Chapter 1: How to conduct public and targeted consultation

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Aims of this chapter

This chapter describes ways to conduct public and targeted consultation during the development of clinical guidelines. It aims to raise awareness of key issues to take into account when developing a consultation strategy and related processes, including best practice principles and different methods to consider. Using the typology of involvement described in Boivin et al¹ the term ‘consultation’ refers to the process of collecting information from patient and public stakeholders to inform guideline development and implementation, as opposed to their ‘participation’ in exchanging information with other stakeholders, for example, as members of a guideline development group.

This chapter focuses on the approach and experience of the UK’s National Institute for Health and Clinical Excellence (NICE), while also drawing on examples from the Scottish Intercollegiate Guidelines Network (SIGN), GuíaSalud in Spain and recommended best practices from guideline bodies in other countries. It includes examples from our experience of how consultation has added value to the process and end product.

The UK and Spanish models are provided for illustrative purposes only and are not meant to be prescriptive: ‘local’ circumstances and the level of support and resources available will influence the type of model adopted.

This chapter concludes with key messages in a summary of tips and best practice principles.

Reasons for consultation

Several key guideline organisations and other major bodies such as the USA’s Institute of Medicine recommend the use of public and targeted consultation to inform the development of clinical guidelines. They concur that there is value in exposing draft guidelines to a wider audience, including all groups that have an interest in the implementation or outcomes of guidelines. There are also strong grounds for consulting patient and public stakeholders from the beginning of the guideline development process; for example, to ensure that issues important to patients and their families or carers are taken into account in the scoping of topics and questions for the guideline to address and in subsequent steps moving forward. In addition, targeted consultation with patients and/or the public can add value when important gaps are identified in the evidence related to their views and experiences.

In its criteria for accrediting producers of clinical guidelines for National Health Service (NHS) Evidence NICE² refers to relevant patient and public groups being included in consultations, and notes that best practice requires a range of patient and public involvement activities in the development of guidelines. The accreditation criteria are based on the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument which was developed to assess the quality of clinical practice guidelines.³
Other key bodies promote public and targeted consultation. For example, in Australia, public consultation on the draft guideline (including relevant professional and patient/consumer organisations) is a requirement for approval of clinical guidelines by the National Health and Medical Research Council, and in the USA the Institute of Medicine promotes this practice in their standards for guideline development.

Some guideline developers have documented their approach to consultation as part of a wider strategy or programme of patient and public involvement in guideline development, for example, NICE, SIGN, and the Spanish national guideline development programme called GuíaSalud.

In summary, there are many good reasons for public and targeted consultation during the development of clinical guidelines. These include:

- Helping to ensure that issues important to patients and the public are appropriately taken into account from the beginning of the guideline project and reflected in the final product, thereby complementing the contribution of patient and public members on a guideline development group
- Supplementing gaps in the evidence or obtaining a wider source of patient/public experiences and views than can be provided by patient and public members on a guideline development group
- Securing an understanding of public perception of the acceptability and relevance of the guideline in the ‘local’ context, for example, the National Health Service in Scotland
- Improving the wording and presentation of the guideline (for example, ensuring that the wording is respectful and the recommendations promote partnership between patient and clinician)
- Helping to ensure the guideline is relevant and acceptable to patients and the public, and to specific groups within the patient population, including those who are unrepresented or ‘seldom heard’
- Paving the way for patient/public support for the final guideline and receptivity to its uptake and dissemination, and in general
- Enhancing the legitimacy of the development process and the end product from a public perspective.

Ways of conducting consultation

Consultations may be open to the public and/or targeted to relevant patient/public groups and other stakeholders. They may be conducted remotely (e.g. online), in meetings or in workshops, or a combination of these. Less commonly, consultation may also take the form of research with patients and/or the public (using methods such as surveys, focus groups and interviews), when participants are not expected to represent the views of other people, but to characterise their own views and experiences. Whichever approach is taken, consultation adds significantly to the time and resource requirements of guideline development and should be factored in at the outset. In most consultation processes—such as feedback on draft scoping documents and draft guidelines—patient/public consultation can occur simultaneously with professional consultation.
Both open and targeted consultation methods have their advantages as outlined in the following table.

