How to conduct public and targeted consultation

Authors: Jane Cowl, Melissa J Armstrong, Corinna Schaefer, Jessica Fielding

Corresponding author: Jane.Cowl@nice.org.uk

Key messages of this chapter

- Consultation processes should involve patients and the public, as well as stakeholders who are health and social care professionals.
- Effective consultation with patients and the public adds value to the process of guideline development and can help support guideline use in practice, leading to more effective care.
- Consultation strategies are particularly useful to gather the views of a lot of individuals regarding their needs, values, preferences and experiences
- 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 topic prioritisation and draft guidelines), patient and public consultation can occur simultaneously with professional consultation.

Top tips

- When planning the guideline process, identify the stages and situations that require patient consultation methods.
- Identify and involve patients and the public at multiple consultation stages if resources allow, including the early stage when determining topic scope and key questions.

- Have a clear aim for consultation and ensure that the method(s) chosen are appropriate for the purpose. When possible, choose a method of consultation that allows input from a range of patient subgroups, including ‘seldom heard’ or unrepresented groups.
- Consider involving patient or public advocates in co-designing a consultation model or novel methods of engagement.
- Show sensitivity and make adjustments 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, while maintaining control of the timetable to ensure the guideline is produced in a timely fashion.
- Consider the optimum time period for consultations, balancing the need to produce an up-to-date guideline while taking into account stakeholders’ expectations (for example, some patient organisations consult their constituencies before responding).
- Set up efficient administrative systems for alerting people to consultations and managing responses in a timely manner, and provide advance notice of consultation dates.
- Create plain language consultation materials to ensure meaningful engagement.
- When consulting on draft documents, provide guidance on what respondents could consider commenting on, for example, a list of questions which incorporate patient or public perspectives and equality considerations. The questions could be translated into a survey for ease of response and analysis.
- Ensure that the final decisions in responding to consultation findings or feedback are in accordance with the guideline development group’s ongoing decision-making processes.
- Document the results of any research with patients and the public, including how the guideline group used the results. Give feedback to participants on how their views, ratings or responses have been taken into account.
- Make comments and responses, and findings from other types of consultation activity, publicly available, or at least offer a summary available on request.

- Document the methods and process used for consultation activities and make this publicly available.
- Consider evaluating whether and how the consultation activity adds value to the guideline, including the particular contribution of patient or public participants or respondents.

Aims of this chapter

This chapter describes ways to conduct public and targeted consultation during the development of 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.

The chapter draws on examples from guideline bodies in several countries, which serve as models. These models are provided for illustrative purposes only and are not meant to be prescriptive because local circumstances, and the level of support and resources available will influence the type of approach adopted.

Terminology

Consultation and participation

Based on the typology of involvement described in Boivin et al. (2010), we use the term ‘consultation’ to refer to the process of collecting information from patient and public stakeholders to inform guideline development and implementation. Whereas ‘participation’ refers to patient and public stakeholders exchanging information with other stakeholders, for example, as members of a guideline development group. However, this distinction is not absolute; we include a few examples of patient engagement that combine or straddle consultation and participation.

Patients and the public

Patients and the public can refer to people with personal experience of a disease, condition or service (patients, consumers, users), their carers or family members, and people representing a collective group of patients or carers (representatives or advocates). It may also refer to members of society interested in health and social

care services, or whose life is affected directly or indirectly by a guideline (citizens, taxpayers, the public).

Reasons for consultation

Consultation strategies are particularly useful to gather the views of a lot of individuals regarding their needs, values, preferences and experiences. Consultation can also be targeted to seldom heard or unrepresented groups who may be less likely to join a guideline group with health and social care professionals. Consultation can identify topics that appear most important for patients and the public and is therefore useful in determining the need for new or updated guidelines. It can also inform the scope of a guideline, its research questions and health or care outcomes of importance to patients. Consultation using research techniques can add to the evidence base being considered to inform the process of guideline development. It can also help assess the public acceptability of draft guideline recommendations. However, a drawback of using consultation strategies only is that they do not recognise the unique expertise of patients and the public and their value as development partners.

Several major bodies recommend using public and targeted consultation to inform the development of guidelines. The National Health and Medical Research Council in Australia (2016) and the US's Institute of Medicine (2011; now the National Academy of Medicine) include public consultation in their standards for developing guidelines. The consumer and stakeholder topic in the GIN-McMaster Checklist for Guideline Development (2014) recommends consulting consumers and stakeholders who are not directly participating on the guideline panel at specific milestones during the guideline development process. This could start at the stage of priority setting and topics for the guideline.

Some guideline developers include consultation as part of a wider strategy or programme of patient and public involvement in guideline development. Documented examples of this approach include:

- the UK's National Institute for Health and Care Excellence (NICE) guidelines manual (PMG20; 2014), and the NICE flowchart and accessible text-only version on how to get involved (2018)

- the Scottish Intercollegiate Guidelines Network (SIGN) handbook for patient and carer representatives (2019) and the SIGN guideline developer's handbook (2019)
- the Nationalen Programms für VersorgungsLeitlinien (German National Disease Management Guidelines Programme) patient involvement handbook (2008) and methods report (2017), and
- the GuíaSalud (Spanish national guideline development programme) methods manual (2016).

