Patient and public involvement in clinical practice guidelines: a knowledge synthesis of existing programs

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<th>Journal:</th>
<th>Medical Decision Making</th>
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<td>Complete List of Authors:</td>
<td>Legare, France; Centre de recherche CHUQ Boivin, Antoine; Radboud University, Scientific Institute for Quality of Healthcare, van der Weijden, Trudy; Maastricht University, School for Public Health and Primary Care Pakenham, Christine; Ministère de la santé et des Services Sociaux de Québec Burgers, Jako; Maastricht University, School for Public Health and Primary Care Légaré, Jean; Canadian Arthritis Alliance St-Jacques, Sylvie; Institut national de santé publique du Québec Gagnon, Susie; Centre de recherche CHUQ</td>
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<td>APPLICATION AREAS:</td>
<td>TRANSLATING RESEARCH INTO PRACTICE</td>
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<td>DETAILED METHODOLOGY:</td>
<td>Shared Decision Making &lt; DECISION AIDS--TOOLS, Clinical Practice Guidelines &lt; HEALTH SERVICE RESEARCH, Systematic Reviews &lt; EVIDENCE SYNTHESIS</td>
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</table>
Title: Patient and public involvement in clinical practice guidelines: a knowledge synthesis of existing programs

Running head: Patient and public involvement in guidelines

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Abstract (271/275 words)

**Background:** The role of patient and public involvement programs (PPIPs) in developing and implementing clinical practice guidelines (CPGs) has generated great interest.

**Purpose:** We sought to identify key components of PPIPs used in developing and implementing CPGs.

**Data sources:** We searched bibliographic databases and contacted relevant organizations.

**Study selection:** We retrieved 2161 articles and reports on PPIPs in the development and implementation of CPGs. Of these, 71 qualified for inclusion in our review.

**Data extraction:** Reviewers independently extracted data on key components of PPIPs and barriers and facilitators to their operation.

**Data synthesis:** Over half of studies were published after 2002 and over half originated from the United States, the United Kingdom, Australia and Germany. CPGs that involved patients and the public addressed a variety of health problems, especially mental health and cancer. The most frequently cited objective for using PPIPs in developing CPGs was to incorporate patients’ values or perspectives in CPG recommendations. Patients and their families and caregivers were the parties most often involved. Methods used to recruit PPIP participants included soliciting through patient/public organizations, sending invitations, and receiving referrals and recruits from clinicians. Patients and the public most often participated by taking part in a CPG working group, workshop, meeting, seminar, literature review, or consultation such as a focus group, individual interview, or survey. Patients and the public principally helped formulate recommendations and revise drafts.
Limitations: We did not contact the authors of the studies.

Conclusion: Our literature review provides an extensive knowledge base for making PPIPs more effective when developing and implementing CPGs. More research is needed to assess the impact of PPIPs and resources they require.
Introduction

Clinical practice guidelines (CPGs) are systematically developed statements designed to help practitioners and patients decide on health care for specific clinical circumstances.\(^1\) The implementation of CPGs in clinical practice is expected to improve patient outcomes by promoting interventions of proven benefits and discouraging ineffective one.\(^2\) Also, CPGs accompanied by consumers’ versions may empower patients to make more informed healthcare choices.\(^2\) Productive interactions—such as shared decision making—between active and informed patients and their healthcare providers have been shown to be a key component of good care.\(^3\) Involving patients in decisions also produces a better decision-making process, more personal comfort with the decision,\(^4\) a reduction in the overuse of options that are not beneficial for the vast majority, an increase in the options known to be beneficial,\(^5\) and better patient quality of life.\(^6\) Nonetheless, implementing CPGs has been a major challenge.\(^7\) CPGs often fail to reconcile patients’ preferences and social norms with best evidence\(^8,9\) and do not always account for patients’ increased demands to play a more active role in their own care.\(^10-12\)

Involving patients and the public when developing and implementing CPGs is therefore attractive because of its potential to address the gaps between patients preferences and best evidence.\(^10,12,13\) Yet there is little guidance as to the design of patient and public involvement programs (PPIPs) in the context of CPGs.\(^14\) Consequently, we reviewed and synthesized the existing knowledge (published and unpublished) to identify and appraise the key components of PPIPs in the development and implementation of CPGs.\(^15\)
Methods

Data sources

A detailed description of our search methods can be found elsewhere. Briefly, with the help of an information specialist, we searched bibliographic databases and the reference lists of relevant articles for English and French documentation on PPIPs in the development and implementation of CPGs published before January 2009. With help from the Guidelines International Network Public Working Group, we searched for grey literature by writing to the email lists of relevant organizations and by contacting provincial and national institutions involved in the production and implementation of CPGs.

Selection criteria

To be included, the document had to (1) refer to the development or implementation of a CPG; (2) refer to patients (people with a personal experience of the disease, the health intervention, or the service discussed in the CPG, as well as their family members and caregivers) and/or members of the public (members of society interested in healthcare services, whose life could be directly or indirectly affected by the CPG); and (3) refer to a PPIP (at a minimum, refer to a formal method of involving patients and/or the public in the development or implementation of a CPG). Eligible documents included original qualitative, quantitative, or mixed methods studies and reports produced by academics or by national, governmental, for-profit or nonprofit organizations.
Two research assistants screened all the documents thus retrieved to determine which were relevant. Any disagreements were resolved in discussions with the co-principal investigators (FL and AB).

**Data extraction**

The data from all relevant documents were independently extracted by pairs of research assistants who used a data extraction form employed in previous work in this field.\(^{16-19}\) The data collected consisted of 1) characteristics of the documents; 2) key components of the PPIP (who was involved, how and for what purpose were they involved, and at what stage of the CPG’s development were they involved); and 3) the context in which the PPIP was developed and tested: namely, perceived barriers and facilitators and the impact of the PPIP on involvement and other outcomes. Pairs of reviewers compared abstracted information. Any disagreements were resolved in research team meetings.

**Data analysis**

A research assistant entered the abstracted information into a data matrix to facilitate comparison of how PPIPs performed on each principal component. Template content analysis was used to organize the principal components into a meaningful framework.\(^{20}\) We computed the frequency of mention of each principal component extracted.

This study was funded by a knowledge synthesis grant from the Canadian Institutes of Health Research (CIHR). CIHR had no role in the study.
Results

Included documents

Of the 2104 articles identified in bibliographic databases, 38 were eligible for our review. In addition, we obtained 57 reports from relevant organizations: of these, we included 33 reports in our review. After reviewing the material, we concluded that 7 of the 38 studies were more akin to grey literature reports than to studies. Our review thus consisted of 71 documents: 31 studies from peer-review publications and 40 reports from the grey literature. Figure 1 shows the flow of the data synthesis.

