A digital version of this toolkit can be found at https://g-i-n.net/toolkit/

Guidelines International Network

Contents

GIN PUBLIC toolkit introduction

How to choose an effective involvement strategy

*Author: Antoine Boivin**

**Corresponding author: Antoine.Boivin@umontreal.ca*

One question we often get asked at GIN PUBLIC is 'how can we incorporate the patient's perspective and what is the best method to involve patients and the public in our guidelines?' to which we invariably respond, 'what do you really hope to achieve?' There are in fact many legitimate reasons why guideline developers want to involve patients and the public, and these reasons can be different from those that would motivate patients and the public to engage in this process. The *best* method is the one that can be used most effectively to achieve those goals, so there is definitely not a one-size-fits-all approach. Furthermore, each method requires time and resources to be implemented successfully, and it is therefore critical to have a clear focus right from the start. Last but not least, although patient and public involvement is widely perceived as a positive component of guideline development, different stakeholders often hold competing and potentially incompatible views over what they consider successful involvement, which may create tensions if these differences are not negotiated early on.[1]

The goal of this chapter is to get you started in developing your involvement plan by:

- Introducing the main involvement strategies discussed in the toolkit
- Helping you identify the strategy that best fits your needs

Three involvement strategies: consultation, participation and communication

Guideline organisations use a number of different methods to involve patients and the public.[2,3] It is helpful to distinguish three general involvement strategies, based on the flow of information between your organisation and the public:[4]

- **Consultation** strategies involve the collection of information *from* patients and the public. This can include methods such as surveys, focus groups, individual interviews, online consultation, the use of primary research on patients' needs and expectations, or the use of a systematic review of studies on patients' and the public's perspective.
- **Participation** involves the *exchange* of information between guideline developers and the public. This can be done through participation of patient and public representatives on guideline development groups and other methods.[5]
- **Communication** strategies involve the communication of information *to* patients and the public to support their individual health care decisions and choices. This can include the production of plain language versions of guidelines or the development of patient decision aids or education material.

Choosing the right strategy

Each involvement strategy has its specific strengths and weaknesses and may be more appropriate to achieve certain goals:

- **Consultation** strategies are especially useful to gather the views of a large number of individuals regarding their needs, experience, and expectations. Consultation methods are often used in research and add to the evidence base being considered to inform the process of guideline development. Consultation can help assess the public acceptability of draft guideline recommendations and identify topics that appear most important for the public, and are therefore useful in early stages of the guideline development process. A drawback of using consultation strategies only is that it tends to seek out individual viewpoints, presenting an average of 'the need' of patients.

- **Participation** methods are useful to foster deliberation and mutual learning between participants with different expertise.[6] Participation as a member of the guideline development group has the advantage of enabling patients or public members to be present and actively participate in deliberation, which can foster mutual influence between patients and professionals, fostering the development of a collective perspective on guideline development. As such, participation methods are usually put in place to agree on *common group decisions* over guideline content and can be useful to support compromise or consensus between people with different perspectives. When used alone, a drawback of the participation method is that it often allows the involvement of a small number of people and may miss the perspective of vulnerable groups who may feel threatened to participate in meetings with health professionals. As discussed in the 'recruitment and support' chapter of the toolkit a critical issue for successful participation is to support participants' legitimacy as patient and public members, and their ability to contribute credible knowledge and experience relevant to guideline development.

- **Communication** strategies are most useful in the dissemination and implementation stage of guideline production. For strong 'black and white' guideline recommendations—where a single best course of action is clear—communication methods can increase the public's knowledge and awareness of recommended interventions in order to influence patients' health behaviours and increase uptake. In cases of 'grey zone' decisions—when more than one alternative is acceptable—patient decision aids can help expand the range of options available to patients and assist them in weighing the pros and cons of different choices.[7, 8]

Finally, it is common to combine different involvement strategies to build more comprehensive patient and public involvement interventions. For example, combining direct patient participation can be complemented with wider patient consultation through focus groups or surveys, which can allow patients to broaden their perspective and experience base, and increase their credibility and legitimacy as guideline development group members.[9] Furthermore, combining communication methods (e.g. development of patient information material) with participation methods (e.g. participation of patient representatives in the development of this information material) can help ensure the relevance and accuracy of the information produced.[10] Box 1 provides an example of a structured patient involvement intervention combining consultation, participation and communication strategies used for health care improvement.

Box 1: Example of a mixed patient involvement intervention in guideline implementation

The effect of a mixed patient involvement intervention combining consultation, participation, and communication components has been tested in a cluster randomised trial and was found to be effective in increasing agreement between patients' and professionals' priorities for clinical care improvement, based on a list of measurable quality indicators derived from clinical practice guidelines.

Recruitment: Chronic disease patients were recruited through local patient organisations and professionals, using structured 'job descriptions'. A list of potential candidates was reviewed by the team, and a group of 15 patients were selected based on pre-defined criteria to ensure a balanced representation in terms of age, gender, disease status, and socioeconomic status.

Preparation: These patients were invited to a one-day preparation meeting to discuss their personal experiences in relation with chronic disease services, which helped broaden their perspective and understanding of patients from their community.

Consultation: At the end of this preparation meeting, all patients voted on their priorities for clinical care improvement for their community.

Participation: Four patients who participated in the preparation meeting agreed to participate in a 2-day deliberation meeting together with health professionals from their community. This meeting allowed patients and professionals to deliberate among themselves and agree on common priorities for improvement. All participants also received feedback about the consultation done with the broader group of 15 patients.

Communication: The quality indicators selected as priorities for health care improvement were implemented locally and its results were communicated to all patients who participated in the prioritisation, as well as to lay board members of the local health authority.

Although this patient involvement strategy was used locally for guideline implementation, its format could easily be applied to guideline development at a larger scale. Details of the intervention have been published elsewhere.[11]

In summary

Guideline organisations have experimented with a vast number of different methods to involve patients and the public. As summarised in Table 1, these involvement methods can usefully be grouped in three basic strategies: *consultation* from the public to inform the guideline development process, *participation* of patients and the public in deliberation with other guidelines developers, and *communication* of guideline content and other health information to patients and the public. Each strategy has its strengths and limitations and their use must be tailored to specific contexts and goals. Effective involvement starts with finding the *right method*, but is also about *doing it right*. The following chapters of the toolkit therefore provide best practice advice on how to implement these methods successfully within your organisation.

Table 1: Methods available to involve patients and the public in guidelines

Involvement strategy	**Goals and strengths**	**Example of methods used by guideline organisations**	**Toolkit chapters**
Consultation (information is collected *from* patients and the public)	• Collect information from a large group of people • Possible to collect data from a variety of perspectives and from groups that are harder to involve in participation methods	• Open (online) consultation on guideline scope and topic • Comments on draft guideline • Focus groups, individual interviews, or surveys of patients' experience of care • Literature review of existing qualitative and quantitative research on patients' needs and expectations	Consultation Research
Participation (information is exchanged *between* the public and other guideline developers)	• Foster *mutual learning* and agreement between the public and other experts • Facilitate compromise and consensus on collective decisions about guideline recommendations, content, and process	• Patient or public participation in guideline development group to foster deliberation with other guideline developers	Recruitment and support Role of the chair Systematic reviews
Communication (information is communicated *to* patients and the public)	• Inform patients and the public about professional standards • Support individual health care decisions and choices among different health options	• Publish patient version of guideline and patient education material • Production of patient decision aids	Patient information Shared decision-making Using guidelines (dissemination and implementation)

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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.

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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.

How to include research on patient and public views in guidelines

Authors: Nancy Santesso, Lyuba Lytvyn, Karen Graham, Jane Cowl, Loes Knaapen

Corresponding author: santesna@mcmaster.ca

Key messages

- Evidence about patient or public views can come from many sources, including research that is already published (such as from studies, reviews, and grey literature).
- Research can be used at all steps of the guideline development process - from scope and priority setting to dissemination and use.
- Both quantitative and qualitative research on patient or public views can provide relevant evidence.
- Several factors will influence how to plan for effective and efficient use of research evidence, such as: the sources, amount and relevance of the evidence; the resources available; and the potential impact of the evidence on the guideline and recommendations.
- Methods to identify, synthesise, assess, present and, most importantly, incorporate research on patient or public views are relatively new, but tools are currently available.

Top tips

- Consider using research, whether in traditional published sources or in reports, as part of a strategy to include patient or public views in a guideline.
- Balance the potential impact of and resources for using research about patient or public views in the various stages of the guideline process.
- Use current methods to find, synthesise, assess and present research about patient or public views. When not possible, be transparent about the methods

used.

- When using previously published research, additional time may be needed to assess the relevance of the research to the guideline and specific recommendations.
- For a more efficient process, search for and use previously synthesised research rather than conducting a new evidence synthesis.
- Remember to clearly document in the guideline and recommendations how evidence for patient views was used.

Aims of this chapter

This chapter provides practical advice on how to incorporate research evidence on patient or public views in all stages of the guideline process. It is not a review of the literature about how patient or public views are not widely included in guidelines, nor a summary of where further exploration of methods are needed. This chapter is meant to assist guideline developers to find, summarise and use research about patient or public views that is already available in order to develop a guideline. The term ‘patient or public views’ (from this point referred to as ‘patient views’) covers several different terms currently in use, including values, preferences, experiences, perspectives, opinions and attitudes. There are many ways to gather information about patient views to inform the guideline development process and the evidence used to make decisions, including by engagement (see the chapters on how to conduct public and targeted consultation and how to recruit and support patients and the public, and overcome barriers to their involvement in guideline development). However, this chapter focuses on evidence from research that has already been conducted or published, whether in peer-reviewed journals or as research reports and other on-line documents. Methods for when and how to find evidence for patient views are relatively new, and we provide guidance based on what is currently known and being done, as well as references for more detailed guidance and other chapters in the toolkit.

This chapter answers the following questions:

- How can we plan for using research about patient views?
- At what stage of the guideline development process can research about patient views be used?
- What types of research can provide evidence about patient views?
- How can we search for research about patient views?
- How can the certainty of evidence on patient views be assessed?
- How can the research be summarised and presented for use?
- How can the research evidence be summarised in the guideline?

- What to do when no methods are available?

How can we plan for using research about patient views?

When making a plan on how to use research about patient views, you will need to balance resources, skills and time with the potential impact of that information on the guideline recommendations. Table 1 summarises the factors to balance when planning to use research about patient views.

Resources needed will depend on the evidence sources, and the amount and type of research available. Evidence about patient views can come from many sources (for example, journals, databases, websites, reports), consist of sparse individual studies or several reviews, span various study designs, and range in their relevance to the guideline topic. So, the plan could require a few to many resources to identify, synthesise, assess, present, and incorporate it into a guideline. The resources needed will also depend on whether the guideline group has capacity to use other methods to gather the evidence. If the existing evidence is limited in scope or relevance, guideline groups may decide to gather their own information about patient views through consultation with an advisory group, guideline panel members, or the general public. Or, they may gather information through primary research by conducting focus groups and interviews. Generally, consultation and primary research may provide evidence that is directly applicable to the guideline, whereas using research that has been previously conducted or published could not be as directly applicable.

In addition, the research could have limited or considerable impact on the guideline recommendations. If there is little debate about the value patients consistently place on the outcomes critical for decision making, meaning that it would be likely to have little impact on the final recommendation, a guideline group may determine that searching for this research evidence may not be an efficient use of resources.

Table 1 Factors to balance when planning to use research about patient views

Resources	The time, budget, and expertise available to gather, synthesise, assess and present the research.
Impact	The research could have a large or small impact on the final recommendations.
Sources	Available sources of research may be different depending on the topic (for example, databases, websites, organisations).
Amount	The amount of research, which can range from sparse to many systematic reviews.
Relevance	How applicable the available research evidence may be to the guideline topic or specific recommendation.
Alternative sources	The capacity and resources to obtain patient views from other sources, such as by patient consultation or by conducting primary research.

At what stage of the guideline development process can research evidence about patient views be used?

Evidence about patient views and experiences can be used throughout the development of a guideline, including its recommendations. This section provides an overview of the development stages with a brief description relating using research on patient views to each stage. (The sections on how research can be summarised and presented for use, how research evidence can be summarised in the guideline, and what to do when no methods are available provide more detail about how to incorporate this evidence.) Each step in the guideline development process is illustrated in figure 1, from the GIN-McMaster Guideline Development Checklist (2014). Although research evidence can be used at all stages, most opportunities are in the inner area of the diagram (outlined by the black box and from Question Generation to Dissemination & Implementation), because many of the stages on the outer perimeter (including Priority Setting, Organisation, and Conflict of Interest Consideration) will be predetermined by macro- and organisational level decisions.

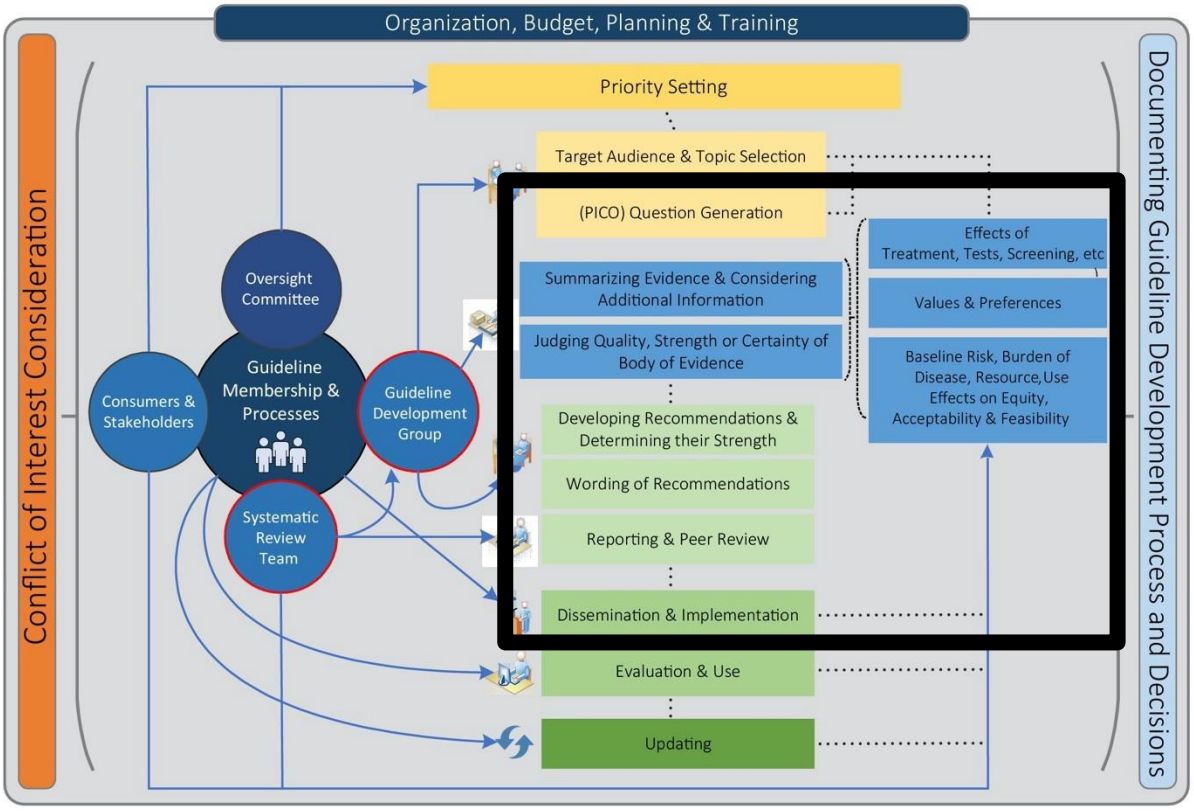

Figure 1 Diagram outlining stages of guideline development provided in the [GIN-McMaster Guideline Development Checklist]

One of the earliest and most important steps to ensure the usefulness of a guideline and its recommendations is answering **questions** that stakeholders (for example, practitioners, policy makers, patients and public) have about a topic. Typically, a guideline group will generate a list of questions about the interventions or tests that should be covered, and the **important outcomes** for which evidence is needed. The questions and the outcomes identified will in turn determine the direction of the systematic reviews to **summarise the evidence**. The group, however, may need to prioritise that list when there are many questions. Guideline developers can consult and conduct their own research with patients and the public, and key population groups, to determine what is important to them (see the chapter on how to conduct public and targeted consultation). However, before embarking on this research, developers may investigate what research is already available (published in

traditional journals or in the grey literature in patient organisations and websites) to inform their own research and avoid conducting new research.