Consultation and participation strategies have complementary roles in guidelines work. Using multiple strategies allows guideline developers to benefit from their different strengths and mitigate the limitations of a single strategy. Consultation can help mitigate the limitation associated with participation strategies when a small group of participants may not represent the broader population. For example, Armstrong et al. (2020) conducted a case study of question development for a single clinical guideline. They found that responses from a consultation survey were particularly helpful for reinforcing that a large group of patient stakeholders agreed with the 4 members of the question development group, who were patients, carers or advocates. This consultation benefit was seen to be particularly important given that these 4 members' views were contrary to professional opinions provided in the public commenting phase.

Table 1 outlines various stages of guidelines work when consultation with a broader group of patients or the public beyond the guideline development group may be helpful. Depending on available resources, guideline developers may need to prioritise key stages (such as early input and draft recommendations) to make consultation meaningful and achievable. Developers may also find it useful to consult Armstrong et al.'s 10 steps framework for continuous patient engagement in guideline development, which covers both consultation and participation approaches (2017).

Table 1 Options for patient or public consultation at different stages of guidelines work

Stage	Purpose of patient or public consultation	Examples of consultation methods
Nominating and prioritising the topic	Identify topics of importance to patients, carers and the community	• Solicit topic nominations from patient advocacy groups and the public • Survey patient groups
Scoping the topic and key research questions (this could extend to consultation on framing research questions, including selection of comparators and prioritisation of outcomes, and the research plan or protocol)	Help identify issues that are important to a broad range of patients and ensure these are taken into account from the beginning of the guideline project. This includes patients' experiences of care (including gaps in delivery), considerations for specific subpopulations, patient preferences and patient-important outcomes	• Solicit feedback on draft scope and questions through public comment or targeted consultation with patient advocacy groups and other stakeholders (workshop and online) • Survey patient groups, for example, using criteria-based rating processes • Conduct focus groups on identified topics to help frame the questions
Identifying evidence on patients' views and experiences	Identify sources of information on patients' views and experiences with a view to supplementing important gaps in the published evidence	• Ask stakeholders to suggest sources of information about patients' views and experiences that are not formally published, such as surveys by patient groups
Developing systematic review and forming conclusions	Suggest alternative interpretations of evidence from a patient, carer or community perspective	• Post draft evidence review for public comment and targeted consultation with stakeholders. To support meaningful public responses, provide draft review in plain language, with questions to guide responses
Developing recommendations	Help translate evidence-based conclusions into meaningful, clear and respectful recommendations that foster patient or family and professional partnerships Provide input on evidence gaps Describe variability in patient preferences	• Conduct focus groups and interviews • Survey patient groups • Post draft recommendations in plain language for public or targeted comment from patient groups and other stakeholders
Developing guideline-based performance measures or quality indicators	Rate recommendations from a patient perspective to ensure the professional expert view doesn't dominate the rating	Survey patient groups using systematic, criteria-based rating

Stage	Purpose of patient or public consultation	Examples of consultation methods
Developing guideline-based patient information or patient versions and patient decision aids	Provide input from a broader range of patients beyond those involved in developing the product	• Invite feedback on the draft product from patients, carers and advocacy groups • Use research techniques to 'user test' the draft product
Disseminating and implementing the guideline	Gain support and endorsement for the guideline Facilitate engagement of other patients in dissemination Improve legitimacy and trustworthiness of the guideline process such that recommendations are more likely to be implemented	• Consult patients, carers and advocacy groups on dissemination and implementation barriers and facilitators (Also engage them in dissemination strategies using a more collaborative approach)
Reviewing the need to update a guideline	Identify when changes in public or stakeholder views might require an update to the guideline (in addition to identifying changes in the formal evidence base)	• Solicit patients' views on when or whether guidelines need updating. Or use a systematic, criteria-based rating or survey
Evaluating methods and impact of patient public involvement	Identify if engagement was meaningful and suggest options for improvement	• Conduct a survey with engaged patients and patient groups. (Evaluation could also take a more collaborative approach, for example, working with patient groups to design a survey and discuss results)

In summary, there are many good reasons for public and targeted consultation during the development of 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. This complements the contribution of patient and public members on a guideline development group.

- Supplementing evidence when there are gaps or obtaining a wider source of patient or public experiences and views than can be provided by patient and public members on a guideline development group.
- Improving the wording and presentation of the guideline and related products (for example, ensuring that the wording is respectful, and the recommendations foster partnership and shared decision making between patient and professional).
- 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 or public support for the final guideline and receptivity to its uptake and dissemination.
- In general, enhancing the legitimacy of the development process and the end product from a public perspective.

