use of a patient held record in a stroke unit.

Author and Year	Reason for Exclusion
Azoulay 2002	Does not examine patient safety initiatives. RCT examining comprehension and satisfaction with information provided by intensive care unit (ICU) caregivers.
Backhouse 2000	Does not examine patient safety initiatives. Patient satisfaction survey on care provided on a rehabilitation unit in the UK.
Bain 2002	Does not examine patient safety initiatives. Qualitative report on patient satisfaction with their care on a colorectal cancer ward.
Baker 2000	Does not examine patient safety initiatives. Opinion on the benefits of patient involvement in their care from the perspective of an organisation representing people with Parkinson’s.
Baker 1999	Does not examine patient safety initiatives. Development of an instrument to assess patient’s attitudes towards care.
Baker 2005	Does not examine patient safety initiatives. Qualitative report on patient’s perceptions of their aspects of care and health outcomes provided by six organisations who participated in a Quality Improvement Collaborative for heart failure. Cross-sectional telephone survey of patients from the organisations who participated compared to patients care provided by six control organisations in the US.
Balabanova 2004	Does not examine patient safety initiatives. Qualitative report – survey, interviews, focus groups with consumers and health professionals on the health financing system in Bulgaria.
Baraitser 2003	Does not examine patient safety initiatives. Qualitative report of interviews with clinic users, by fellow clinic users, on sexual health service use.
Barrister 2005	Does not examine patient safety initiatives. Qualitative report of focus groups with consumers on their experience with family planning and genitourinary medicine clinics.
Barnes 2006	Does not examine patient safety initiatives. Discusses use of a forum as a tool for consulting women users of mental health services.
Baron-Epel 2001	Does not examine patient safety initiatives. Patient satisfaction interviews on visits to the primary care physician.
Baron-Epel 2003	Does not examine patient safety initiatives. Patient interviews on the health education provided by physicians at health educations units.
Bates 2007	Does not examine patient safety initiatives. Consumer evaluations of different health information web pages.
Beresford 2007	Does not examine patient safety initiatives. Qualitative report - the role of service user’s involvement in health inequalities research and access to health provision and outcomes.

Author and Year	Reason for Exclusion
Berger 1996	Does not examine patient safety initiatives. Presents several points of view regarding consumer empowerment and methods to achieve it in mental health.
Berkman 2001	Does not examine patient safety initiatives. Qualitative report describing the challenges in conducting research with hospitalised older patients.
Bernsten 2001	Does not examine patient safety initiatives. Randomised trail evaluating the effectiveness of pharmaceutical care provision via community pharmacists in older patients. Outcomes examined were health related (health related quality of life, hospitalisations, clinical signs and symptom control, patient satisfaction) and economic outcomes (health related resource usage).
Beyea 2007	Does not examine patient safety initiatives. Report discussing resource options for patient involvement in care.
Birnberg 2004	Does not examine patient safety initiatives. Announcement of the creation of the Iowa Healthcare Collaborative.
Blenkiron 2003	Does not examine patient safety initiatives. Report on quality of life and satisfaction with mental health services using a scale developed by users (rather than professionals).
Boivin 2007	Does not examine patient safety initiatives. Letter which argues that members of the public should be involved in clinical practice guideline (CPG) development in order to reduce bias and increase legitimacy and accountability to the development process.
Bond 1999	Does not examine patient safety initiatives. Qualitative report examining the different approaches and challenges in conducting research with hospitalised older patients with dementia and their care givers.
Bond 2001	Does not examine patient safety initiatives. Report on the effectiveness of the assertive community treatment model for people with severe mental illness.
Boote 2002	Does not examine patient safety initiatives. Review of the different levels of consumer involvement in research, and the various objections to consumer involvement put forward by clinicians and researchers.
Brazil 1998	Does not examine patient safety initiatives. Patient, hospital and community provider satisfaction surveys on the provision of a home-based rapid access service to avoid hospital admission of older people.
Brown 1982	Does not examine patient safety initiatives in the hospital setting. Commentary on ways of preventing household accidents and dangers in some consumer services (e.g., tanning salon).
Burrington-Brown, 2006	Does not examine patient safety initiatives. Opinion piece focused on four American Health Information Community projects to help patients manage their healthcare and advocate for themselves.
Butcher 2000	Does not examine patient safety initiatives. Qualitative report describing the approach and methods used to improve service delivery in primary care in Nepal by engaging partnerships between health care providers, managers and users.

Author and Year	Reason for Exclusion
Carlson 1990	Does not examine patient safety initiatives. Report on a program which allowed healthcare providers and consumers to identify problems with diabetes care in local health-care centres, and implement solutions to these problems.
Carney 2006	Does not examine patient safety initiatives. Report on the development of an information booklet by colorectal cancer patients, which has subsequently been used to personalise patient information.
Carroll 2006	Does not examine any patient safety initiatives. Commentary discussing consumer driven mental health care.
Challans 2006	Does not examine any patient safety initiatives. Focuses on involving patients in health service and social care improvements.
Chamberlin 2005	Does not examine patient safety initiatives. Commentary regarding the involvement of consumers in all aspects of the mental health service delivery system, including professional training, service design, delivery, evaluation, and research.
Chisholm 2007	Does not examine patient safety initiatives. Letter to the editor regarding use of patient questionnaires to improve healthcare provision in general practice.
Clough 2003	Does not examine patient safety initiatives. Commentary on how patient involvement can lead to changes in the design and delivery of health services, and why the public should be involved in this design.
Connell 1998	Does not examine patient safety initiatives. Describes the development of a method to assess the quality of care given by agencies.
Coulter 2007	Does not examine patient safety initiatives. Overview of evidence regarding efficacy of patient engagement.
Coulter 2002	Does not examine patient safety initiatives. Editorial discussing the importance of consumer representativeness in patient evaluations of health services.
Coulter 2003	Does not examine patient safety initiatives or involve consumers. Editorial on involving citizens in health care priority setting equitable distribution of health care resources.
Council on Chiropractic Practice 1998	Does not examine patient safety initiatives and does not involve consumers. Clinical practice guideline for vertebral subluxation in chiropractic practice.
Cowden 2007	Does not examine patient safety initiatives. Discussion of consumer (‘User’) involvement in decision making, from historical antecedents in the UK in the 1970s to present.
Crawford 2002	Does not examine patient safety initiatives. Systematic review summarising evidence (largely from case studies) which suggests that patient involvement has contributed to changes in the provision of health care.
Crawford, 2003	Commentary on the review by Crawford.