When **developing recommendations**, a guideline group will consider the evidence for benefits and harms of an intervention or test, and in doing so will need to consider the **magnitude of the benefit or harm** and the **value** placed on those outcomes. For example, suppose the question is about whether to recommend a new intervention to prevent cancer that may also have some side effects? The new intervention may reduce the risk of cancer by 5/100,000 over 20 years, but increase the risk of a debilitating stroke by 10/100,000. If the values placed on the risk of cancer and strokes are equal, then the new intervention may not be recommended because it increases strokes. However, if the value placed on the risk of cancer is greater than the value placed on a stroke, then the recommendation may be to provide the new intervention. This is because, although there are fewer cancers, reducing the risk of cancer has a greater weight than the risk of strokes. Another consideration is whether patients value outcomes differently from each other, which may also have an impact on weighing the benefits and harms. It is clear from this example, how important it is to consider the value placed on outcomes. But developers may not consider this information and, in particular, may not consider the value that patients place on those outcomes (Gärtner et al. 2019).

Considerations of the effects of interventions is 1 component of developing recommendations for which evidence should be summarised. But other factors, such as acceptability and burden of an intervention to stakeholders, costs and resource use, effects on equity, and feasibility, will also need to be considered. The Evidence to Decision framework can be used to help guideline groups move from evidence to making recommendations or /decisions by considering all of the factors (Alonso-Coello et al. 2016). To illustrate the importance of summarising and using this type of information, consider that there may be evidence that 1 intervention is more **acceptable** to (or preferred by) most patients because it involves less burden. For example, patients might prefer a single intramuscular injection every 6 months rather than a pill once daily. This preference could have an impact on whether

1 intervention is recommended rather than another. In the same way, **costs and resources** may influence recommendations. If patients consider a new intervention

to prevent cancer more costly compared with a currently used intervention, decision makers may decide to recommend against it. In another example, if an intervention is more **accessible** with good uptake by patients, for example, in poorly-resourced settings (potentially increasing **equity** as well), a guideline group may consider recommending it rather than less accessible treatments. Or the guideline group may consider how to make other treatments equally accessible.

Information from research on patient views about the challenges when **disseminating and implementing** recommendations may also be used to inform the guideline. Some research has indicated that the wording of recommendations can have an impact (Gagliardi et al. 2011). For example, the language used, if appropriate to the context of the specific patient population, may predict the success of implementation. Therefore, research on terminology and phrasing for patients on a topic or disease area may be helpful when **writing recommendations** (see more in chapter about how to develop information from guidelines for patients and the public)]. In addition, research evidence about different strategies to reach patients that is related to the guideline topic will also be useful when a guideline group is determining how to disseminate and implement their specific guideline and recommendations to the target population. Examples include use of decision aids, pamphlets, or social media. (See more in the chapter on involving patients and the public in guideline dissemination and implementation.)

What types of research can provide evidence about patient views?

Published and unpublished research about patient views can come from a single study or from a systematic review, and can include of a variety of study designs for different purposes:

- qualitative research, such as interviews and focus groups
- surveys
- comparative studies (non-randomised and randomised)
- studies providing utility and non-utility estimates for an outcome, and
- studies that determine minimally important differences (MIDs) in an outcome.

Qualitative research studies

Information about patient views will often come from qualitative research studies, such as interviews and focus groups. This evidence can highlight areas of concern to patients, which may inform the scope of the guideline, the significance of guideline questions, the relative importance of outcomes, and acceptability of interventions. In turn, these concerns can be considered by the guideline group when deciding which questions and outcomes to address, and when incorporating values and other factors into recommendations. For example, in a guideline about different care models for people with haemophilia, a qualitative study, consisting of interviews with patients and the results of a thematic analysis, was published (Lane et al. 2016). The study reported important aspects to patients related to different models of care, 2 of which were equal access to comprehensive models of care, and the perception that integrated care is better. Consequently, when making the recommendation for the integrated care model, the guideline panel included additional guidance about overcoming system level and patient level barriers to ensure equal access.

Surveys

Surveys can provide valuable information about patient views. In particular, surveys are often used to ascertain the important questions patients have about a topic. An example of a primary study is an online self-administered survey of members of the Canadian Osteoporosis Patient Network, who were asked what priority interventions should be covered in a new guideline for osteoporosis management (Morin et al. 2020). Over 1,000 people rated interventions, such as physical activity or nutrition, from ‘1 = not important’ to ‘5 = critical’. The ratings were used to prioritise topics for the new guideline. Published surveys can also be used to determine the important outcomes to review for a particular question. The Core Outcome Measures in Effectiveness Trials (COMET) initiative is a database of studies, including surveys, that identifies outcomes to measure and report in trials for different health conditions. The surveys can be used to inform guideline developers about which outcomes should be covered in the systematic reviews and should be weighed when making the recommendations.

Comparative studies

Although quantitative research is typically used to determine the effects of interventions and tests, comparative studies can also include outcomes directly

related to patient views. Acceptability of an intervention can be assessed in participants and compared between a group that receives the intervention and a group that does not. Whether patients experience barriers or other challenges because of costs, resources, equity or feasibility issues can also be measured and compared between groups. Both randomised controlled trials and comparative non-randomised studies may provide this evidence. For example, for a World Health Organization (WHO) guideline with recommendations on treatments for precancerous lesions, the guideline group was considering whether to recommend 1 surgical treatment (loop electrosurgical excision procedure) rather than another (cryotherapy). A randomised controlled trial measured important health outcomes with either treatment and also how many participants felt the procedure they received was acceptable (Chirenje et al. 2001). Acceptability was found to be similar and contributed to the decision of the guideline group to suggest treatment with either procedure.

In another WHO guideline, recommendations for treatment of chlamydia were made. Randomised controlled trials provided information about the difference in effects of various treatments and adherence to those treatments. The information about adherence was used to inform decisions about patient preference for single-dose compared with multi-dose regimens (Hillis et al. 1998)

Studies providing utility and non-utility estimates

Studies may also quantify the value placed on an outcome as utility and non-utility estimates. The use of these estimates in guideline development is relatively new and methods for incorporating this evidence are still being developed (Zhang et al. 2017) Essentially, studies will use different methods to measure utilities (such as Standard gamble or Time trade off) and report the utility of a health state (for example, a health outcome) on a scale from 0 (death) to 1 (perfect health). When comparing utilities for different outcomes, guideline groups could consider outcomes with lower utilities as an indicator of less desirable outcomes that may carry greater weight when balancing effects, and a wide range in a utility score as an indicator that patients may not value the outcome (or health state) similarly.

Studies that determine MIDs

Another type of study related to patient experiences and views is a study that measures MIDs, defined as the smallest change, either positive or negative, that patients perceive as important (Schünemann and Guyatt 2005). This information can be used by guideline developers to interpret the magnitude of the effect of an intervention on an outcome. For example, in a guideline comparing a surgical procedure with non-operative treatment for shoulder pain, studies were available that determined the MIDs for instruments used to assess shoulder pain, function, and health-related quality of life (Hao et al. 2019). When the guideline panel had to decide how large the benefits of the surgery were and how large the harms were, they used the MIDs identified by patients. They determined that the magnitude of the benefits of surgery were less than the MIDs, and magnitude of the harms were greater than the MIDs, and therefore recommended against the surgery.

Systematic reviews

Finally, guideline groups can use the evidence from any of the above studies individually or synthesise such studies. If a systematic review of these studies is already available, that may be preferable because it reduces time and resources necessary to gather evidence about patient views. It could also save resources if there is a diverse or large body of evidence already available. When searching for systematic reviews, guideline groups should be aware that there is no standard for reviews of patient views, and groups will likely need to delve into the reviews for the details. Systematic reviews will have different purposes and therefore specific inclusion and exclusion criteria that guideline developers will need to assess as relevant before using the reviews. Systematic reviews may

- cover broad questions about patient views related to priority questions (see the series about how to use this type of review [Downe et al. 2019])
- cover all factors related to patient views, such as values, and acceptability and equity issues (see the series on how to use this type of review [Lewin et al. 2019])
- cover implementation issues (see the series about how to use a review for this topic [Glenton et al. 2019], and box 1 for an example), or

- restrict types of study designs included, such as qualitative research (see the series on how to use this type of review [Lewin et al. 2019]).

BOX 1: A systematic review of patient values and preferences

The American Society of Hematology developed guidelines for management of venous thromboembolism (VTE) disease. There are important trade-offs in VTE management, in particular, because interventions that reduce the risk of thrombosis increase the risk of bleeding. A systematic review of patient values and preferences related to VTE was conducted (Etxeandia-Ikobaltzeta et al. 2020). Multiple databases were searched for both quantitative and qualitative studies.

When summarising the data, the authors combined the results of quantitative and qualitative studies, and also conducted a separate analysis of the themes and quotes from the qualitative studies. The evidence from quantitative studies included utility estimates for outcomes (for example, deep vein thrombosis, gastrointestinal tract bleeding), and non-utility estimates about outcome priorities (for example, VTE risk reduction), willingness to accept a particular intervention (for example, treatment burden of vitamin K agonists), treatment method preference (for example, injection compared with oral medication), and testing method preference (for example, thrombophilia testing). The qualitative studies provided important information from patients related to disease treatment benefits and burden, healthcare provider communication and relationships, awareness and perceptions of risk, and day-to-day routines. Overall, the evidence suggested that patients put higher value on VTE risk reduction than on the potential harms of the treatment, and likely prefer oral medication rather than subcutaneous medication.

The guideline panel used this information to inform the:

- values placed on outcomes and whether the values are consistent across populations, and
- acceptability and feasibility of the interventions when making the recommendations and writing additional guidance about implementation.

When systematic reviews are not available, a guideline group may decide to conduct their own systematic review. In this chapter, we do not provide details of how to conduct a systematic review, but we will describe some of the unique elements pertaining to syntheses of research about patient views in the next sections. For details about how to conduct systematic reviews that include a variety of different study designs, the resources in table 2 may be helpful.

Table 2 Resources for how to conduct systematic reviews

Type of systematic review	Guidance for conducting the review
Review of randomised and non-randomised studies	Cochrane Handbook
Synthesis of qualitative research	Cochrane Handbook: Chapter 21: Qualitative evidence Additional guidance – Cochrane Qualitative & Implementation Methods Group
Synthesis specific to quantitative patient values	General guidance: Zhang Y, Coello PA, Brożek J et al. (2017) Using patient values and preferences to inform the importance of health outcomes in practice guideline development following the GRADE approach. Health Quality Life Outcomes, 15: 52
Overviews of reviews	Cochrane handbook: Chapter 5: Collecting data
Rapid reviews	Cochrane Rapid Reviews Methods Group

How can we search for research about patient views?

Evidence for patient views and preferences may be found by searching traditional databases, such as Medline, Embase or the Cochrane Library. Other sources of this evidence may include:

- grey literature, such as health technology reports (whether indexed or not)
- patient organisation websites and forums
- professional organisation websites (in particular, in other guidelines), and
- research sites.

The James Lind Alliance website, for example, is dedicated to communicating research priorities and can inform questions about topics of interest to patients.

Finding research about patient views in the published literature can be challenging, but some work has been done to create standard search strategies for key databases that can focus the search. The choice of strategy may often depend on the breadth of your topic area (for example, broad strategies may be appropriate in very specific diseases or conditions). Or the choice may depend on the expected types of studies conducted on the topic (for example, search strategies with specific terms for qualitative research or for studies measuring utilities are available). Guideline groups will need to consider their time and resources when choosing a strategy. A restricted search rather than a comprehensive search may be best if resources are limited (see table 3). When searching within specific organisation websites or in Google, for example, guideline groups could also consider using terms that are similar to those used in the strategies in table 3.

Table 3 Search strategies to find research in traditional databases related to patient views able

Search strategy	
Search strategy to systematically identify evidence addressing views and preferences with terms specific to different study designs	Selva A, Solà I, Zhang Y et al. (2017) Development and use of a content search strategy for retrieving studies on patients' views and preferences. Health and Quality of Life Outcomes 15(1):126
Search strategy from Scottish Intercollegiate Guidelines Network (SIGN) for publications related to 'patient issues'	SIGN search filters for patient issues
Further development of a search strategy for literature addressing patients' knowledge, views, and values based on the SIGN strategy	Wessels M, Hielkema L, van der Weijden T. How to identify existing literature on patients' knowledge, views, and values: the development of a validated search filter. Journal of the Medical Library Association 104(4):320–324
Search strategy available from the Health Information Research Unit for finding studies in qualitative research	Health Information Research Unit Qualitative – Medline

Alternatively, a search for already published systematic reviews may be preferred if reviews are potentially available. If a guideline group has decided to search for

systematic reviews (as opposed to individually published studies), groups can consider:

- adding a search filter for systematic reviews, such as the McMaster University Health Information Research Unit's Clinical Hedges database
- searching databases of systematic reviews, such as the Cochrane Library or Epistemonikos, or
- searching in other guidelines for synthesised evidence in the G-I-N International Guidelines Database or the TRIP database.

How can the certainty of evidence on patient views be assessed?

When thinking about the certainty of evidence, guideline groups will typically think about certainty or confidence in the evidence for benefits and harms. Consider a group making a recommendation who have been presented with the benefits and harms of an intervention from a systematic review of the literature. Drug X increases the number of people cured by 10 out of 100, and the risk of stroke increases by 5 out of 100 compared with no drug. The evidence that contributed to the estimates of the cures is very different from the evidence that contributed to the strokes. So, the certainty of the evidence is different. There is very low certainty that 10 more cures may occur, but high certainty that 5 more strokes could occur. Because of the certainty in the evidence, a guideline group may make a recommendation against the drug to avoid the 5 more strokes that could occur. In contrast, if the certainty was the other way around, that is, high certainty of 10 more cures, and very low certainty of 5 more strokes, the group may decide to suggest the drug as treatment because they are very uncertain about the increase in strokes. Assessing and presenting the certainty of evidence for benefits and harms is therefore important, and various systems do this, such as the GRADE approach (see the GRADE Handbook).

These systems can also be used to assess the evidence for patient views. If a guideline group is conducting a systematic review of research on patient views (using rigorous methods provided in table 2), the group should also convey the certainty of the results about those views. Consider a guideline group deciding

whether to recommend a procedure with outcomes for precancerous cervical lesions and infertility. Research evidence about the value that couples place on fertility could

be gathered. If evidence is certain that women who are trying to conceive place a very high value on avoiding infertility compared with preventing recurrence of a precancerous lesion, more so than women not trying to conceive, the guideline group may make a recommendation against the procedure for women trying to conceive, but a recommendation for the procedure in women not trying to conceive. In contrast, if the research evidence is very uncertain about the values, then the guideline group may make the same recommendation for both groups of women. In this way, the certainty of the evidence can have an impact on the recommendations that are made, and it is therefore important to assess the certainty of the research evidence about patient views.

One component of assessing the certainty of evidence is to judge the quality or limitations of the studies. For individual qualitative studies, there is no agreement on the best tool to use, but 2 have been more widely used:

- the CASP qualitative studies checklist
- an adapted version of the CASP tool (Atkins et al. 2008).

These tools continue to be developed as methods progress and as the debate persists about the impact of the assessment criteria, such as ethics approval, on the validity of a study. For now, either of these tools could be used to assess the limitations of each study that contributes information on patient views. However, assessing the limitations of studies is only 1 part of the overall assessment of evidence. There are other factors that need to be considered when evaluating the certainty of the evidence, and these factors depend on the study design contributing to the evidence.

To assess and present **confidence in the evidence from a review of qualitative research studies**, reviewers may use the GRADE-CERQual approach. GRADE-CERQual asks groups to assess 4 domains:

- quality or limitations of the studies
- whether the results from the studies are directly relevant to the recommendation

question

- whether the results are coherent across the studies, and

- whether the data from the studies is sufficiently rich or adequate.