Ways of conducting consultation

Open or targeted consultation

Consultations may be open to the public, targeted to relevant patient or public groups and other stakeholders, or both. Open and targeted consultation methods each have potential advantages and disadvantages, as outlined in table 2. Awareness of these can help developers to select the most suitable method for a specific guideline.

Table 2 Open or targeted consultation – selecting a suitable approach

Type of consultation	Description	Potential advantages	Potential disadvantages
Open	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	This option has the merit of transparency and, in theory, opens up the process to all interested parties and viewpoints	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
Targeted	By invitation to all relevant stakeholder organisations, or to groups and individuals with relevant interest	Targeting invitations may be more effective in generating responses When patient or 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 Invited organisations can be more willing to partner in other stages of the guideline, such as dissemination (sometimes organisations who have not had any involvement are reluctant to help with dissemination strategies) The volume of feedback should be manageable	Important viewpoints may be overlooked or avoided if targeted consultation is not combined with an open invitation to contribute Invited individuals or organisations may not be interested or able to respond in a timely manner
Open and targeted	Public posting of draft documents and questions combined with targeted invitations to all relevant stakeholder organisations or groups and individuals with relevant interest	Combines openness and transparency with reaching all relevant stakeholder organisations or targeted groups or individuals	Guideline developers may be overwhelmed with the volume of feedback

Different approaches to consultation

Consultations may be conducted remotely (online for example), in face-to-face meetings or workshops, or a combination of these. Consultation may take the form of peer review with patient and public expert reviewers. It can also include research with patients and carers (using methods such as surveys, focus groups and interviews). Research participants are typically 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 or public consultation can occur simultaneously with professional consultation. As Cluzeau et al. (2012) concluded, for stakeholder engagement to be successful, it needs to be inclusive, equitable and adequately resourced. The box contains a summary of the main consultation approaches.

Main consultation approaches:

- inviting public comment including patient organisations and other stakeholders
- consulting patient and public experts as part of a peer review process
- using online engagement methods, such as modified-Delphi approaches, with patients, carers and others
- using research techniques with patients, carers and others, such as surveys, focus groups, interviews.

These different approaches can be combined, for example, inviting public comment or feedback from patient organisations and others through a survey.

Public comment

Background

In public comment, guideline developers post guideline materials in a public forum for feedback. This typically involves posting materials online but can include an open forum for discussion. Materials shared for public comment include guideline scopes and research protocols (to obtain feedback before starting the systematic review) or draft guideline documents (to obtain feedback before final publication). Public comment can include feedback from individual professional and patient experts, but is generally considered distinct from external peer review, which is solicited.

In the US, the Institute of Medicine (now, the National Academy of Medicine) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines (CPGs) includes public comment in its external review standard 7.4:

'A draft of the CPG at the external review stage or immediately following it (i.e., prior to the final draft) should be made available to the general public for comment. Reasonable notice of impending publication should be provided to interested public stakeholders'. (Chapter 5; 2011).

Despite the fact that public comment is recommended by the Institute of Medicine, a review of guideline developer methodology manuals by Armstrong et al. (2017) found that only 6 of 101 US-based guideline developers posted protocols for guideline development at least some of the time. Only 1 organisation, the United States Preventive Services Task Force, posted a draft research plan using a public-friendly template (for example, using plain language, avoiding excessive background or technical information). Only a quarter of US guideline developers posted draft guidelines for public comment. One developer used a public hearing for public comment, while the remainder used online mechanisms. Most developers using online feedback posted materials for comment for 1 month (range 14 days to 60 days). There was no evidence that any guideline developer posted a patient-friendly version of the draft guideline for comment.

By way of comparison, Ollenschläger et al.'s (2018) assessment of all guidelines in the German national guideline registry in 2018/19 found that 58% had involved

patients on the guideline group. However, only 14% (39/270) had provided plain language versions of the draft guideline for consultation.

Practical approaches for using public comment

As with other consultation approaches, guideline developers need to be intentional about using public comment approaches. Desired feedback will vary at different stages, such as between draft scope, protocols and draft guidelines, and may differ between developer types. For example, guideline developers representing national health systems or governing bodies may desire different feedback than professional organisations. Guideline developers must also consider available resources when considering public comment. Potential costs associated with public comment include developing public-friendly materials for posting, hosting a public forum or website, publicising the comment period, and allowing time to respond to public comments (including decision making, documenting comments and responses).

After choosing to use public comment as a consultation strategy, developers decide the stage(s) at which to use public comment (for example, scoping the topic, research protocol, draft guideline). To make optimal use of public comment, developers need to create materials that are likely to result in meaningful engagement and avoid tokenistic public comment. Many guidelines are aimed at professional audiences and can be hundreds of pages long. Difficulty in understanding medical terminology is one of the most common barriers to patient and public involvement in guidelines. (Jarrett et al. 2004; Légaré et al. 2011; Qaseem et al. 2012; van de Bovenkamp et al. 2009; van Wersch et al. 2001.) Thus, developers desiring meaningful feedback need to prepare patient- and public-friendly guideline documents for draft review. For developers working with patients to create patient guideline versions, this could also include preparing and posting a draft for public comment (see the chapter on how to develop information from guidelines for patients and the public for further information).