Author and Year	Reason for Exclusion
Crowe 2006	Does not examine patient safety initiatives. Commentary discussing accountability in the health system.
Culyer 2005	Does not examine patient safety initiatives. Report on the way NICE involves patients.
Curry 1999	Does not examine patient safety initiatives. Qualitative article – describes the use of two techniques (the Servqual Instrument in residential care and the nominal group technique in a large hospital) to address the issue of consultation in healthcare.
Curtis 2005	Does not involve consumers. Cluster RCT comparing audit/feedback and educational materials for physicians versus no intervention on non-steroidal anti-inflammatory drug-related safety practices.
Davis 2007	Does not examine patient safety initiatives from an organisational level. Narrative review of the factors that could influence patients to participate and engage in safety issues in their own health care.
Dickens 2006	Does not examine patient safety initiatives. Qualitative report on the use of focus groups as a method of user participation in the commission and review of mental health services.
Dijkstra 2005	Does not examine patient safety initiatives. Cluster RCT evaluating effect of enhancing patient self-care and the patient-professional ‘partners in care’ for diabetes management using a patient held record.
Duff 1996	Does not examine patient safety initiatives. Article on involving patients in developing clinical guidelines.
Duff 1996	Does not examine patient safety initiatives. Report on involving patients in quality improvement strategies.
Edelenbos 2006	Non health care related. Qualitative report – evaluation of six cases to involve the public in decision making in the context of local policy processes in the Netherlands.
Editorial 2006	Does not examine patient safety initiatives and does not involve consumers. Report on hospital compliance with new national patient safety goals in suicide prevention.
Entwistle 2007	Does not examine patient safety initiative at an organisational level. Commentary article, response to a previous article by Lyons 2007. Focuses on patient involvement in their own health care.
Fallowfield 2001	Does not examine patient safety initiatives. Editorial on patient involvement in decisions on their own care for cancer treatment.
Finch 1999	Non health care related. Exploratory study on the use of internet discussion groups between customers and manufacturers.
Flanagan 1999	Does not examine patient safety initiatives. Patient involvement in developing nursing education programmes.

Author and Year	Reason for Exclusion
Freedman 2006	Does not examine patient safety initiatives. Review of engagement of patients in Clinical Governance framework within the National Health Service (NHS).
Fudge 2007	Does not examine patient safety initiatives. Review of studies involving older people in the conducting of health research.
Gagliardi 2008	Does not examine patient safety initiatives. Qualitative report of interviews with cancer patients and health professionals on barriers to patient involvement in health service planning and evaluation.
Geller 1998	Does not examine patient safety initiatives and does not involve consumers. Survey of US mental health authorities on consumer empowerment and responsibility in the public mental health system.
Ghersi 2002	Does not examine patient safety initiatives. Discussion of methods to involve consumers in creating Cochrane Reviews.
Gilbert 1998	Does not examine patient safety initiatives. Comment on methods of involving patients in their care and discusses the Promoting Action on Clinical Effectiveness (PACE) programme which has sought to involve patients at both the policy and planning level.
Goodare 1999	Does not examine patient safety initiatives. Editorial on the importance of and barriers to patient involvement in research. Some brief examples of patient involvement are discussed.
Goodman 2004	Not patient safety. Describes different options for healthcare packages and consumer involvement in decisions.
Gott 2002	Does not examine patient safety initiatives. Qualitative summary report of user involvement in cancer service development in the UK. Recommendations on approaches to providers, users and for both are outlined.
Grantmakers in Health 2007	Does not examine patient safety initiatives. Report on engaging consumers in health care decisions.
Gray	Does not examine patient safety initiatives. Short summary of consumer involvement in priority-setting for increasing quality of care for maternity services.
Guerin 2006	Does not examine patient safety initiatives. Case study highlighting the essential role of advocacy in Community Based Participatory Research (CBPR) in assisting women refugees to identify their needs and acceptable solutions with health services. Interviews and focus groups were conducted.
Hainsworth 2006	Does not examine patient safety initiatives. Comment on the benefits of involving patients in their care and makes suggestions for facilitating patient involvement.
Hammond 2007	Does not examine patient safety initiatives from an organisational perspective. Report on using disproportionality analysis to determine the effect that consumer reporting has on the detection of safety signals.

Author and Year	Reason for Exclusion
Hanley 2001	Does not examine patient safety initiatives. UK national survey of clinical trial coordinators/investigators, to determine how many current trials involved consumers in the design, conduct and interpretation of the research.
Harrington 2004	Does not examine patient safety initiatives. Systematic review on increasing patient participation in medical consultations in predominantly outpatient settings or primary care.
Hayes 1998	Does not examine patient safety initiatives. Report on management of cardiac failure via consulting patients on education strategies.
Haymes 2003	Does not examine patient safety initiatives and non health care related. Case study of a violence prevention program as a co-operative effort between the university and local schools.
Hays 2006	Does not examine patient safety initiatives. Survey of hospitalised patients' experiences with care and health related quality of life.
Hearn 2004	Does not examine patient safety initiatives. Case study of collaboration between local state authorities and community groups.
Henderson 2006	Does not examine patient safety initiatives. Qualitative study on patient satisfaction with the information provided to them about their care and responses to their questions, by health care professionals in an acute hospital setting.
Hermiz 2002	Does not examine patient safety initiatives and does not involve consumers. RCT of home based care compared with usual care in patients with chronic obstructive pulmonary disease.
Hibbard 2003	Does not examine patient safety initiatives. Narrative review of three roles (informed choice, co-producer and evaluator) of consumer contribution to improving the quality of care.
Hibbard 2004	Does not examine patient safety initiatives. Development of a tool to assess the degree to which patients are likely to take an active role in their care.
Hill 2000	Does not examine patient safety initiatives and no consumer involvement. Qualitative report on evaluation of a programme designed to maximise staff involvement in capturing user views for the development of services at a hospital in the UK.
Hiller 1997	Does not examine patient safety initiatives. Report on public involvement in formulating and implementing medical policy for newborn screening programs in the US.
Hilty 2004	Does not examine patient safety initiatives and no consumer involvement. Physician evaluation of a multispecialty telephone and email consultation for patients with developmental disabilities.
Hochlehnert 2006	Does not examine patient safety initiatives and no patient involvement in development and implementation. Trial to improve shared decision making regarding management for fibromyalgia patients using a computerised information tool aimed.