Together, consideration of these domains determines the confidence in the conclusions from a review of qualitative research about patient views. For example, a systematic review of qualitative research was conducted to synthesise evidence about parents' and informal caregivers' views and experiences of how information about routine childhood vaccination is communicated (Ames, Glenton, and Lewin 2017). The authors found that scientific sources of vaccine information were seen to be more reliable than discussion forums or lay opinions. The review authors then assessed the certainty of the evidence using GRADE-CERQual. They had minor concerns with the limitations in the studies, no concern with coherence of the results across studies, but moderate concern with the setting of the original studies (being directly applicable to their question), and the richness of the data. They therefore had low confidence that scientific sources were seen as more reliable than discussion forums or lay opinions. Details about how to assess the confidence in qualitative research findings using the GRADE-CERQual approach can be found in a series of papers, each addressing how to assess 1 domain (Lewin et al. 2018).

To assess the **certainty of evidence specific to the importance of health outcomes**, a new method has been developed (Zhang et al. 2019a, Zhang et al. 2019b). The method is based on the GRADE approach in which evidence for patient values is assessed using the domains: risk of bias, inconsistency, indirectness, imprecision, publication bias, and others. Details are provided in the articles published by Zhang et al. 2019a and 2019b, but the concept for each domain is similar to what would be applied to a review of studies evaluating benefits and harms of an intervention. Of note is the consideration of inconsistency across study results. When research shows that values are variable, further exploration, for example by subgroups, is recommended in order to determine if there are true differences in how people value a health outcome. Differences in values would likely influence whether different recommendations are made for 1 group compared with another based on what they value most, or whether there should be a conditional rather than a strong recommendation (that is, a conditional recommendation requires shared decision

making).

For **evidence about patient views from a synthesis of studies, such as randomised controlled trials or non-randomised studies**, GRADE or other systems for assessing the certainty of evidence from these study designs should be used. For example, if there was a review of randomised controlled trials that reported the acceptability of 1 procedure compared with another. In this hypothetical review, the difference in how acceptable the 1 procedure is compared to how acceptable the other procedure was calculated from each study and then the differences from each study were pooled together to create 1 estimate of the difference. To express the certainty in such estimated differences, groups should assess the risk of bias of all the studies providing data, the number of participants providing data, the width of the confidence interval around the difference, the heterogeneity of the overall difference, and the applicability and risk of publication bias. Based on this assessment, the guideline group will know how certain to be in the difference from the review of studies.

Finally, in special circumstances when a guideline group is not using a standard approach to assess the evidence, there should be some description about how believable the overall conclusions are about the patient views and why they are believable. The following principles should be considered and communicated:

- whether the individual studies were well done
- how many studies (or participants) were included
- how relevant the studies are to the recommendation topic, and
- how consistent or coherent the results are across the studies.

How can the research be summarised and presented for use?

As explained in the section on the stage of the guideline development process at which research evidence about patient views can be used, research about patient views may contribute to multiple stages of a guideline and to many factors when making a recommendation. In this section, we provide several examples of how this research may be summarised and presented so it can be incorporated into guideline recommendations.

A list of patient research priorities based on research

At the guideline development stage of generating questions to cover in a guideline, the guideline group may search the grey literature for research about what is important to key stakeholders. The James Lind Alliance website can be searched to find research about patients' top research priorities for a topic. Figure 2 shows the James Lind Alliance website's top 10 questions on diabetes and pregnancy (as well as information about how the research was conducted to inform the priorities). Presented this way, the guideline panel can easily incorporate this information when generating questions.

Figure 2: Information from the James Lind Alliance website about priority questions related to diabetes and pregnancy

A thematic summary of patient views from evidence syntheses of qualitative research about acceptability presented narratively and in a table with rating of certainty

A synthesis of systematic reviews of qualitative research was conducted and informed the development of the WHO guideline: recommendations on digital interventions for health system strengthening (2019a). It includes recommendations on using digital health interventions for reproductive, maternal, newborn, child and adolescent health, in particular, for the use of telemedicine. An overview of systematic reviews of qualitative research on patient views of telemedicine was conducted. The evidence was summarised in themes and presented narratively and in tables, along with the confidence in the evidence. Figure 3 shows the research evidence on acceptability that was used to make the recommendation for using client-to-provider telemedicine (Glenton et al. 2019). The evidence statement 'Some clients believe that telemedicine has increased their independence and self-care, but some healthcare workers may be concerned about clients' ability to manage their own conditions (low confidence)' from the thematic text is reflected in the table item F7.

Some clients see client-to-provider telemedicine services as offering reassurance and a sense of safety and appreciate the increased access, consistency and continuity of care (low confidence). Some clients appreciate the convenience of telemedicine as it saves time and money and reduces the burden of travel, although others may see it as difficult to engage with or too time consuming (low confidence). Some clients also appreciate being able to communicate with healthcare workers from their home environment, while others miss face-to-face contact (low confidence). Some clients believe that telemedicine has increased their independence and self-care, but some healthcare workers may be concerned about clients' ability to manage their own conditions (low confidence). Telemedicine services can give clients who speak minority languages access to providers who speak these languages. However, access may be difficult for others to achieve, for instance because of hearing impairments, poor computer literacy or technical issues (high confidence).

Summary of Qualitative Findings

Summary of overview finding		Reviews contributing to the overview finding	Methodological limitations	Relevance	Adequacy	Coherence	Overall CERQual assessment of confidence in the evidence
F7	Some clients may believe that telemedicine has increased their independence and self-care, but healthcare workers may be concerned about this transfer of responsibilities	Brewster 2013[1]; Cox 2017[2]; Raphael 2016[4]	No or very minor concerns	Moderate concerns because of partial relevance. Healthcare provider perspectives are from review of cancer patients only, while client perspectives are from COPD and from adults over 65.	Moderate concerns because of thin data	No or very minor concerns	**Low confidence** because of concerns about partial relevance and data adequacy

Figure 3: Narrative summary of the themes from the systematic reviews and summary in a table

A narrative summary of themes from a systematic review of qualitative research as evidence of benefits and harms

A systematic review of qualitative research was conducted for the Scottish Intercollegiate Guidelines Network (SIGN) guideline on managing long-term effects of COVID-19. Based on a search of bibliographic databases, grey literature and pre-print databases, 6 studies were included, and a thematic synthesis was done. Each of the themes was summarised and presented in the COVID-19 rapid evidence review. Managing the long-term effects of COVID-19: the views and experiences of patients, their families and carers (Healthcare Improvement Scotland 2020). One of the themes (Analytical theme 9) identified desirable features of healthcare services or service delivery, which in turn led to recommendations for health care

professionals to perform person-centred assessments (figure 4).

Analytical theme 9: desirable features of healthcare services/service delivery

Patients asked for face-to-face assessments; they talked about the need for one-stop clinics with multidisciplinary teams (MDT) who could look at their wide-ranging symptoms and treat them holistically. A case manager to oversee individual patients and ensure that all aspects of their care had been considered was suggested, along with meaningful referral pathways and criteria.

> "What would be most helpful is if all main hospitals could have a Covid clinic that had experts from respiratory, cardiology, rheumatology, neurology, physiotherapy etc, so you could go along for half a day and see people from these different departments, they can refer you for tests and you can get a plan in place, we are having such a range of symptoms that GPs are struggling to know what to do with you" (Maxwell, p17)[4]

> "... there was a view that it would be helpful if people living with Covid19 could have a 'quarter back' or case manager to oversee and coordinate investigations and support services across different medical specialities." (Maxwell, p17)[4]

When asked what features of healthcare delivery or services they would like to see, patients with long-term symptoms spoke about wanting to be listened to, to be believed and understood, and to be offered practical advice on coping.

> "... actually just the experience of being heard and feeling like somebody got it and was being kind about it, but you know it was okay that they couldn't do anything, I just kind of needed to know that I wasn't losing it really and it was real what I was experiencing, I think so that was really helpful." (Kingstone *et al*, p8)[2]

Figure 4: Example of a narrative summary of themes from qualitative research on the views and experiences of patients, their families and carers (Healthcare Improvement Scotland 2020)

A table summarising a synthesis of quantitative studies about patient acceptability and the certainty of that evidence along with other benefits and harms

A systematic review of randomised and non-randomised studies was conducted to inform recommendations for treatments, including thermal ablation or cryotherapy, to

treat precancerous lesions in the WHO guideline on for the use of thermal ablation for cervical pre-cancer lesions (2019b). Acceptability was measured in the trials. The

effects from the individual studies were pooled and presented along with the benefits and harms of the treatments in a Summary of Findings Table (Annex D Evidence to decision frameworks, page 43), shown in figure 5. The effect was that it was likely that there was little difference in acceptability between the 2 treatments.

Outcome N° of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Certainty
		Risk with cryotherapy	Risk with thermal ablation	Difference with thermal ablation	
Cure № of participants: 85 (1 RCT)	RR 1.14 (0.89 to 1.46)	Moderate			Moderate
		90.0%	100.0% (80.1 to 100.0)	12.6% more (9.9 fewer to 41.4 more)	
Cure № of participants: 157 (1 observational study)	RR 1.01 (0.89 to 1.14)	Moderate			Very low
		90.0%	90.9% (80.1 to 100.0)	0.9% more (9.9 fewer to 12.6 more)	
Cure № of participants: (23 case series)	not estimable	Moderate			Low
		90.0% (87 to 93)	92% (90 to 95) 2 probe: 95 (93 to 98) Not 2 probe: 85 (80 to 90)		
Pain immediately № of participants: 413 (4 RCTs)	RR 0.93 (0.76 to 1.15)	65.4%	60.8% (49.7 to 75.2)	4.6% fewer (15.7 fewer to 9.8 more)	Moderate
Pain immediately № of participants: (case series)	not estimable	Moderate			Low
		30.0% (19 to 41)	63% (42 to 83)	33% more	
Major bleeding № of participants: 817 (6 RCTs)	RR 0.62 (0.37 to 1.02)	1.7%	1.0% (0.6 to 1.7)	0.6% fewer (1.1 fewer to 0 fewer)	Moderate
Major bleeding № of participants: (case series)	not estimable	4 / 9941	9 / 4634		Low
Infection (including fever) № of participants: 816 (6 RCTs)	RR 0.81 (0.10 to 6.33)	0.3%	0.2% (0.0 to 1.6)	0.0% fewer (0.2 fewer to 1.3 more)	Moderate
Infections (including fever) (45 case series)	not estimable	60 / 8674	17 / 4082		Low
Acceptability – whether they would recommend it № of participants: 631 (3 RCTs)	Acceptability is likely not different between thermal ablation and cryotherapy. Risk Ratio 1.01 (0.99 to 1.02)				Moderate

Figure 5: Summary of findings table including patient acceptability between 2 treatments (WHO 2019b)

A summary of quantitative and qualitative research about patient views related to equity using the Evidence to Decision framework to present the evidence

A systematic review of research was conducted for a recommendation comparing different models of care for people with haemophilia (Pai et al. I2016). The review included any quantitative or qualitative research, such as focus groups, interviews and surveys, about barriers to accessing an integrated model of care. The review provided evidence about the impact of the model on health inequities and was summarised by analysis of thematic areas. The evidence was presented to the guideline group in a section on Equity in the Evidence to Decision Framework and then used by the group to make the recommendation (see figure 6).

	Criteria	Judgements	Research evidence	Additional considerations
Equity	**What would be the impact on health inequities?**	○ Increased ○ Probably increased ○ Uncertain ● **Probably reduced** ○ Reduced ○ Varies	**Summary of the evidence** There are no randomized controlled trials or non-randomized studies comparing integrated care to non-integrated care for people with hemophilia There are 7 non-randomized studies which provided data from one group of people who received integrated care. Ethnicity/race • Baker 2013 analyzed data from the U.S. HTC network (129 HTCs) from 1990-2010. In 2010, 71% of HTC patients were White, 13% Hispanic, 9% Black and 7% 'Other' (this was slightly lower than U.S. population of 64% White, 16% Hispanic, 13% Black and 6% 'Other'). From 1990 to 2010, the numbers of HTC Hispanic and Black patients grew, but remained under represented. • Monahan 2011 analyzed data from >130 HTCs from 1998-2008 in boys with hemophilia and found that the racial/ethnic composition reflected general demographics. • Forsberg 2014 (supplemented by Aschman 2014) report survey of 4,004 households with people with hemophilia in HTCs in 2013. The odds of having 5 or more problems were twice as high for minority groups relative to Whites categories, and almost thrice as high for African Americans. Distance/access • Soucie 2000 analyzed data from 1993-1995 and found more people with severe hemophilia accessed HTCs than mild or moderate (and more than non-HTCs). • Zhou 2011 (from the HUGS study) interviewed 327 adults and parents with children with hemophilia. 14% reported barriers to HTC, which included distance. • Hacker 2006 conducted a survey from 1999-2001 of ~120 adults and parents with children hemophilia at an HTC. 32% had limited access to HTC often due to transportation, inconvenient times, or problems with staff. • Forsberg 2014 (supplemented by Aschman 2014) found that moderate or severe barriers included time off from work/school for appointments (11% moderate, 4% severe), and distance to HTC (14%, 4%). The odds of having 5 or more problems were twice as high for minority groups relative to Whites categories (African Americans almost 3 times). • Nugent 2015 (from the HERO study) surveyed people with and parents of children with hemophilia in 10 countries [supplementary data also was available]. In the U.S., 22% of people with hemophilia report that it is quite/very difficult to visit HTCs in the U.S. Accessibility was the key issue; 71% of 42 respondents cited the long distance to their HTC, and 45% cited long/expensive travel.	Core question: will we do away with equity problems if we do away with HTCs? Or will we introduce more inequity? General demographic data on PWH is scant. Further, the bulk of published data is from HTCs. Thus we don't know if inequity also exists in individuals outside of HTCs. The issue of capacity looms large – does it affect access issues? Panelists felt that the HTC system's capacity was not truly a problem, but that access is being limited by insurance companies. Modifiers of inequity may include telehealth, empowering local healthcare providers, broader access to HTCs (e.g. through more appropriate implementation of recommendations and optimized utilization).

Figure 6: Equity section of an Evidence to Decision Framework with a summary of the studies by theme (Pai et al. 2016, see hae13008-sup-0003-AppendixS3-S4.docx)

A summary of a systematic review of research about values placed on outcomes

As described in box 1, a systematic review of patient values and preferences was conducted for the American Society of Hematology guidelines for management of venous thromboembolism (VTE) disease (Etxeandia-Ikobaltzeta et al. 2020) Multiple databases were searched for both quantitative and qualitative studies. The authors summarised the research from non-utility studies on which outcomes patients with cancer valued more (along with the certainty of that evidence). This information was used when deciding how much weight to put on the benefits and harms of the different treatments (see table 7).

Trade-off between treatment burden and benefits with LMWH (Cajfinger et al,[46] Noble et al[54])	Cancer patients place highest value on "the interference with cancer treatment," followed by "efficacy of the VTE treatment" and "risk for major bleeding." They place low value on monitoring through blood tests, frequency of administration, mistakes, and costs. 509 participants from 2 cross-sectional studies	⊕⊕⊕◯ Moderate certainty due to RoB[a]

Figure 7: Summary of non-utility studies about the value placed on different outcomes in the treatment of venous thromboembolism (in table 4 of Etxeandia-Ikobaltzeta et al. 2020)

How can research evidence be summarised in the guideline?

The previous evidence presentations are most useful to the guideline group when making recommendations. After the evidence has been used in the guideline process there are 2 options for how to write about patient views in the final guideline. Options can include:

- summarising the evidence on patient views across many recommendations in 1 section of the guideline
- providing the patient views for each recommendation.

The choice may depend on how many recommendations are in the guideline. If there are few recommendations, then 1 summary may be appropriate because readers will

be able to apply the summary easily to each recommendation. If there are many recommendations, readers may appreciate having a summary of the views and experiences for each recommendation. If the recommendations are closely related and the views and experiences are similar across those recommendations, then 1 summary is adequate. However, if views, values, and experiences differ from recommendation to recommendation, specific descriptions within each recommendation would be necessary. Finally, if it is expected that each recommendation may not be read, may be made into a stand-alone document, or be copied into other related guidelines (that is, not necessarily always together with the other recommendations) then including a summary with each recommendation is likely the better choice.

For an example of how to summarise patient views **across multiple recommendations in 1 section**, see the American Society of Hematology 2018 guidelines for management of venous thromboembolism.

For an example of how to summarise patient values and preferences **for a recommendation in a guideline**, see the CMAJ recommendation on screening for chlamydia and gonorrhea in primary care for individuals not known to be at high risk.

