



December 2010 – SUPPORT Summary of a systematic review

## What are the impacts of consumer involvement in developing healthcare policy, research and patient information material?

The importance of consumer involvement in healthcare is widely recognised. Through consultations to elicit views or through collaborative processes, consumers may be involved in developing healthcare policy and research, clinical practice guidelines and patient information material. Consultations can be single or repeated events, and their scale can be large or small. They can involve debate amongst individuals or groups of consumers; and groups can be convened especially for the consultation process or be established by consumer organisations themselves. Consultations can also be organised in different forums and different types of media can be used.

### Key messages

- **Patient information developed through consumer consultations probably helps to decrease slightly the anxieties that patients may associate with clinical procedures. Moreover, such consultations probably facilitate the development of material that is more relevant, readable and understandable to patients, and probably improves patient knowledge.**
- **There may be small differences in the results of satisfaction surveys depending on whether the interviewers are consumers or healthcare professionals.**
- **The comparative effectiveness of different communication forums (face-to-face, telephone discussions, mail surveys, etc.) for consumer involvement in healthcare policy is uncertain.**
- **There are good arguments for introducing consumer involvement in low- and middle-income countries. To accomplish this:**
  - Strategies to overcome barriers such as low baseline levels of social participation, organisation and education should be explored
  - Efforts to include consumers or families of disadvantaged groups should be considered in order to achieve inclusive representation



### Who is this summary for?

People making decisions concerning the involvement of consumers in developing healthcare policy, research and patient information material.

### ! This summary includes:

- **Key findings** from research based on a systematic review
- **Considerations about the relevance of this research** for low- and middle-income countries

### ✗ Not included:

- Recommendations
- Additional evidence not included in the systematic review
- Detailed descriptions of interventions or their implementation

### This summary is based on the following systematic review:

Nilsen ES, Myrhaug HT, Johansen M, Oliver S, Oxman AD. Methods of consumer involvement in developing healthcare policy and research, clinical practice guidelines and patient information material. Cochrane Database of Systematic Reviews 2006, Issue 3.

### What is a systematic review?

A summary of studies addressing a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise the relevant research, and to collect and analyse data from the included studies.

**SUPPORT** – an international collaboration funded by the EU 6th Framework Programme to support the use of policy relevant reviews and trials to inform decisions about maternal and child health in low- and middle-income countries. [www.support-collaboration.org](http://www.support-collaboration.org)

**Glossary of terms used in this report:** [www.support-collaboration.org/summaries/explanations.htm](http://www.support-collaboration.org/summaries/explanations.htm)

**Background references on this topic:** See back page.

–Evaluations are needed of the effects of consumer involvement on healthcare decisions and how to achieve more effective consumer involvement

## Background

This review examined the effects of promoting and organising consumer involvement to inform, or participate in, decisions related to healthcare, including decisions about healthcare policies and planning (e.g. inequalities in healthcare); clinical policies (e.g. clinical practice guidelines); patient information material (e.g. material designed to inform patients about personal healthcare decisions); and healthcare research (e.g. the design of clinical or epidemiological studies, the identification of relevant outcomes, and setting priorities). Participation is widely regarded as a human right, and this review provides information to inform policies regarding participation.

### How this summary was prepared

After searching widely for systematic reviews that can help inform decisions about health systems, we have selected ones that provide information that is relevant to low- and middle-income countries. The methods used to assess the quality of the review and to make judgements about its relevance are described here:

[www.support-collaboration.org/summaries/methods.htm](http://www.support-collaboration.org/summaries/methods.htm)

### Knowing what's not known is important

A good quality review might not find any studies from low- and middle-income countries or might not find any well-designed studies. Although that is disappointing, it is important to know what is not known as well as what is known.