Author and Year	Reason for Exclusion
Holmes-Rover 2005	Does not examine patient safety initiatives. Development of a patient plain language decision aid for the initial management of prostrate cancer following a biopsy. Patients were involved in the development.
Hooker 2006	Does not involve consumers. Poster abstract describing an ICU Nursing Council, comprised of nurses, directors, managers and colleagues from other disciplines, who meet monthly to share ideas and solutions focusing on patient safety.
Hooser 2002	Does not examine patient safety initiatives. Short, general commentary discussing the potential benefits of consumer empowerment.
Howard-Grabman 2000	Does not examine patient safety initiatives. Report on approaches used to develop partnerships between communities and service providers to improve the quality of health care provided from the community perspective and to facilitate joint decision making at the service development.
Howe 2006	Does not examine patient safety initiatives. Discussion paper on approaches to improving safety via patient involvement in interprofessional care
Humphreys 2005	Does not examine patient safety initiatives. Qualitative report on the quality of care in rural Australia reported by consumers.
Hunter 2006	Does not examine patient safety initiatives. Letter arguing that the encouragement of patients to become active participants who take responsibility for working towards their treatment goal could improve health care quality.
Huston 2004	Does not examine patient safety initiatives. Qualitative study on the public’s views of placebo use in placebo-controlled trial for research.
Hutchison 1998	Does not examine patient safety initiatives. Reasons for patient participation and discussion of the ethical considerations of Phase 1 trials in cancer patients from participant viewpoint.
Hyrakas 2003	Does not examine patient safety initiatives. Describes patient satisfaction with the quality of care provided in a hospital during a continuous quality improvement initiative targeting the care provided by nursing staff.
Isham 2002	Does not examine patient safety initiatives. Case study – evaluation of local community involvement in designing water services in Sri Lanka and India and reports on the circumstances under which a community-based approach is likely to succeed.
Ishikawa 2005	Does not examine patient safety initiatives. Observational study of older Japanese adults’ ratings of perceived patient-centeredness of their medical visits.
Ismael 2002	Does not examine patient safety initiatives. Case study – describes the use of the participatory action approach in the planning of community health programs in a Canadian rural community. The public participated in interviews and surveys.

Author and Year	Reason for Exclusion
Jack 2005	Does not examine patient safety initiatives. Report on a theoretical approach to engage mothers of children at-risk with public health nurses during home visits.
JCAHO 2002	Discusses methods and strategies on how patients can be involved in improving the safety of their own health care via the ‘SpeakUp’ program. Uses example from a children’s hospital.
JCAHO 2004	Discusses methods and strategies on five steps to involve patients in anaesthesia safety and improve the safety of their own health care via the ‘SpeakUp’ program.
JCAHO 2004	Discusses five steps health card professionals can take to engage patients in improving the safety of their own health care via the ‘SpeakUp’ program.
JCAHO 2006	Discusses ‘SpeakUp’ initiative from the Joint Commission, and how this can positively affect hospitals and healthcare providers.
Jeacocke 2002	Does not examine patient safety initiatives. Narrative review on engaging consumers and other stakeholders to develop a list of specific indicators of quality in general practice.
Johnson 2001	Does not examine patient safety initiatives. Describes research supporting active consumer participation in decision making.
Joint Commission Perspectives 1999	Does not examine any patient safety initiatives. Commentary discussing joint commission initiatives to improve the quality of care provided to the public.
Kapiriri 2003	Does not examine patient safety initiatives. Qualitative report of interviews with health planners and consumers on their experiences with health priority setting in Uganda.
Kaulio 1998	Non health care related. Review of seven methods of consumer involvement in product development in manufacturing, of which quality function is one of them.
Kaur 2004	Does not examine patient safety initiatives and does not involve consumers. Discussion on the importance of patient involvement in improving service provision in the NHS.
Kelly 2007	Non health care related. Qualitative report on the development of interventions, by community members, to increase the involvement of the community in physical activity programs.
Kelson 2001	Does not examine patient safety initiatives. Commentary on patient and carer involvement in clinical practice guideline development within the National Institute of Clinical Excellence guideline development programme.
Kent 2002	Does not examine patient safety initiatives from an organisational level. Report on the development towards user-oriented influence on the regulation of human implant technologies (e.g., breast implants, hip prosthesis).

Author and Year	Reason for Exclusion
Kerfoot 2006	Does not involve consumers. Describes clinician-oriented patient safety programmes.
Kimmelman 2004	Does not examine patient safety initiatives. Qualitative report on the ethical conduct of research in humans, with a focus on the role of Institutional Review Boards in evaluation of clinical trial risks.
Kinney 1998	No consumer involvement. Case study – describes a community health improvement model used in a collaborative to reduce motor vehicle injuries. Focuses on the teams undertaking the work with no reference to engaging the public.
Koutantji 2005	Does not examine patient safety initiatives. Focuses on strategies to facilitate patients improving their own care.
Laerum 1998	Does not examine patient safety initiatives. Development and user evaluation of an instrument for consultation improvement and patient involvement.
Laerum 2004	Does not examine patient safety initiatives. Evaluation of a tool developed by consumers and GPs to improve patient-physician communication, decision making and patient knowledge, for the management of complex health problems in general practice.
Lakeman 2008	Does not examine patient safety initiatives. Case study of the introduction, development and evaluation of practice standards for family / carers and service users in a mental health services in Queensland, Australia. Family and carer surveys were completed.
Lamboray 2001	Does not examine patient safety initiatives. Qualitative report describing a bottom–up approach of community empowerment in the development of an action plan to reduce HIV infection in HIV-infected communities in Africa.
Langston 2005	Does not examine patient safety initiatives. Report on the experiences of the organisers of a multicentre randomised controlled trial and a consumer organisation who were involved in the peer-review, steering committee, and promotion of the trial amongst target participants.
Le Var 2002	Does not examine patient safety initiatives. Report on patient involvement in nursing practitioner education.
Leff 2004	Does not examine patient safety initiatives. Describes actions one agency undertook to improve patient participation in order to improve patient satisfaction survey ratings, with an emphasis on involvement in decisions.
Louch 2005	Does not examine patient safety initiatives. Needs assessment using interviews of patients with depression to identify service gaps and contribute to service evaluation and redesign of a single general practice in the UK.
Love 1999	Does not examine patient safety initiatives. Report on patients interventions to improve the quality and safety of their own health care.
Mackillop 2006	Not patient safety and no consumer involvement. Describes development of a patient survey to appraise consultant quality.