What to do when no methods are available?

This chapter has provided practical advice on how to incorporate research evidence about patient views in the guideline process using examples. There are many more examples and more detailed guidance available in the references. However, there are still gaps in these methods, and guideline developers may need to develop novel methods when there are gaps. We suggest the following if no guidance is available:

- **be transparent** about what was done or not done
- **document** in the guideline or evidence syntheses what was done
- determine if it is possible to **adapt** methods for including stakeholder views from other fields to methods for including patient views in guideline development
- **conduct research** into what does and does not work, and
- **share** experiences.

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How to recruit and support patients and the public, and overcome barriers to their involvement in guideline development

Authors: Sarah Scott, Jane Cowl, Corinna Schaefer, Karen Graham, Jessica Fielding, Lyndsay Howitt, Mark Rasburn and Verity Scott

Corresponding author: Sarah.Scott@nice.org.uk

Key messages

- Guideline developers can experience several barriers to recruiting and engaging patient and public members in guideline development work. These include the lack of a clear cost-effective recruitment strategy, the ability to achieve genuine representation, and members lacking the appropriate skills to conduct the work (for example, good communication or research knowledge).
- The patient and public member's role will influence the tasks, experiences and qualities required to perform in the guideline group. This might influence the number and type of patient and public members, such as patients, carers and advocates from patient organisations. Information outlining the role and person specification should be carefully planned from the outset and openly advertised to reduce barriers to recruitment and engagement.
- There are 2 types of recruitment methods: open recruitment and nomination through patient organisations. But each method has advantages and disadvantages that need to be considered, taking into account the developer's resources and availability of patient organisations for specific conditions. Whichever method is selected, the way it was implemented must be documented and transparent.
- Barriers to effective patient and public member engagement during guideline development can be overcome with careful planning and:
  - delivering practical support (for example, providing easy read versions of documents)
  - informal support (such as providing advice and support)
  - financial compensation for time and travel expenses

  - co-learning (during guideline development in the form of presentations or seminars)
  - training, performance feedback and managing group dynamics.
- There are occasions when patient and public members cannot be included in guideline groups (for example, children) or it is difficult to recruit seldom heard groups (for example, people in secure settings). Alternative approaches to consider are reference groups, additional sources of data on patient and public views, patient expert testimony, and consultation using research methods.
- Very specific barriers to involvement will need to be considered when engaging seldom heard groups, such as children, people with learning disabilities, and people with severe mental illness. Such barriers include legislation, cognitive capacity, and illness fluctuations. The practical and informal support strategies will need to be very carefully considered, adapted and tailored to each individual.

Top tips

- Plan, develop and advertise a role description and person specification during the planning stage of the guideline. It should outline in advance, the roles, tasks, experiences and qualities, and the type and number of patient and public members to gain a broad representation needed for the guideline.
- Involve patient and public members from the start, and throughout development, to ensure the scope applies to the people who will use the guideline and to encourage ongoing engagement.
- Recruit at least 2 patient or public members, who might be patients, parents, carers or advocates from patient organisations, with a range of perspectives, experiences and characteristics to gain a breadth of representation.
- Recruit people based on their experiences and understanding of the issues that matter to people with the condition.
- Consider the open recruitment method to reach a large pool of people if your organisation has the time and resources to produce recruitment documents and conduct interviews.
- Consider the nomination process if you have less resources to conduct open recruitment and have access to relevant patient organisations for the topic of interest.

- When openly recruiting, advertise opportunities through websites, patient organisations, health professionals and social media, which can help recruit from seldom heard groups.
- Assess practical and informal support needs, including training needs, from the outset and during guideline development in case needs change. Tailor support and training to each individual member.
- Provide initial training and implement co-learning in which the whole guideline group learns and shares knowledge on guideline development and research, using presentations, seminars, and discussions.
- Create and offer opportunities for new members to meet an experienced patient and public member 'buddy' to allow them to discuss their role and any concerns.
- Regularly assess the patient or public member's performance and provide feedback to ensure ongoing learning and to address any issues that arise, such as feeling unable to contribute.
- Manage group dynamics through training for the chair to ensure patient and public members are treated equally and can contribute and feel valued.
- Carefully plan and tailor specific practical and informal support strategies when engaging seldom heard groups, such as children, people with learning disabilities and people with severe mental illness. Take into consideration legislation, cognitive capacity, and illness fluctuations.

Aims of the chapter

This chapter provides guideline developers with advice on how to identify, recruit and support patients and members of the public as participants in guideline development groups. It will also explore how facilitators can overcome some of the main barriers to recruitment and effective involvement. Published literature has highlighted several barriers for involving patient and public members (Armstrong et al. 2017b; Légaré et al. 2011; Ocloo and Matthews 2016), including:

- the developer being unclear of recruitment strategy, including the number or type of patient or public members to recruit to achieve genuine representation
- the developer, patient or public member being unclear of their role in guideline development
- scheduling and planning issues, or having the resources to adequately engage patient and public members
- lack of relevance of the scope to patient and public members
- difficulties in gaining meaningful involvement or avoiding tokenism
- patient or public member not respected, not seen as equal, or feeling devalued
- achieving a breadth of perspective or adequate representativity of patients and the public
- recruitment difficulties
- lack of methodological expertise, skills or knowledge related to guideline development
- patient and public members feeling isolated or lacking in confidence to speak up in a large group of experts.

The 4 sections of this chapter will address these barriers. The first section focuses on the role of patient and public members, including the qualities, experience, type and number, and skills needed. The second section focuses on the recruitment process and strategies. Support, including practical and informal support, group dynamics, training and co-learning, and re-assessment and feedback procedures, is addressed in the third section. The fourth section focuses specifically on the barriers and solutions to recruiting people who might face barriers to participating, such as children, and outlines a series of alternative approaches. Practical examples will be

provided, based largely on the expertise and best practice of guideline developers from around the world, These include the National Institute for Health and Care Excellence (NICE) in England, Ärztliches Zentrum für Qualität in der Medizin (ÄZQ) in Germany (or the German Agency for Quality in Medicine [AEZQ]), the Registered Nurses' Association of Ontario (RNAO) in Canada, and the Scottish Intercollegiate Guideline Network (SIGN) in Scotland. Reference is made to published research where relevant. The advice in this chapter will help guideline developers avoid tokenism, defined as the ‘difference between…the empty ritual of participation and having the real power needed to affect the outcome’ (Arnstein 1969).

The role of patient and public members

Research has found that a barrier to involving patients and the public in guideline development can occur when the role and required skills, experience and knowledge have not been clearly outlined (Armstrong et al. 2017b, Carroll et al. 2017). At the planning stage of a new guideline, developers need to have a clear understanding of the role requirements and expectations of the patient and public members. This helps developers carefully plan the offer of support, training and any additional resources needed, and ensures that only suitable members are recruited. The information will also help patient and public members to understand what is required of them, including the time commitment, which enables better engagement because they will be able to plan their work. This section will explore the factors that guideline developers should consider during the planning phase, including:

- the role and tasks of patient and public members
- the type and number of members
- gaining appropriate representation
- the required skills and experience.

The role and tasks of patient and public members

Developers should be clear of the purpose and rationale for patient and public involvement because the role will influence the tasks, skills, and the qualities that developers will need to recruit for. The role is defined as their function in a group, including being an equal partner in decision making during guideline development.

Knaapen and Lehoux (2016) defined 3 models that might be useful to consider when developing roles based on the tasks to be achieved: consumerist, democratic, and expert. A consumerist model emphasises an individual's right to have autonomy in making choices in healthcare decision making and that healthcare improves when tailored to patients' needs and preferences. This model applies if the task is to identify patient preferences and develop decision aids. A democratic model refers to the 'rights of citizens (and taxpayers) to democratic decision making on a policy or collective level' (Knaapen and Lehoux 2016). This model applies if the tasks are to develop policy documents that influence the design or redesign of healthcare services. An expert model emphasises the patient and public's experiences and knowledge of a condition, treatment, and quality-of-life outcomes. So, it offers a different kind of expertise to that of health professionals and is useful when producing guidance.

Although the models might be a useful starting point to consider roles and tasks, they can be contradictory because patient and public members are sometimes required to perform multiple tasks. For example, formulating recommendations, synthesising knowledge, revising drafts and, occasionally, strategic decision making such as deciding committee membership, outlining the scope, and producing decision aids (Légaré et al. 2011). The type and range of tasks will influence the number and type of patient and public members to recruit.

It is also important to ensure that the patient and public members' role, ideally, spans every stage of the development process, including the scoping stage. This can help prevent patient and public members disagreeing with the topic scope and disengaging from the guideline group (van Wersch et al. 2001). When it is not feasible to involve members early on, or at all stages of the development process, an alternative is to invite additional representatives, to attend 1 meeting or contribute to a consultation (see the chapter on how to conduct targeted and public consultation).

Role and tasks in practice

NICE in England involves patient and public members throughout the guideline development process. They have the same role and tasks as health and social care professionals. Tasks include:

- agreeing the review questions and protocol
- assessing and interpreting the evidence
- producing recommendations
- identifying relevant stakeholders for consultation
- contributing to draft documents
- producing information for the public.

The RNAO involves patients and members of the public in similar ways to NICE. For some topics, NICE recruits patients or carers early on to help develop the guideline scope, as part of a smaller scoping group, and possibly also to support the development of patient-decision aids. When patients or public members cannot be involved in all stages of the guideline development, SIGN in Scotland invites additional representatives, living with the condition, to specific meetings. Patient and public members might also be recruited for different types of roles and tasks. NICE in England, ÄZQ in Germany, and RNAO in Canada all involve patients and the public when developing quality standards and indicators, based on guidelines, which includes the rating and assessment process.

The type and number of patient or public members

What type of patient or public member should we recruit?

The guideline topic and role and tasks will influence the type of members to include. The members can include patients, carers, parents or advocates from patient organisations. A carer or parent might be important to include when relatives are affected by the condition, or they have an integral role in caring for the person with the condition (for example, dementia). Parents or carers can be recruited if it is difficult to involve a patient living with the condition, such as young children (for more information, see the section on overcoming barriers to involving those who are seldom heard, in this chapter). Developers may also consider an employee or volunteer from a patient organisation. Even if this person does not have personal experience of the condition, they can provide a broad perspective on the condition and population. It is important to note that a patient, carer or advocate from an organisation will have different perspectives and it can be helpful to include all types of perspectives.

How many patient or public members should we recruit?

NICE advocates that at least 2 patient or public members should be recruited to any guideline group, who might be patients, parents, carers or advocates from patient organisations. More members could be recruited if the guideline covers multiple issues, a complex condition, or requires multiple roles and tasks. The advantages of this are that it:

- broadens the experiences of the group and ensures different aspects of the guideline are covered from the patient or public member's perspective
- can build confidence, provide social support and empower patients to contribute
- reduces feelings of isolation, which is a known barrier to patient engagement
- provides peers to work with other patient and public members.

Consideration can be given to socio-demographic representation, such as the age range, which is likely to influence how many patients and public members are needed. For example, for the NICE guideline on babies, children and young people's experience of healthcare that is in development (2020), NICE recruited6 members (out of 16), including 2 parents and 4 young people aged between 18 and 25, with experience of different aspects of healthcare.

Representing compared with representative

It is important to recruit patient and public members who represent the condition or issues of those affected by the guideline. A common barrier to effective involvement is the difficulty in recruiting people to the guideline group who can broadly represent the guideline without heavily focusing on their own individual subjective experience or agenda (Carroll et al. 2017, Légaré et al. 2011). The individuals should be able to represent the commonalities and different aspects of the condition in question. However, patient and public members cannot be representative of everyone or all the socio-demographic characteristics (for example, age, gender, ethnicity) that make up the population of concern. Therefore, developers need to consider multiple patient and public members, who might be patients, parents, carers or members of a patient organisation, to achieve such broad representation. Additional approaches to involvement should be considered to address gaps in representation (see the section on supporting individual patient and public members in this chapter).

Guideline developers and patient organisations report that a barrier to achieving sufficient representation on guideline groups is the lack of interest from patient and public members to get involved in guideline development. Solutions can be to engage other patient organisations who are associated with the health topic of interest. Alternatively, engage organisations who focus on a different condition that produces similar symptoms or experiences to the condition of interest. For example, if the guideline topic covers blood pressure then consider engaging organisations associated with coronary heart disease.

The experience, knowledge and skills required

After the role, type and number of patient and public members have been defined, developers should consider creating plain language information outlining the role and person specification. An important attribute of patients and public members is their experience of the condition and this should be included in the role specification. Exclude people who do not have experience but have only an intellectual or professional interest in the condition. Outline additional skills required, such as communication and team working skills. Ideally, recruit people who will actively contribute to group discussions and be able to represent the views of a wider patient or public group, which could be gained through membership of a support group or patient organisation. Depending on the roles and tasks of the guideline group, developers might need to recruit for different types of skills or they might need to recruit multiple people to achieve such diversity. The role and person specification should explain such skill requirements, what the work entails, the time commitment, expenses or payment arrangements, and what support or training is available. The SIGN 100 handbook for patient and carer representatives provides an example of the roles and skills required to be involved in guideline development (2019) and an example role description from NICE can be found in resource file 1.

The role specification should not disqualify people who may be able make a highly valued contribution to the group. For example, asking for academic levels of attainment or research experience can present a barrier to achieving genuine lay representation (Boivin et al. 2009). At RNAO and NICE, persons with lived experience are not required to submit a curriculum vitae when applying but are required to describe their experience relevant to the topic. Developers could consider

that certain knowledge or skills can be gained ‘on the job’ with adequate co-learning with project teams (for example, research terminology) or through formal training. Some courses exist online, either free or with a small charge (see resource file 2 for a list of training resources). A greater emphasis should be placed on ‘soft’ skills, experience or knowledge that cannot be learned in the role, such as having contact with other people living with the relevant condition and being able to reflect on their experiences.

To recruit 2 or more patient or public members with a range of experience, knowledge and skills, the following factors could be considered:

- relevant experience of the condition
- an understanding of the issues that matter to people with that condition
- the ability to reflect and advocate on the experiences of a wide group of people living with the condition gained from contact with people through patient organisations, forums or self-help groups
- the time and commitment to attend the meetings and complete associated work
- good communication and teamworking skills
- a commitment to maintain confidentiality
- declaration of interests, such as receiving funds from pharmaceutical companies.

Recruitment of patient and public members

Successful recruitment strategies are key to recruiting appropriate people with different skills and experiences (Boivin et al. 2010). Research suggests that a barrier to recruitment for clinical guideline developers is not having the resources to implement recruitment strategies (Armstrong and Bloom 2017b). Therefore, this section provides advice on a range of recruitment methods, some of which are cost neutral.

Nomination and open recruitment

There are 2 key methods of recruitment: open recruitment and nomination. In open recruitment, guideline developers advertise the post using the role and person specification. Applications are reviewed against criteria and the developer is responsible for selecting people who meet the criteria. Nomination is used when

developers approach patient organisations to nominate someone who, in their opinion, can reflect and understand patient or public issues relevant to the guideline. With nomination, the patient organisation is responsible for recruiting and the developer should not have any input. It is possible to combine elements of both approaches, but whatever method is selected it should be an accepted, transparent, and justifiable approach that can be documented.

Advantages and disadvantages of each method

Each method has advantages and disadvantages to consider when deciding which to use. These are outlined in table 1. In summary, open recruitment enables a wider range of people to become involved and is transparent. It helps minimise bias by allowing developers to choose between people from different geographical locations, treatment centres, and groups in society. However, it can increase bias if the developer chooses people who appear to be more ‘compatible’ with the interests or culture of the guideline group. To help avoid that bias, involve a suitable person external to the guideline team in the selection and ratification process, such as a patient involvement specialist. Open recruitment can be costly in terms of human resources and time compared with nomination. Timescales should account for developing recruitment criteria, administering the recruitment process, and reviewing applications. Templates of application forms and person specifications can help speed up the process.

Alternatively, nomination is rapid but can narrow the pool of potential candidates. To prevent this, a predefined nomination process should be outlined from the outset and strategies should be implemented to ensure people are nominated from a broad pool of candidates. Sometimes patients and public members recruited from patient organisations can pursue their organisation’s agenda. This should be prevented through induction and training that emphasises that the individual is to represent their experiences and those of others living with the condition.