Characteristics of the documents

All documents included in our review (table 1) were produced from 1996 to 2008. More than half (49/71) were produced after 2002. Most originated from the United States (23/71), the United Kingdom (15/71), Australia (8/71) and Germany (5/71). Most of the published studies were descriptive (22/31) and used qualitative methods (22/31). CPGs that had involved a PPIP addressed a variety of health problems. Mental health (13/71) and cancer (8/71) were overly represented. The CPGs mainly targeted users: patients (13/71),
physicians (13/71), 25, 35, 40, 45, 54, 60, 69, 71, 75, 87-90, other health professionals (12/71) 26, 28, 31, 41, 42, 54, 64, 75, 77, 78, 87 and the public (8/71). 22, 37, 38, 44, 49, 86, 89

Patient and public involvement programs in CPGs

The patient and public involvement programs and interventions discussed in the documentation are described in table 1. In general, the studies and reports provided a superficial description of the process of development of the CPG and the components of the PPIP involved. Only one study, from Australia, assessed the PPIP’s impact on participants. 88 Reports from organizations made more detailed presentations of the components of the PPIP and the practicalities of involving patients and the public in CPG development and implementation activities.

The most frequently cited objective of using PPIPs to develop CPGs was to incorporate patients’ values, preferences, knowledge or perspectives in CPG recommendations (23/71). 21, 25, 28, 30, 33, 37-39, 41, 47, 50, 51, 54, 57, 60, 61, 64, 67, 77, 81, 83, 85, 87 Other objectives were to improve the implementation of the CPG (7/71), 26, 39, 50, 55, 59, 65, 66 increase the comprehensiveness of the CPG (7/38), 49, 58, 72, 76, 85, 86, 89 promote patients’ or the public’s influence over the CPG development process (6/71), 22, 25, 43, 82, 85, 88 and adapt CPGs to the target population (5/71). 32, 46, 70, 79, 80

Individual patients (45/71) 24-33, 35-39, 41, 46, 48, 50-53, 55-57, 60, 62, 64-67, 69-73, 76, 77, 80, 82, 83, 85, 87, 91 and patient representatives (family, caregivers) (32/71) 23, 25, 28, 30, 32-34, 36-41, 43, 50, 51, 53, 54, 59, 60, 62, 63, 65, 66, 69, 70, 76, 83, 85, 88, 91 were the parties most frequently involved in PPIPs,
followed by a more diverse group of individuals (e.g., community leaders and individuals without health problems but who might use the CPG in future) (14/71). Methods used to recruit patients or the public in the CPG development process were rarely described, but recruiting through patient/public organizations (12/71), sending invitations (8/71) and receiving referrals and/or recruits by clinicians (6/71) were mentioned.

Most often, patients and the public helped develop CPGs by participating in a CPG working group (28/71); a workshop, meeting or seminar (10/71); a literature review (7/71); or a consultation such as a focus group (24/71), an individual interview (11/71), or a public poll or survey (9/71).

Patients and the public were mainly involved at the stage of formulating recommendations (28/71), synthesizing the knowledge (25/71) and revising drafts (23/71). In some reports, patients and the public helped make strategic decisions about the CPG development process (e.g., the scope, what actors to involve) (15/40) or the development of products for patients or the public (e.g., information material, decision aids) (14/40).
The studies and reports indicated that PPIPs require the following material resources:

- written documentation (publications, reports, reminders, booklets, handbooks) (15/71), draft or existing CPGs (14/71),
- questionnaires (e.g. validated, self-administered questionnaires or interview guides) (12/71),
- recording material (tape recorders and video cameras) (9/71),
- and financial resources (4/71).

The human resources required by PPIPs were:

- a facilitator or chairperson (6/71),
- a project coordinator (4/71),
- a translator,
- a trained interviewer and a trained moderator.

**Lessons learned by CPG development organizations**

Few documents reported detailed lessons learned by CPG development organizations that had employed a PPIP. Some organizations held a positive opinion of their experience with the PPIP, feeling that the PPIP had helped formulate extra key questions, had changed existing questions, or had encouraged patients to join healthcare practitioners in making decisions. For example, for one organization, patients’ input helped ensure that the complex medical terminology used in the CPG would be widely understood. This was felt to be necessary for enhancing the community’s understanding of current health and disability issues and increasing community access to the most appropriate health services.

Another organization reported extensively on its experience with the PPIP. This organization felt that patients experienced difficulty with the technical language and
contributed infrequently to the discussion. The organization therefore developed a series of workshops in which it explained the technical elements of CPG development to patients, who then made relevant suggestions. However, this process was resource-intensive. This organization also felt that involving an “expert” patient was helpful but acknowledged that this “expert patient may not be representative.” The organization concluded that a range of methods for involving patients and the public was ideal and suggested that involving consumers both in CPG development groups and in other structures, such as focus groups or surveys that informed the CPG development groups, should be considered. Two organizations opined that it was necessary to involve patients or the public at every stage of the CPG development process and at individuals’ desired level of involvement. Other organizations suggested that it was better to involve patients before the process officially began. The organizations also pointed out that participation in a CPG development group requires abilities or skills necessary for effective group processes, such as communication skills, teamwork skills, and the ability to represent the views of a wider group.

**Feedback by PPIP participants**

One organization reported that patients felt that they had little or no influence on finance, group composition, literature searches, and the measurement of the effects of the CPG. However, patients considered they had some influence on defining key questions for the CPG, writing questions used to search the literature, selecting and reviewing the literature, writing text, implementing the CPG, and developing information for patients. Patients believed their greatest influence was defining key problems for CPGs to address,
writing recommendations, and reviewing draft guidelines. This feedback is congruent with what other organizations have reported: the impact of patients’ involvement is felt to be small (e.g., patients help choose the words used to formulate recommendations) and their influence on debates is rarely measured. Some experts expressed reserve toward PPIPs because of what they felt was patients’ inability to act on highly technical documents.

Few organizations formally assessed patients’ and the public’s satisfaction following their participation in a CPG development process. Overall, and despite the variability of the experiences reported, the respondents were generally satisfied with having been part of a CPG development group. For example, 72 percent of participants in CPG development groups led by the National Institute for Health and Clinical Excellence (NICE) rated their overall experiences as excellent or very good. These participants were generally positive about the methodology adopted and the final CPG. Lay members were enthusiastic about the version for patients and caregivers and its intended use and they valued the personal development opportunities that involvement in the guideline development group had afforded them. In a study by Wilson et al, 90 percent of parents felt that participating in a CPG development group was an informative process and nearly 67 percent said that they gained valuable knowledge and felt more confident in caring for their sick children.

