Patient representatives need various methods to be involved in clinical practice guidelines – a qualitative study in Finland

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Header: Patient involvement in guidelines

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Abstract

Background

Patient involvement in guideline development has been endorsed. The international guideline community has developed a toolkit to describe methods and facilitate patient involvement. The most used methods are commentary on the draft guideline and acting as guideline panel members. However, knowledge of the patient organizations’ (PO) perception of involvement is scarce.

Methods

The aim of the study was to identify POs’ views on best ways to involve patient representatives and POs potential roles in the guideline process. Representatives from 12 POs (n=20) in Finland were invited to group interviews (n=4, á 1.5 h). In the qualitative analysis we deductively identified using G-I-N public toolkit the best ways to involve patient representatives, and inductively analyzed general principles for involvement and how the POs consider their potential roles.

Results

The interviewees raised three major principles for organizing patient involvement in guideline development: 1) different means of involvement, 2) representativeness, and 3) genuine and equal interaction. The interviewees endorsed involvement through statements and comments throughout the guideline process, and instead of participating in guideline panels as a member, they preferred reference
groups or patients’ networks. The interviewees saw various roles for POs in guideline development, for example acting as confidants for patient representatives, information production, active participation, commenting, and communication activities to population.

**Conclusions**

Guideline developers should offer various and easy ways of patient involvement. POs representatives considered reference groups to be a superior method of participation compared to guideline panel member. Organizations are willing to support guideline development and patient representatives.

**Key words:** guidelines, patient participation, interviews, quality improvement
Introduction

During the last decade, the patient involvement in guideline development and implementation has been stressed and the Guidelines International Network (G-I-N), a global network of developers and implementers of evidence-based guidelines, has identified importance of involvement [1]. The benefit of patient involvement includes priority setting, defining the key questions, gaining information on values, preferences, acceptability and feasibility of interventions, and dissemination [2]. The most evident value seems to be defining the key clinical questions and setting the scope of the guideline [3-6].

G-I-N has offered guidance and a toolkit to facilitate the process of public involvement [2]. The toolkit gathers both research findings and international experiences on the topic. Its latest update describes three levels of involvement: consultation, participation, and communication (including implementation) [2]. The most common means of involvement have been consultations through statements and comments during external review [7]. According to the G-I-N toolkit, consultations are particularly useful to gather the views of a large group of individuals [2]. They can be conducted at all stages of the guideline development process including the scoping, development, draft review, and implementation. Consultations may be remote or face-to-face organized meetings or workshops, review of the guideline material or research like surveys, focus groups and interviews. Therefore, consultations include a variety of different methods of both passive and more active ways of involving in the guideline process, but they do not recognize patients’ value as development partners. In many guideline organizational method handbooks, various channels and methods of involvement are endorsed. However, it seems that in the guideline developers’ narrative, the gold standard has been to involve patient representatives as guideline panel members.

The possible role of patient organizations (PO) in guideline development has been acknowledged for example by NICE in UK (National Institute for Health and Care Excellence) [8]. NICE involves relevant POs by informing them on the public comment period and asking them to invite their members to participate. To limit the volume of comments, NICE encourages individuals to respond through a relevant stakeholder
organization. The G-I-N toolkit introduces several examples of PO participation [2], but the research evidence on their role is scarce.

In Finland, the Current Care Guidelines (CCG) have reached the position of national clinical practice guidelines (CPGs), although they are produced by medical scientific societies, not by health authorities [9,10]. Until today, there has not been a tradition of patients being directly involved in the production of CCGs. To fulfill the G-I-N requirements for trustworthy guidelines [1], in early 2020 we launched a project to involve patients in our guideline process.

Objectives

The primary aim of this study was to identify POs’ views on best ways to involve patient representatives in the guideline production and implementation. The secondary aim was to study how the POs see their potential roles in the guideline production and implementation.