If developers choose nomination as a method, they need to consider how this might affect the status of the individual within the group if the professional members had to compete to ‘earn’ their place. Conversely, if health professionals are nominated there may be no perceived unfairness. Open recruitment can increase patient and public members’ confidence by knowing that they were selected from a pool of applicants.

Regardless of the method selected, the way in which it was implemented needs to be documented and transparent.

Table 1 Advantages and disadvantages of open and nomination recruitment methods

-	Open recruitment	Nomination
Advantages	• Attracts a wider range of people • Reduces bias by recruiting people who are unknown to rest of guideline development group, which lowers the chance of people agreeing with group in fear of disagreeing with their own doctor • Phone interviewing shortlisted applicants helps screen out people with narrow perspectives and those who cannot reflect on broader patient issues. Advice from a patient and public involvement specialist can be helpful in eliminating unsuitable applicants • Attracts people with broader perspectives • Transparent - can answer questions about why certain people were recruited and demonstrate where procedures have followed equality legislation	• Less resource demanding • The guideline developer has no influence on the choice of the group members and so no risk of influencing group composition through selective recruitment • Could increase the chance of recruiting individuals who you might not have considered because of the joint expertise of patient organisations and people with specific aspects of a disease • In most cases, patients nominated by a patient organisation are trained in championing patient perspectives • Can be faster than open recruitment although it depends on how long it takes the patient organisation to respond • Can recruit patients with a background in user-led research or known ability to work well in groups • Assures that patient organisations decide themselves who is best to provide their perspective (respects patient autonomy) • May facilitate reaching specific seldom heard groups, especially if there are barriers to patients or public engagement

-	Open recruitment	Nomination
Disadvantages	• Time consuming • Costs of advertising, if paying for advertising to be placed • Costs of preparing and processing paperwork and applications • Risk of biased choice, that is, a risk that the guideline developer actively influences group composition in a way that 'easy to handle' patients are recruited • Needs rigorous and transparent documentation of the selection process to avoid risk of bias or being selective • If relying on patient organisations to circulate the advert, this could be perceived as nomination • Risks of failed recruitment - if the condition is rare or the affected population is less likely to use recruitment channels like the internet • Ethical concerns if organisations persuade a vulnerable person to apply and they are unsuccessful	• Risk of missing people with a very unique expertise and experience • When nominating from patient organisations, there is a risk of recruiting people with biased perspectives, such as those who have only had negative experiences of healthcare systems • Can exclude patients who have not had experience of similar work, but might still be able to make valuable contributions • May introduce bias. In some countries, nominated members from patient organisations could be associated with teaching hospitals, pharmaceutical companies or campaign organisations, and have different experiences from those in rural areas or general clinics • Risk of narrow patient perspectives if patients with a background in lobbying on one aspect of a condition are nominated • For some guideline topics (for example, rare conditions or symptom-based topics) there may not be any relevant patient organisations who can nominate patients • Some patient organisations may not have the capacity to identify appropriate nominees

Selection of methods in practice

The method to choose will depend on the developer's requirements and resources. Local circumstances may dictate which approach would work best. For example, in

countries with well-resourced or well-developed patient organisations, the nomination process can work well (especially for main condition areas like cancer). Open recruitment works well for well-resourced guideline development agencies with specialist patient or public involvement support (like NICE).

NICE uses open recruitment and has found that it leads to a range of individuals applying for the role, including many who are not associated with patient organisations. NICE advertises positions for patients and public members for 4 weeks thereby allowing patient organisations time to contact their members and for the advertisement to get maximum exposure through websites and other social networks.

The Dutch Institute for Healthcare Improvement (CBO) in the Netherlands, the German ÄZQ and SIGN in Scotland, recruit primarily through umbrella patient organisations, such as The Richmond Group of Charities or National Voices in the UK. The ÄZQ uses a predefined nomination method, which is outlined in detail in their manual (Sänger, 2008). It recruits from 4 umbrella organisations to ensure people are nominated from a broad pool of candidates. ÄZQ asks them to select all the patient organisations they think are appropriate for the condition in question, and then have a discussion with every organisation about the patients they want to nominate. This results in a list of members for the guideline development group for the developer, who then starts training and support for them. During the initial meeting, the guideline group is asked if there any expertise is missing from the group and the developer then seeks to fill any gaps in experience.

Advertising the role

Open recruitment works best when patient organisations, or healthcare professional organisations with public involvement functions, can inform their members of the vacancy by promoting it on their websites, through social media, email distribution or newsletters. Patient organisations can also provide advice on how to recruit people from seldom heard groups.

Healthcare professionals in the development group may also be able to support recruitment, either by advertising the opportunity through their networks or by nominating a patient. However, this can increase the likelihood of recruiting a patient

or public member who is treated by the same health professional on the panel. This should be avoided because it can prevent the patient from speaking freely during discussions.

If using social media to advertise, developers can reach a larger audience who are invested in the guidance topic by 'tagging' relevant patient organisations in any social media posts. Developers can engage seldom heard groups, such as black, Asian, and minority ethnic groups (BAME), on Twitter, Facebook or patient forums. Permission should be obtained before sharing any opportunities. Starting online conversations with public members who express interest in the recruitment opportunity can increase applications by addressing any concerns or queries that arise. This approach is relatively cost effective although time is required to build online relationships with the public. Not everyone has easy access to the internet, so additional methods of publicising the vacancy should still be used to reduce inequalities in the recruitment process. If seldom heard groups are not active on one form of social media (for example, Twitter) then they might be more active on another channel, such as Facebook. If not, it will be difficult to engage them through this means.

When advertising the role, state explicitly the kinds of support that individuals can receive to encourage more people to apply. This should be realistic and deliverable in practice. The section on supporting individual patient and public members describes the types of support that can be provided.

Documents for recruitment

It is helpful to publish the role and person specification (in both open and nomination recruitment methods), either as a detailed advertisement or as additional information to help applicants decide if they are suitable for the role. The application or nomination form should be well structured, which will make it easier for people to provide the relevant information. NICE also includes an equality monitoring form for applicants in line with the UK's Equality Act (2010). Guidance on this act can be found in the further reading section. The form collects personal information, such as age and gender, and can be used to evaluate and review the diversity of membership. The form is processed separately from the main application form to ensure anonymity.

To enable people with various disabilities to apply (for example, people with sight impairment), developers need to consider the accessibility of their information, such as ensuring documents can be read using a screen reader. Guideline developers should check government or organisation guidelines on accessibility for further information.

Interviewing candidates after open recruitment

Interviewing candidates after open recruitment can help overcome some of the known barriers to effective patient and public involvement. These include concerns over skills, breadth of experience and the ability to reflect on experience, objectively review the evidence, or work critically within a group. People who have had only negative experiences of care, or people who are opposed to the methodology behind evidence-based care, may not be appropriate candidates. Developers should consider how to interview people with specific health conditions or disabilities, or those who work full time. Interviewing over the phone or by video conference (for example, Skype or Zoom) are useful alternatives if some people cannot attend face-to-face interviews. Group interviews might also help assess communication and group working skills.

Making the appointment

Successful candidates should be notified in writing. Consider whether they should complete a declaration of interests form, to identify possible conflicts, and a contract. Some organisations designate alternate members at the interview stage in case the appointed member has a change in circumstance and cannot take up the role. But, in some cases, it may be better to re-advertise or get new nominations.

It is also important to ensure the recruitment process is fair and to document the process, including the reasons for who to recruit, to avoid any potential accusations about discriminatory practices. Unsuccessful candidates can be offered other involvement opportunities, such as being a peer reviewer. Candidates should have a named contact and details, so the developers know who contact for further information or to discuss the outcome of their application or interview.

Supporting individual patient and public members

Appropriate and adequate support strategies play a large part in overcoming barriers and facilitating effective patient and public engagement during guideline development. According to Armstrong et al (2017a), these include:

- practical support (for example, making reasonable adjustments to support people who are ill or disabled)
- informal support (for example, listening, advice and emotional support)
- financial compensation
- co-learning and training
- managing group dynamics
- enabling re-assessment and feedback on the patient or public member's role.

Practical support

Qualitative research suggests that practical support can consist of providing multiple shorter meetings instead of full-day meetings, providing the premeeting papers in good time before a meeting, providing physical resources (for example, paper versions of documents), and agreeing mechanisms for soliciting opinions (Armstrong et al. 2017a). However, individuals might have various practical support needs associated with their work and provision should be made for 'reasonable adjustments' to respect those needs. This might include changes to the physical environment for the group's meetings (for example, accessibility of the rooms). How meetings are conducted should be considered (for example, with a hearing loop induction system or chairing techniques in a virtual meeting), and the communication used in the group (for example, avoiding jargon and titles such as doctor, explaining medical and research terms, and agreeing appropriate communication channels, such as email). The length of meetings might need to be altered, and breaks added, if a person's condition affcets their level of concentration (such as those with pain or some mental health conditions). Catering requirements should also be considered for those with diabetes or other conditions affected by diet. If conducting virtual meetings by tele- or video-conferencing, provide regular breaks.

When to assess support needs

Patient and public members should have the opportunity to discuss their practical support needs at interview, on appointment, and throughout their role. This is because many physical and mental health conditions fluctuate, and additional needs might arise during guideline development. In some countries, the laws on disability discrimination or equality cover the provision of aspects of practical support. For example, the Accessibility for Ontarians with Disabilities Act (Thompson 2020) in Ontario outlines and enforces accessibility standards that developers would need to follow to remove barriers. This could include providing accessible formats on request.

Practical support examples

There are many examples of practical support for guideline developers to consider and include (but are not limited to):

- Making adjustments for people with sensory impairments, like providing large print documents, microphones in meetings, or a hearing induction loop system. An interpreter could attend guideline meetings to assist members who have hearing loss.
- Offering the chance to participate virtually by video call (for people with high-grade conditions that prevent them from leaving home, like late stage heart failure, or individuals who cannot attend a meeting in person).
- Providing hints and tips on having an effect in virtual meetings, such as keeping oneself on mute when not speaking and methods to get the chair's attention.
- Booking meeting rooms large enough for an electric wheelchair or other medical devices and stair-free access.
- Making adjustments for people who experience fatigue, such as longer breaks or having a room available in which people can rest.
- Adjusting the room lighting or lighting of screens, such as illumination levels, glare and direction.
- Providing chairs that meet the needs of individuals with musculoskeletal conditions.
- Creating a 'break out' room for young people, or anyone, to take a break if they find the meeting too emotional (for example, when discussing sensitive topics).

- Providing documents on coloured paper for people who have an autism spectrum condition or those with dyslexia. Also, providing documents in plain language, or at very low-level language and offering support to explain these for people with low literacy or numeracy.
- Providing a dedicated toilet for people who need one.
- Providing financial support for care for a dependent relative if a carer has been recruited, or for childcare if someone has children.
- Providing financial information to ensure any payments do not adversely affect individual's state benefits.
- Ensuring any food provided meet people's dietary requirements.
- Texting a person with dementia or with memory problems half an hour before a pre-arranged telephone conversation or to remind them that support is available.
- Having a neutral support person (to minimise bias) highlight the most important sections of papers to read or comment on, or ask them specific questions with a patient or public focus.

For some topics, a patient organisation could offer practical support to individuals. For example, for the NICE guideline on tuberculosis (TB) among under-represented groups (NG33; NICE 2019), members who had experienced TB were involved and received additional practical support from a homeless charity. This included use of a permanent address for communications because they lived in temporary homeless shelters, and access to a computer for communications between meetings.

Valuing members

Patients and public members largely volunteer their time to be involved in guideline development activities so their time, effort and value should be acknowledged. At a G-I-N PUBLIC workshop, patients collectively stated that being welcomed and respected for their dedication was more important than financial compensation for their time. However, taking part in guideline development for some people can mean taking unpaid time off work or can incur costs. The advantages of offering compensation outlined by INVOLVE (2011) include:

- Supporting equity of access, by compensating people for lost income if they must take time off work or arrange childcare, travelling costs, access to journals and technology, access to care or personal assistants and so on.
- Supporting equity of power in groups.
- Acknowledging the professionalism and contributions to public service of group members.

Types of compensation

As a minimum, G-I-N PUBLIC recommends providing expenses, such as travel costs or accommodation, and providing compensation for time and effort. Compensation might also cover carer or childcare responsibilities and should be fair and appropriate for their role. Compensation could be provided in other cases, such as for attending training events or other preparation work. Payment in kind, such as vouchers, can also be offered. This is likely to be governed by local and national policies. Whatever the type of compensation, developers should be transparent during recruitment about any compensation arrangements.

Lack of budget

Some organisations may rely on volunteers to conduct patient involvement. In this case, be clear in recruitment documents that volunteers are needed. A lack of funds to cover payment or reimbursement of expenses may affect the ability to recruit people, especially those from a lower socio-economic background. In rare cases, patient organisations may offer support. There may be policies or laws that govern unpaid work so check the local context.

Consideration for those receiving state benefits

In some cases, receiving a payment will qualify as paid work and could cancel any state benefits (unemployment or disability payments) received. Furthermore, payments may qualify as taxable income, which can affect members who are self-employed. In this case, expenses (for example, train tickets and accommodation) should be booked by the organisation and paid from organisational budgets, which should avoid the individual being taxed. There may be an organisation in your country who can advise on this. If so, get their advice before the recruitment stage so that enquiries from potential applicants can be answered.

Compensation in practice

NICE's lay member payments and expenses provides an attendance fee for patient and public members that covers either a half-day or full-day rate (2020a). Travel, subsistence expenses, accommodation costs and contributions to carer costs (for example, childcare or carer arrangements) are covered. NICE will book and pay for any such expenses so that the members are not out of pocket while they wait for reimbursement. If the member is an employee from a patient organisation, then it is possible to reimburse or pay the attendance fee to their organisation rather than the individual.

Informal support

Informal support might consist of emotional support and building trust and rapport, which can make someone feel welcome in their role. The amount of informal support someone might need will vary so it will need to be tailored to the individual. Some individuals might have a strong background in patient advocacy, committee work and decision making, whereas other people might find guideline development group work a completely new experience.

Methods of informal support

Examples of informal support include:

- Providing individuals with a key contact person who can help if they need further information or encounter any difficulties, either with practicalities or with the personal effect of working in a group.
- Offering to contact a 'peer group' of other patients who have been involved in previous guideline panels. Additionally, developers can offer contact with a one-to-one 'buddy', who is an experienced patient or public member at your institution. It is usually advisable to have someone who is not another member of the same guideline development group. Another contact could be a guideline project manager.
- Contacting each individual before the group's first meeting. This will provide an opportunity to address any questions about the first meeting and assess any additional practical or informal support needs for the meeting. It is useful for a key

contact person to introduce individuals to both the guideline group and the supporting staff.

- Following up each individual after the group's first meeting and any other key meetings. This will provide an opportunity to receive feedback of their experience and identify if anything can be improved for the next meeting.
- Making additional check-in calls or sending emails can be useful for specific tasks (for example, reviewing materials) to find out if any supports are needed.

Managing emotional impact

Taking part in a guideline development group can have an emotional impact for some individuals. They might become frustrated if they feel their ideas are not fairly considered, or they can become upset when the group discusses sensitive issues, for example. It is important that individuals discuss any difficulty they have early on. Guideline developers should make it clear that that these are normal reactions, not unprofessional, and they should identify any support networks and coping strategies if the need arises. If left unresolved, it could lead to patient members stepping down from the guideline group.

Informal support in practice

To provide informal support, NICE in England and the ÄZQ in Germany provide a key contact person for patient and public members, so that they know who to contact for support or to discuss any issues that arise. At NICE, the key person will contact the patient member before the first group meeting and this is an opportunity to confirm any additional support needs. They will also greet the member at the first meeting. After that, the key person makes contact by email after the first and second meeting and then every 3 months (for shorter guidelines) or 6 months by phone or email. NICE also provides the opportunity for new members to meet existing experienced patient and public members, either face-to-face or virtually, to discuss the guideline development process and their role. Individuals are also able to contact their key person at any point. Similarly, SIGN offers a buddy who can provide support on a one-off basis or throughout the guideline development process (SIGN 2019).

Sometimes patient organisations or support groups can provide informal support, particularly for specialist groups. For example, when working with migrant groups, the ÄZQ works with migrant interest groups who could help or give support for certain conditions when possible, such as diabetes.