The New Zealand Guidelines Group (NZGG) conducted an evaluation survey of consumers involved in the development of their CPGs. Although respondents were
generally satisfied with the final guideline, some had experienced resistance to their input and had felt isolated, while others had felt accepted and valued. Interestingly, 11 of 12 respondents said that they would be willing to participate in a CPG development group again.\textsuperscript{52} In contrast, some participants mentioned that they were often concerned that the hard work that had gone into developing the recommendations had not translated into actual changes in practice.\textsuperscript{63} Some parents involved in focus groups in the Wilson study mentioned that more information at the outset would have been useful and felt that the discussions had been one-sided.\textsuperscript{88} Other patients reported having had great difficulty in understanding the complexity and technicality of the subject, and having felt maladjusted to the procedure. These feelings were compensated by a strong sense of belonging to the working group.\textsuperscript{28}

**Barriers and facilitators to PPIPs**

Table 2 details barriers and table 3, facilitators to PPIPs in the development of CPGs, based on excerpts from the publications included in our review.

Notably, a discrepancy between the perspectives of experts and patients/the public was the most frequently reported barrier (8/71).\textsuperscript{28, 38, 55, 57, 63, 65, 66, 91} Other frequently mentioned barriers were the difficulty of recruiting patients or representatives of the public (7/71),\textsuperscript{27, 28, 37, 39, 47, 66, 67}, the lack of representativity of patients and members of the public (6/71),\textsuperscript{52, 65} 28, 39, 55, 66 and PPIP participants’ lack of familiarity with the scientific and medical terminology (5/71).\textsuperscript{27, 28, 67, 85, 91}
The two most frequently reported facilitators were training (14/71) and support from the staff and the organization (12/71).

For example, some organizations offered training days and seminars to assist PPIP participants with technical matters and critical appraisal skills. Support took the form of telephone and email assistance, mentoring, a supportive chair of the guideline development group, an analysis grid for knowledge synthesis, or a “welcome pack” for selected patients. Providing assistance with complex scientific and technical issues was another valuable way to optimize the participation of patients and public, as was offering participants opportunities to interact with other patients who had participated in the development of CPGs. Other facilitators included clear expectations about the process (e.g., who was involved and what role they were expected to fill, disclosure of the funds available, and specification of the time commitment expected) and involving a group of patients rather than a single patient.

Discussion

We identified 71 documents that reported on PPIPs in the context of the development and implementation of CPGs. Only a few of these documents contained substantial information about the key components of PPIP and the resources needed including financial resources. Very few documents provided information on the impact of PPIPs on the development and implementation of CPGs in clinical practice and none discussed health outcomes. Although reports were more likely than studies to provide information
on participants’ perceptions of their experience, very little quantitative impact assessment took place. Nonetheless, this knowledge synthesis is among the first to provide decision-makers with several elements of practical guidance.

First, there is a perception that it is difficult to reconcile the preferences of patients and the public with the views of experts (health professionals). Also, patients find it difficult to affirm their views and experiences in the presence of evidence-based information and complex scientific and medical terminology. Several CPG organizations have developed structured training and support to address these issues. Therefore, it is possible to adapt PPIPs so as to deepen patients’ and the public’s understanding of and confidence in scientific information.

Second, many fear that patients or members of the public who participate in a PPIP may not be representative. The World Health Organization has reviewed NICE’s experience of involving patients and public in CPGs and concluded that it is uncertain whether the right stakeholders were involved and whether their input was as efficient as it could have been. However, prevalent participation methods (such as involving patients in CPG development groups) dictate small numbers of participants, and it may be inappropriate to expect one or two patients to represent the views of large segments of the population. Other authors have challenged PPIP sponsors to clarify their understanding of representativeness and adapt their involvement methods and recruitment strategies accordingly. Some organizations have responded by using structured open recruitment methods.
strategies and by complementing their participation methods with larger consultations such as surveys and online comment options.⁵¹

Third, and related to the above, better evaluations of the methods used to involve patients and members of the public are essential. A Cochrane systematic review on methods of involving consumers in developing healthcare policy and research, CPGs and patient information material found 6 eligible trials.¹⁴ None focused on CPGs.

Fourth, training and supporting patients and members of the public who are participating in a PPIP should focus not only on critical appraisal skills but also on the skills needed to participate in a group process. Attention should also be paid to the role that chairs and other guideline developers can play in supporting PPIP participants.

Notwithstanding its interesting results, this knowledge synthesis has limitations. First, the significant proportion of grey literature in our source material (33/71) is evidence of the extensiveness of our search for eligible documents. However, we cannot exclude that we may have overlooked important documents. Second, we did not contact the authors of the studies or reports for elaboration on their findings. More research is needed to identify the key components of successful PPIPs and the resources they need, and to assess their impact on the quality of care.

Nonetheless, our knowledge syntheses’ provides an extensive knowledge base for elaborating effective PPIPs in the context of developing and implementing CPGs in the
future. This could also help standardize PPIP reporting. The review provides three main lessons. First, there are many ways to involve patients in developing CPGs and patient information material. Second, patients’ involvement tends to produce material that is more relevant, readable, understandable, and less likely to make the reader anxious. However, future research will need to assess the impact of PPIP in the context of CPGs on the quality of care and health outcomes.
Acknowledgements

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For Peer Review


Table 1. Characteristics of included patient and public involvement programs (PPIP) in the context of clinical practice guidelines

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<th>First author</th>
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<th>Objective of the PPIP</th>
<th>Description of activity (ies)</th>
<th>Who was involved</th>
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For Peer Review
(before/after);
qualitative
group;
meetings
Schofield
Published study; descriptive study; mixed study; mixed University of Newcastle
Cancer
To incorporate patients’ values, preferences, knowledge and perspectives in CPG recommendations
Individual
Individual
Review of draft

Collège des Médecins du Québec
Report by organization
Collège des Médecins du Québec
Prostate cancer
To validate the clarity and acceptability of information leaflet designed for the public
Focus groups; participation in the CPG working group
Individual
Knowledge synthesis, evaluation of specific products for patients/public

Friedman
Published study; descriptive study; qualitative
Lovelace Health System
Diabetes
Not mentioned
Patient
Individual
Knowledge synthesis, dissemination/implementation

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For Peer Review
in the CPG
working
group;
team meetings

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<td>Individual patients’ understanding of the CPG guideline</td>
<td>Focus groups; written consultations.</td>
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<td>Frances A. Matsuda Foundation; Hawaii Community Liaisons Nurse's Association</td>
<td>Alcohol, smoking and drug use</td>
<td>To adapt CPGs to the population’s characteristics</td>
<td>Focus groups; individual interviews</td>
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Sigma Theta Tau

van Wersch  Report by  North of England  Evidence Based Guideline Development Programme

2000  organization  Asthma, angina, myocardial infarction  To promote patients’/the public’s influence over the CPG working group process; to incorporate patient’s values, preferences, knowledge and perspectives in CPG recommendations; to increase the general population’s understanding of the CPG

Wilson  Published study; Information not available  Acute respiratory patient/public  To promote Focus groups Patients’ representatives  Formulation of recommendations

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<td>Published study:</td>
<td>The Pacific Diabetes Today</td>
<td>To adapt the CPG to the population’s characteristics study (before/after); qualitative</td>
<td>Training of community members to lead discussion groups; focus groups</td>
<td>Individual citizens and patient representatives</td>
</tr>
<tr>
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<td>---------------------------------------------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>2002</td>
<td>intervention study</td>
<td>Resources Center (PDTRC)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kelson</td>
<td>Report by organization</td>
<td>National Guidelines and Audit Patient Involvement Unit in collaboration with National Institute for Clinical Excellence (NICE)</td>
<td>To develop fair, transparent and defensible methods for patient/caregiver involvement; to ensure that patient issues and perspectives are directly addressed</td>
<td>Unclear Individual patients and patients’ representatives</td>
<td>Individual patients and patients’ representatives</td>
</tr>
<tr>
<td>2002</td>
<td>report</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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and presented in ways that are meaningful and acceptable to patients.