Materials and methods

Study design, sample and setting

The study applied a pragmatic approach [11] and a qualitative cross-sectional design with semi-structured group interviews. Twelve POs who were co-operating with the CCG organization to develop a patient involvement programme for the national CCG were asked to nominate representatives for four semi-structured group interviews (a 1.5 hours) (a convenience sample) and were invited to reserve an interview time for the organization from possible interview dates. The POs represented large organizations and a diversity of conditions (f.ex. respiratory diseases, diabetes, heart diseases, mental diseases, allergies and skin diseases, pain, and osteoporosis). All organizations had been involved in guideline development through acting as peer reviewers in the final consultation of a guideline. In addition, approximately half had been involved in other ways. All organizations can be described as charities.

Data Collection

Due to COVID-19 pandemic, the group interviews were conducted via Teams® in May and June of 2020. The interviews followed a semi-structured interview guide developed by the researchers (see Supplementary
material 1. Interview questions). It included three main themes and nine subthemes related to how to develop CCGs to serve patients’ needs, what are the best methods to involve patients in the development of CCGs were, and how CCGs could be used in health care. Results section has the results for main theme number two. The interviewees were asked to comment on the guidelines related to the organization’s target group. RS, experienced in guideline development and group facilitation was responsible for the CCGs patient involvement project, and conducted the interviews. In addition, two persons from the CCG organization participated, one to address possible technical problems and one to make notes.

Ethics
The participants were informed about the aims of the interview and the planned use of the data (both development of the patient involvement programme and publication of a scientific article) when they were invited to participate and at the beginning of the interview. The consent process was audio-recorded as verification. All participants who gave consent were interviewed and audio-recorded, and transcripts were transcribed verbatim by an outside service. The data was anonymised for reporting.

Data Analysis
The data was analysed thematically using both deductive and inductive approaches [12]. The data on the different ways of involving patients was analysed deductively against the three main categories described in the 2015 version of the G-I-N framework: statements and comments, participation, and communication (Table 1) [13]. The general principles of involvement described by the interviewees as well as the role of POs were analysed inductively. The analysis was done for the original interview data (in Finnish) and the quotes selected for publication were translated into English.

Rigour and Trustworthiness
Two researchers independently created a draft of the themes and subthemes. The final coding frame was agreed between two researchers (RS and JK). Subsequently, one researcher carried out the analysis of the qualitative data (RS) while another researcher commented on it (JK). Agreement was sought through discussions with all researchers. Both sentences and groups of sentences were used as units of analysis. Saturation of the data was ensured during the analysis, so that in the fourth interview, no new themes
were generated. A report and interpretation of the interviews was sent to the participants and comments were invited, but not gained. In addition, the results were discussed with the PO representatives active in the programme.
Results

Altogether, 22 people nominated by the POs enrolled, and 20 participated in the interviews. The reason for non-participation is not known. Sixteen were employees of the PO they represented, three persons elected to a position of trust and one a patient representative. Nine had an education related to health care.

Participants were actively involved in the current PO from 6 months to 33 years.

Three general principles for involvement were inductively identified in the thematic analysis from the data. First, different ways of involvement should be available enabling involvement throughout the process.

...So, more or less quite low criterion [for patient representatives]. And maybe also so, that there would be different ways to participate... [interviewee 5, group 1]

...I think that a sort of a mix [of methods for involvement]. To seek these statements and comments as widely as possible. Well, there are also literature searches here and so, you have a great deal of this text on experience and that information. Then there is also the fact, that even professionals have knowledge on [patient] experience, and they know a great deal about how that knowledge can be utilized. Yes, I would think that as wide as possible range of methods for involvement [should be used]. [interviewee, group 3]

Second, the process should enable the involvement of a larger group of people to ensure representativeness and “multi-voiced views.”