It is also particularly important to develop trust and rapport with certain groups and this can involve considering specific cultural norms and traditions. In Canada, when working with indigenous populations, RNAOs integrate traditional cultural ceremonies or practices, such as sharing a gift of traditional tobacco or smudging, into guideline development processes. Providing culturally relevant support demonstrates respectful engagement and can establish trust and rapport between the individuals with lived experiences and the developers.

Training and co-learning

A barrier to patient engagement is the concern over whether the patient or public member has the skills and knowledge associated with research and group working to participate effectively in the guideline development process (Armstrong et al. 2017). As previously discussed, it is not necessary or advisable to only recruit individuals who have existing research and technical skills. Furthermore, patient members fear that professional members will dominate the meeting with their knowledge and ideas (Shippee et al. 2015). Training and co-learning are useful strategies to overcome such barriers and can increase patient confidence by encouraging capacity building, which is a fundamental principle of patient and public involvement. However, there are also concerns that too much training may result in ‘professional’ patients who no longer bring their individual experience. Even basic training in evidence-based medicine can automatically exclude people with low numeracy skills. Therefore, training should be tailored to the needs of everyone. An explanation of the difference between training and co-learning follows.

Training

Training should improve members’ confidence about their roles and how to make an impact in the guideline development process. Training is more formal than co-learning and can consist of 1 or more days of structured learning with specific

learning outcomes related to patient and public involvement in guideline development.

Training can include different topics, including:

- guideline development processes
- research methods and terminology
- technical skills
- critical appraisal skills
- specific guideline development knowledge (for example, GRADE)
- strategies for participating effectively in the group (for example, assertiveness)
- building positive working relationships
- managing group dynamics.

There are different formats for delivering training. It can be provided in-house, by an external organisation, patient organisation or international society (for example, the European Lung Foundation), or be self-directed (for example, online training). Large organisations might be better equipped to provide their own training either face-to-face or electronically, which might not be possible in smaller organisations. Organisations may choose to use external training events or courses covering research and critical appraisal skills. If neither internal nor external organisations can offer training, free online resources to support self-directed learning exist. Several organisations offer free online courses to patients and members of the public, including Cochrane and CUE – Consumer's United for Evidence-based healthcare. A list of courses and websites offering free training can be found in resource file 2.

Co-learning

One fundamental principle of effective patient and public involvement is co-learning (Nguyen et al. 2020). Co-learning differs from training because it is mainly informal and is an ongoing process that should occur throughout the entire guideline development process. It is the process by which patient and public members, professional members and the guideline developer team teach, learn and share research knowledge and skills together. The process also benefits professional members. There are several ways to encourage co-learning:

- Providing training on guideline methods and processes, research strategies and overviews of the evidence retrieved from a review at the start of a meeting. This could be in the form of a presentation or verbal description by the technical team to the whole group, with an opportunity for the group to discuss their understanding. Presentations or learning resources can also be sent before the meeting when appropriate.
- Providing an online repository for all documents and sections for different working groups, which might include a specific section for patient group members.
- Avoiding jargon, explaining technical terms in the meeting, and having a glossary of medical, or guideline-related definitions and acronyms. Professional members should be aware that it is also their responsibility to explain medical acronyms and terms. Different professional groups may have different terms for the same concept or use the same term, but with a different meaning.
- Providing resources, in the form of toolkits or a ‘hints and tips’ document that informs the individuals about their role, the processes and resources to support their work.
- Holding lay-friendly seminars on specific topics, such as health economics.
- Offering networking opportunities with other patient and public members, which can be face-to-face or through an online forum.
- Providing free access to online journals.
- Providing regular contact with a key contact person to discuss ideas and any issues.
- Providing feedback on performance to encourage learning and development.

Co-learning is a valuable process to consider, especially if your organisation cannot offer formal training. Networking opportunities can be provided either before the start of a group or during development in the form of a lunch, an event, a workshop or by providing people with contact details for other patient and public members. New members can meet more experienced patient members and discuss the guideline development process or how to contribute effectively. During development, the patient and public members may be willing to support each other by sharing contact details but local data protection rules need to be followed and details should not be shared without permission.

Training and co-learning in practice

NICE provides a formal full-day training event (either face-to-face or virtually through Zoom) for new patient and public members, including presentations and group exercises covering the following: research terminology, the guideline development process, critically appraising scientific research using the GRADE system, group working and skills, producing recommendations, and a chance to learn from experienced patient and public members. Similarly, the ÄZQ initially assesses patient and public member's training needs and provides them with reading materials, such as 'testing treatments' (Evans et al. 2011). If required, ÄZQ offers a full-training day, or shorter units, tailored to their training needs. Digital modules are also provided using software such as Microsoft PowerPoint with audio narrations.

In terms of co-learning, NICE's Public Involvement team delivers a presentation on patient and public involvement at the first group meeting. The developer team provides brief training on the guideline development process, the roles and responsibilities of staff, and health economics. Any learning materials are sent to members before meetings. Technical or research leads are available to answer any questions from all group members. Patient or public members are provided with a paper or digital toolkit of resources and information for working effectively. They are also given the chance to meet an experienced lay member before the start of some guidelines. Their key contact person will also provide knowledge, by telephone or email, on the various stages including consultation, publication, and action to support guideline implementation.

Re-assessment and feedback

Another strategy for enhancing co-development is through re-assessment of the roles and expectations and providing feedback on the patient and public members' performance throughout guideline development (Shippee et al. 2015). This process can identify areas for development, which can be addressed through further training and co-learning. It can also help to address barriers associated with performance, such as not contributing or attending, or advocating their own agenda, which undermines the guideline. The process can also highlight the need for additional practical support strategies and areas where the member is having the most impact.

Providing feedback can ensure continual upskilling of the participants and is important to ensure meaningful and valuable involvement throughout the development process. For those with limited committee experience, it can increase confidence by confirming they are fulfilling the role to an acceptable standard and contributing effectively. Furthermore, it can ensure that the members feel supported and valued, which enhances engagement by empowering the individual. For some guidance programmes at NICE that are longer than 1 year, assessment of the role and feedback is provided every 6 months during telephone check-ins, or yearly for more formal feedback by the group's chair.

Managing group dynamics

There is a large body of psychological and sociological literature on how groups form and behave, including the factors that create productive groups and the effects of power dynamics and status on the productivity of groups (for example, Forsyth, 2019). Power dynamics can occur as a result of age, gender, race, culture and socio-economic status, which largely operate at the unconscious level through stereotypes (for example, as discussed in Guinote and Vescio 2010). There are many useful texts focusing on this topic, which go beyond the scope of this chapter, some of which are listed in the section on further reading.

Understanding group dynamics is important and can help guideline development groups operate effectively and ensure that patient and public members' insight is included. This responsibility largely lies with the chair or moderator of the group and some useful general strategies are:

- Highlight the importance of patient and public involvement: Consider delivering an early presentation to the guideline development group on the importance of patient and public involvement. Stress that these members have equal status with valuable contributions and provide examples of where patient and public members have had an impact on previous guidelines.
- Chair training: Brief the chair to discourage the use of medical and other jargon in meetings, which can exclude patients. Ensure they have the skills for running effective and inclusive meetings and understand the importance of meaningful patient or public involvement (see the chapter on how the chair can facilitate

patient and public involvement). At NICE, chairs are assigned to topics in which they have no professional experience so that they remain objective and limit bias, rather than trying to contribute their own opinions.

- Management of the meeting: Patient and public members should not be seated in an isolated area of the meeting and should be able to get the chair's attention. The chair should be briefed to bring the patient and public member into conversations, and some groups find it helpful to have a specific agenda item on patient and public matters associated with the guideline.
- Relationship building: Encourage individuals to identify potential allies in the group who can be a source of support for patient and public members during meetings. Alternative methods should be considered if meetings are conducted virtually when individuals need to connect by email, telephone and other digital means of communication.

The upcoming chapter on how the chair can facilitate patient and public involvement has further information on this topic. It is important to reassure patient and public members that their experience may differ from other patients and public members. Confirm that this difference of opinion is encouraged, and they should share this with the guideline group.

Overcoming barriers to involving those who are seldom heard

Throughout this chapter, we have highlighted several generic barriers and facilitators that guideline developers can take into account when recruiting and encouraging meaningful involvement of patient and public members in guideline development. These barriers and facilitators are summarised in table 2. Although these can apply to all patient and public members, including those who are seldom heard, there are specific barriers and facilitators to be considered when guideline developers cannot recruit patient and public members or when specific groups of people might have very specific support needs because of:

- age, such as babies and children
- circumstance, such as those living in prisons and other secure settings, or

- condition, such as people with learning (developmental) disabilities, or severe and complex mental or physical health conditions.

Table 2 Summary of generic barriers and facilitators for recruiting and promoting effective patient and public involvement in guideline development

Barrier	Facilitator
Developer unclear of recruitment strategy in terms of the number or type of patient or public members to recruit to achieve genuine representation	Consider open recruitment as opposed to nomination methods, including where to advertise. Recruit through patient organisations and social media (for example, Twitter, Facebook and other online patient or support forums). Recruit at least 2 patient or public members who might be patients, carers, parents or advocates from patient organisations. The organisations should represent a breadth of views and experiences associated with the guideline and other important socio-demographic (for example, age range) factors. Re-advertise the position if there are no suitable applicants. Consider other involvement methods.
Developer or patient or public member unclear of their role in guideline development	Plan the role and associated tasks early in the planning phase. Develop and advertise a role description and person specification. Consider patient demographics and characteristics. Provide induction materials and discuss the role requirements before the first group meeting.
Scheduling and planning, such as meetings clashing with personal commitments	Ensure meeting dates are planned and shared with all guideline group members in advance of the first meeting. This will allow patient and public members to plan and arrange any necessary time off work or childcare arrangement, for example. Any changes to meeting dates must be communicated and agreed with all group members and communicated as soon as possible.
Lack of relevance of the scope to patient and public members	Involve patient or public members early in guideline development and invite them to smaller scoping groups. If this is not feasible, then involve a patient advocate from a patient organisation to represent the views of patient and public members in scoping discussions.
Gaining meaningful involvement or avoiding tokenism	Interview applicants to ensure they have the right skills and experience and recruit early so they can contribute to the topic prioritisation or scope development stage. For meaningful engagement, include members in strategic decision making (for example, in developing the scope), development of decision aids, or implementation strategies.
Patient and public member not respected, not seen as equal, or feeling devalued	Make certain that the group's chair understands group dynamics and ensures equal power balance, including a right to vote to reach consensus and providing feedback on patient contributions. Include a specific slot for patient and public members to provide input during discussions. Encourage relationship building between patient and public members on the same group or with health professionals to build allies.
Achieving a breadth of perspective	Recruit members according to their personal experience of guideline topic, wider understanding of patient issues from patient networks or support groups, and soft skills (for example, communication skills).

Barrier	Facilitator
Recruitment can be resource intensive or costly	Use nomination as a recruitment strategy through patient organisations, if possible. Use social media to advertise.
Lack of methodological expertise, skills or knowledge related to guideline development	Deliver or signpost to relevant training (for example, research methods and critical appraisal skills) and consider ongoing co-learning (for example, presentations in meetings) or regular feedback on performance.
Lack of confidence to speak up in a large group of experts	Consider including hints and tips in induction materials, training, and also in catch-up calls with a patient and public involvement specialist, or key support person. Peer support from other patient and public members from previous or different guideline groups can help.
Supporting people with a range of practical support needs	Assess support needs early in the recruitment phase and continue to re-assess throughout guideline development. Make reasonable adjustments and offer practical and informal support through. During development, conduct regular check-ins (by email, phone or video call) to identify issues or to assess ongoing support needs.
Lacking peer support	Recruit more than 1 patient and public member. Offer a 'buddy' or a chance to meet or talk to someone from a previous or different guideline group to discuss the role and any issues at the beginning and throughout guideline development.
Limited funds to re-imburse members	Consider vouchers (gift in kind), offer free training to upskill members to improve their curriculum vitae. If possible, pay travel expenses or offer virtual participation in meetings (for example, using video-conferences or tele-conferences).

The remainder of the chapter will discuss alternative approaches to involvement and specific considerations for different groups who are seldom heard, such as children or people with learning disabilities.

Alternative approaches

Specific groups of people might not be able to be full members of the guideline development group (for example, children or people with advanced dementia). In addition to involving parents, carers and advocates, there are alternative approaches to involving people with the condition or from the affected population. These include a reference group, additional sources of data on patient and public views, patient expert testimony, consultation using research methods.

Reference groups

A reference group in this context, is a group of people who use the relevant services or experience a particular condition. They can help the guideline group identify patients' perspectives and priorities at key stages of guideline development. Reference groups have the advantage of generating a wider range of patient and carer views by including people with different experiences of the condition, treatment and care, or people from a specific socio-demographic background. For example, for the NICE guideline on child abuse and neglect (NG76; 2017), the developer commissioned an independent charity to recruit and facilitate a reference group to inform the guideline group's deliberations and development of recommendations (Fielding et al. 2018). If considering involving a reference group, guideline developers should carefully plan the work including:

- the objectives
- involvement methods
- time and costs
- travel arrangements and incentives or reward for participation
- demographics and other characteristics or experiences of the group
- ethical issues, such as safeguarding
- methods for presenting findings to the guideline development group.

The work of the reference group should be facilitated by people with expertise in facilitation and a track record in working with the group of interest.

Additional sources of data on patient and public views

In addition to using peer-reviewed literature, guideline developers may find relevant information on patient and public views and experiences in surveys conducted by stakeholder organisations. SIGN, in Scotland will contact relevant patient organisations and charities before starting the development of a guideline (SIGN, 2019). They are asked for their views on the important issues that they think the guideline should focus on. Their input on these issues could be based on data gathered through surveys or telephone helpline experience.

Patient and the public views and experiences can also be found on patient forums or patient-focused websites. For example, a UK-based reputable website, HealthTalk,

covers many health conditions or groups, such as young people. It is informed by the Health Experiences Research Group at Oxford University's Department of Primary Care. The team uses rigorous qualitative research methods to capture the full range of patients' experiences associated with each health issue, condition, or intervention. Similar websites exist in other countries (for further information, see the section on consulting patient and public members using online engagement methods in the chapter on how to conduct public and targeted consultation).

Patient and public expert testimony

When there are gaps in the patient and public evidence, an alternative option is getting such evidence from the expert testimony of people in the affected population (in person, in writing or by video). Such expert testimony may be sought one or more times during guideline development because the need for expert testimony may only become apparent later in the process. It is important to support the individual providing the testimony. Support should include giving them information about the guideline group and what information is required, and preparing them for questions they may receive. Stakeholder organisations may also be able to support people providing a testimony. At NICE there is no minimum age for people providing expert testimony, but if they are under 16 years, or a vulnerable adult, they must be accompanied by an appropriate adult with responsibility for their welfare. When children or vulnerable adults contribute evidence to meetings, the testimony might need to be given through a video-recording or in a closed, confidential session if meetings are usually held in public.

Consultation using research methods

When important gaps in the evidence are unlikely to be filled through consultation with stakeholder organisations or using any of the above approaches, some guideline developers may consider consulting the affected population using research techniques. This is an exceptional option requiring additional resources. Types of methods and when to use research methods for consultation have been covered in detail in the chapter on how to conduct public and targeted consultation.

Involving people who are seldom heard in guideline development

Developers are likely to produce guidelines for a range of topics where the barriers to involvement can be greater for certain people. This section considers 3 groups of people: children and young people, people with learning disabilities, and people with severe and complex mental health conditions.

Children and young people

The UN Convention on the Rights of the Child (UNICEF 2016) enshrines the rights of children to be involved in decisions that affect their lives and to be heard. In the UK, health researchers, policy makers and services have increasingly engaged children and young people in matters that affect their health and wellbeing. Qualitative research indicates that children can provide their views, including those who are less articulate because of age, ability or culture. It also suggests that most children are acutely aware of the way in which they are treated, and their perceptions do not mirror those of adults (Doorbar et al. 1999). However, guideline developers find involving children and young people difficult and have several questions concerning when and how to involve children and young people (Schalkers et al. 2017). Some strategies for addressing common questions follow.

When should children be included in guideline development?