<table>
<thead>
<tr>
<th>National Kidney Foundation Report by National Kidney Foundation Chronic kidney disease</th>
<th>To review National Kidney Foundation clinical practice guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pell 2002 Published study; intervention study available Prophylactic oophorectomy study (before/after); mixed</td>
<td>To use patient-specific information on risks and preferences to provide guidance</td>
</tr>
<tr>
<td>Scherer 2002 Published study; descriptive study; mixed The Institute for Matching Person &amp; Technology Inc Rehabilitation</td>
<td>To incorporate patients’ values, nominal group preferences, technique knowledge and perspectives in CPG</td>
</tr>
</tbody>
</table>

Review of draft

Focus groups Representative of citizens’ recommendations, review of draft

Survey; Individual patients recommendations

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<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Study Type</th>
<th>Location</th>
<th>Domain</th>
<th>Methodology</th>
<th>Focus</th>
<th>Setting</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shoultz</td>
<td>2002</td>
<td>descriptive</td>
<td>University of Hawaii School of Nursing and Dental Hygiene, Kauai Community College</td>
<td>Violence against women</td>
<td>qualitative</td>
<td>To adapt CPG to the population’s characteristics</td>
<td>Focus groups</td>
<td>Individual citizens</td>
</tr>
<tr>
<td>Behets</td>
<td>2003</td>
<td>descriptive</td>
<td>The nongovernmental “67 Ha Clinic” in Antananarivo; the public dispensary in Tamatave</td>
<td>Sexually transmitted infections</td>
<td>mixed</td>
<td>To promote patients’/the public’s influence over the process</td>
<td>CPG working group</td>
<td>Representatives of citizens’ group (sex workers)</td>
</tr>
<tr>
<td>Bond</td>
<td>2003</td>
<td>descriptive</td>
<td>Grampian Evidence Based Community Pharmacy</td>
<td>Vulvovaginal candidiasis</td>
<td>qualitative</td>
<td>Not mentioned</td>
<td>Meetings; literature review; nominal group</td>
<td>Patients’ representatives</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Organization</th>
<th>Published Source</th>
<th>Type</th>
<th>Case Management</th>
<th>Approach Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global Program on Evidence for Health Policy</td>
<td>Report by World Health Organization</td>
<td>Not mentioned</td>
<td>Participation in the CPG working group</td>
<td>To adapt the CPG to the population's characteristics for elderly clients</td>
</tr>
<tr>
<td>Hadjistavropoulos</td>
<td>Published study; descriptive study; qualitative study</td>
<td>Community case management</td>
<td>To adapt the CPG to the population's characteristics for elderly clients</td>
<td>To better advocate for an approach to elders' health, participation that meets consumers' preferences</td>
</tr>
<tr>
<td>NZGG</td>
<td>Report by New Zealand Guidelines Group Inc. (NZGG)</td>
<td>Atrial fibrillation, elders' health, women's health</td>
<td>Public polls and surveys</td>
<td>Evaluation survey of consumers involved in CPGs</td>
</tr>
</tbody>
</table>

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health needs and (caesarean), mental health (depression, suicide prevention), hormone replacement therapy, diabetes

<table>
<thead>
<tr>
<th>Pijnenborg</th>
<th>Report by</th>
<th>Dutch College of</th>
<th>Low back pain, eczema, rheumatoid arthritis, psoriasis</th>
<th>To improve CPG implementation and quality</th>
<th>Focus groups</th>
<th>Individual patients</th>
<th>Strategic decisions, formulation of recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
<td>organization</td>
<td>General Practitioners; Dutch Institute for Healthcare Improvement</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Royal Australian and New</th>
<th>Published study; descriptive</th>
<th>The Royal Australian and New</th>
<th>Panic disorder,</th>
<th>Not mentioned</th>
<th>Not mentioned</th>
<th>Individual patients</th>
<th>Review of draft</th>
</tr>
</thead>
</table>

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Zealand College of Psychiatrists Clinical Practice Guidelines Team for Panic Disorder and Agoraphobia 2003

<table>
<thead>
<tr>
<th>Guihan</th>
<th>Report by Organization</th>
<th>The Veterans Health Administration, Department of Veterans Affairs</th>
<th>Spinal cord injury</th>
<th>To foster patients’ adherence to recommendations</th>
<th>Patient information material</th>
<th>Individual patients</th>
<th>Dissemination/implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>National Institute for Health and Clinical Excellence (NICE)</td>
<td>Not mentioned</td>
<td>Individual patients and patients’ caregivers</td>
<td>Individual interviews; participation in the CPG representatives</td>
<td>Development of development groups; development</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Landier</th>
<th>Report by</th>
<th>Organization</th>
<th>Children's</th>
<th>Children's</th>
<th>Not mentioned</th>
<th>Participation</th>
<th>Representatives</th>
<th>Knowledge synthesis, development of a draft, review of draft; development of patient products</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td></td>
<td>Children’s Oncology Group (National Cancer Institute)</td>
<td>cancer aftermath</td>
<td></td>
<td></td>
<td>in the CPG of patients’ working group group(s)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Luboldt | Published study; | The German Urology Association, European Randomised Screening for Prostate Cancer | Prostate cancer | Not mentioned | Participation in the CPG of patients’ working group(s) | Representatives | Literature review, final revision |
| 2004    | descriptive     |                            |                |               |                                                      |                |                                          |
|         | qualitative study; |                            |                |               |                                                      |                |                                          |

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(ERSPC), German Association of the Scientific Medical Societies or AWMF