### About the systematic review underlying this summary

**Review objective:** To assess the effects of consumer involvement and to compare different methods of involvement in developing healthcare policy and research, clinical practice guidelines, and patient information material

|                      | What the review authors searched for  | What the review authors found   |
|----------------------|---|---|
| <b>Interventions</b> | Randomised trials of ways to involve consumers and enable them to inform and participate in decisions about healthcare policy and research, clinical practice guidelines or patient information material  | 6 randomised trials of involvement compared with no involvement in developing patient information (2), satisfaction interviews conducted by patients compared with staff (2), informed consent forms developed by consumers versus investigators, and methods of consulting consumers (1) regarding priorities [do you need to give more detail here?] for improving community health (1) |
| <b>Participants</b>  | Healthcare consumers or professionals involved in decisions about healthcare at the population level, or evaluating the effects of consumer involvement   | Involvement in research (3), developing patient information (2) and healthcare policy (1)   |
| <b>Settings</b>      | No specific settings  | Canada (2), the United States of America (USA) (2), Norway (1) and the United Kingdom (UK) (1)  |
| <b>Outcomes</b>      | Participation or response rates of consumers; consumer views elicited; consumer influence on decisions, healthcare outcomes or resource utilisation; consumer or professional satisfaction with the involvement process or resulting products; impact on participating consumers; costs | Levels of patient satisfaction with different health services, self-reported participant understanding, satisfaction with study participation, adherence to the protocol and refusal to participate; knowledge and anxiety with a specific medical procedure; impact on prioritising health concerns and determinants   |

**Date of most recent search:** October 2009

**Limitations:** This is a good quality systematic review with only minor limitations

Nilsen ES, Myrhaug HT, Johansen M, Oliver S, Oxman AD. Methods of consumer involvement in developing healthcare policy and research, clinical practice guidelines and patient information material. *Cochrane Database of Systematic Reviews* 2006, Issue 3. Art. No.: CD004563. DOI: 10.1002/14651858.CD004563.pub2

# Summary of findings

The systematic review identified six trials of consumer involvement in research, the development of patient information material and healthcare policy. No trials were found of consumer involvement in decision-making, different methods of recruiting consumers or different ways of providing training and support for consumer involvement.

## 1) Different communication forums for involvement in health policy

One study compared two forms of deliberative consumer involvement, namely telephone discussions and a group face-to-face meeting. Participants were members of community organisations. Both methods achieved a greater level of participation than a mailed survey.

➔ **It is very uncertain whether telephone discussions compared with face-to-face meetings change consumer priorities for community health goals**

### About the quality of evidence (GRADE)

⊕⊕⊕⊕

**High:** Further research is very unlikely to change our confidence in the estimate of effect.

⊕⊕⊕○

**Moderate:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

⊕⊕○○

**Low:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

⊕○○○

**Very low:** We are very uncertain about the estimate.

For more information, see last page

| Face-to-face meetings compared with telephone meetings for obtaining change of views on health issues  |   |                                  |                                 |
|--|---|----------------------------------|---------------------------------|
| <b>Patients or population:</b> Consumers of a community organisation<br><b>Settings:</b> Local community in Ontario, Canada<br><b>Intervention:</b> Face-to-face meetings<br><b>Comparison:</b> Telephone meetings |   |                                  |                                 |
| Outcomes   | Impact  | Number of participants (studies) | Quality of the evidence (GRADE) |
| Healthcare priorities  | A statistically significant difference was found between groups for one out of the seven reported health-related community strengths. In this study the proportion of people indicating it is very important to health increasing by 7% in the phone group and decreasing by 31% in the face-to-face meeting group (P < 0.05) | 29<br>(1 study)                  | ⊕○○○<br>Very low <sup>§</sup>   |

p: p-value GRADE: GRADE Working Group grades of evidence (see above and last page)  
 § Very serious limitations due to concealment of allocation and blinded assessment of primary outcome(s) not clear, and follow-up of patients not done (results from one group (mail group) were excluded because of low response rate). Sparse data due to small number of participants (46 divided into three trial groups)

## 2) Consumer involvement compared with no consumer involvement in research

Two trials compared the use of consumers (patients) and professionals as data collectors in patient satisfaction surveys. The trials compared the data collected to investigate if the patient responses given to consumer interviewers differed from the patient responses given when they were interviewed by staff (i.e. medical professionals). Any influence on subsequent decision-making was not reported.