There is consensus that developers should seek the views of children and young people when the guideline specifically looks at a condition that affects this group or when the treatment or disease affects children differently compared with adults (Schalkers et al. 2017). It is likely that their views and experiences will differ from adults around symptoms, treatments, side effects, recovery, and care. An addendum to guidance for adults could suffice if the experience of the disease for children does not differ that much from adults.

Developers may need to prioritise involving children and young people in certain guidelines over others. Schalkers et al (2017) list 14 criteria for supporting this decision, with the top 3 criteria being when:

- there is a clear expected health benefit for children
- professionals identify that guidance is needed for children

- there is difference of opinion between professionals around the treatment of children.

The criteria that are least important in deciding whether to involve children are when the disease has high expected healthcare costs, the lack of availability of scientific evidence, and when the focus is on pharmacological treatments.

What is the minimum age of children for involvement in guideline development?

Developers can be concerned about the ability and competence of a child or young person to be able to understand, contribute to and engage in decision making. The UN Convention on the Rights of the Child defines a child as a person under 18 years (UNICEF 2016), as does UK child protection legislation. In the UK, a child is deemed competent to decide about their treatment without parental or guardian consent from 16 years. This is the minimum age for a young person to join a NICE guideline development group without being accompanied by an appropriate adult. However, mental capacity should be considered. Some young people aged 16 and over might have a specific vulnerability, such as a learning (developmental) disability, and would need to be accompanied by an appropriate adult. But a child under 16 years, who does not have a specific vulnerability, might demonstrate sufficient mental capacity, known as Gillick competence, and be able to contribute to decision making.

Qualitative health research has demonstrated that children as young as 6 can share their views and provide useful information (Gibson 2007). However, young children would be unable to participate in a guideline development group and additional approaches to elicit their views would be needed, such as focus groups or reference groups. There may be country-specific age thresholds and so developers should consider local legislation and policies on children and young people, and their mental capacity.

Should a parent or primary caregiver provide the views of children?

One debate that could arise is whether parents or caregivers should provide the views of the child younger than 16 years. At NICE, an appropriate adult would likely need to be involved in a guideline group if the child is under 16 years. Although NICE acknowledges that parents and carers can bring valuable insights, they should not

be regarded as a proxy for children. If guideline developers have the available resources, it is useful to work with a specialist external organisation, or a stakeholder organisation, with expertise and access to appropriate networks to elicit views from children.

How do you recruit children and young people?

Strategies outlined in this chapter also apply here, particularly working with relevant patient organisations, charities or other voluntary and community organisations for children and young people. Advertising on social media can also be useful for parents to identify the involvement opportunity for themselves and their child.

How do you involve children and young people and what approaches can be used to elicit their views?

NICE has developed a systematic approach, outlined in the NICE manual for developing guidelines, to ensuring that the views of children and young people are included in guideline development for relevant topics (NICE 2020b). The approach also includes involving parents or other family members. There is much research in the social sciences on how to elicit the views from people of different age groups, and it highlights the need for age-appropriate techniques (see Gibson 2007). But it is likely that for working with young and very young children, specialist input and training from an external organisation will be needed. Some general strategies to consider when involving children and young people aged 16 to 25 years are:

- Involve children and young people in a meaningful way, setting out clear objectives and working with sensitivity and flexibility, especially if the topic is sensitive.
- Consider measures for protecting the safety and welfare of children, including following local ‘safeguarding’ policies.
- Make adaptations, such as providing age-appropriate training, ensuring the chair asks specific questions or provides opportunities to contribute during meetings, and allowing regular breaks.

SIGN involved children and young people in the development of its guideline on diagnosis and management of epilepsies in children and young people. Two young people were full members of the guideline development group. Young people,

associated with Epilepsy Scotland, engaged in an interactive session to discuss the issues identified from a patient-focused literature search. They explored what the additional priorities were for them and whether there were any other issues that the guideline group should consider. For further information, the Royal College of Paediatrics and Child Health provides guidance on how to involve children and young people in committees (2018; see the section on further reading).

People with learning disabilities

People with learning disabilities and their carers are increasingly being involved in guideline development groups (Caldwell et al. 2008). Although it is important to follow the guidance in the sections on the role of patient and public members, their recruitment, and supporting individual patient and public members, guideline developers must consider very specific reasonable adjustments to meetings and practical support to encourage meaningful involvement. Table 3 lists several considerations and adjustments that have been documented in the literature and implemented in NICE guidelines on learning disabilities (Caldwell et al. 2008; Karpusheff et al. 2020). There is no exhaustive list of strategies, but they can be categorised into accessibility of meetings, communication adjustments, environmental adjustments, financial support, and transportation.

Table 3 List of reasonable adjustments for supporting people with learning disabilities

Category	Adjustment strategy
Meeting accessibility	• Provide physically accessible meeting locations • Be aware of the pace of the meeting – not too fast • Provide opportunities for discussions and questions • Ensure members with learning disabilities have had the opportunity to give input by asking them what they think and making them feel comfortable to talk • Provide meeting papers a few days in advance of the meeting • Prepare the individual about the topic of meeting discussions in advance of the meeting
Communication adjustments	• Consider whether sign language interpreters are needed, as well as closed captioning services and amplified hearing devices • Create easy read versions of meeting documents, including large print, or use braille or disk formats. Avoid jargon and use simple language
Environmental adjustments	• Consider scent-free meeting environments or rooms with specific lighting
Financial support	• Consider paying expenses, and accommodation and travel costs upfront because some people with learning disabilities do not have the financial capacity to pay for costs upfront • Offer childcare support or cover costs of a carer, support worker or other advocate • Provide an honorarium or stipend if possible
Transportation	• Offer transportation options, such as a taxi or cab from and to home, train station, airport and bus station

Support and reasonable adjustments will need to be tailored and continually assessed throughout the guideline process through regular contact and feedback from the individual and the group's chair. At NICE, a key contact person was beneficial for supporting individuals with learning disabilities to formulate their ideas before and after the meeting.

People with severe or complex mental health conditions

People living with severe or complex mental health conditions (for example, psychosis, alcohol misuse or schizophrenia) still experience barriers to participating in guideline development (van der Ham et al. 2014). There are several specific

barriers and facilitators to consider, which van der Ham et al. (2014 and 2016) have reviewed in detail. In summary, guideline developers could consider the following:

- Value and contribution: People living with mental health conditions may be perceived as unable to make valuable contributions or valid statements about different therapeutic treatments (medical or psychological) because of their impaired cognitive state. This can be an inaccurate assumption. A review of mental health guidelines in the Netherlands revealed that the number of patient members with mental health conditions on a guideline group ranged from 2 to 5 per guideline (van der Ham et al. 2014). For Norwegian guidelines on mental health, 5 user representatives had significant influence in scoping the topic and formulating recommendations (Helsedirektoratel [The Norwegian Directorate of Health] 2013).
- Recruitment and representation: Gaining sufficient representation across the different classifications of mental health conditions can be difficult if the guideline topic is broad. Recruiting through patient organisations can help but could lead to over-representation of a particular mental health condition, depending on the focus of the organisation. In this instance, multiple recruitments and additional involvement methods will help gain representation, including incorporating existing patient research, panel or dialogue meetings, questionnaires or user focus groups, case studies or personal narratives. However, depending on available funds and resources, guideline developers will need to find a balance between gaining in-depth insight that requires fewer participants (for example, case studies) and methods that give broad perspectives but require large numbers of respondents (for example, questionnaires). If the right level of perspective is not achieved, there is a risk that patient organisations will reject the guideline, which would prevent it from being implemented.
- Topic of interest and scope: Members with mental health conditions are likely to be less interested in traditional biomedical approaches and more interested in holistic approaches, social support, quality of life, and non-medical implications, for example, the ability to retain employment (van der Ham et al. 2014). Such factors should be considered in the scope of mental-health related guidelines, and their inclusion is achieved by inviting mental-health related patient organisations to scoping meetings at NICE.

- Dropout and support: Dropout from a guideline group is a risk that developers will need to consider from the outset. Mental health can vary and fluctuate over time leading to patient members either joining the group late or resigning. Additionally, patient members might struggle to read lengthy guideline documentation. Solutions involve recruiting multiple patient members and providing and adapting specific content and process-related support. For example, documents should be summarised or discussed with the patient members before a meeting and a key contact person should have regular contact with the patient member throughout the guideline process. Developers could also consider enabling input for specific parts of the guideline that need the patient's perspective. For the NICE guideline on violence and aggression in mental health and community settings (NG10; 2015), the developer encouraged peer support by providing a room for 4 patient and public members to meet before and after meetings to support each other. Members often experienced fluctuations in their conditions resulting in non-attendance at meetings. Peer support empowered the members to share experiences, encouraged a healthy critical debate, and ensured opinions were voiced in meetings.

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Resources

Resource file 1: Example role description

What we're looking for and what's involved

What is a lay member?

We use the phrase 'lay member' to refer to a member of one of our committees who has personal experience of using health or care services. The phrase can also mean someone from a community affected by the committee's topic area or an advocate or unpaid carer.

What will the committee be doing?

The committee will look at the evidence that is available, and develop NICE guidance on Thyroid cancer: assessment and management. The NICE guidance will be written recommendations about the best types of treatment, support and services.

For more information about our committees and what they do, visit the committee area of our website.

What knowledge and experience will I need?

We're looking for people with an understanding of Thyroid cancer: assessment and management and the issues important to patients, people using services, unpaid carers, communities and the public.

As a lay member, you will have this understanding:

- through personal experience you have of treatment and care provided for you by the NHS
- as a relative or unpaid carer of someone who has used relevant health services
- as an advocate, volunteer, or officer of a relevant charity or organisation.

You will also have:

- good communication and team-working skills
- the ability to listen and take part in constructive debate, while being respectful of other people's views

- knowledge of the experiences and needs of lots of people which gives you the ability to champion a range of different perspectives on this topic.

Who sits on the committee?

NICE committees develop our guidance. As well as lay members, committees are also made up of professional members. This includes people who work in health or social care, as well as a range of other roles.

Lay members have the same status and carry out the same functions as other committee members.

What does the role involve?

- attending committee meetings (see time commitment below for more information) and taking part in discussions to shape the guidance
- reading committee papers
- commenting on documents between meetings
- keeping the committee's work confidential.

What am I expected to do?

- Make sure the views, experiences and interests of patients or people who use health and social care services are taken into account by the committee.
- Identify areas of concern to people using NHS, public health or social care services.
- Review topic information and the draft guidance from a patient, service user, carer or community perspective. For instance, does the information address issues important to people affected by the guidance? Does the guidance take their views into account?
- Make sure the guidance considers people from different backgrounds.

How much time will I need to give and where?

It's important that you are available for the committee's meetings.

- Meetings for this committee will take place from 1 May 2020
- Committee meetings will usually last for 1 day, but sometimes 2 day meetings are held
- The meetings will happen every 4-6 weeks for a period of 18 months
- The meetings will take place in central London
- If you are appointed, you will be invited to a training day in Central London on 12 May 2020

What's in it for me?

- You will be helping to make national and local health and social care services work better for patients, people who use services, carers or the public.
- Previous lay members have said they found their confidence improved, as well as developing other skills like public speaking and critical thinking.
- Being a member of a NICE committee shows you are an expert by experience. It also shows you are able to work in a team, as an equal contributor to the committee alongside healthcare and other professionals.

What support will I get?

A named member of the public involvement team will be available throughout your time working with us, to offer help and support.

You will be offered training and guidance to make sure you feel confident on the committee, as well as regular chats with your named contact.

If you have any special requirements, for example access or travel needs, we can discuss this with you and make adjustments where needed.

What happens after I apply?

The public involvement team passes on applications to the team running this committee. Your application is then shortlisted against the required skills and abilities set out in this document.

If you are shortlisted you will be contacted for a phone interview to talk about the position, your application and what is involved before a formal invitation is offered to sit on the committee. The date for interviews has been set for the 14 and 17 February 2020. They will take place on the phone and will last no more than 30 minutes.

More information

For more information about becoming a member on this committee, read our additional information.

This gives more information about:

- payment and expenses, including how this could affect any benefits you receive
- how we can help you to apply if you have a disability
- how we monitor equality and diversity in NICE's work
- what we expect from our committee members
- what might prevent you from sitting on a NICE committee
- how we will use the personal information you give us
- what you can do if you're not happy with our recruitment process

Resource file 2: List of training resources

Title	Description	Website	Cost
Cochrane Evidence Essentials	Modules cover: Evidence-based medicine, randomised controlled trials, introduction to systematic reviews, and understanding and using systematic reviews	https://training.cochrane.org/essentials	Free, login required
CUE - Consumers United for Evidence-based Healthcare	Multiple educational resources and free courses covering: evidence-based healthcare, FDA and the regulation of healthcare interventions and advisory panel engagement resources. There is a video covering consumer involvement in guideline development.	http://consumersunited.org/education&training http://consumersunited.org/rrguideline	Free
EUPATI: Patient engagement through education	Toolkit of resources and a course on patient engagement and medicines research and development	https://eupati.eu/	Application process for course. Resources are free.

Title	Description	Website	Cost
Coursera	Coursera is a platform that hosts free and paid courses offered from reputable institutions around the world. There is a range of courses on research methods, statistics, and quantitative and qualitative research methods. Many other courses are offered that might be relevant to specific guideline topics, such as public health courses.	https://www.coursera.org/	Most courses are free, unless you want a certificate. There is a fee for specialisations, which are a series of courses.
Future Learn	Future Learn is similar to Coursera and offers courses from reputable institutions covering many aspects of healthcare and medicine, science, psychology and mental health topics that might be relevant for specific guideline groups.	https://www.futurelearn.com/	Courses are free for 6 weeks with the option to pay a fee to upgrade.

Title	Description	Website	Cost
Testing Treatments	A valuable resource on critically appraising treatment claims. The book is available for free in PDF and audiobook formats. The book is available in different languages. The website also includes an interactive toolkit of additional resources.	https://en.testingtreatments.org/	Free
The NICE glossary	NICE provides a glossary and definitions of the terms used in guidance development	https://www.nice.org.uk/glossary	Free
Bandolier	The website provides a free resource of journal articles related to evidence-based medicine. There is also a learning zone with free articles related to different aspects of trials, meta-analyses, statistics, guidelines and health economics. A glossary of terms is also provided.	http://www.bandolier.org.uk/ http://www.bandolier.org.uk/learnzone.html http://www.bandolier.org.uk/glossary.html	Free
HTA Glossary	A free glossary for members working in health technology assessments.	http://htaglossary.net/HomePage	Free

Role of the guideline committee chair in supporting patient and public involvement: recruitment, training and support

Authors: Victoria Thomas, Jane Cowl

Corresponding author: victoria.thomas@nice.org.uk

Key messages

- When a guideline agency commits to involving patients and the public in its processes, its committee chairs need to be committed to this principle and to support guideline development committees with patient and public members.
- If the chair of a guideline committee is properly recruited, supported, and trained to be facilitative and inclusive, successful patient and public participation in the guideline's development is more likely. A skilled chair can improve group dynamics by empowering patient/public members, who can then contribute more meaningfully.
- A skilled and well-trained chair will ensure that their guideline committee is an integrated group in which all members are treated equally and can contribute to the best of their ability.
- Good chairing will lead to good group dynamics so that committee members feel able to challenge and discuss the evidence presented to them in a rigorous but respectful way.
- All guideline committee chairs, however skilled and experienced, need support, induction and training to ensure they understand the specific requirements of the guideline development agency. All newly recruited chairs should be encouraged to take advantage of any training on offer.
- In recruiting or identifying guideline committee chairs, facilitation skills are more important than topic expertise because others on the committee will have this knowledge.
- All chairs need to commit to developing guidelines within the framework of the guideline agency's established principles of working, methods and processes, and

organisational culture. This might include use of language according to the agency's corporate style guide.

Top tips

- Recruit your chairs openly and transparently or be clear about how your chairs are identified and selected.
- Train and support your chairs, weaving in patient and public involvement rather than having it as a stand-alone training module.
- When inducting your chairs, make sure they have the opportunity to hear from someone who has previously chaired a guideline committee within your agency, which included patient/public members.
- Offer your chairs regular appraisal and feedback on their performance and encourage them to offer something similar to their committee members.
- Offer chairs reimbursement for their time or reimburse their employers for the time they take working on the committee.
- Consider patient/public chairs – they may have valuable expertise your agency could benefit from.