<table>
<thead>
<tr>
<th>Phelan</th>
<th>Report by</th>
<th>Children's health</th>
<th>To incorporate patient's values, preferences, knowledge and perspectives in CPG recommendations</th>
<th>Participation in the CPG working group of (parents of affected children)</th>
<th>Patient representatives</th>
<th>Knowledge synthesis, review of draft CPG recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>organization</td>
<td>Children's Hospital Medical Center</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>van Vuuren</th>
<th>Report by</th>
<th>Dutch Institute for Healthcare Improvement</th>
<th>Not mentioned implementation in the CPG working group of patients' representatives</th>
<th>Participation in the CPG working group of patients' representatives</th>
<th>Individual patients,</th>
<th>Unclear</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>organization</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
Marshall 2005
Report by organization
German Agency for Quality in Medicine and New Zealand Guideline Group (NZGG)
Not mentioned
To incorporate patients’ values, preferences, stakeholders’ knowledge and perspectives in CPG recommendations
Participation in individual citizens’ groups; in the CPG working group; focus groups; public polls or surveys
Stakeholders, strategic decisions, development of products for patients/the public, dissemination/implementation

Sänger 2005
Report by organization
German Agency for Quality in Medicine
Not mentioned
To better adapt CPGs to patients' needs; to address patients’ most important problems; to encourage patient autonomy;
Unclear Representatives of patients and knowledge synthesis, development of a draft, review of the draft, final revision
Strategic decisions, (6 patient representatives)
to foster acceptance of patients’ version of CPGs; to improve implementation by supporting the implementation process

<table>
<thead>
<tr>
<th>Suppes</th>
<th>Published study; The Texas Department of State Health Services (TDSHS), formerly the Texas Bipolar 1 disorder study; qualitative study;</th>
<th>To review the newest available evidence to guide the selection of treatments, maintenance of patients’ version of CPGs; to improve implementation by supporting the implementation process</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>descriptive study;</td>
<td>Consensus conference patients and Individual patients’ representatives Knowledge synthesis, formulation of recommendations</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Year</th>
<th>Report by organization</th>
<th>Department of</th>
<th>Treatment, and issues regarding safety and adverse effects in the treatment of bipolar disorder</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>Dutch Institute for Healthcare Improvement</td>
<td>Not mentioned</td>
<td>Focus groups; public polls or surveys; individual patient, patients’ representatives in the CPG working group; development of products for patients/public dissemination/implementation</td>
</tr>
<tr>
<td>2006</td>
<td>National Institute for Health and Clinical Excellence (NICE)</td>
<td>Nutrition, tuberculosis, anxiety, obsessive-compulsive disorder,</td>
<td>Not mentioned</td>
</tr>
<tr>
<td>Author</td>
<td>Study Type</td>
<td>Study Design</td>
<td>Study Group</td>
</tr>
<tr>
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<td>-------------</td>
</tr>
<tr>
<td>Deschepper</td>
<td>Published study; descriptive study; qualitative study;</td>
<td>Information not available; End-of-life (heterogeneity regarding disease); To promote patients' influence over the process; to incorporate patient's values/preferences knowledge and perspectives in CPG recommendations;</td>
<td>Focus groups; quality circle discussion sessions; individual interviews;</td>
</tr>
<tr>
<td>Dijkstra</td>
<td>Published study; randomized controlled trial; quantitative study;</td>
<td>Centre for Quality of Care Research; Type 2 diabetes; implementation of CPG information material; educational meetings;</td>
<td>Patient; Individual; Development of products for patients; dissemination/ implementation;</td>
</tr>
<tr>
<td>Name</td>
<td>Year</td>
<td>Study Type</td>
<td>Institution</td>
</tr>
<tr>
<td>-----------</td>
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</tr>
<tr>
<td>Landsman</td>
<td>2006</td>
<td>Report by</td>
<td>New York State</td>
</tr>
<tr>
<td>Maputle</td>
<td>2006</td>
<td>Published study;</td>
<td>University of Limpopo; Level III</td>
</tr>
<tr>
<td>Murie</td>
<td>2006</td>
<td>Published study;</td>
<td>Royal College of General Practitioners</td>
</tr>
</tbody>
</table>

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to foster patients’ adherence to recommendations

NICE Report by National Institute Not To incorporate Patient Individual Strategic decisions,
organization for Health and mentioned patients’ values, version of patients, formulation of
Clinical Excellence (NICE)

2006 Tunner Published study; Two large mental Schizophrenia To incorporate Individual Individual Formulation of
organization descriptive health agencies in patients’ values, interviews patients recommendations
study; Philadelphia, preferences, knowledge and
qualitative Pennsylvania perspectives in CPG

Individual patients, patients’ representatives, individual citizens public;

improve working implementation group dissemination/implementation

Formulation of
<table>
<thead>
<tr>
<th>Baumann</th>
<th>Report by organization</th>
<th>American College of Chest Physicians (ACCP)</th>
<th>Not mentioned</th>
<th>To incorporate patients’ values, preferences, knowledge and perspectives in CPG recommendations</th>
<th>Unclear</th>
<th>Unclear</th>
<th>Unclear</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fervers</td>
<td>Report by organization</td>
<td>Fédération Nationale des Centres de lutte contre le cancer</td>
<td>To incorporate patients’ participation in the CPG patients’ knowledge and working representatives, formulation of CPG recommendations</td>
<td>Focus groups; Individual patients</td>
<td>Strategic decisions, knowledge synthesis, formulation of recommendations, development of a draft, final revision, development of products for patients/ the public; dissemination/implementation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hoes</td>
<td>Published study; review of European League Against Rheumatic diseases</td>
<td>Not mentioned</td>
<td>Delphi process; Individual patients</td>
<td>Knowledge synthesis, formulation of</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
For Peer Review

literature; qualitative Rheumatism (EULAR) literature review; generate and validate recommendations

Kelson 2007 Report by organization American Thoracic Society and European Respiratory Society Chronic obstructive pulmonary disease To incorporate patients’ values, preferences, knowledge and perspectives in CPG recommendations; to improve implementation Workshop; focus groups; patients’ interviews; representatives, consultation representatives of draft knowledge synthesis, formulation of recommendations, review

Individual patients, groups; patients’ focus patients, separate Strategic decisions, knowledge synthesis, formulation of recommendations, review

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<table>
<thead>
<tr>
<th>NICE 2007 Report by National Institute for Health and Clinical Excellence (NICE)</th>
<th>Consumer panels</th>
</tr>
</thead>
<tbody>
<tr>
<td>To incorporate patients’ values, preferences, knowledge and perspectives in CPG recommendations</td>
<td></td>
</tr>
<tr>
<td>Participation in the CPG working group of patients’ knowledge and representatives</td>
<td></td>
</tr>
</tbody>
</table>

Yardley 2007 Published study; ProFaNE Thematic Network Falls To foster patients’ adherence with older people’s citizens |
| Formulate evidence-based recommendations |
| Surveys of recommendations views on falls prevention |

Zuckerbrot 2007 Published study; Center for the Advancement of Children’s Mental Health at Adolescent depression To understand the obstacles faced by patients’ primary care representatives |
| Formulation of recommendations |
| Focus groups patients, |
| study; qualitative |
| qualitative |
| Health at |