→ **Consumer interviewers may slightly improve patient satisfaction than staff interviewers.**

| <b>Mental health patients compared with mental health staff used as interviewers of mental health patients</b>  |  |   |  |
|---|--|---|--|
| <b>Patients or population:</b> Mental health patients<br><b>Settings:</b> Mental health outpatient facilities in Toronto (Canada) and Suffolk County New York (USA)<br><b>Intervention:</b> Mental health patient interviewers<br><b>Comparison:</b> Mental health staff interviewers |  |   |  |
| <b>Outcomes</b>   | <b>Impact</b>  | <b>Number of participants (studies)</b> | <b>Quality of the evidence (GRADE)</b> |
| <b>Satisfaction with mental health services</b>   | The overall difference was small but statistically significant. Interviews undertaken by mental health patients showed slightly greater levels of patient satisfaction (Mean Difference -0.14 [-0.23 to -0.06]). | 650<br>(2 studies)                      | ⊕⊕○○<br>Low <sup>§</sup>               |
| <p>p: p-value    GRADE: GRADE Working Group grades of evidence (see above and last page)</p> <p>§ Serious limitation due to concealment of allocation and blinded assessment of primary outcome(s) not clear. Some uncertainty about directness</p>                                   |  |   |  |

One trial compared an informed consent document developed with consumer input (from potential trial participants) with a consent document developed by professionals (the trial investigators).

→ **Consumer consultation in the development of consent documents may have little if any impact on self-reported participant understanding of the trial described in the consent document, satisfaction with the study participation, adherence to the [study?] protocol or the refusal to participate**

| <b>Informed consent document developed with input from a consumer group compared with investigator-developed consent document for understanding, satisfaction and adherence of patients with Gulf War Illness</b>   |  |   |                          |                                  |                                 |
|---|--|---|--------------------------|----------------------------------|---------------------------------|
| <b>Patients or population:</b> Mental health patients<br><b>Settings:</b> Patients with Gulf War illness<br><b>Intervention:</b> Consumer-developed consent document<br><b>Comparison:</b> Investigator-developed consent document  |  |   |                          |                                  |                                 |
| Outcomes  | Illustrative comparative risks*                        |   | Relative effect (95% CI) | Number of participants (studies) | Quality of the evidence (GRADE) |
|   | Assumed risk investigator-developed consent document   | Correspondent risk consumer-developed consent document  |                          |                                  |                                 |
| <b>Understanding (consumer influence on healthcare outcomes)</b><br><b>Informed Consent Questionnaire-4</b><br><b>Scale: From: 0 to 1</b><br><b>(Follow-up: 12 months)</b>  | The mean understanding in the control groups was 0.728 | The mean understanding in the intervention groups was 0.006 higher (0.029 lower to 0.04 higher) |                          | 1,092 (1 study)                  | ⊕⊕○○<br>Low <sup>§#</sup>       |
| CI: Confidence interval RR: Risk ratio GRADE: GRADE Working Group grades of evidence (see above and last page)<br>*Illustrative comparative risks. The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk WITH the intervention (and its 95% confidence interval) are based on the overall relative effect (and its 95% confidence interval).<br>§Cluster randomised trial. Unclear allocation concealment and blinding. Drop out less than 20%, however only 71% of the participants completed primary outcome measure at all four visits<br># Not validated questionnaire prior to the trial. Only one trial with 1,092 participants |  |   |                          |                                  |                                 |

### 3) Consumer involvement compared with no consumer involvement in preparing patient information

Two trials evaluated products (patient information leaflets) developed following consumer consultation. The leaflets were compared with patient information developed without consumer consultation.

- Patients probably experience little or no difference in their levels of worry or anxiety associated with procedures when they receive information material that has been developed following consumer consultation
- Consumer consultation before the development of patient information material probably results in material that is more relevant, readable and understandable to patients
- Consumer consultation before the development of patient information material probably improves the knowledge of patients who read the material