Maybe it’s just this kind of open consultation, that may give more strongly the feeling of being heard, and especially that it involves several people. [interviewee 2, group 1]

But I underline and repeat again, about that patient multi-perspective, we think it’s important precisely because the symptoms have different manifestations and differences in various ages, and in various life situations different things are important. Thus, it is important to have many representatives, or many voices heard there. [interviewee 5, group 4]

Third, an open and inclusive process should lead to a genuine and equal interaction with the possibility to influence to the guideline content.
If we are talking about participating as a panel member. Then it is definitely really important to emphasize genuine inclusion, that is, being an equal representative, even though being a so-called layperson. But that patient experience is what he brings to it, and that is valued. [interviewee 5, group 2]

Or I could say that at some other point than at the very end [of the guideline development process], when there is perhaps a more genuine opportunity to influence the content... [interviewee 4, group 3]

All methods of involvement included in the G-I-N framework were identified by the interviewees (Table I). The general principles were seen to be fulfilled if statements and comments were possible especially at the beginning of the guideline development and thereafter throughout the process, and if participation was arranged in reference groups or patients’ networks. Reference group is a group of patients with separate but parallel meetings with the guideline panel throughout the guideline process. Instead of participating in guideline panels as a member, the interviewees preferred reference groups or patients’ network as a method of participation.

According to the interviewees, POs were willing to play an active role in guideline development. The main suggested roles were support for patient representatives who could participate in the guideline development, information production for guideline developers, active participation in the development of guideline drafts, commenting, and participating in communication to the general population (Table 2).

Generally, the views of the interviewees were alike and there were no conflicting views.

Discussion

Representatives from POs raised three principles for organizing patient involvement in guideline development: different and easy means of involvement throughout the development process, representativeness, and the possibility to influence things in genuine and equal interaction. Instead of participating in guideline panels as a member, the interviewees endorsed involvement through statements and comments throughout the work and reference groups or patients’ network.

The results of our study on the three general principles reflect the need to overcome previously observed barriers to meaningful patient involvement [14-17]. A major discussion has been how to ensure sufficient
representativeness. Another challenge is to combine patient perspectives based on the experiences of individuals with research findings. This and the aim of genuine interaction of health care professionals and patient representatives call for skilled facilitation and empowering patient representatives.

Interestingly, the PO representatives did not find patient participation in the guideline panel the most practical method to involve patients in the CPG development. This is contradictory to the most common international practices. According to earlier studies [18, 19], more recent study [20] and our communications with several guideline development organizations at the beginning of our project, the most common method is to have a patient as a panel member along with the possibility to review the guideline draft. The interviewees endorsed reference groups instead of a patient acting as a guideline panel member. Our results support G-I-N recommendations to use various methods of patient involvement and to choose the methods according to the aims of the involvement [2]. Different methods, especially accessible consultation methods, have been described in the G-I-N toolkit [2]. However, reference group is offered in the toolkit as an alternative approach for participation especially for groups of people who might not be able to be full members of the guideline panel.

For example, through emphasizing the need for introduction and education the interviewees expressed the lack of knowledge as a major barrier for equal participation. Additionally, a commonly cited barrier is the ability of patients to understand medical terminology and to participate meaningfully in assessing research quality [14]. Often the proposed solution for meaningful involvement is training and support, but these are resource-intensive and thus not necessarily possible for guideline organizations with limited resources. According to our results, reference group might be one solution to overcome this barrier. Therefore, in the beginning of the work the guideline panel should decide what is the aim of patient involvement and choose a method that allows meaningful contribution for the patient representatives.

In accordance with our interviewees, we suggest patient representatives to be included in guideline production as active followers and commentators. In addition to final consultation of the guideline draft our interviewees proposed consultations at different stages of guideline development and questionnaires.
A case study of question development for a single clinical guideline found that responses from a consultation survey were particularly helpful for reinforcing the views of patient members of the question development group [21]. This suggests the value of combining both approaches - consultation and participation in the guideline panel. According to experiences of G-I-N network, practical consultation methods include for example statements, questionnaires, using research evidence, and focus groups [2].

POs are willing to assist in recognising suitable persons and supporting them during the process. Obviously, the guideline producers need to tailor suitable methods for each guideline, preferable in cooperation with the POs. In addition, guideline producers need to be able to offer support and resources for the patient involvement. Khodyakov et al., (2020) suggested that POs can help locate patients, caregivers, and others with relevant perspectives, assess the feasibility of proposed engagement activities, appropriate participation burden, and acceptable remuneration for participation [22].