Author and Year	Reason for Exclusion
Marshall 2007	Does not examine patient safety initiatives. Review of consumer involvement in case management evaluations.
Master 2003	Does not examine patient safety initiatives. Report on the history and efforts of Commonwealth Care Alliance – an integrated approach to coordinated care for chronically ill and frail elderly.
Mawdsley 2007	No consumer involvement. Commentary article discussing the success of two intensive care units (ICUs) in implementing grassroots change.
McGriffin 2000	No consumer involvement. Conference workshop summary - Government employees discuss different aspects of public participation such as communication tools, management of meetings, conflict and dispute resolution.
Middleton 2004	Does not examine patient safety initiatives. Qualitative study of the experiences of consumer consultants in the Victorian public mental health system, focusing on their perceived areas of influence, areas of difficulty and suggestions for improvement. Organisational features that help or hinder the consumer consultants in their work are described.
Milewa 2002	Does not examine patient safety initiatives and no consumer involvement. Interviews with heath care organisations to determine the effects of user and public involvement in primary healthcare planning.
Mikles 2006	Does not examine any patient safety initiatives and does not mention consumer involvement. Commentary on the role of the Association of Dialysis Advocates (ADA) and the need to strengthen existing infection control practices.
Minogue 2002	Does not examine patient safety initiatives. Narrative review – review of existing literature on the extent and type of consumer involvement (consultation; collaboration or partnership; user-commissioned; user-controlled or led; user disseminated) in the NHS Mental Health NHS Trust.
Molnar 2001	Does not examine patient safety initiatives. Explores barriers to consumer participation in health care policy.
Molnar 2005	Not healthcare; strategy for preventing violence in young girls.
Monroe 2002	Does not examine patient safety initiatives. Summary of methods to improve accountability of healthcare in the US via consumer education.
Morris 2001	Does not examine patient safety initiatives. Commentary on the greater role of patient representatives and carers in decisions on policy and practice by the Royal College of Psychiatrists in the UK.
Morris 2002	Does not examine patient safety initiatives. Announcement of the appointment of a new role in the Department of Health - NHS Director of Patient Experience and Public Involvement.

Author and Year	Reason for Exclusion
Murie 2004	Does not examine patient safety initiatives. Summary article on the experience of patient and public involvement in primary care, citing two case studies from Scotland. Provides an overview of some of the challenges and opportunities for meaningful patient and public involvement.
Nathan 2004	Does not examine patient safety initiatives. Commentary on the challenges of engaging marginalised groups in consumer and community participation in health services
Newcastle Anticoagulation Study Group 1998	Does not examine patient safety initiatives or involve consumer participation. Retrospective study reporting on anticoagulation control seen in general practice among patients discharged form hospital.
Newton 1996	Report on involving consumers in medical audit processes in general practice.
Newton 2001	Does not examine patient safety initiatives. Commentary on the methods of involving consumers in the evaluation of dental care.
Newton 2001	Does not examine patient safety initiatives. Commentary on consumer appraisal of treatments for eating disorders
Nilsen 2006	Does not examine patient safety initiatives. Cochrane review on consumer involvement in developing policy, research, CPGs and patient information materials.
Noseworthy 1999	Does not examine patient safety initiatives. Opinion piece on involving consumers and families/carers in design and planning of mental health services in New Zealand.
O'Connor 2007	Does not examine patient safety initiatives. Qualitative report of interviews with stakeholders on consumer involvement in the Irish Health Services accreditation.
O'Donnell 1999	Does not examine patient safety initiatives. Report on client satisfaction after standard case management, client-focussed case management, or client focussed case management with consumer advocacy.
O'Keefe 1999	Does not examine patient safety initiatives. Report on developing ways to enable house-bound people to give their views on planning and monitoring of health and social care.
O'Reilly 2007	Does not examine patient safety initiatives. Evaluation of a tool measuring the quality of services, from the consumer's perspective, provided by an Irish physical disability service.
Ong 2003	Does not examine patient safety initiatives. Experiences of patients and professionals involved in low back pain research.
Oz 2001	Does not examine patient safety initiatives. Qualitative summary of results of a patient satisfaction survey on hospital services.
Ozer 1999	Does not examine patient safety initiatives or involve consumers. Case study describing changes to team case conferences to increase patient participation in stroke rehabilitation.

Author and Year	Reason for Exclusion
Paterson 2005	Does not examine patient safety initiatives. Qualitative report on patients’ satisfaction of massage therapy in their treatment for Parkinson’s Disease.
Patrick 2007	Does not examine patient safety initiatives. Qualitative report on users, carers and staff views of local palliative care services.
Paul 2001	Does not examine patient safety initiatives. Report on the development of written patient safety information in a hospital.
Payne 2007	Does not examine patient safety initiatives. Qualitative report involving patients and health professionals in the development of a set of outcome measures to evaluate the quality of clinical genetics services.
Perkins 2002	Does not examine patient safety initiatives. Qualitative report of interviews with members of the Illawarra Division of General Practice consumer consultative committee.
Perry 2000	Does not examine patient safety initiatives and does not involve consumers. Evaluation of costs and benefits of alternative systems of coronary heart disease monitoring.
Peter 2003	Does not examine patient safety initiatives. Commentary of a systematic review of involving former and current users of mental health services in the delivery and evaluation mental health services.
Peterson 2003	Does not examine patient safety initiatives. Qualitative study on consumer experiences in searching for and appraising Internet-based information on medicines.
Peyrot 2006	Does not examine patient safety initiatives. Report of cross-national interviews with diabetic patients and healthcare providers on their satisfaction with chronic-care of diabetes.
Phillips 2008	Does not examine patient safety initiatives. Commentary and presentation of results of a postal survey of 47 active nursing-home consumer advocacy groups in the US.
Polivka 2003	Does not examine patient safety initiatives. Book chapter on the evaluation of findings from consumer-directed-care programs in the US. Concludes these programs are popular with consumers and carers and are a cost-effective alternative to institutional and agency-directed care for seriously impaired older people.
Poon 2007	Does not examine patient safety initiative. Involves patients in improving the quality of their own care. Describes an online module to facilitate discussion between patients and their carer.
Porter 2005	Does not examine patient safety initiatives. Report on involving patients and carers in the development, delivery and evaluation of healthcare higher education programmes.
Prewo 2000	Does not examine patient safety initiatives. Opinion piece on consumer empowerment and health system financing.