| Leaflets written by patients and professionals together compared with leaflets written by professionals alone used by patients undergoing an endoscopy procedure or patients who receive patient-controlled analgesia (PCA)   |  |                                  |                                 |
|---|--|----------------------------------|---------------------------------|
| <p><b>Patients or population:</b> Patients undergoing an endoscopy procedure or patients who receive PCA<br/> <b>Settings:</b> Hospitals in the UK and Norway<br/> <b>Intervention:</b> Leaflets written by patients and professionals together<br/> <b>Comparison:</b> Leaflets written by professionals alone</p> |  |                                  |                                 |
| Outcomes  | Impact   | Number of participants (studies) | Quality of the evidence (GRADE) |
| <b>Anxiety</b>  | There probably is little or no difference in the levels of worry or anxiety associated with procedures for those patients receiving information material developed following consumer consultation, compared with patients who receive material developed without consumer consultation  | 335 (2 studies)                  | ⊕⊕⊕○<br>Moderate <sup>§</sup>   |
| <b>Satisfaction with information material</b>   | Patients rated the information given in leaflets developed following consumer consultation as being very or extremely clear (84%), compared with patients who received leaflets which had been developed with no prior consumer consultation (48%, $P < 0.001$ ). 30% of the first group required no more information about the PCA, compared with 8% in the second ( $P = 0.002$ ). Also, patients of the first group were significantly more satisfied than the second group with leaflets containing information about endoscopy [procedures?] ( $P = 0.04$ ) | 335 (2 studies)                  | ⊕⊕⊕○<br>Moderate <sup>§</sup>   |
| <b>Knowledge of patient-controlled analgesia</b>  | 58% of those who read the leaflet developed following consumer consultation recognised that all the side-effects listed could be caused by PCA, whereas none of the second group gave the correct answer ( $P < 0.001$ ). 49% of the first group knew that morphine was used in PCA compared with 7% of those in the second group ( $P < 0.001$ ).   | 100 (1 study)                    | ⊕⊕⊕○<br>Moderate <sup>§</sup>   |
| <p>p: p-value    GRADE: GRADE Working Group grades of evidence (see above and last page)<br/>           § Serious limitation due to blinded assessment of primary outcome(s) and baseline measurement not clear</p>   |  |                                  |                                 |

# Relevance of the review for low- and middle-income countries

| → Findings  | ▷ Interpretation*   |
|---|---|
| <b>APPLICABILITY</b>  |   |
| <ul style="list-style-type: none"><li>→ All the studies were conducted in high-income countries</li><li>→ Some interventions used technologies such as telephones and e-mail</li><li>→ Baseline levels of consumers involvement were not reported</li></ul> | <ul style="list-style-type: none"><li>▷ <i>Strategies to overcome barriers such as low baseline levels of social participation and education should be explored when considering consumer involvement in low- and middle-income countries. Training and support may be essential</i></li><li>▷ <i>The attitudes and the perspectives of health professionals and policymakers regarding consumer involvement should also be considered</i></li><li>▷ <i>As the availability of communication technologies may be a problem, face-to-face involvement may be most appropriate</i></li></ul>  |
| <b>EQUITY</b>   |   |
| <ul style="list-style-type: none"><li>→ Equity considerations were not addressed in the systematic review</li></ul>   | <ul style="list-style-type: none"><li>▷ <i>Efforts to include disadvantaged groups should be considered in order to achieve more inclusive participation and ensure that the perspectives of such groups are represented</i></li></ul>  |
| <b>ECONOMIC CONSIDERATIONS</b>  |   |
| <ul style="list-style-type: none"><li>→ No evidence related to costs was found in the review</li></ul>  | <ul style="list-style-type: none"><li>▷ <i>The involvement of consumers in healthcare policy processes might be helpful in deciding how to use resources in ways that correspond to the needs and expectations of the population</i></li><li>▷ <i>Consideration should be given to the costs of consumer involvement, including the amount of staff time needed to support consumer involvement, the reimbursement of consumer expenses, and fees or honoraria [for participation?]</i></li></ul>   |
| <b>MONITORING &amp; EVALUATION</b>  |   |
| <ul style="list-style-type: none"><li>→ There is little evidence from randomised trials of the effects of consumer involvement in healthcare decisions at the population level</li></ul>  | <ul style="list-style-type: none"><li>▷ <i>Impact evaluations are needed to evaluate the intended and unintended effects of strategies to involve consumers in healthcare decisions at the population level. Randomised trials are more likely to provide reliable evidence than other study designs</i></li><li>▷ <i>Monitoring might be needed, particularly for healthcare policymaking processes, to ensure that strategies to involve consumers are implemented as intended and that resources are used as intended</i></li><li>▷ <i>This review presents a framework that can be used to plan and evaluate strategies for consumers involvement in healthcare decisions at the population level</i></li></ul> |

\*Judgements made by the authors of this summary, not necessarily those of the review authors, based on the findings of the review and consultation with researchers and policymakers in low- and middle-income countries. For additional details about how these judgements were made see: <http://www.support-collaboration.org/summaries/methods.htm>

# Additional information

## Related literature

Crawford MJ, Rutter D, Manley C, Weaver T, Bhui K, Fulop N, et al. Systematic review of involving patients in the planning and development of health care. *BMJ* 2002;325:1263–7.