In conjunction with creating the materials for posting, developers must determine the feedback desired from respondents. For example, the U.S. Preventive Services Task Force (2017) posts 3 types of documents for public comment, as shown in table 3.

Table 3 Public comment feedback requested by U.S. Preventive Services Task Force

Type of document	Response requested
Draft research plans	Respondents to indicate level of agreement and provide free-form comments on the: • analytic framework • proposed questions • proposed research approach (presented in tabular form)
Draft evidence review	Asks if the respondent: • thinks the report includes all of the relevant studies • agrees with the interpretation of the evidence • has suggestions for making the findings clearer
Recommendation statements	Asks the respondent: • how to make the statements clearer • if expected information is missing • whether the conclusions reflect the evidence • what associated tools would be useful • other experiences and comments

Many online public comment approaches are similar to those of the U.S. Preventive Services Task Force in that they use a web-based survey to ask the respondent to indicate his or her level of agreement (with questions, evidence synthesis, recommendations) and then allow open comments.

For meaningful feedback, developers must create a plan for notifying key public members regarding upcoming public comment periods. Potential strategies include notifying relevant professional and patient organisations regarding the public comment period and asking them to invite their members to participate. Government organisations desiring feedback may also provide advance notice to broader populations. For example, the external review standard 7.4 of the US Institute of Medicine Committee on Standards for Developing Trustworthy Clinical Practice Guidelines recommends that developers provide reasonable notice of impending publication prior to posting (Chapter 5 2011). There are no best practices for posting length, but 1 month is a typical time frame (Armstrong et al. 2017). As with other consultation strategies, guideline developers should be prepared to respond to

feedback provided through public comment (see responding to consultation comments).

Consulting patient and public stakeholder organisations

The UK's NICE uses an open consultation process, with draft consultation documents posted on its website at key stages in the guideline development process. This is similar to the public comment approach; however, to manage the volume of comments in a transparent way, NICE encourages individuals to respond through 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. Responses from individuals are acknowledged and considered, but 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 and the key questions.
- Circulating NICE website advertisements to their members and networks for recruitment to the guideline development group (health and social care professional and patient or 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 patient surveys and other real-world evidence 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 and invites them to register their interest for new guideline topics. Staff in NICE's Public Involvement Programme help identify relevant organisations and offer information and advice to support their involvement.

Identifying and reaching patient and public groups

Not all guideline developers have the structure and resources needed for 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 patient advocacy groups and charities may provide a useful avenue for reaching relevant patient or public stakeholders. For example, SIGN's Patient and Public Involvement Network members are notified of involvement opportunities when a new guideline is being developed.

Other sources for identifying relevant patient or public stakeholders include health professionals and their organisations, patient organisations that are already known to guideline developers, the internet and social media. 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 or public groups, because 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 US and Foro Español de Pacientes in Spain
- International groups, such as G-I-N Public (Guideline International Network's Public Working Group), CCNet (the Cochrane Consumer Network), and the Health Technology Assessment international's (HTAi) subgroup on Patient and Citizen Involvement in Health Technology Assessment.

Social media can be an excellent way to promote a consultation, by posting details about it and tagging in patient and public advocacy groups from the guideline's topic area. If the consultation is open to the public, this can also be an effective way of reaching a wider audience of people beyond the usual patients the guideline developers may work with. Increase the reach by using hashtags that are commonly used by patients or public in the topic field and post details of the consultation with

relevant advocacy groups on social media or online patient forums. NICE has found social media helpful in building relationships with key patient and public stakeholders and supporting their involvement with NICE guidelines. NICE also uses social media to promote published guidelines, working with key stakeholders and communities to ensure the main messages reach the public.

Examples of 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 include 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 2 guidelines on anxiety and insomnia (Díaz del Campo et al. 2011).

Four months before the first meeting of a new guideline development group, SIGN invites patient and carer organisations to highlight 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 helpline data, surveys). SIGN then summarises the information received and presents it to the guideline group at its first meeting. When published evidence is scarce and there is inadequate feedback from patient organisations, SIGN may seek patient and public views through 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. (SIGN 100 2019; SIGN 50 2019.)

NICE involves patient organisations and other stakeholders in the scoping process in 2 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. It sets out what the guideline will and will not cover, defines the aspects of care that will be addressed, and outlines the key research questions. A draft scope is then produced, and stakeholders are invited to comment on it during a 4-week online consultation. This online process is designed to ensure openness and transparency, because all written comments receive a formal response from guideline developers, and both comments and responses are published on the NICE website. NICE encourages patient organisations to comment on the draft scope and provides prompting questions in its guide for stakeholders (NICE 2018). The purpose of the prompts is to seek their views on key issues (such as whether the identified outcome measures are in line with what matters to people with the condition or people using services), and to ask what should be included or excluded.