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<table>
<thead>
<tr>
<th>Publication</th>
<th>Organization</th>
<th>Chronic Illnesses</th>
<th>Focus Group Participation</th>
<th>Individual Involvement</th>
<th>Knowledge Synthesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domus Medica 2008</td>
<td>Domus Medica organization</td>
<td>Chronic illnesses, diabetes, depression</td>
<td>Focus group; participation in the CPG working group and consensus conference</td>
<td>Individual patients, representatives</td>
<td>Knowledge synthesis</td>
</tr>
<tr>
<td>Harbour 2008</td>
<td>Scottish Intercollegiate Guidelines Network (SIGN)</td>
<td>Not mentioned</td>
<td>To incorporate patients’ values, preferences, knowledge and perspectives in CPG recommendations; public polls or surveys; focus groups; group meetings; representatives, development of products</td>
<td>Individual patients, representatives</td>
<td>Strategic decisions, knowledge synthesis, development of a draft, review of the draft, dissemination/</td>
</tr>
<tr>
<td>Harris</td>
<td>Report by Organization</td>
<td>Health for Kids in the South East (HFK)</td>
<td>Children's Health</td>
<td>Not mentioned</td>
<td>Participation in the CPG working group</td>
</tr>
<tr>
<td>--------</td>
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</tr>
<tr>
<td>2008</td>
<td>Report by organization</td>
<td>Health for Kids in the South East (HFK)</td>
<td>Children's health</td>
<td>Not mentioned</td>
<td>Participation in the CPG working group</td>
</tr>
<tr>
<td>Kelly</td>
<td>Published study; ORYGEN Research Centre</td>
<td>Deliberate non-suicidal self-injury</td>
<td>To incorporate patients’ values, preferences, knowledge and perspectives in CPG recommendations</td>
<td>Delphi</td>
<td>Individual</td>
</tr>
<tr>
<td>2008</td>
<td>Delphi study; qualitative</td>
<td>Deliberate non-suicidal self-injury</td>
<td>To incorporate patients’ values, preferences, knowledge and perspectives in CPG recommendations</td>
<td>Delphi</td>
<td>Individual</td>
</tr>
<tr>
<td>(a)</td>
<td>Delphi study; qualitative</td>
<td>Deliberate non-suicidal self-injury</td>
<td>To incorporate patients’ values, preferences, knowledge and perspectives in CPG recommendations</td>
<td>Delphi</td>
<td>Individual</td>
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http://mc.manuscriptcentral.com/mdm
<table>
<thead>
<tr>
<th>Author</th>
<th>Study Type</th>
<th>Institution</th>
<th>Topic</th>
<th>Methodology</th>
<th>Process</th>
<th>Participants</th>
<th>Contribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kelly</td>
<td>Published study; delphi study; qualitative</td>
<td>ORYGEN Research Centre</td>
<td>Suicidal behaviour</td>
<td>To incorporate patients’ values, preferences, knowledge and perspectives in CPG recommendations</td>
<td>Delphi process</td>
<td>Individual patients’ preferences, knowledge and perspectives</td>
<td>Development of a draft</td>
</tr>
<tr>
<td>Konety</td>
<td>Published study; descriptive study; qualitative</td>
<td>Iowa Prostate Cancer Consensus Project</td>
<td>Prostate cancer</td>
<td>Not mentioned</td>
<td>Attending a 1-day conference; evaluating the available literature</td>
<td>Patients’ representatives</td>
<td>Knowledge synthesis, formulation of CPGs</td>
</tr>
</tbody>
</table>
Stroke prevention and treatment of obesity in children and adolescents, tuberculosis, safety of the surgical patient, dementias, eating disorders, schizophrenia, osteoporosis, bronchiolitis of the nursing infant,

Incorporate patients’ values, preferences, knowledge and perspectives in CPG recommendations

Focus groups; individual interviews patients’ representatives, development of a draft, knowledge synthesis, draft review, development of products for patients/the public, dissemination/implementation

Individual patients, representatives, representatives of citizens’ group
hyperactivity
and attention
deficit
syndrome,
pathological
gambling,
behavioural
addictions,
borderline
personality
disorders

Love 2008
Published study; descriptive study; mixed South Africa food-based dietary guidelines (FBDGs) work
Nutrition To foster patients’ adherence to recommendations Focus groups; Individual citizens Dissemination/implementation
group

Murray 2008
Published study; descriptive study; South Africa food-based dietary guidelines
Pediatric diet To increase the general public’s Focus groups Mothers with infants younger
Review of draft
<p>| Organization | Study; qualitative guidelines (FBDGs) work | Group | Duration | To incorporate | Participation | Individual | Strategic decisions, | Knowledge synthesis, | Formulation of recommendations, | Development of a draft, | Development of products for patients/the public, | Dissemination/implementation |
|--------------|-------------------------------------------|-------|----------|----------------|---------------|------------|----------------------|------------------------|-----------------------------|---------------------------|-------------------------------------------------|
| SIGN 2008    | - Not mentioned                           | Patient's values, preferences, knowledge and perspectives in CPG recommendations | | in the patients, CPG working group of patients, individual citizens | | | | | | | | |
| Southern Health 2008 | - Not mentioned                           | Patient's values, preferences, public polls or surveys; knowledge and perspectives in CPG focus groups; | | | | | | | | | | |</p>
<table>
<thead>
<tr>
<th>Organization</th>
<th>Year</th>
<th>Report by</th>
<th>Conditions</th>
<th>Methodology</th>
<th>Participants</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Institute for Health and Clinical Excellence (NICE)</td>
<td>2008</td>
<td>Thomas</td>
<td>Mental health, maternity, chronic and acute conditions</td>
<td>To evaluate lay members’ experiences of being part of a CPG development group</td>
<td>Public polls or surveys</td>
<td>Individual participants’ experience of being part of the CPG development group</td>
</tr>
<tr>
<td>World Health Organization (WHO)</td>
<td>2008</td>
<td>WHO</td>
<td>Not mentioned</td>
<td>To incorporate patient’s values, preferences, knowledge and perspectives in CPG recommendations</td>
<td>Participation in the CPG working group</td>
<td>Individual</td>
</tr>
<tr>
<td>NZGG</td>
<td>Report by Organization</td>
<td>New Zealand Guidelines Group, Inc. (NZGG)</td>
<td>Not mentioned</td>
<td>To encourage greater involvement by consumers of health and disability services in the activities of NZGG</td>
<td>Participation in the CPG working group</td>
<td>Individual patients’ representatives</td>
</tr>
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</tr>
<tr>
<td>2009</td>
<td></td>
<td></td>
<td></td>
<td>To incorporate patient’s participation in the CPG</td>
<td>Draft, product development</td>
<td>Individual patients’ knowledge synthesis, formulation of recommendations, review of draft, development of products for patients/the public</td>
</tr>
<tr>
<td>Graham</td>
<td>Report by Organization</td>
<td>Scottish Intercollegiate Guidelines Network (SIGN)</td>
<td>Cancer, bronchiolitis in children, peripheral arterial disease</td>
<td>To incorporate patient’s participation in the CPG</td>
<td>Draft, product development</td>
<td>Individual patients’ knowledge synthesis, formulation of recommendations, review of draft, development of products for patients/the public</td>
</tr>
</tbody>
</table>
epilepsy in children, autism spectrum disorders, dementia, coronary heart disease, chronic heart failure