Through the above-mentioned methods of involvement, it is possible to fulfil the main advantages of patient involvement — to incorporate their values and perspectives in the guidelines and involve them in defining the key clinical issues [3, 15, 18] and hear the views of patients in different situations. However, these methods of involvement do not provide an opportunity to participate in the decision making during the guideline development. Rather, patients are seen as experts who should be heard during the process.

Still, the possibility to influence the guideline content may be superior to that of one or two patient representatives acting as guideline panel members. This indicates that guideline producers should decide about policy regarding conflicts of interests of patient representatives, who are not directly participating in the decision making. It should be considered, that in Finland many POs rely partly on state funding, but also partly on fundraising, including potential funding from pharma industry. Another important issue to agree with patient representatives is the confidentiality during the guideline process.

**Implications for policy, practice, and research**

We suggest that POs should be actively involved in guideline development. POs are willing to provide active support and feedback to the patient representatives, actively participate in the guideline development, and
recruit capable patient representatives. However, possible conflicts of interests must be acknowledged and managed according to general principles of guideline development when working with POs and patient representatives [23, 24]. In addition, various stakeholders, including POs have their own agendas in guideline development [24, 25]. This stresses the requirement for clearly described methods when developing CPGs and making decisions on recommendations [1].

Strengths and limitations

The main strength of the study is that the group interview participants represented a variety of POs thus providing a wide perspective on patient involvement methods. On the other hand, the study had a pragmatic approach and used a convenience sample, including a representative of each organization involved in the project. In addition, only one of the interviewees was a patient representative. The interview guide was not piloted beforehand; however, it was considered feasible during the first interview as the discussion proceeded well and focused on the topics of the study as planned. The trustworthiness of qualitative research may be assessed by transferability, dependability, credibility, and confirmability [26]. The data reached a saturation point in four interviews, the data was analysed systematically by two researchers, member checking, quantification, as well as tabulations were used. Finally, interview guide and quotes from the interviews are shown to allow confirmability of the results.

A weakness of the study may be that almost half of the participants had an education related to health care. Only one had participated in guideline development as a guideline panel member, which may have been either an advantage or a disadvantage to the discussions. The interviewer represented the CCG organization, which may have affected the discussions. Furthermore, we acknowledge that the methods of developing guidelines may differentiate in different countries; thus, diminish the potential for transferability of our findings.

Conclusions

Guideline developers should offer various and accessible methods of patient involvement, including reference groups. The guideline process should enable the involvement of a group of people, that is large
enough to ensure representativeness of different patients and “multi-voiced views.” An open and inclusive process should lead to a genuine and equal interaction between professionals and patient representatives participating in the guideline development. This must be emphasized in processes regardless of patient representatives’ possibility to participate in the actual decision making. Since POs are able and willing to participate in guideline development and implementation in different ways, opportunities to participate should be offered.

Contributorship

RS and JK had the main responsibility for the conception and design of the work, execution of the work, and analysis of the data. KHA has actively contributed to the conception and design of the work, execution of the work, and analysis of the data. All authors contributed their methodological expertise and contributed to the writing of the manuscript and approved the final version.

Ethics and other permissions

The study was followed the guidelines of the Finnish Advisory Board on Research Integrity (https://tenk.fi/en/ethical-review/ethical-review-human-sciences). According to the guidelines, the study did not require ethical approval. Willingness to participate in the interviews was considered to be informed consent and consent for planned data use was requested and recorded at the beginning of the interviews. All participants accepted tape-recording and the anonymity of the participants were secured throughout the analysis process and reporting.

Funding

The Current Care Guidelines’ development project for patient involvement was funded by the Funding Centre for Social Welfare and Health Organizations. The group interviews were part of the project, but the funding was not used for the analysis of these results.

Conflict of interests

No known conflict of interests.
Acknowledgments

We thank the POs and their representatives who participated in the group interviews. In addition, we thank the CCG project group for their valuable comments on the interview questions.

Data sharing statement

Data cannot be shared for privacy reasons.

References


Table 1. Interviewees’ (n=20) comments on various methods to involve patient in the guideline processes, analyzed against the G-I-N framework [8].