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Priebe 2002	Does not examine patient safety initiatives. Cluster RCT on an intervention of regular key worker- patient meetings every two months to improve joint decision making regarding treatment and health care provision in community mental health care.
Puertas 2001	Does not examine patient safety initiatives or involve consumers. Report on the results of community health assessment conducted in indigenous communities in rural Ecuador.
Quennell 2003	Does not examine patient safety initiatives. Commentary on the involvement of patient organisations in the technology appraisal process of the National Institute of Clinical Excellence.
Rankin 2000	Does not examine patient safety initiatives. Describes methodology for involving consumers in clinical practice guidelines for breast cancer.
Ravesloot 2005	Does not examine patient safety initiatives. Report on the effectiveness of a consumer-directed health promotion program to improve the health in adults with mobility impairments.
Rea 2004	Does not examine patient safety initiatives. RCT comparing a disease management programme (patient specific care plan, pulmonary rehabilitation, and collaboration of primary care providers) versus usual care of patients with chronic obstructive pulmonary disease.
Redmond 2003	Does not examine patient safety initiatives. Commentary on collaboration with patient advocates.
Reece 2006	Does not examine patient safety initiatives. Clinical practice guideline for the use of bortezomib in multiple myeloma and lymphoma which was reviewed and approved by a multispecialty group including a patient representative.
Reid 1999	Does not examine patient safety initiatives. Patient satisfaction with the care provided by their pharmacist.
Renberg 2006	Does not examine patient safety initiatives. Qualitative study on patient satisfaction with their community pharmacy service.
Renne 2006	Does not examine patient safety initiatives. Community-based collaborative framework for involving participants in their own primary health care.
Rennie 2003	Non health care related. Participant satisfaction with their chosen working environment.
Reynolds 2006	Does not examine patient safety initiatives or involvement of consumers. Commentary on the importance of a collaborative physician-stakeholder relationship in disability management.
Richards 1998	Does not examine patient safety initiatives; pragmatic RCT comparing hospital at home care versus routine hospital care
Richman 2005	Does not examine patient safety initiatives. Trial comparing a computer based physician-patient decision making model to the traditional disease management model for prostrate cancer.

Author and Year	Reason for Exclusion
Ringdal 2002	Does not examine patient safety initiatives. Cluster–RCT examining the satisfaction of family members of patients participating in a palliative care program in Norway.
Ritter 2003	Does not examine patient safety initiatives. Drug trial results.
Roberts 1999	Does not examine patient safety initiatives. Assessing consumer involvement in the Quality Adjusted Life Years method for priority setting
Roth 2002	Does not examine patient safety initiatives. Longitudinal study of consumer perspectives and needs, obtained by interviews, of their care provided by a mental health.
Runeson 2007	Does not examine patient safety initiatives. Qualitative study on children's knowledge, participation in discussion and decision making and experience of hospitalisation for a diagnostic procedure.
Ruskin 1999	Does not examine patient safety initiatives. Commentary on changes to the managed care health system in the US.
Ryan 2001	Does not examine patient safety initiatives. Systematic review of techniques to elicit public views on the provision of healthcare. Does not involve patients in the planning of the methods.
Salzer 1997	Does not examine patient safety initiatives. Discussion paper on a framework for consumer empowerment in organisational decision-making in mental health.
Sanders 2001	Non health care related. Discussion paper on the reorganisation of social services to the private sector in an attempt to improve health of impoverished children and families.
Sanderson 2002	Does not examine patient safety initiatives. Qualitative report on the barriers and enablers to physical activity in African American women in a rural community.
Schunemann 2005	Does not examine patient safety initiatives. An evaluation of a self administered chronic respiratory questionnaire measuring patient health related quality of life.
Schwartz 1996	Does not examine patient safety initiatives. Cross sectional study on the validity of patient-reported cognitive ability compared to neuropsychological testing in patients with multiple sclerosis.
Scott 2004	Does not examine patient safety initiatives. Repeated-measures design of a nursing intervention targeting patient participation in decision making in the management of their heart failure.
Smith 2007	Does not examine patient safety initiatives. Literature review to identify approaches taken to obtain patient experiences of their interactions with health services. Identifies important practical issues for involving service users in planning and development of patient focused care pathways.

Author and Year	Reason for Exclusion
Spath 2007	Does not examine patient safety initiatives. Opinion piece discussing ways to overcome communication barriers in mistake prevention
Staniszewska 2000	Does not examine patient safety initiatives. Discussion on the difficulties of measuring patient satisfaction and the implications this has for involving patients in evaluating health care.
Stevenson 2004	Does not examine patient safety initiatives. Discussion piece on the involvement of patients in improving service quality in primary care.
Street 1997	Does not examine patient safety initiatives. Patient involvement in decisions about their own health care for breast cancer.
Sullivan 2005	Does not examine patient safety initiatives. Case study of involving advocates and female victims of domestic violence in the research design, implementation, analysis and dissemination of domestic violence research.
Svarstad 2005	Does not examine patient safety initiatives. Observational study which involved experts and consumers evaluating patient medication leaflets provided in US pharmacies in terms of their accuracy and descriptions of contraindications, precautions, and ways to avoid harm.
Sykes 2007	Does not examine patient safety initiatives. Study identifies different types of involvement in healthcare and establishes a questionnaire to measure quality of involvement.
Tannenbaum 2006	Does not examine patient safety initiatives at an organisational level. Editorial calling for greater facilitation by physicians to empower patients to choose the best therapies for themselves after weighing the individual risks associated with these.
Tarrier 2000	Does not examine patient safety initiatives. Review of psychosocial interventions and patient involvement in the treatment of schizophrenia
Tat-Kei Ho 2002	Non health related. Qualitative report on the involvement of citizens in local government performance measurement of city operations and responsibilities of departments.
Terry 2000	Does not examine patient safety initiatives. Commentary on engaging the genetics research community, lay advocacy organisations and the general public in building public awareness of genetic technologies and services.
Thomas 2001	Does not examine patient safety initiatives. Discussion on three strategies to empower patients regarding their health care.
Thornton 2003	Does not examine patient safety initiatives. Commentary on consumers’ experiences in a cluster randomised trial of professional skill development which was informed by consumer and patient engagement.
Truman 2001	Does not examine patient safety initiatives. Evaluation of a home option of integrated care for older people. Patients were involved in the evaluation.