Sänger (a) Report by German Agency for Quality in Medicine Not mentioned To incorporate patient’s version of guideline; knowledge and participation of patients’ group perspectives in CPG recommendations working group Individual patients, representatives Knowledge synthesis, formulation of recommendations; development of the draft, review the draft, development of products for patients/ the public; dissemination/implementation

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Sänger (b) Report by German Agency Not To establish a program Establishment of an Internet German Patient Forum products for patients/the public
organization for Quality in Medicine mentioned whereby laypeople can evaluate and improve health critical appraisal information posted online

Notes: *DISCERN is a brief questionnaire that gives users a valid and reliable way to assess the quality of written information on treatment choices for a health problem.

**NICE invites all the organizations that have been stakeholders in previous clinical guidelines, to register an interest in new topics relevant to them. It also invites organizations that might be interested but have not been involved with NICE before. NICE asks them to submit nominations to the CPG development group. This request is published on the NICE website, where anyone may apply to participate. When nominations have closed, the national collaborating centre chooses whom to invite to join the group.
*** NICE's Patient and Public Involvement Programme (PPIP) supports the application process for patient and caregiver members of the CPG development group. Patients, caregiver and members of the public can apply by responding to ads posted on the NICE website. The PPIP alerts all registered patient and caregiver stakeholder organizations to these ads. Applicants do not need to be members of a registered stakeholder organization to apply.

****SIGN recruits a minimum of 2 patients’ representatives per CPG development groups by inviting nominations from the relevant umbrella organization, national organization, and/or local patient-focused organizations in Scotland. Where organizations are unable to nominate, patients’ representatives are sought through other means, e.g., consultations with health boards or public involvement staff. Prior direct patient or caregiver consultation mechanisms (e.g., a focus group) may also furnish participants.

CPG=clinical practice guideline; PPIP=patient and public involvement program; USA=United States of America
Table 2. Barriers to patient and public involvement programs

<table>
<thead>
<tr>
<th>Barriers</th>
<th>Organizations’ reports (n)</th>
<th>Empirical studies (n)</th>
<th>Excerpts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discrepancies between experts’ and patients’/the public’s perspectives</td>
<td>28, 55, 57, 63, 66, 91</td>
<td>38</td>
<td>- Main topics form patients’ point of view differed from topics in the guideline 66</td>
</tr>
<tr>
<td>(n=6)</td>
<td>(n=2)</td>
<td></td>
<td>- There may not be shared agreement about the most important issues 91</td>
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<td>(n=8)</td>
<td></td>
<td></td>
<td>- Experience versus evidence 55</td>
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<td></td>
<td>- Difficulty of integrating patients’ views into professionals’ recommendations 66</td>
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<td></td>
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<td></td>
<td>- An evidence-biased atmosphere 65</td>
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<td></td>
<td>- Difficult for the patient to judge whether his/her comment regarding &quot;evidence-based&quot; information was relevant 28</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>- Apparent marginalization of the evidence from patients’ and caregivers’ experiences (insufficient</td>
</tr>
</tbody>
</table>
worth afforded to published qualitative studies) 63
- Patients and health professionals can weigh healthcare issues differently 57
  - Hard to find/recruit patients capable of and interested in participating 66
  - Difficulty of identifying patients and caregivers who are willing and able to contribute directly to guideline development 39
  - Lack of a suitable consumer group 67
  - Caregivers were difficult to recruit for this study and, after the first round of the questionnaire, only one remained involved 37
  - “As one person with a large group of medical people (...) I felt the weight of being the only person specifically representing consumers” 52
  - A small number of patients does not guarantee representativity in terms of sex, ages, social
- Patient advocates may be perceived as particularly unrepresentative.
- Variability of patients’ values and preferences at different stages of the disease, at different levels of the disease’s severity, and with respect to different issues. Values and preferences may also differ by age, sex, socioeconomic status, ethnicity, and culture. This poses a challenge to integrating consumers’ values into guideline recommendations.
- Technicality and complexity of the subject does not encourage patients’ participation.
- It was not possible to meaningfully discuss any of the scientific content of the guideline.

Lack of familiarity with complex scientific and medical language (patients/the public found the material difficult to understand) (n=4) (n=1)

Significant work commitment (n=3) (n=3)

- Very hard work and exhausting.
Time constraints (n=3) 52, 65, 67 (n=3)  
- Duration of project 28  
- Training is not practical for consumers with other employment responsibilities—they would have to take time off work without pay 52  
- No time 65

Professionals’ resistance to patients’ participation (n=2) 39, 57 (n=2)  
- Professionals’ resistance to patient membership 39

Feeling isolated (n=2) 47, 52 (n=2)  
- Consumers can feel isolated and uneasy at guideline meetings 47

Financial issues (n=1) 65 (n=1)  
- No money 65

Resource-intensive (n=1) 39 (n=1)  
- Patient involvement can be resource-intensive 39

Feeling little affected by the problem (n=1) 28 (n=1)  
- Feeling little affected by the problem 28

Patients’ contributions are sometimes limited (n=1) 39 (n=1)  
- Patients’ contributions are sometimes limited 39

Patients underestimate their capabilities (n=1) 27 (n=1)  
- Patients underestimate their capabilities 27
Large documents sent by email - not practical for consumers (too expensive to print at home) (n=1) - Sending large documents by email as an alternative to face-to-face meetings makes it difficult to negotiate and reach consensus.\(^{52}\)
Table 3. Facilitators to patient and public involvement programs

<table>
<thead>
<tr>
<th>Facilitators</th>
<th>Organizations’ reports (n)</th>
<th>Empirical studies (n)</th>
<th>Excerpts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training (n=14)</td>
<td>28, 30, 33, 36, 39, 30-33, 60, 63, 65-67 (n=14)</td>
<td>- Training in technical aspects of the guidelines 32</td>
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<td></td>
<td></td>
<td>- Training day 50 30</td>
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<td></td>
<td></td>
<td>- Training seminars 30</td>
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<tr>
<td></td>
<td></td>
<td>- Critical appraisal training and seminars 60 33</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>- SIGN ensure opportunities to attend training events 33</td>
<td></td>
</tr>
<tr>
<td>Support (n=12)</td>
<td>27, 28, 30, 33, 36, 39, 50, 53, 60, 63, 65 (n=11)</td>
<td>85 (n=1)</td>
<td>- Telephone support 28</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Telephone and email support 33 30</td>
<td></td>
</tr>
<tr>
<td>o Supporting staff</td>
<td>33, 47, 50, 53, 55, 63, 65 (n=7)</td>
<td>- Select a supportive chair to lead the guideline group 55</td>
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<td></td>
<td></td>
<td>- Availability of a mentor/coach 55, 66</td>
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<td></td>
<td></td>
<td>- Chair of each guideline development group is asked to support patient representatives by ensuring they are fully engaged with the group, addressing the</td>
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</tbody>
</table>
group if their contributions are not acknowledged appropriately, and welcoming and encouraging their contributions.  