<table>
<thead>
<tr>
<th>Method of involvement, G-I-N framework</th>
<th>Summary from the interviews by researchers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statements and comments</td>
<td>It is important that there is a possibility to comment at the beginning of the guideline development, especially when updating a guideline. In addition, commenting should be possible throughout the process and before publication. If commenting is possible solely at the end of the guideline process, before publication, the possibilities to influence were seen poor. A questionnaire could be an easy way to collect views of a large group of people. Experience experts were seen as a good source to get a range of views.</td>
</tr>
<tr>
<td>At the beginning</td>
<td></td>
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<tr>
<td>Before the publication</td>
<td></td>
</tr>
<tr>
<td>Seminar</td>
<td></td>
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<tr>
<td>Questionnaires</td>
<td></td>
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<tr>
<td>Literature searches</td>
<td></td>
</tr>
<tr>
<td>Experience experts</td>
<td></td>
</tr>
<tr>
<td>Participation</td>
<td>Reference groups and patient networks were seen as the best ways to participate. These enable participation at the beginning, in the middle and before publication and participation of a larger group of people with different viewpoints. Although guideline panel membership was seen as an important way to participate, significant problems were identified. The interviewees pondered who could represent the patient population and saw the situation for the patient representative to be difficult. They called for but at the same time questioned the possibility for</td>
</tr>
<tr>
<td>Representative in selected guideline panel meetings</td>
<td></td>
</tr>
<tr>
<td>Guideline panel member</td>
<td></td>
</tr>
<tr>
<td>Representative in the guidelines board</td>
<td></td>
</tr>
<tr>
<td>Reference group</td>
<td></td>
</tr>
<tr>
<td>Take the floor as an</td>
<td></td>
</tr>
</tbody>
</table>
experience expert in a guideline panel meeting
- Patient networks

genuine and equal interaction in the guideline panel. One option for fulltime panel members could be participation in selected meetings based on the meeting aims or experience expert presentations on “what it means to live with the disease”. Regardless of the method of participation introduction or education is needed and the aim for participation should be clear.

Communication
- Information
- Patients’ versions of the guidelines
- Implementation tools

Consistent communication in cooperation was seen to be an important and self-evident method of involvement. The participation in the development of patients’ versions of guidelines could make them more relevant and comprehensible. Discussion on implementation tools and implementation was scarce but seminars were mentioned.

Table 2. The various proposed roles for patient organizations (PO) in the guideline process identified by the interviewees (n=20).

<table>
<thead>
<tr>
<th>Proposed roles</th>
<th>Summary from the interviews by researchers</th>
<th>Example quote¹</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Produce information</strong> (n=4)</td>
<td>Conduct and analyze a questionnaire. In addition, other usable material can be produced or compiled in POs.</td>
<td>“In addition, the thing is how POs can be involved. For example, a questionnaire for the members could be one option.” [interviewee 2, group 1] “...to be included also in a support group, to potentially collect material,”</td>
</tr>
</tbody>
</table>
| **Recruit participants or act as a patient representative (n=4)** | **POs could suggest or recruit guideline panel or reference group members. Organizations could train and recruit experts by experience. Give presentations to the panel.** | **“...If there were a development group or something, the experience experts educated by our association and others who are actively involved in the association’s activities could be utilized...” [interviewee 4, group 4]**

“...But of course, maybe the fact that when it’s [recruitment of patient representatives] done through organizations [POs], then I guess it’s cost effective in the sense that we organizations [POs] are able to do prequalification.” [interviewee 3, group 3]** |
| **Offer support group or support person (n=3)** | **Patient representatives need a contact person and POs are able to provide it. Support could be “debriefing” of meetings, going through feelings and discussing the guideline issues. A support group could facilitate the panel member to gain wider point of view. A support person or group could** | **“Those situations will be broke down and the feelings will be discussed. I think that it can initiate large processes for the participants. In this way we, the employees of the [patient] organizations, act as confidants for them. Going through the situations is also a responsible way to do things.” [interviewee 3, group 3]**