Some developers have used surveys to inform the research plan or protocol, as part of a strategy to incorporate evidence on patients' values and preferences in guideline development. For example, the German National Disease Management Guidelines Programme found a benefit in surveying patients with anal cancer to obtain their feedback on the relative importance of a range of health outcomes (Werner et al. 2020. In the survey, they asked patients (n=37) and members of the guideline group (n=25) to rate the relative importance of outcomes in different clinical situations using the GRADE scale. For example, they found that agreement between the expert and patient ratings was fair for stage I-II anal cancer, but low for stage III anal cancer. In another example, whereas patients rated some adverse effects (such as early morbidity, proctitis or urge, radiodermatitis) as critical, experts rated these as important but not critical. The survey results informed the development of the guideline and helped with the trade-off between desired and undesired effects of interventions when making recommendations.

The draft guideline

Consulting patients and the public on draft recommendations helps ensure the range of their values and preferences has been integrated into the recommendations. As noted by Kelson et al. (2012), such feedback can include desired outcomes, the ways in which people weigh up risks and benefits, preferred treatment and

management options, and whether the draft recommendations have real-world applicability.

Patient or public stakeholders can make an important contribution at this stage. For example, Chambers and Cowl (2018) analysed documentary evidence of comments from consumer organisations on the draft recommendations from 7 NICE maternity guidelines. Their aim was to assess the levels of engagement, along with the impact of that engagement. For each of the 7 guidelines, comments from consumer organisations resulted in 5 or more changes to the wording or meaning of the recommendations. For a more detailed look at the impact of consumer organisation comments see the Slideshare presentation on NICE maternity services evaluation.

SIGN combines open consultation on the draft guideline with a later period of peer review. During the open consultation, SIGN may hold a national open meeting with professionals, patients and the public to discuss the draft recommendations. Draft guidelines are presented on the SIGN website and through social media. Anyone can respond to the online consultation and particular efforts are made to ensure all equality groups with a potential interest in the topic are made aware of the opportunity to comment.

NICE follows a similar online consultation process, inviting stakeholder organisations to comment on the draft guideline during a set period, using email, social media and other promotional channels to encourage responses. Consultation usually lasts for 6 weeks, during which stakeholders can review the draft recommendations and supporting information.

In NICE's experience, some patient or public stakeholders find it helpful to have questions or a checklist to guide their response. NICE encourages patient organisations and other stakeholders to consider issues such as:

- How well do the recommendations:
  - cover the issues in the guideline scope that patients, their families, and carers consider important?
  - reflect what the evidence says about treatment and care
  - take account of the choices and preferences of people affected by the guideline, and the information and support they need

  - consider the needs of different groups (for example, children and young people, and people from black, Asian and minority ethnic groups)
  - use wording that is clear, easy to follow and respectful.
- Do the recommendations include anything that people affected by the guideline might find unacceptable?
- Is there any other evidence that should be included?
- Do the research recommendations cover key gaps in the evidence about important areas of patient and public experience? (NICE 2018)

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. This inclusive approach to external review is recommended by major standard-setting agencies, such as the Institute of Medicine (2011; now the National Academy of Medicine). So, for example, all SIGN guidelines are reviewed in draft form by independent experts including at least 2 patient or public reviewers (SIGN 50 2019). At NICE, external review is mainly conducted through consultation with stakeholder organisations (2014). However, guideline developers may also consider arranging additional expert review of part or all of a 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. Expert reviewers are required to complete a declaration of interests form (NICE 2014; SIGN 50 2019).

Consulting patients and the public using online engagement methods

As discussed earlier in this chapter, public commenting is typically conducted online. Some guideline developers have used other online methods such as Delphi processes, voting tools, Wikis and discussion forums. Discussions could also be facilitated through social media channels, like Twitter, Facebook or an online patient forum. This kind of approach may be particularly useful for topics in which consultation with patient organisations might be limited and so a range of patient or public views is needed. It also allows the important flashpoints for patients, that

appear in the guideline, to be framed in language that is easily understandable and relatable for members of the public.

Online methods can be particularly useful for engaging a lot of people who are geographically dispersed. This includes those who have difficulty attending face-to-face meetings because of illness or disability, and people who prefer a more anonymous method of contributing. Grant et al. (2018) examined the potential advantages and disadvantages of online engagement as part of a project to create a protocol that patients with Duchenne muscular dystrophy (DMD) and their carers could use to rate the perceived patient-centredness of guideline recommendations. From a rapid review of the literature on patient involvement in guideline development, the authors found that online methods can facilitate greater openness and honesty by patients, as well as having the potential to reflect the diversity of patient views. This can increase the utility of guideline products. The challenges of using online methods may include the extra time, skill and resources needed for patient engagement, and also the potential difficulty of involving specific patient populations. The authors concluded that online methods are most likely to be useful when guideline developers wish to engage a large, diverse and geographically dispersed group of patients, and have the required resources. The authors also suggest that online methods are particularly suitable when patients seek anonymity in order to share their views, and they are able to use online technology.