Author and Year	Reason for Exclusion
Twible 1992	Does not examine patient safety initiatives. Case study of consumer participation in planning a health promotion programme for a Veteran’s Quality of Life Project.
Valentine 2003	Does not examine patient safety initiatives. Study examining patient involvement in shared decision making regarding their care in a mental health rehabilitation unit.
Vitiello 2001	Does not examine patient safety initiatives. Summary report, from a workshop, on the need for further research on psychotropic medication use in young children, specifically the efficacy and safety of pharmacologic treatments. The report provides a list of recommendations, including the need for research on the safety of medication use in this group. Patients and carers were involved.
Warrack 2004	Workplace related. Commentary on the involvement of consumers in a review of Manitoba’s health and safety legislation in 2001.
Westermann-Cicio 2003	Neither patient safety nor consumer involvement. Library collaboration strategies to better inform healthcare consumers via electronic information.
White 2001	Does not examine patient safety initiatives. Report on the role of consumers as collaborators (via participatory action research) in disability research conducted in the community.
Whitlock 2001	Does not examine patient safety initiatives and does not involve consumers. Report on the development of a nutritional supplement program for end stage renal disease patients of the Missouri Kidney Program.
Whitty 2005	Does not examine patient safety initiatives. Report on the process of setting up and running an area-wide ‘extended’ computerised diabetes register which actively involved patients in improving their own diabetes own care with primary care clinicians.
Williams 2002	Does not examine a patient safety initiative. Commentary on the importance of patient views and actions taken at a hospital following a review of patient views.
Wilt 2003	Does not examine patient safety initiatives. Commentary of the involvement of patients in their treatment of prostate cancer.

Appendix 3 - Summary of articles identified in Part Two but not directly relevant to the review questions

Even though a number of the articles and reports below do not meet the selection criteria for this review (i.e. patient safety initiatives at an *organisational* level) they may provide some insight into the more common methods adopted to engage consumers.

A number of these articles describe the involvement of consumers in the development of patient information leaflets, with an emphasis on medication information leaflets, and the development of evidence-based guidelines. Medication-related adverse events are the most frequently reported and there has been much focus on improving medication safety for consumers over the last ten years.

Nilsen et al (2006) identified five randomised control trials of moderate or low methodological quality on consumer involvement in the health care policy (n=1); healthcare research (n=2) and development of patient information (n=2). All evaluated consumer consultation in the development stage and none evaluated consumer involvement in decision making during this process. This review concludes there is little evidence from comparative studies about the effect of consumer involvement in healthcare decisions at the population level. The review also highlights that little research has been done to find the best ways of involving consumers in healthcare decision at the population level. Most of the studies included in the review compared consultations with consumers to no consultations with consumers. There was moderate quality evidence from two studies that involving consumers in the development of patient information material results in material that is more relevant, readable and understandable.

In the following tables a summary is provided of articles that may be of interest, including one systematic review on the methods of consumer involvement in the development of healthcare policy and research, clinical practice guidelines and patient information material (Nilsen 2006).

Many studies were retrieved that discussed strategies focusing on empowering the consumer to speak up and have an active role in their health. These have not been summarised as they do not relate to patient safety initiatives at an organisational level.

Similarly no eligible reports or documents were located in the grey literature. Many of the documents found related to methods of consumer participation. Reports that may be of interest but not directly relevant to this review have been summarised in Table 18.

The tables below summarise the articles that were not directly relevant to the topic of the literature review but may provide some useful information on consumer participation in other areas of health care.

Table 12 **Part Two – summary one (not directly relevant but of interest)**

Title: Methods of consumer involvement in developing healthcare policy and research, clinical practice guidelines and patient information material (Review)

Author: Nilsen E, Mryhaug HT, Oliver S, Oxman AD

Research Purpose	Methods	Findings	Authors Conclusions	Comments
To assess the effects of consumer involvement and compare different methods of consumer involvement in developing health care policy, research, clinical practice guidelines and patient information.	Systematic review. Searching yielded 7943 citations. Two reviewers independently selected trials for inclusion, assessed their quality and extracted their data. Five randomised controlled trials of moderate or low methodological quality involving 1031 participants were included. Participants: Patients, unpaid carers, parents/guardians, health service users, disabled people, the public, groups asking for research, organisations representing service users and carers. Types of intervention: Healthcare policy, research, clinical practice guidelines, patient information material. Outcome measures: To be included a study must have had a quantitative measure requiring the use of validated instruments, of one of the following outcomes; Participation or response rates of consumers, consumer views	The authors identified the following studies on consumer involvement: • Health care policy (n=1) • Healthcare research (n=2) • Development of patient information (n=2) All evaluated consumer consultation in the development stage and none evaluated consumer involvement in decision making during this process. There is moderate quality evidence that involving consumers in the development of patient information material results in material that is more relevant, readable and understandable to patients, without affecting their anxiety. Consumer-informed material can also improve patients' knowledge. There is low quality evidence that using consumer interviewers instead of staff interviewers in satisfaction surveys can have a small influence on the survey results. There is very low quality evidence of telephone discussions and face-	There is a huge gap in the evidence from comparative studies about desirable and adverse effects of consumer involvement in healthcare decisions at the population level, or how to achieve effective consumer involvement. There is evidence, from two studies of moderate quality, that consumer involvement in developing patient information material can improve the clarity of the information and knowledge of those who read the material. There is evidence, from two studies of moderate quality that using consumer interviewers instead of staff interviewers can result in small differences in satisfaction surveys. There is evidence, from one study of low quality, of differences in the views of participants towards priorities for community health goals when telephone discussions were used, compared to face-to-face meetings, to involve the public.	This review highlights the lack of evidence from comparative studies of the effects of consumer involvement in health care decisions at the population level. The studies included in the review demonstrate that randomised controlled trails are feasible for providing evidence about the effects of consulting consumers. There are good arguments for attempting to achieve effective consumer involvement.

	elicited, effects of consumer involvement on decisions, healthcare outcomes or resource utilisation, satisfaction with the involvement process, costs and impact on participating consumers.	to-face group meetings engaging consumers better than mailed surveys in order to set priorities for community health goals, and resulting in different priorities being set for these goals.		