“...That’s why I thought that it would be...” [interviewee 1, group 2] |
<table>
<thead>
<tr>
<th>Activity</th>
<th>Comments and Expert Opinion Statements (n=2)</th>
<th>Participate in Writing the Patient Version of the Guidelines (n=1)</th>
<th>Participate in Communications</th>
</tr>
</thead>
<tbody>
<tr>
<td>collect material and participate in giving statements.</td>
<td>POs are willing to give comments and statements throughout the guideline development process.</td>
<td>“POs could consider what the patient view is in this situation, where to start the development. They could also review the present guideline. Maybe comment on it, how it has served and what is missing. Of course, they could give statements during the process and give feedback on the guideline.” [interviewee 4, group 2]</td>
<td>“Well, I don’t remember at the moment, who said earlier about communication as...” [interviewee 1, group 1]</td>
</tr>
<tr>
<td>Give comments and expert opinion statements (n=2)</td>
<td>POs are willing to give comments and statements throughout the guideline development process.</td>
<td>“POs could consider what the patient view is in this situation, where to start the development. They could also review the present guideline. Maybe comment on it, how it has served and what is missing. Of course, they could give statements during the process and give feedback on the guideline.” [interviewee 4, group 2]</td>
<td>“Well, I don’t remember at the moment, who said earlier about communication as...” [interviewee 1, group 1]</td>
</tr>
<tr>
<td>Participate in writing the patient version of the guidelines (n=1)</td>
<td>POs are willing to participate in writing the patient version of a guideline.</td>
<td>“…Surely then in the development of these patient versions [of the guidelines], the patient representative or the PO could...and the experience expertise that would rise would be noteworthy.” [interviewee 1, group 2]</td>
<td>“Well, I don’t remember at the moment, who said earlier about communication as...” [interviewee 1, group 1]</td>
</tr>
<tr>
<td>Participate in communications</td>
<td>POs could communicate guidelines to their members and target groups.</td>
<td>“Well, I don’t remember at the moment, who said earlier about communication as...” [interviewee 1, group 1]</td>
<td>“Well, I don’t remember at the moment, who said earlier about communication as...” [interviewee 1, group 1]</td>
</tr>
</tbody>
</table>
POs are willing to carry out the communicative activities. if it is self-evident. I raise it maybe because it is something that should follow automatically.”

[1] Text in brackets are additions from the research group to make the quote clearer and more explicit due to translation.

Supplementary material

Supplementary material 1. Interview questions

Supplementary material 2. Reporting guideline: COREQ

Supplementary material 3. Reporting guideline: SRQR

Supplementary material 1. Interview questions
Related to Sipilä R et al. Patient representatives need various methods to be involved in clinical practice guidelines – a qualitative study

Theme 1: Current Care Guidelines

1. What good do you find in Current Care Guidelines?
2. How would you develop Current Care Guidelines to measure them up with patients’ needs?
3. How would you develop Current Care Guidelines to support shared decision making between professionals and patients?
4. How does your patient organization use Current Care Guidelines?

Theme 2: Involvement in development of Current Care Guidelines

5. How has your patient organization been involved in Current Care Guidelines development?
6. What are the benefits of involving patients in Current Care Guidelines development?
7. What methods of involving patients would be the most suitable in Current Care Guidelines development?
8. What would this involvement require (from patient representatives and on the other hand from the developing organization)?

Theme 3: Health care and guidelines
9. How are the Current Care Guidelines used in shared decision making between professionals and patients?

Supplementary material 2. Consolidated criteria for reporting qualitative research (COREQ)

Related to Sipilä R et al. Patient representatives need various methods to be involved in clinical practice guidelines – a qualitative study

Domain 1: Research team and reflexivity

Personal Characteristics

1. Interviewer/facilitator: Which author/s conducted the interview or focus group?
   RS conducted the interview. Stated in the manuscript, page 5.