Khodyakov et al. (2020) suggest that an online modified-Delphi approach combining rounds of rating, anonymous feedback on group results, and a moderated online discussion forum is a promising way to involve large and diverse groups of patients and carers. They offer guidance on using such online approaches to facilitate engagement with patients, carers and other stakeholders in the guideline development process. The authors outline 11 practical considerations covering the preparation, implementation, evaluation and dissemination stages. Their first step is to co-develop an engagement approach with relevant patient representatives, such as a key patient advocacy organisation. The complete set of considerations proposed by Khodyakov et al. are reproduced below:

- co-develop an engagement approach with relevant patient representatives
- mirror methods used for expert and stakeholder engagement

- pilot-test the engagement approach
- recruit patients with diverse perspectives
- assemble a panel of adequate size and composition
- build participant research and engagement capacity
- build 2-way interaction
- ensure continuous engagement and retention of patients
- conduct scientifically rigorous data analysis
- evaluate engagement activities
- disseminate results.

Consulting individual patients and the public using research techniques

Guideline developers may undertake consultation using research techniques with individual patients and others, either to inform the scoping, review questions or development stages, or to test the relevance and acceptability of draft recommendations. This work typically uses methods such as focus group discussions, interviews and surveys. Some guideline developers use surveys as part of, or alongside, a routine public comment consultation process. Other developers use research techniques with patients and carers to supplement gaps in one or more of the following areas:

- important gaps in the evidence base on patient views, values, preferences and experiences
- insufficient involvement or 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, a broader range of experience is required or the guideline covers a population not directly represented on the group, such as children and young people)
- gaps in 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.

Before considering such work, it is important to check whether the information that the guideline developers are looking for might already be available. There may be relevant information on the views and experiences of patients and the public in the grey literature or from real-world evidence, including surveys conducted by advocacy organisations. For example, in the US 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 have been developed in concert with multi-stakeholder advisory groups, including consumer representatives.

Consulting patients and the public using research techniques is an exceptional option requiring additional human and financial resources. Guideline developers need to consider the recruitment strategy and choice of methods carefully, including the methods for analysing data to ensure the data generated produces robust evidence to feed into work on the guideline. Group-based methods and interviews are best for exploring how people feel and exploring topics in detail. Surveys or questionnaires are useful for quantifying the extent to which people hold beliefs, values and attitudes, and how much they vary between groups of people, for example.

Guideline developers need to ensure that those conducting this type of consultation have the relevant knowledge and skills, including expertise in research methodology and ideally expertise in conducting research with the relevant population. NICE commissions such work using a tender process. This involves interviewing prospective contractors to ensure they have appropriate expertise, policies and procedures for ensuring the safety and welfare of participants, as well as following best practice and the country's legal requirements for working with the affected population. Consent, incentives, and other ethical issues should be considered, including whether formal ethical approval is required from the relevant research governance body. Ethical approval can take time, in some cases many months, and this should be considered in the timelines. Researchers and guideline developers

should also consider how participants will receive feedback about their impact during and on completion of the work, including how they will be acknowledged.

Techniques for eliciting people's views need to be tailored to the age, cognitive ability, and culture of participants. Materials and activities should be adjusted to suit participants and take into account any adaptations needed for people with physical or sensory impairments. In the UK, the National Children's Bureau has produced guidance on how to conduct research with children and young people, as well as advice on involving them more actively in the research process (Shaw et al. 2011). Also in the UK, the Alzheimer's Society's toolkit provides information on how to recruit adults with dementia and gain their consent for research.

Case studies of consultation

Netherlands

Pittens et al. (2013) reported on a consultation model for a guideline on the resumption of (work) activities after gynaecological surgery, for which there was no patient organisation. They consulted gynaecological patients and professionals separately, in 2 parallel trajectories. They found that to ensure the motivated involvement of an unorganised patient population, like gynaecological patients, a skilled facilitator was essential. The researchers convened 3 focus groups with patients at the beginning of the project to identify their problems, needs and preferences for peri-operative care and counselling in the resumption of (work) activities. They also sought participants' ideas for the development of a web-based patient version of the guideline. Participants received regular feedback during the project and were involved in the testing of the patient version. The researchers used an evaluation framework to assess the impact of this involvement and concluded that patients' input helped ensure the guideline was applicable in daily practice. The authors suggested that increased patient involvement could be achieved by integration of the 2 parallel trajectories with additional participatory activities, such as a dialogue meeting. They also suggested that more patient involvement in the development of the recommendations

of the clinical guideline may result in increased relevance and quality of the recommendations.