- Mentoring  

- Need to take special care to ensure that consumers have a voice at meetings and to feed back to constituencies.  

- Provide extra assistance, explanations and background information, particularly if the matter under consideration is technical.  

- More time on practical statistics would have been helpful.  

- Explain evidence-based process.  

- Develop competencies in the design and development of information for consumers, including the use of plain language for all consumer-oriented documents and, where possible, the use of
Supporting documents/material (n=5)
(28, 50, 53, 55, 66)

Contact and interactions with other consumers (n=3)
(28, 52, 60)

Support from organizations (n=1)
(53)

Clear expectations (details about the process, who is involved, roles, etc.) (n=9)
(33, 36, 50-52, 55, 91, 65, 66)

formats that are accessible to the visually impaired (n=5)

- Clear analysis grid for knowledge synthesis (n=28)
- NICE’s “welcome pack” for selected patients (n=50)
- Templates and processes for the preparation of evidence-based consumer information (n=53)
- They can explain and listen (n=28)
- They can offer one-off or ongoing support (n=60)

- Work collaboratively with other organizations to develop strong partnerships with government and nongovernment organizations, and agencies supportive of initiatives to strengthen consumers’ voice (n=53)
- Disclose the funds available for the service or matter under discussion (n=91)
- Information about the time frame and expected time...
commitment 52
- Why the patient is invited, who s/he represents, what is expected – tasks and level of participation – whether time and costs are reimbursed 66
- Ensure that everyone recruited to the guideline development group is fully aware of the scope of the guideline and agrees to work within it 36
- Well-defined goal 65
- A member of the patient and public involvement program contacts patients and caregivers to give them background information about what they might expect at the first meeting 50
- The NICE PPIP gives a short presentation to all members, at the first meeting, on the role of patient and caregiver members 51
- SIGN provides clear guidance on patients’ roles and responsibilities within the group 33
More than one patient \(^41, 47, 51-53, 55, 65, 67\) (n=8)

- Need to involve more than one consumer \(^47\)

- Recruitment of a minimum of 2 representatives, following a transparent selection process and a well-established protocol \(^41\)

- Participants should be as representative as possible of the whole population \(^65\)

- Gender representation and balance should be considered in selecting group members \(^67\)

  o Representation of different patients’ perspectives \(^47, 55, 65\) (n=3)

  o Gender representation and balance (n=1)
Development group committed to and in favor of patient involvement (n=4)

Sensitivity of other group members to consumers’ non-professional status (recognition that consumers should feel that they are listened to and that their opinions are valued) 52

A belief, especially on the part of the chair and opinion leaders, that it works 65

Members of the guideline development group – mainly medical doctors – put the professionals and the laypeople on an equal footing 63

The health professionals in the group seemed open to the view that consumers can contribute a valid and valuable perspective 52

Good preparation (n=4)

Working group meetings preceded by preparatory meetings and training 28

Reimbursement/sufficient financial assistance (n=4)

Ensure there is sufficient funding to pay consumers and to cover additional expenses, such as child care
<table>
<thead>
<tr>
<th>Keeping patients/the public informed and maintaining dialogue</th>
<th>(n=3)</th>
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</thead>
<tbody>
<tr>
<td>Involving patients from the start</td>
<td>(n=3)</td>
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<tr>
<td>Past experiences</td>
<td>(n=1)</td>
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<tr>
<td>Smaller subgroups</td>
<td>(n=1)</td>
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<tr>
<td>Sense of belonging</td>
<td>(n=1)</td>
</tr>
<tr>
<td>Actively involving patients at every stage of the process</td>
<td>(n=1)</td>
</tr>
<tr>
<td>and transportation</td>
<td>91</td>
</tr>
<tr>
<td>- Cover certain expenses (transportation, childcare, loss of earnings)</td>
<td>60</td>
</tr>
<tr>
<td>- Email is a good way to keep in touch and keep up-to-date on progress</td>
<td>52</td>
</tr>
<tr>
<td>- Organization gives feedback and information and acknowledges results</td>
<td>52</td>
</tr>
<tr>
<td>- Participation from (before) the start</td>
<td>55, 65</td>
</tr>
<tr>
<td>- Consumer involvement should be considered and encouraged from the start</td>
<td>67</td>
</tr>
<tr>
<td>- Past experience with other groups helps</td>
<td>52</td>
</tr>
<tr>
<td>- Smaller subgroups definitely helped progress</td>
<td>52</td>
</tr>
<tr>
<td>- Sense of belonging</td>
<td>28</td>
</tr>
<tr>
<td>- Actively involving patients at every stage of the process</td>
<td>66</td>
</tr>
<tr>
<td>- Actively involving patients at patients’ desired level of involvement</td>
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</tbody>
</table>
desired level of involvement (n=1)

Combining methods of involving patients (n=1) - Combining methods of involving patients

Atmosphere of mutual respect and positive working relationships with other members of the group (n=1)

- Leads to constructive debate and agreement

Notes: NICE = National Institute for Health and Clinical Excellence; SIGN = Scottish Intercollegiate Guidelines Network
Figure 1. Flow of Data Synthesis

**DATABASES**
- MEDLINE: n=1315
- Embase: n= 513
- CINHAL: n= 83
- Web of Science: n= 72
- Cochrane: n= 104
- PsychINFO: n= 17

Publications retrieved n= 2104
Unique publications n= 1668
Potentially eligible publications n= 227
Eligible publications n= 72
Included publications n=38

**GREY LITERATURE**
- G-I-N* steering committee members: n=19
- G-I-N* members: n=11
- Investigators’ personal database: n=15
- Email distribution list: n=12

Documents retrieved n=57
Unique documents n=55
Screening 1
Not about a CPG: n= 13
Not about a PPIP: n= 2
Not about the development or implementation of a CPG: n= 2
N= 17
Screening 2
Not about the development or implementation of a CPG: n= 1
Not about a PPIP: n= 3
Missing information: n= 1
N= 5
Included documents n=33

Excluded based on abstracts n=1441
Duplicates: n=339
No abstract: n=97

Included publications n=38
Included references n=71

Extraction
7 publications moved to grey literature

Included publications n=31
Included documents n=40

*G-I-N= Guidelines International Network