2. Credentials: What were the researcher’s credentials? E.g. PhD, MD
   Stated in the title page.

3. Occupation: What was their occupation at the time of the study?
   Stated in the title page.

4. Gender: Was the researcher male or female?
   Not separately stated in the manuscript. We consider that the gender has no impact to the interview discussions on the topic studied, and thus, to the quality of results in this study.

5. Experience and training: What experience or training did the researcher have?
   The researcher conducting the interviews (RS) is experienced in guideline development and group facilitation and responsible for the Current Care Guideline (CCG) patient involvement project. Stated in page 5.

Relationship with participants

6. Relationship established: Was a relationship established prior to study commencement?
   The POs were involved in the patient involvement programme of the guideline development organization. RS was responsible for the CCG patient involvement project. Stated in the methods section, page 5.

7. Participant knowledge of the interviewer: What did the participants know about the researcher? e.g. personal goals, reasons for doing the research.
   The participants were informed about the aims of the interview to develop methods of involving patients in Current Care guideline development and the planned use for a publication. They knew that the interviewer was employed by the guideline development organization. Described in page 4 (study design, sample and setting) and in page 5 (data collection).

8. Interviewer characteristics: What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic
The researcher conducting the interviews (RS) is experienced in guideline development and group facilitation and responsible for the CCG patient involvement project. Stated in page 5 and discussed as a potential limitation in page 11.

Domain 2: study design

Theoretical framework

9. Methodological orientation and Theory: What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis

The study applied a pragmatic approach which is described in page 4 (study design, sample and setting).

Participant selection

10. Sampling: How were participants selected? e.g. purposive, convenience, consecutive, snowball

Twelve patient organization who were co-operating with the CCG organization to develop a patient involvement programme for the national CCGs were asked to nominate representatives for the group interviews. Therefore, a convenience sample was used. Stated in pages 4-5.

11. Method of approach: How were participants approached? e.g. face-to-face, telephone, mail, email

The patient organizations (PO) collaborating in the patient involvement programme were asked to nominate representatives for group interviews. Stated in page 4 (study design, sample and setting).

12. Sample size: How many participants were in the study?

There were 20 participants, stated in page 7.

13. Non-participation: How many people refused to participate or dropped out? Reasons?

Two of the recruited persons did not attend the interviews. The reason for non-participation is not known. Stated in page 7 (Results)

Setting

14. Setting of data collection: Where was the data collected? e.g. home, clinic, workplace

Due to pandemic the interview was conducted thru remote connection. Stated in page 4.

15. Presence of non-participants: Was anyone else present besides the participants and researchers?

One person from the CCG organization participated to ensure technical issues and one to make notes. Stated in page 5.

16. Description of sample: What are the important characteristics of the sample? e.g. demographic data, date

Stated in the Methods (Study design, sample and setting) and Results section. See pages 4,5 and 7.

Data collection

17. Interview guide: Were questions, prompts, guides provided by the authors? Was it pilot tested?
The interview guide for the semi-structured group interviews is described in page 5 (data collection) and provided as supplementary material. The interview guide was not piloted in forehand, however, it was considered feasible during the first interview. Stated in page 11 (limitations).

18. Repeat interviews: Were repeat interviews carried out? If yes, how many?

Repeat interviews were not applied. In page 4, it is stated that the study followed a qualitative cross-sectional design.

19. Audio/visual recording: Did the research use audio or visual recording to collect the data?

The interviews were audio-recorded. Stated in the Methods section, see page 5.

20. Field notes: Were field notes made during and/or after the interview or focus group?

One person participated in the interviews as a note-taker. Stated in page 5.

21. Duration: What was the duration of the interviews or focus group?

The group interviews lasted 1.5 hours. Stated in page 4.

22. Data saturation: Was data saturation discussed?

The data saturation was reached. Stated in Methods (page 6) and Discussion (page 10).

23. Transcripts returned: Were transcripts returned to participants for comment and/or correction?

A summary of the interview results was sent to the participants. Member checking is stated in page 4 (rigour and trustworthiness) and in pages 10-11 (strengths and limitations).