NICE in the UK

Focus groups for the NICE guideline on end of life care for infants, children and young people with life-limiting conditions: planning and management (NG61; 2016): Because of limited evidence and in the absence of representative views from the guideline committee, young people with life-limiting and life-threatening conditions were asked for their views and opinions on selected review questions. This included their preferences for place of care, information and communication provision, personalised care planning, and psychological care (Report, appendix L, NG61).

Focus groups for the NICE guideline on self-harm in over 8s: short-term management and prevention of recurrence (CG16; 2004): The development of this guideline was informed by focus 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 analgesia should be offered throughout the process of suturing or other painful treatments in people who have self-harmed. Other recommendations included staff training. See chapter 5 of the full guideline for further information.

Survey for the NICE guideline on sedation in under 19s (CG112; 2010): 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

through hand-held touch screen computers, which young children can use. The survey results were found to be very useful for the guideline development group's work. (See chapter 7 of the full guideline for further information.)

Spain

In-depth interviews and group discussions were conducted with patients for 2 GuíaSalud guidelines on anxiety and insomnia (Díaz del Campo et al. 2011). 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.

Serrano-Aguilar et al. (2015) report on a consultation with Spanish patients for a guideline on systematic lupus erythematosus. The project's aim was to incorporate patients' perspectives in the design of this guideline. To this end, they conducted a systematic review of literature and consulted patients using a Delphi-based approach. Relevant topics from both sources were merged and discussed by the guideline development group (which included a patient representative) to set the key questions for the guideline to address. The authors recommended such a multi-component strategy to address the gap between the available evidence and current patient needs and preferences.

Responding to consultation comments

The guideline development group's chair or moderator has a key role in ensuring the group takes into account patient and carer perspectives from consultation feedback and other sources. The patient and public members can also help the group consider the inclusion of any material or amendment arising from patient or 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 or 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 US's Institute of Medicine (2011; now the National Academy of Medicine) 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 2016) approval process, guideline developers must provide details of consultation responses and explain why and how the guideline was altered. The NHMRC also advocates making a summary of submissions and developers' responses publicly available (2018). 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 (2014). Other major guideline developers, such as GuíaSalud in Spain and the German Agency for Quality in Medicine (AEZQ), follow a similar open and transparent process for responding to feedback, including making the consultation comments and responses publicly available.

On publication of a guideline, thank all those who responded to the consultation. Consider using social media to publicly thank patient and public advocacy groups who took part in the consultation because this helps them to showcase their involvement in important guidelines work, as well as building relationships with key stakeholders. Doing this can also increase awareness of the guideline among patients and the public who follow the group on social media.

Acknowledgements

The authors would like to thank the following for their contributions to this chapter:

Peer reviewers: Karen Graham, Kenneth McLean

Contributors to the 2012 version of this chapter: Jane Cowl, Helen Tyrrell, Carol Sakala, Javier Gracia, Nancy Huang

References

Armstrong MJ, Bloom JA (2017) Patient involvement in guidelines is poor five years after Institute of Medicine standards: review of guideline methodologies. Research Involvement and Engagement 3:19

Armstrong MJ, Gronseth GS, Gagliardi AR et al. (2020) Participation and consultation engagement strategies have complementary roles: A case study of patient and public involvement in clinical practice guideline development. Health Expectations 23(2): 423–32

Armstrong MJ, Rueda J-D, Gronseth G et al. (2017) Framework for enhancing clinical practice guidelines through continuous patient engagement. Health Expectations 20(1):3–10

Boivin A, Currie K, Fervers B et al. on behalf of G-I-N PUBLIC (2010) Patient and public involvement in clinical guidelines: international experiences and future perspectives. BMJ Quality & Safety in Health Care 19(5):1–4

Chambers E, Cowl J (2018) Consumer organisation engagement in maternity services guidelines. Poster presented at the Guidelines International Network conference 12-14 September 2018 in Manchester, UK.

Cluzeau F, Wedzicha JA, Kelson M et al. (2012) Stakeholder involvement: How to do it right. Article 9 in Integrating and coordinating efforts in COPD guideline development. An official ATS/ERS workshop report. Proceedings of the American Thoracic Society 9(5): 269–73

Díaz del Campo P, Gracia J, Blasco JA et al. (2011) A strategy for patient involvement in clinical practice guidelines: methodological approaches. BMJ Quality & Safety 20(9):779–84

Grant S, Hazlewood GS, Peay HL et al. (2018) Practical considerations for using online methods to engage patients in guideline development. The Patient – Patient-Centered Outcomes Research 11(2):155–66

Grupo de trabajo sobre GPC (2016) Elaboración de Guías de Práctica Clínica en el Sistema Nacional de Salud. Manual Metodológico. Madrid: Plan Nacional para el SNS del MSC. Instituto Aragonés de Ciencias de la Salud-I+CS. Guías de Práctica Clínica en el SNS: I+CS Nº 2006/0I

Guidelines International Network and McMaster University (2014) The GIN-McMaster Guideline Development Checklist