**Open or targeted consultation?**

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<td>Public posting of draft documents and questions, which would need to be well publicised. Guideline developers could have an interactive online feature to notify interested parties of the topics, anticipated comment periods, and actual postings</td>
<td>By invitation to all relevant stakeholder organisations, or to groups and individuals with interest, expertise and responsibility</td>
<td>Public posting of draft documents and questions combined with targeted invitations to all relevant stakeholder organisations or groups and individuals with interest, expertise and responsibility</td>
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**Potential advantages**

- This option has the merit of transparency and in theory opens up the process to all interested parties and viewpoints

- Targeting invitations may be more effective in generating responses

- Where patient/public stakeholders are not known to guideline developers (or key organisations have not registered their interest), a focus on targeted consultation can help developers plan ahead to find individuals or groups and invite them to contribute to the guideline development process

- The volume of feedback should be manageable

**Potential disadvantages**

- Guideline developers may be overwhelmed with the volume of feedback

- Guideline developers may receive inadequate feedback if publicity is limited and no one feels responsible

- Important viewpoints may be overlooked or avoided if targeted consultation is not combined with an open invitation to contribute

- Invited individuals/organisations may not be interested or able to respond in a timely manner

- Guideline developers may be overwhelmed with the volume of feedback
Consulting patient and public (carer) organisations

In the development of its own guidelines, NICE uses an open consultation process, with draft consultation documents posted on its website at key stages in the guideline development process. However, to manage the volume of comments in a transparent way, NICE encourages individuals to respond via a relevant stakeholder organisation. These organisations receive a response to each of their comments, and both the comments and the developers’ responses are published on the NICE website. Individuals do not receive a response unless they are designated peer reviewers.

In the NICE model, all registered stakeholder organisations are invited to contribute at key stages of the guideline development process. This includes:

- Setting the scope of the guideline
- Circulating NICE website advertisements to their members and networks for recruitment to the guideline development group (health professional and patient/public members)
- Responding to calls for evidence if the guideline developers believe that their literature search has not found all the relevant information. Such evidence could include grey literature (written material or documents not published commercially) on the impact of the condition on people’s lives, the views of patients and carers about their treatment or care, or the difference a particular type of care or treatment might make
- Commenting on the draft guideline.

To support stakeholder engagement, NICE maintains an extensive database of contacts for organisations representing patient and public interests (including ‘equality’ groups), and invites them to register their interest for new guideline topics. Staff in NICE’s Patient and Public Involvement Programme help identify relevant organisations and offer information and advice to support their involvement.

Identifying and reaching patient and public groups

For guideline developers who lack the structure and resources indicated by the NICE model, the following suggestions may be helpful in identifying relevant patient and public groups (organisations and individuals) and inviting them to take part in consultations.

Networks of voluntary organisations, charities and non-governmental organisations (NGOs) may provide a useful avenue for reaching relevant patient/public stakeholders. For example, the patient and public involvement officer at SIGN puts out a call for patient involvement through Voluntary Health Scotland (VHS) when a new clinical guideline is being developed. VHS acts as a hub for several hundred health charities and patient groups.

Other sources for identifying relevant patient/public stakeholders include health professionals and their organisations, patient organisations that are already known to guideline developers, and the Internet. In addition, if the guideline development group has been convened, it may be fruitful to work with patient and public members to identify key organisations and individuals with the desired perspectives and experiences.

Consider contacting national and international patient/public groups, as they can be a useful source of contacts and advice as well as an avenue for collaboration. Examples include:
• National groups, such as Consumers United for Evidence-based Practice (CUE) in the USA and Foro Español de Pacientes in Spain

• International groups, such as G-I-N PUBLIC (Guideline International Network’s Patient and Public Involvement Working Group), CCNet—the Cochrane Consumer Network, and the Health Technology Assessment international’s (HTAi) Interest Sub-group on Patient and Citizen Involvement in HTA (Health Technology Assessment).