Domain 3: analysis and findings

Data analysis

24. Number of data coders: How many data coders coded the data?

Two researchers independently created a draft of the themes and subthemes. The final coding frame was agreed between two researchers (RS and JK). Subsequently, one researcher carried out the analysis of the qualitative data, while another researcher commented on it. Stated in the Methods section, page 5.

25. Description of the coding tree: Did authors provide a description of the coding tree?

The data on the different ways of involving patients was analysed deductively against the three main categories described in the 2015 version of the G-I-N framework: statements and comments, participation, and communication. Stated in page 5 (data analysis) and shown in table 1. The general principles of involvement and the role of patient organizations was analyzed inductively. Stated in page 5 (data analysis) and shown in table 2. Three general principles of involvement are mentioned in page 7 (results).

26. Derivation of themes: Were themes identified in advance or derived from the data?

Both deductive and inductive analysis was used. Described in Methods, page 5.

27. Software: What software, if applicable, was used to manage the data?

Not applicable.

28. Participant checking: Did participants provide feedback on the findings?
A report and interpretation of the interviews was sent to the participants and comments were asked, but not gained. In addition, the results were discussed with the PO representatives active in the programme. Member checking is stated in page 6 (rigour and trustworthiness) and in pages 11 (strength and limitations).

**Reporting**

29. Quotations presented: Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number

Quotations are provided in the Results section (pages 7-8) and Table 2 (pages 18-21) on the various proposed roles for patient organizations in the guideline process identified by the interviewees.

30. Data and findings consistent: Was there consistency between the data presented and the findings?

Interview guide and quotes from the interviews are shown to allow confirmability of the results.

31. Clarity of major themes: Were major themes clearly presented in the findings?

Major themes are presented in results-section (page 7) as well as in tables 1 and 2.

32. Clarity of minor themes: Is there a description of diverse cases or discussion of minor themes?

The number of interview groups which discussed various roles for patient organizations in the guideline process is presented in table 2. Generally, the views of the interviewees were alike and there were no conflicting views. (Results, page 7-8).

**Standards for Reporting Qualitative Research (SRQR)**

http://www.equator-network.org/reporting-guidelines/srqr/

**Title and abstract**
<table>
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<th>Page/line no(s.)</th>
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<tbody>
<tr>
<td><strong>Title</strong> - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended</td>
</tr>
<tr>
<td><strong>Abstract</strong> - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions</td>
</tr>
<tr>
<td><strong>Introduction</strong></td>
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<tr>
<td><strong>Problem formulation</strong> - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement</td>
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<tr>
<td><strong>Purpose or research question</strong> - Purpose of the study and specific objectives or questions</td>
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<tr>
<td>“Objectives” page 4,</td>
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<td><strong>Methods</strong></td>
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<tr>
<td><strong>Qualitative approach and research paradigm</strong> - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**</td>
</tr>
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<td><strong>Researcher characteristics and reflexivity</strong> - Researchers’ characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers’ characteristics and the research questions, approach, methods, results, and/or transferability</td>
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<td><strong>Context</strong> - Setting/site and salient contextual factors; rationale**</td>
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<td><strong>Sampling strategy</strong> - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**</td>
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<td><strong>Ethical issues pertaining to human subjects</strong></td>
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<td><strong>Techniques to enhance trustworthiness</strong></td>
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**Results/findings**

| **Synthesis and interpretation** | Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory | “Results” Pages 7–8, Tables 1 (page 17-18) and 2 (pages 18-21) |
| **Links to empirical data** | Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings | Pages 7–8 Table 2 (pages 18-21) |

**Discussion**
**The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.**

**Integration with prior work, implications, transferability, and contribution(s) to the field** - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field

**Limitations** - Trustworthiness and limitations of findings

**Other**

<table>
<thead>
<tr>
<th><strong>Conflicts of interest</strong></th>
<th>Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed</th>
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<td><strong>Funding</strong></td>
<td>Sources of funding and other support; role of funders in data collection, interpretation, and reporting</td>
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</tbody>
</table>

**Discussion** Pages 8–11

**Strengths and limitations** Pages 11-12

**Reference:**
DOI: 10.1097/ACM.0000000000000388

**The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.**