Table 13 **Part Two – summary two (not directly relevant but of interest)**

Title: Expert and consumer evaluation of patient medication leaflets provided in US pharmacies

Author: Svarstad B, Mount J, Tabak E

Research Purpose	Methods	Findings	Limitations	Comments
To evaluate the distribution and quality of patient medication leaflets provided in US pharmacies.	Observational study. Random sample of 384 community pharmacies in 44 states of the US. Professional shoppers obtained medication leaflets for four new prescriptions. The medication leaflets were evaluated by 16 experts and 154 consumers recruited by consumers. Consumers were reimbursed for travel expenses. Adherence to the eight criteria below on 1,367 leaflets was completed: • Drug names and indication • Contraindications and actions • Directions on monitoring • Specific precautions and how to avoid harm • Symptoms of serious or frequent side effects • General information and encouragement to ask questions • Were scientifically accurate, unbiased and up to date.	Leaflets were provided at 89% of pharmacies for 1,536 prescriptions presented by expert shoppers. Leaflet quality varied; 95% rated as high for accuracy but only 19% rated as high on specificity of directions. Fewer than 10% met quality criteria regarding contraindications, precautions and how to avoid harm. 25% had poor print size. Consumer ratings were higher than expert ratings.	Data was collected by English-speaking shoppers so the findings are not generalisable to other populations, scenarios or settings. Consumer panelists provide new information regarding leaflet quality and it is not known if similar results would be obtained using other methods of selecting consumers or other methods of assessing comprehensibility or legibility. The study focused on written information and does not assess how consumer perceptions are affected by verbal counselling that accompanies written information.	This study is one of the first to evaluate the distribution and quality of patient medication leaflets in a national sample of community pharmacies. It highlights the need for consumer medicines information leaflets to ensure the information provided meets the needs of consumers.

Table 14 **Part Two - summary three (not directly relevant but of interest)**

Title: Patient Information: involving the user group

Author: Paul F, Cumming P, Fleck E

Research Purpose	Methods	Findings	Limitations	Comments
To improve the information production of patient information leaflets within an acute hospital trust. Specifically to: 1. Identify specific problems with existing patient information leaflet; 2. Facilitate staff training in information development and to encourage patient involvement in the process; and 3. Evaluation of the training provided to staff and the new information.	Case study. Describes the process of changing the development of patient information brochures in a UK health trust. A previous review identified problems with in-house information, including a lack of patient involvement, poor quality print and over-use of technical language. Staff were trained in strategies to facilitate patient involvement, by conducting small surveys and interviews with patients to ensure information was developed according to their needs and acknowledged their experiences and role as holders of knowledge.	There is no analysis of data or outcomes stated. Anecdotal reports from patient evaluations of the revised leaflets were positive. Staff found the training in the production of effective patient information useful as they had little or no prior knowledge in this area. Challenges discussed relate to implementation practice changes and staff engagement in the project. No details are provided on the success of staff training on engaging patients in the development of information leaflets. Recommendations are made for improving the ease of reading.	This is a case study so there is no evaluation. Limitations or success factors are not described either.	Highlights the importance of applying evidence-based and good practice guidelines to information development and valuing patient's views throughout the process to enhance communication with health care professionals. Critical success factors reported as: • senior management leadership and commitment • multidisciplinary staff commitment • dedicated patient involvement • an action oriented approach • mix of internal and external expertise • wide and sensitive communication.

Evidence-based Clinical Practice Guidelines

Table 15 Part Two - summary four (not directly relevant but of interest)

Title: Patient involvement in clinical guideline development – where are we now?

Author: Kelson M

Research Purpose	Methods	Findings	Limitations	Comments
Describes the potential for and progress made in involving patients and carers in the development of national clinical guidelines.	Describes the advances and current approaches of patient and carer involvement: • In the development of clinical guidelines (local, nationally and for the National Institute for Health and Clinical Excellence) • As stakeholders for input into individual guideline topics • In guideline development groups • In development of patient and carer versions of NICE guidelines • In the implementation of guidelines.	A summary of the key considerations when involving patients and consumers in the development of guidelines is provided. The key messages are: • Involve patients, consumers, consumer reps on working parties and steering groups. • Survey consumers to identify their perceptions on areas requiring guidelines development. • Be clear about the purpose of consumer involvement and their tasks. • Ensure consumers have relevant experience and skills. • Provide support, training and financial reimbursement. • Enhance effectiveness by providing training where appropriate.	This is a case study so there are no outcomes reported. Limitations are not described either.	This paper considers how patient and carer involvement in clinical guideline development has developed over time and describes the increased opportunities for patient and carer involvement. Provides a list of potential strategies for engaging consumers in guideline development at an organisational level. The transferability of these strategies is high.

Table 16 **Part Two - summary five (not directly relevant but of interest)**

Title: Improving services for people with diabetes: lessons from setting up the DREAM trial

Author: Whitty P, Eccles MP, Hawthorne G, Steen N, Grimshaw JM, Wood L, Speed C, McDowell M

Research Purpose	Methods	Findings	Limitations	Comments
This paper describes the process of setting up and running a trial* and presents findings on the lessons learnt. *The aim of the trial was to evaluate the effectiveness and efficiency of an area-wide 'extended' computerised diabetes register. This was done by: 1. Developing an extended register covering a range of geographically separated settings. 2. Incorporating a structured recall and management system. 3. Actively involving patients and including clinical management prompts to primary care clinicians based on locally adapted, evidence-based guidelines for diabetes.	Cluster RCT study of 58 general practices. Practices were stratified by primary care trust (PCT). Intervention practices (29) worked with the extended computerised diabetes register Control practices (29) were served by the pre-existing register. Developing and setting up the extended computerised comprised a number of steps: 1. Development of locally adapted evidence-based CPG. 2. Development of structured management sheet. 3. Support patient representatives in designing 'patient prompts' or reminder letters. 4. Adapt the diabetes register software. 5. Liaise with primary and secondary care representatives and local patient organisations. Consumer representatives were involved in the planning and development of the project.	Overview of the issues encountered for obtaining patient consent to be on register, the installation of new software, pilot testing of the new register and the process of designing and implementing the register. Lessons learnt include: 1. Wide involvement and consultation, both in and out side of meetings. 2. Explicit timescales, with commitment to only single meetings. 3. Focus within the meetings on a very specific task. 4. Several rounds of paper consultations subsequent to meetings. 5. Credibility of the original draft of the evidence-based guidelines. Success factors for involving patients include: • Expecting commitment to only one meeting to focus on a very specific task. • Asking patients to draft the patient letters was a simple and effective additional strategy that deserves wider application. Patients were particularly keen to avoid 'consequence oriented' phrasing in communication, such as "Diabetes can effect your eyes" and the use of jargon.	Limitations in the discussion include the lack of explanation on the 'pragmatic methods' used to achieve agreement and what in this actually relates to.	This article provides useful insight into the involvement of patients and/or consumers in the development of evidence-based clinical practice guidelines, the language to use in asking patients questions during the assessment process and reminder letters to patients.