Patient and public expert reviewers

When peer review by external individuals is a routine part of the process of guideline development, patients, members of the public or advocates should be included as expert reviewers. For example, all SIGN guidelines are reviewed in draft form by independent experts including at least two patient/public reviewers.9 At NICE, external review is mainly conducted through consultation with stakeholder organisations; however guideline developers may also consider arranging additional expert review of part or all of a clinical guideline. Expert reviewers may include patients, members of the public and advocates, as well as health professionals. This review may take place during guideline development or at the final consultation stage.6 Expert reviewers are required to complete a declaration of interests form.6,9

Consultation at key stages: setting the scope of the guideline

It is important to include patient and public perspectives from the beginning of the guideline development process. With this end in mind, SIGN and NICE consult patient and public groups on the scope of a new guideline before the first meeting of the guideline development group. GuíaSalud in Spain also includes consultation with patients at this preparatory stage of guideline development, for example, they used focus groups and interviews with patients to inform the scope and key questions for two guidelines on anxiety and insomnia.11

Four months before the first meeting of a new guideline development group, SIGN invites patient and public (carer) organisations to put forward the issues they think the guideline should address. A form is supplied to enable them to structure their feedback in a useful way and to indicate the source of their suggestions (such as telephone help line data, surveys). SIGN then summarises the information received and presents it to the guideline group at its first meeting. Where published evidence is scarce and when there is inadequate feedback from patient organisations, SIGN may seek patient and public views via direct contact with users of the service. This has been achieved using focus groups with patients in different regions of Scotland, attendance of SIGN staff at patient support group meetings, and SIGN-organised meetings for patients and members of the public. The information obtained from these approaches is reported to guideline groups to influence the development of key questions underpinning the guideline.8,9

NICE involves patient organisations and other stakeholders in the scoping process in two ways: participation in a meeting and online consultation. All organisations that have registered an interest in a new guideline project are invited to attend the scoping meeting. This gives patient organisations and other stakeholders an opportunity to become familiar with the guideline development process and to take part in detailed discussions about the scope, which sets out what the guideline will and will not cover, and defines the aspects of care that will be addressed. A draft scope is then produced and stakeholders are invited to comment on it (using a standard form) during a 4-week online consultation. This online process is designed to ensure openness and transparency, as all
written comments receive a formal response from guideline developers, and both comments and responses are published on the NICE website.

NICE encourages patient and public (carer) organisations to comment on the draft scope, in particular on the following:

- Does the scope take into account issues that are important to patients and members of the public, such as the medicines, treatments, or advice that they think are important?
- Should the guideline include recommendations about treatments that are in current use but may not be considered by patients to be effective, acceptable or tolerable?
- Are there any groups of patients who might need particular consideration given their circumstances (for example, because of particular details of their condition, or because of factors such as their age, disability, culture, ethnicity or gender)?
- Does the scope unfairly exclude any groups of patients (for instance by their age or their general health)?
- Does the scope take into account patients’ and public members’ needs for information and support specific to the condition?
- Is the wording of the scope respectful of patients, and does it enable a partnership between patient and health care professional?

Impact of patient stakeholders on the scoping stage—case study

**Clinical guideline for lower back pain (CG88)**—The draft scope specified that the NICE guideline would only cover the care of patients with low-back pain up to 6 months’ duration. Comments from a key patient organisation about the evidence, patient characteristics, and need for pain management over a longer period of time resulted in a change to the scope by extending the duration of coverage to 12 months.

Consultation at key stages: the draft guideline

SIGN combines open consultation on the draft guideline with a later period of peer review. A national open meeting is held with health professionals and patients to discuss the draft version of the guideline. The draft guideline is also posted on the SIGN website for four weeks for those who cannot attend. Anyone can respond to the online consultation.

NICE and GuíaSalud follow a similar online consultation process, inviting stakeholder organisations to comment on the draft guideline during a set period. NICE has a 6-week consultation period in which stakeholders can review the full draft guideline or just refer to a short version which lists the draft recommendations.

In our experience, some patient organisations find it helpful to have questions or a checklist to guide their response. NICE encourages patient organisations to comment on issues such as:

- Does the guideline make recommendations about all the issues from the scope that patients and members of the public consider important?
- Do the guideline recommendations reflect what the evidence says about treatment and care?
- Do you know about any important evidence that the guideline has not taken into account?
- Do you agree with the recommendations? If you don’t, please explain why.
- Does the guideline recommend treatments and care that patients and the public might consider unacceptable? Your comments could take into account, for example, what you know about the potential benefits and disadvantages (including side effects) of medicines and other treatments.
- Do the recommendations clearly show the need to take into account patients’ preferences, for example, if evidence suggests that two treatments may be equally effective?
- Do the recommendations take into account patient and public needs for information and support specific to the condition?
- If appropriate, do the recommendations consider the specific needs of different groups of patients (for example, children or young people, people from specific ethnic groups or cultures)?
- Are the recommendations clear and unambiguous?
- Is the wording respectful to patients and the public?
- Does the wording reflect the importance of partnership between health care professionals and patients?
- Do the research recommendations cover gaps in the evidence about important areas of patient and public experience?