Telford R, Boote JD, Cooper CL. What does it mean to involve consumers successfully in NHS research? A consensus study. *Health Expectations* 2004;7(3):209–20.

Ward PR, Thompson J, Barber R, Armitage C, Boote J, Cooper C, Jones G. Critical perspectives on ‘consumer involvement’ in health research. Epistemological dissonance and the know-do gap. *Journal of Sociology* March 2010 vol. 46 no. 1 63–82.

Pivik J, Rode E, Ward C. A consumer involvement model for health technology assessment in Canada. *Health Policy – August* 2004. Vol. 69, Issue 2, Pages 253–268.

Oliver S, Clarke-Jones L, Rees R, Milne R, Buchanan P, Gabbay J, Gyte G, Oakley A, Stein K. Involving consumers in research and development agenda setting for the NHS: developing an evidence-based approach. *Health Technol Assess.* 2004 Apr;8(15):1–148, III–IV.

Boote J, Telford R, Cooper C. Consumer involvement in health research: a review and research agenda. *Health Policy.* 2002 Aug;61(2):213–36.

Oliver SR, Rees RW, Clarke-Jones L, Milne R, Oakley AR, Gabbay J, Stein K, Buchanan P, Gyte G. A multidimensional conceptual framework for analysing public involvement in health services research. *Health Expect.* 2008 Mar; 11(1):72–84.

## This summary was prepared by

Cristian Herrera, Unit for Health Policy and Systems Research, School of Medicine, Pontificia Universidad Católica de Chile, Chile

## Conflict of interest

None declared. For details, see: [www.support-collaboration.org/summaries/coi.htm](http://www.support-collaboration.org/summaries/coi.htm)

## Acknowledgements

This summary has been peer reviewed by: Elin Strømme Nilsen, Norway; Rakhil Gaitonde, India

## This summary should be cited as

Herrera C. What are the impacts of consumer involvement in developing healthcare policy, research and patient information material? A SUPPORT Summary of a systematic review. December 2010. [www.support-collaboration.org/summaries.htm](http://www.support-collaboration.org/summaries.htm)

## Keywords

*All Summaries:* evidence-informed health policy, evidence-based, systematic review, health systems research, health care, low- and middle-income countries, developing countries, primary health care.

## About quality of evidence (GRADE)

The quality of the evidence is a judgement about the extent to which we can be confident that the estimates of effect are correct. These judgements are made using the GRADE system, and are provided for each outcome. The judgements are based on the type of study design (randomised trials versus observational studies), the risk of bias, the consistency of the results across studies, and the precision of the overall estimate across studies. For each outcome, the quality of the evidence is rated as high, moderate, low or very low using the definitions on page 3.

### For more information about GRADE:

[www.support-collaboration.org/summaries/grade.htm](http://www.support-collaboration.org/summaries/grade.htm)

## SUPPORT collaborators:

**The Alliance for Health Policy and Systems Research (HPSR)** is an international collaboration aiming to promote the generation and use of health policy and systems research as a means to improve the health systems of developing countries. [www.who.int/alliance-hpsr](http://www.who.int/alliance-hpsr)

**The Cochrane Effective Practice and Organisation of Care Group (EPOC)** is a Collaborative Review Group of the Cochrane Collaboration: an international organisation that aims to help people make well informed decisions about health care by preparing, maintaining and ensuring the accessibility of systematic reviews of the effects of health care interventions.

[www.epocoslo.cochrane.org](http://www.epocoslo.cochrane.org)

**The Evidence-Informed Policy Network (EVIPNet)** is an initiative to promote the use of health research in policymaking. Focusing on low- and middle-income countries, EVIPNet promotes partnerships at the country level between policy-makers, researchers and civil society in order to facilitate both policy development and policy implementation through the use of the best scientific evidence available. [www.evipnet.org](http://www.evipnet.org)

### For more information:

[www.support-collaboration.org](http://www.support-collaboration.org)

**To provide feedback on this summary:**  
<http://www.support-collaboration.org/contact.htm>