Table 17 **Part Two - summary six (not directly relevant but of interest)**

Title: Developing an evidence base for patient and public involvement

Author: Murie J and Douglas-Scott G

Research Purpose	Methods	Findings	Limitations	Comments
To provide evidence of health policy being translated into practice by providing a summary of five years experience of patient and public involvement in primary care.	Two case studies are cited. This article describes public and patient involvement in a range of initiatives in Scotland. It describes the development and uses case studies to illustrate the alignment of primary care with a framework for patient and public involvement. Examples are derived from clinical governance, health promotion and needs assessment include patient and public involvement in significant event analysis and audit, joint training and patient held-record cards. Factors contributing to six drug-related deaths were analysed from the perspective of patient, carer and community.	Positive outcomes reported are effective dialogue between health professionals, patients and the public, service developments and quality improvements. The success of initiatives is retrospectively rated against the Audit Commission's User Focus and Citizen Engagement Critical Success Factors (CSFs). The need for work to be done to validate success criteria for in relation to health-related matters is identified. Key success factors of the projects were the involvement of users in design, content and evaluation.	Outcomes reported do not relate to patient safety. The ability of the model described being replicated elsewhere is unlikely given the geographical, historical and administrative differences.	This article provides an overview of some of the challenges and opportunities for meaningful patient and public involvement. Advocates for significant event analysis to be undertaken with consumers as a powerful learning experience with the potential to improve patient care and safety.

Reports on methods on consumer participation

The tables below summarise the grey literature that was not directly relevant to the literature review but may provide some useful insights on methods of consumer participation.

Table 18 Part Two - summary of grey literature reports on methods of consumer participation

Author, Year	Type	Summary
Oliver 2004	Report	Review of the literature of consumer involvement in research and development. Provides an overview of methods for involving consumers in research and development. Methods of inviting consumer involvement include: • Consumer group involvement through collaboration e.g. committee membership, team working, combining with consultation • Consumer group involvement through consultation e.g. written consultations, face to face consultations, multiple face-to-face consultations, combination of written and face-to-face • Individual consumers through collaboration e.g. team working • Individual consumers through consultation e.g. opinion surveys • Responding to consumer action with collaboration e.g. multi level participation in partnership with consumers, consumer activism leading to organisational change and multi level participation • Responding to consumer action with consultation • Responding to consumer action with research e.g. research about patient views, matching consumer priorities • Independent consumer action
Johnson 2002	Report on a research project	This is a very good report on the different definitions and methods of consumer participation along the continuum of care. It explores some of the issues for consumers and consumer representatives which may inhibit or enhance their participation in initiatives. The results inform the development of a model of consumer participation at a large teaching hospital. A developmental model, focusing on capacity building or the organisation, staff and consumers, was found to be more useful than a consumer participation model that formalises participation through structures such as consumer advisory committees etc. It highlights the lack of evidence on the methods and approaches of involving consumers in improving the safety of health services.

Author, Year	Type	Summary
Wadhwa 2002	Commentary	This commentary provides an overview on the number of ways in which the consumers can participate and advocates boosting consumer involvement. The four key ways consumers may participate are; consultation, participation, substantive participant and structural participation • Consultation which asks for people's opinions and reactions to plans. The consultation is limited, initiated by organisations outside the community and usually controlled by the organisation initiating consultation • Participation is used to achieve a defined end. Again it is initiated by organisations outside the community. An example is the establishment of community panels for priority setting in health. • Substantive participation occurs where people are actively involved in determining priorities and implementation, but when the imitative is externally controlled. Although people outside the community may initiate it, this type of participation may lead to structural participation over time. If the initiative becomes developmental, it may involve a shift in power to the community. Examples include initiatives by a community health centre staff and community heart health programs working with local agencies. • Structural participation is an engaged and developmental process in which community control predominates. The initiative may develop from outside the community initially but eventually control is handed over to the community. It is a developmental, ongoing relationship, which is driven by the community and potentially hands back power to individuals, organisations and communities. Examples include Aboriginal-controlled health services and resident action groups. Highlights that efforts to involve consumers in safety initiatives will only succeed if change is implemented at the senior management level, actively supported by middle management and staff.
Johnson 2001	Background paper and literature review	This is a short review of the literature on the dimensions and definitions of consumer participation. It emphasises the choice of method should be aligned to the purpose of; the consumers involved; time factors; skills and resources of the professionals. Key elements identified as critical before any effort can be made to develop a consumer participation model are organisational commitment and leadership, workforce development and consumer development.
Clark 2001	Report	Describes results from a comprehensive population telephone survey (n = 1501) of Australian attitudes and preferences to participation in health care and perception of patient safety. Response rate was 43% overall, with the majority of respondents from NSW and Victoria. A total of 103 people reported having experienced an adverse event during the past 12 months (~6.5%). The main category of adverse vents is medication related, which is consistent with previous studies.
Comden 2002	Report	This document is targeted to patient safety coalition leaders, policy makers and stakeholders. It provides an overview of organisations and agencies contributing to patient safety (American bias) and details lessons learned in membership development, communication, successful activities and building trust. Specific remarks on patient safety coalitions as increasing in number; their important role as forums to share new idea about error prevention; consumer participation is a critical element; and factors influencing success are the relationships between stakeholders; the purpose; membership heterogeneity; independence; and responsiveness. It is noted the lack of evaluation on the effectiveness.

Author, Year	Type	Summary
Consumer Focus Collaboration May 2001	Review	Summary of the evidence that supports active consumer participation at in health. Does not present information on specific methods of involving consumers. Articulates the lack of research and hence literature on consumer participation. Reported research does not at this time (2001) often use methodologies such as randomised trails and systematic reviews; rather is descriptive studies and process evaluations. Advocates the need for research in this area.
Farley 2003-04	Report	Annual evaluation on AHRQ’s activities, progress and issues. In addition, a framework and possible measures for evaluating the effects of patient safety initiatives on outcomes for patients and stakeholders other than patients. This paper identifies the need to provide mechanisms to support consumer-led organisations in their pursuit of active patient involvement with health care organizations for actions to achieve safer care, including dissemination of the models they are using to a broader health care audience.