**Responding to consultation comments**

The patient and public members of the guideline development group can help the group consider the inclusion of any material or amendment arising from patient/carer feedback that will strengthen and improve the guideline. Some recommendations will not be feasible for various reasons. Some patient and public members may be well-placed to present the proposed modifications and rationale to the broader guideline development group. (This is a model that has been effective with systematic review development and has worked well in guideline groups with patient/public members who choose to take on this role.) For all types of comments received, final uptake decisions should be in accord with the guideline development group’s ongoing decision-making processes.

Key guideline bodies promote openness and transparency in the consultation process. The Institute of Medicine (IOM) advises guideline developers to keep a written record of the rationale for modifying or not modifying a guideline, in response to reviewers’ comments. Similarly, as part of Australia’s National Health and Medical Research Council’s (NHMRC) approval process, guideline developers must provide details of consultation responses and explain why and how the guideline was altered. As part of their desirable criteria for approval, the NHMRC also advocates making a
summary of submissions and developers’ responses publicly available.4 In its accreditation of other guideline producers, NICE2 stipulates that if the views of patients are not taken directly into account, the reasons must be explained. For its own guidelines, NICE enters all comments into a table, which includes a ‘responses’ column for acknowledging and answering each comment, including setting out what changes have been made to the guideline or explaining why no change has been made. The NICE guidelines manual sets out its process for dealing with stakeholder comments.6 Other major guideline developers, such as GuíaSalud in Spain, follow a similar open and transparent process for responding to feedback, including making the consultation comments and responses publicly available.

Best practice principles for consultations

- Establish a transparent consultation process
- Identify and involve patients, carers and the public and/or organisations representing their interests at all consultation stages
- Show sensitivity and accommodation for ways that patients and carers may be affected by the specific condition being addressed, for example, different visual, cognitive, or mobility abilities
- Allocate time and resources for consultation in the guideline development process whilst maintaining control of the timetable to ensure the guideline is produced in a timely fashion
- Consider the optimum time period for consultation, balancing the need to produce an up-to-date guideline while taking into account stakeholders’ expectations (for example, some organisations consult their constituencies before responding)
- Set up efficient administrative systems for alerting people to consultations and managing responses in a timely manner
- Provide advance notice of consultation dates
- Provide guidance on what respondents could consider commenting on, for example, a list of questions which incorporate patient/public perspectives
- Include equality considerations in the list of questions⁵ and ensure the method of consultation allows input from the range of patient sub-groups, including vulnerable or under-represented groups
- Ask respondents to give a page/section reference to the draft document where relevant to their comment; providing a standard form for responses can be helpful

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⁵NICE includes the following equality question in its scoping and draft guideline consultations: ‘Do you think this scope/guideline could be changed to better promote equality of opportunity relating to age, disability, gender, gender identity, ethnicity, religion and belief, sexual orientation or socioeconomic status? In answering this question, please include details of:
Which particular parts of the scope/guidance you think affect equality of opportunity.
Why and how you think equality of opportunity is affected’.
- Obtain declarations of interest from any individual expert reviewers, including identification of sources of funding or support in kind for patient organisations
- Ensure that the final decisions in responding to feedback are in accordance with the guideline development group’s ongoing decision-making processes
- List comments in a table with guideline developers’ responses
- Make comments and responses publicly available, or at least a summary available on request
- Document the consultation process that was followed and make it publicly available
- Consider evaluating whether and how the consultation process adds value to the guideline
- Consider evaluating the particular contribution of patient/public respondents.

Consulting individual patients and members of the public using research techniques

In addition to formal consultation processes, guideline developers may undertake consultation or research with individual patients and members of the public, either to inform the scoping or development stages, or to test the relevance and acceptability of draft recommendations. This work typically uses methods such as group discussions (focus groups), interviews and surveys. The main reason for such projects is to supplement gaps in one or more of the following areas:

- Important gaps in the evidence base
- Insufficient feedback from patient organisations (for example, for some guidelines or topics there may be no patient organisation with a focus on the topic)
- Gaps in membership of the guideline development group in terms of patients’ perspectives, for example, for guidelines covering children or people with learning (developmental) disabilities
- Information on the perspectives of ‘seldom heard’ patients who are not part of an organised group or who don’t have an organisation to advocate for them, or potentially excluded groups such as people from certain minority cultures or ethnic groups.