Institute of Medicine (US) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines (2011) Clinical practice guidelines we can trust: Standards for developing trustworthy clinical practice guidelines. Washington (DC): National Academies Press (US)

Institute of Medicine (US) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines Chapter 5 Current best practices and standards for development of trustworthy CPGs: Part II, traversing the process. In (2011) Clinical practice guidelines we can trust: Standards for developing trustworthy clinical practice guidelines. Washington (DC): National Academies Press (US)

Jarrett L, Patient Involvement Unit (2004) A report on a study to evaluate patient/carer membership of the first NICE Guideline Development Groups

Kelson M, Akl EA, Bastian H et al. (2012) Integrating values and consumer involvement in guidelines with the patient at the center. Article 8 in Integrating and coordinating efforts in COPD guideline development. An official ATS/ERS workshop report. Proceedings of the American Thoracic Society 9(5): 262–8

Khodyakov D, Grant S, Denger B et al. (2020) Practical considerations in using online modified-Delphi approaches to engage patients and other stakeholders in clinical practice guideline development. The Patient – Patient-Centered Outcomes Research 13(1):11–21

Légaré F, Boivin A, van der Weijden et al. (2011) Patient and public involvement in clinical practice guidelines: a knowledge synthesis of existing programs. Medical Decision Making, 31(6):E45–E74

National Health and Medical Research Council (2016) 2016 NHMRC Standards for Guidelines in Guidelines for guidelines handbook.

National Health and Medical Research Council (2018) Public consultation in Guidelines for guidelines handbook.

National Institute for Health and Care Excellence (2014) Developing NICE guidelines: the manual. Introduction. Process and methods 20. Updated 2018

National Institute for Health and Care Excellence (2018) Developing NICE guidelines: how to get involved: flowchart and Developing NICE guidelines: how to get involved: Fully accessible text-only version. Process and methods 20

Nationalen Programms für VersorgungsLeitlinien (German National Disease Management Guidelines Programme) (2017) Methodenreport. 1 Ziele und grundlagen des NVL-Programms

Nationalen Programms für VersorgungsLeitlinien (German National Disease Management Guidelines Programme) (2008) Handbuch patientenbeteiligung (Patient involvement handbook)

Ollenschläger G, Wirth T, Schwarz S et al. (2018) Unzureichende patientenbeteiligung an der leitlinienentwicklung in Deutschland – eine analyse der von der AWMF verbreiteten ärztlichen empfehlungen. Zeitschrift Für Evidenz, Fortbildung Und Qualität Im Gesundhwesen135–136: 50–5

Pittens CACM, Vonk Noordegraaf A, van Veen SC et al. (2015) The involvement of gynaecological patients in the development of a clinical guideline for resumption of (work) activities in the Netherlands. Health Expectations 18(5): 1397–1412

Qaseem A, Forland F, Macbeth F et al. (2012) Guidelines International Network: toward international standards for clinical practice guidelines. Annals of Internal Medicine 156(7):525–31

Scottish Intercollegiate Guidelines Network (2019) SIGN 50: A guideline developer's handbook.

Scottish Intercollegiate Guidelines Network (2019) SIGN 100: A handbook for patient and carer representatives.

Serrano-Aguilar P, Mdel T-M, Pérez de la Rosa A et al. (2015) Patient participation in a clinical guideline development for systemic lupus erythematosus. Patient Education and Counselling 98(9): 1156–63

Shaw C, Brady L-M. Davey C (2011) Guidelines for research with children and young people. National Children's Bureau Research Centre: London.

U.S. Preventive Services Task Force (2017) Public comments & nominations. [Accessed 4 January 2021]

Van de Bovenkamp HM, Trappenburg MJ (2009) Reconsidering patient participation in guideline development. Health Care Analysis 17(3):198–216

Van Wersch A, Eccles M (2001) Involvement of consumers in the development of evidence based clinical guidelines: practical experiences from the North of England evidence based guideline development programme. Quality in Health Care, 10(1):10–16

Werner RN, Gaskins M, Dressler C et al. (2020) Measuring importance of outcomes to patients: a cross-sectional survey for the German anal cancer guideline. Journal of Clinical Epidemiology 129: 40–50

Resources

Planning and managing consultations

The VOICE tool (Visioning outcomes in community engagement) provides planning and recording software that assists individuals, organisations and partnerships to design and deliver effective community engagement.

Online research-based patient and public views and experiences

DIPEx International is an association of expert researchers conducting qualitative research into people's personal experiences of health and illness. Member countries disseminate the results to the public and professionals in the form of multimedia resources on their websites. For example, healthtalk.org in the UK

Involving patients and public in research

Involve, part of the UK's National Institute for Health Research, provides advice and guidance on public involvement in research (research carried out with or by members of the public). Involve resources contains briefing notes for researchers on how to involve the public in research.

Research with specific patient populations

Children and young people – Guidance from the National Children's Bureau, a UK charity

People with Alzheimer's disease – Toolkit from the Alzheimer's Society, a UK charity.