Guideline developers need to ensure that those conducting consultation using research techniques have the relevant knowledge and skills.

Before considering such work, it is important to check whether the information you’re looking for might already be available. There may be relevant information on the views and experiences of patients and members of the public in the grey literature, including surveys conducted by advocacy organisations. For example, in the USA the *Listening to Mothers* surveys are good examples of population-level resources about women’s experiences of care, their knowledge and preferences, with coverage of topics from before pregnancy to well into the postpartum period. These Childbirth
Connection surveys are developed in concert with multi-stakeholder National Advisory Councils, including consumer representatives.\(^{b}\)

## Case Studies

### NICE in the UK

**Survey for ‘Sedation in children and young people’ (CG112)**—Guideline developers worked with a children’s hospital to survey children and young people about their views and experiences of sedation for diagnostic and therapeutic procedures. Hospital staff obtained feedback via hand-held touch screen computers which young children can use. The survey results were found to be very useful to the guideline development group’s work. See [chapter 7 of the full guideline](#) for further information.

**Focus groups for ‘Self-harm: short-term treatment and management’ (CG16)**—The development of this guideline was informed by group discussions with people who experience mental distress and self-harm, in addition to a review of published and grey literature on their views and experiences. Both sources reported health services to be of variable quality. One finding from the group discussions was that people who self-harmed were not routinely offered anaesthesia for stitching their wounds in the emergency department. There was nothing in the literature to indicate this was an issue. As a result the guideline included a recommendation that adequate anaesthesia and/or analgesia should be offered to people who have self-harmed throughout the process of suturing or other painful treatments. Other recommendations included staff training. See [chapter 5 of the full guideline](#) for further information.

**Survey using formal consensus methods for ‘Feverish illness in children: assessment and initial management in children younger than 5 years’ (CG47)**—The guideline development group found an absence of robust evidence on some important questions. In light of this and the divergent opinions among clinicians and parents, the group used formal consensus methods (a modified form of the Delphi technique) involving a larger external group of consultees on selected questions. Participants included parents as well as health care professionals. This process assisted the guideline group in making relevant recommendations where the research evidence was deficient. See [appendix A](#) of the full guideline for further information.

**Consultation day for ‘Diagnosis and management of type 1 diabetes in children, young people and adults’ (CG15)**—In light of a lack of evidence on teenagers’ perspectives of living with type 1 diabetes, the guideline developers worked with youth participation experts to organise a consultation day. The objective of the event was to elicit the views of young people with type 1 diabetes and their carers in relation to topics considered in the guideline. Specific points arising from the event were considered by the guideline group and informed the development of recommendations. For example, one finding was that young people with type 1 diabetes, particularly young women, were sensitive about body weight and wanted weighing to be carried out in a private room. This evidence formed the basis of a recommendation that weighing should be carried out in a private room—see pages 107-108 of the full guideline or appendix C for a report of the consultation day.

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\(^{b}\) [www.childbirthconnection.org/listeningtomothers/](#)
GuíaSalud in Spain

In-depth interviews and group discussions were conducted with patients for two guidelines on anxiety and insomnia. The findings, combined with information from a systematic review of the evidence, were used to inform the scope and key questions for each guideline. The information provided an important orientation on patient-focused outcomes.11

Key messages of this chapter

- Consultation processes should always involve patients and carers and/or organisations representing their interests, as well as health professional stakeholders
- Effective consultation with patients, members of the public and advocates adds value to the process of guideline development and can help support use of the guideline in practice, leading to more effective care
- Best practice requires transparent and inclusive consultation
- Consultation can be conducted at all key stages of the guideline development process, including the scoping, development, draft review, implementation, and updating stages
- A diversity of methods, individuals and organisations are likely to be needed to capture the full range of relevant patient and public issues and perspectives
- Consultation requires additional time and resources, which need to be factored in from the start; in standard consultation processes (such as feedback on draft scoping documents and draft guidelines), patient and public consultation can occur simultaneously with professional consultation.

References