Aims of the chapter

This chapter describes the method for recruiting, selecting and supporting the chairs of guideline committees (GCs), developed for the National Institute for Health and Care Excellence (NICE) in the UK. The model places particular emphasis on involving and engaging with patient/public members (known as 'lay members' at NICE) of GCs as an integral part of the overall responsibilities of chairs.

Interactive discussions throughout an induction session take account of this aspect of the chair's role, alongside other elements that NICE feels are important. The approach described has been developed over time, specifically tailored to the needs of the chairs of NICE GCs. Elements of the model will be generalisable to other organisations, even when the NICE guideline development process and methodology is not being used.

The context for the process described in this chapter is the NICE policy for including patients and/or members of the public on all of its standing and ad hoc advisory committees.

Readers of this chapter should gain an understanding of:

- key issues for inducting and supporting chairs of GCs
- a sample mechanism for recruiting and selecting GC chairs
- the inherent value in providing formal and structured induction for chairs of GCs
- particular issues for chairs of groups with patient/public members
- organisational and resource implications for adequately supporting and inducting GC chairs
- the barriers to effective chairing, and some potential solutions for overcoming them.

Terminology

Guideline committee

NICE uses the term 'guideline committee' to refer to the decision-making groups that develop its guidelines. Other agencies may use different terms such as 'guideline development group' or 'guideline panel'.

Patient/public members

For the purposes of this chapter the term ‘patient/public members’ is used throughout to describe the people NICE terms as ‘lay members’. The patient/public members of NICE’s GCs are recruited as individuals with a breadth of knowledge and experience about a particular topic, population, disease, condition or disability. They are not considered ‘representative’ of any particular group, organisation or patient population. We recognise that other terms are in common use but in this context ‘patient/public member’ refers to people with personal experience of a disease, condition or service (patients, consumers, users), their carers or family members, and those representing a collective group of patients, people using services or carers (representatives or advocates).

NICE’s approach to inducting and supporting GC chairs

Background

A NICE GC is a multidisciplinary group, supported by a technical team (systematic reviewer, information specialist, health economist). It is an advisory group to NICE and sits independently. As a minimum, a GC comprises:

- healthcare professionals, and for relevant topics, public health or social care practitioners (both specialists in the topic and generalists)
- patients, carers or members of the public.

The role of a GC chair should be rooted in the cultural norms of an organisation in terms of its identity and the methodological approaches it takes to guideline development. The wider legislative and policy framework within which the guideline agency operates is also relevant to the chair’s role. For example, legislative and policy imperatives to promote equality. NICE’s GC chairs are responsible for running independent groups, but knowledge of the methodological and process expectations of NICE is crucial in ensuring the chairs can run a group effectively.

Chairs must focus on their main objective, delivering a high-quality guideline, within the resource and time constraints allowed. If a guideline developer has yet to establish explicit methods and processes, the chair should apply core principles that

are recognised as key to good quality guideline development (such as the AGREE II criteria [Brouwers at al. 2010]).

We strongly believe that the underlying philosophy of involving patients and the public in guideline development is important. It may well support guidance development organisations when convening such groups, and in chairing them in a facilitative and inclusive manner.

Training for chairs

In May 2006, the World Health Organization (WHO) conducted a review of NICE's guidelines development programme (de Joncheere et al. 2006), and made several recommendations. One was that chairs of GCs should be recruited through a standard process, preferably through open advertising, and that NICE should develop standardised training for GC chairs.

The first of these recommendations was quickly adopted. NICE developed an 'induction' programme, discussed more fully in the section on NICE's chairs' induction programme. It addresses, among other things, the involvement of the patient/public members of the GC. This approach reflects the results of reviews carried out by NICE's Public Involvement Programme, which identify the role of the chairs of GCs as crucial to the success of the way the GCs function and how well GC patient/public members feel integrated into the group and its workings. GC patient/public members have variously described characteristics of 'good' chairs as:

- *'inclusive'*
- *'skilled'*
- *open'*
- *'honest'*
- *'able to influence'*
- *'encouraging healthy rivalry'.*

One patient/public member said of their chair *'He went to some length to draw out or ensure that the patient/lay view and information was given to the group, and that the patient/public members were on an equal footing to the professionals'.* Another said *'The Chairman was very accommodating to the patient/public members but not so*

awfully PC [politically correct] that he was not averse to arguing with them; in short he behaved like a reasonable human being'.

The PIP's evaluations revealed that the patient/public members felt that the chairs could either be 'weak' or 'skilled'. This perception depended on how well they managed their guideline group and how well they offered appropriate support to the patient/public members of the group.

As found in studies of other kinds of small group work (such as in Elwyn et al. 2001), the PIP's evaluations found a relationship between the skills of the chair and the success of the group. The chair is clearly a key element determining how well a GC functions. Success, or otherwise, of a group rests on the skills of the chair.

Recruitment of chairs

Each guideline agency will have different models for chairing their GCs. NICE recruits external independent chairs whereas other agencies may recruit skilled moderators from the agency's staff or well-known topic experts. This section details NICE's approach to recruiting chairs.

To ensure transparency, NICE adopts an open recruitment process, whereby anyone with an interest can apply to chair a group. NICE's appointments to advisory bodies policy and procedure, a corporate recruitment policy, has been developed to support this (2020). Potential chairs must submit an application (as they would for a position of employment), and then a formal process for selection and recruitment follows.

Applicants are assessed against criteria in a 'role description', and then short-listed. Short-listed candidates are interviewed by a panel comprising senior staff members and a member of the NICE Board. Further information on vacancies for chairs of NICE groups can be found on NICE's join a committee webpage. GC chairs are most often health or social care professionals with extensive commitments, although NICE has experience of recruiting lay people to chair its committees.

This process, although transparent, carries a significant administrative burden, for drafting recruitment paperwork, short-listing the applicants, and the interview process itself. But, because this follows a standardised process, after the template

recruitment documents have been developed, they only require minor amendments to tailor them to each new recruitment.

NICE's chairs' induction programme

Because of the WHO report and the subsequent reviews, a programme for inducting GC chairs was developed jointly by NICE's Centre for Guidelines and NICE's Public Involvement Programme. It was specifically tailored to NICE's needs and the context in which it works.

NICE operates a mixed model of guideline development in which many of its guidelines are developed by 2 external contractor organisations, according to methods and processes set out in the publicly-available NICE guidelines manual. A new chair is recruited for each GC addressing each new guideline topic but some chairs are recruited to a broad topic area, such as diabetes, obstetrics, weight management.

Alongside the work contracted externally, some of NICE's guideline development work is undertaken 'in-house'. These guidelines are developed by GCs with a pool of chairs who oversee the development of a variety of guidelines on different topics. NICE invites both newly recruited GC chairs and chairs from this pool to attend induction sessions with their peers.

The induction process for NICE's GC chairs is constantly reviewed and refined, reflecting the accumulated experience of GCs, their chairs and members, and, importantly, changes in the guideline development methods and processes. During the COVID-19 pandemic, NICE's chairs' training was adapted for the online environment.

At NICE, the chair's role in supporting the patient/public members of the GC is part of the overall induction programme, and discussion of this is woven into the different sessions. This emphasises that patient/public member involvement is an integral part of the guideline development process and of the work of the GC. If there were a separate section of the induction programme, specifically focusing on patient/public involvement, it might suggest that patient/public involvement is an 'added extra' and not an integral and essential part of the process.

The day-long programme comprises a mix of presentations, discussions and interactive sessions, intended to introduce chairs to the NICE guideline development methods (NICE 2014). (During the COVID-19 pandemic this was reduced to a half-day videoconference session with training material sent in advance.) It also covers practical issues related to running GCs, such as declaring and managing interests (NICE 2021), good facilitation skills, the importance of NICE's duties under equalities legislation (see the NICE equality scheme), and the NICE policy on participation of patient/public members of GCs. The session also expands on the role of NICE as commissioner, and how that sits alongside and independently of the guideline development staff and GC. Presentations are given by methodological and process specialists, and patient and public involvement specialists, thereby reinforcing the importance of an inclusive approach to guideline development. Participants also benefit from the contribution of an experienced chair (someone who has chaired 1 or more NICE GCs) who discusses their experience and offers tips and strategies for effectively chairing a GC in the NICE context.

Overall objectives of the day are to:

- provide a specific opportunity for GC chairs and NICE staff to meet, share experiences and discuss the work of NICE in context
- provide an overview of key NICE processes and methods
- identify key resources and support.

The format is flexible and interactive, with structured presentations designed both to inform and to act as the basis for discussion. The day gives chairs the opportunity to work collaboratively with their peers, as well as with the guideline development professionals from NICE.

Additional resources

General information about the role of chairs in running groups on which patient/public members sit can be found in 2 key additional resources:

- Patient and Public Involvement Toolkit, Chapter 4 Building relationships (Cartwright and Crowe 2011)

- Patient and public involvement in research groups - Guidance for chairs (TwoCan Associates for the UKCRC and NCRI 2010).

Other useful information to support the chair's role on guideline development groups:

- Supporting effective participation in health guideline development groups: The Guideline Participation Tool (Piggott et al. 2020)
- Checklist for Guideline Panel Chairs (Department of Health Research Methods, Evidence and Impact, McMaster University 2017)
- Groups. A guide to small group work in healthcare, management, education and research (Elwyn et al. 2001).

Resource and planning requirements

Inducting and supporting GC chairs needs to be planned and sufficient resources allocated. Some of these are financial, but the most significant is the staff time to deliver the induction and provide ongoing support.

Organisation of induction

Given the large number of guidelines that NICE develops at any one time, it can be difficult to identify suitable times and dates for induction sessions. NICE has therefore appointed a dedicated person within the Centre for Guidelines to lead and coordinate the chairs' induction.

Financial commitment

At NICE, either the chair's employing organisation is re-imbursed or payment is made directly to the chair for each GC meeting. In addition, travel and subsistence expenses are covered, according to NICE's non-staff reimbursement policy. It is a requirement for all GC chairs to attend the induction session (see section 3.7 of NICE's guidelines manual 2014). NICE does not provide remuneration for attending the induction, but other agencies might consider it worth doing to encourage attendance.

Barriers and strategies to address them

This section outlines some of the key barriers to appropriately supporting and inducting GC chairs, and some proposed solutions, based on the NICE model. The section is presented as a series of questions and answers.

What is the relationship between a GC chair's facilitation skills and their topic expertise? Is there a potential for tension between these 2 functions?

Although there are clear advantages to recruiting GC chairs with highly developed facilitation skills, NICE recognises that these can sometimes go hand in hand with expertise in a particular topic area. However NICE's policy on declaring and managing interests does not generally support the recruitment of topic expert chairs. NICE's current position is that its chairs are recruited for their facilitation skills, and that a 'topic adviser' with expertise in the topic under discussion should be recruited to work alongside the chair. This ensures the chair is more likely to be objective about the evidence the committee considers.

To facilitate inclusive group dynamics and support lay members, there are distinct advantages in having a well-informed chair with highly developed facilitation skills, but one who is not an expert in the guideline topic. These advantages include:

- Being able to ask naive questions of the topic experts and technical staff in order to clarify things for everybody, especially the patient/public members. A topic expert chair will either not realise that there might be a problem understanding something or not be prepared to lose face by asking. These may be genuine questions because the non-expert chair does not understand or might be deliberately asked to help the patient/public members and other committee members.
- Non-expert chairs are less likely to engage in esoteric arguments with specialists about details of the condition or intervention, or the evidence, and forget their chairing responsibility of engaging everyone in the discussion.
- They are more likely to be seen as impartial and someone to whom the patient/public members can turn for support, advice and comment, either in the meeting or in breaks or other informal settings.

We recognise that other guideline development organisations may wish to recruit chairs with expertise in the topic under discussion. The key to identifying an appropriate approach is to be clear about the role of the chair in running the GC. There will need to be measures in place for managing any conflicts of interest that arise for a 'topic expert' chair, because the goals for facilitating discussion and debate on the evidence within the group may not always coincide with the desire for a particular approach to the guideline topic.

Should induction for GC chairs be compulsory?

Chairs should be encouraged to take advantage of any induction or training on offer. NICE's experience is that GC chairs who have been through the induction are more likely to run functional and successful groups.

The NICE guidelines manual states 'Anyone appointed as a committee chair is required to attend the chairs 'induction session' (NICE 2014, section 3.7). But a strong recommendation from a senior member of the guideline organisation's staff about the value of induction will encourage newly recruited chairs to attend them. It is also important to encourage chairs to attend refresher sessions if they have worked with the guideline agency for many years. This will ensure they are up to date with organisational processes, the policy context, and other relevant changes.

Is there a 'one-size-fits-all' approach to developing and delivering an induction programme for GC chairs from different guidance-producing organisations?

Induction programmes for chairs need to be tailored to the specific context, methods and processes of the guidance-producing organisation. Induction programmes also need to be constantly refined and modified in light of external changes (for example, political priorities and legislation), organisational changes, developments in guideline methods, and in response to feedback from participants. However, there are likely to be common themes that apply across differing processes for guideline development. See, for instance, the generic guidance listed in the Resources section.

How do those offering the induction for GC chairs take account of the differences between guideline topics, between chairs, and between guideline groups?

There are inevitable differences between the topics, chairs and groups, and this variation is entirely appropriate.

The induction sessions include a lot of time for open discussion. This is an opportunity for participants to think about NICE's guideline development methodology, and their particular topic. For instance, in the presentation about NICE guideline methodology, the first section on scoping ends with time for participants to reflect on and discuss themes relevant for their particular guideline topic, using prompts such as those in Box 1:

BOX 1 Chairs' induction – discussion prompts

Each topic has unique characteristics

Will there be problems in managing the expectations of GC members about the limitations of scope, time, and resources?

Taking into account patient and public perspectives:

- are there some topics specific to this guideline? (information, psychosocial issues, support, alternative or complementary treatments)
- are there any population sub-groups of patients who might need specific consideration?

In the induction sessions, it is crucial to have input from someone with previous experience as a GC chair for the same guideline development organisation. Their experience of having been through the process enables them to provide practical tips for the newly recruited chairs on how to be an effective chair in this very specific environment. Feedback from GC chairs who have attended the NICE induction session consistently rate the session with an experienced GC chair as the most valuable aspect of the induction session.

Will someone who is a good committee chair automatically be a good GC chair?

Not necessarily - the skills needed to chair a formal committee may not meet the requirements for chairing and facilitating a dynamic, reactive, and discursive GC. A skilled GC chair will be expected to run the practical aspects of the group (for example, keeping to time and process) and also to foster debate and discussion among group members. They will also need to be able to draw together discussions about research evidence into practical recommendations for practice, taking into account all group members' input.

What is the role of the chair in relation to GC processes and methodologies?

The GC chair needs to be familiar with the 'rules' (of methods and process). Induction sessions are an ideal opportunity for these rules and expectations to be clearly outlined. The GC chair needs to fully understand the methodology and the rules, and both champion and follow them during GC meetings. The induction session should be a chance not only to explain them but also to discuss them with methodologists and support staff.

Might the new chairs find the idea of an induction patronising?

This is quite possible and needs to be recognised. But it is very important that a new chair is able to successfully work with a small group that includes patient/public members, while following a specific methodology.

How do you address the fact that the GC chairs may or may not be used to working with patient/public members?

As part of the induction, there needs to be an exploration of the chairs' experience in working with groups, including patient/public members. Their questions and concerns about this can be addressed and shared in a safe environment. At NICE, experience of working with groups, including patient/public members, is now an expectation of a chair's experience and is explored as part of their recruitment.

Providing the chairs with good practice examples (such as those cited in Cartwright and Crowe [2011] and TwoCan Associates [2010]) can give them practical tips to

help them support the patient/public members of the GC. It is important for them to understand and recognise that the individual patient/public members of the GC may have quite different knowledge, experience and self-confidence. Some may be very experienced professionals with specialist knowledge of a small topic area, but others may be working on a committee at a national level for the first time.

How do you ensure that the GC chairs get the best possible experience from the induction?

One of the key things that NICE has identified as enriching the induction experience for GC chairs, is to ensure the participation of more than one new chair at the induction session. This allows them to share their concerns and issues, and provides them with a small peer group with whom they can share experiences and discuss problems.

It should be possible for several guideline development organisations to pool resources for chairs' induction sessions, especially with the use of video-conferencing. But care would be needed to take account of different methodologies if these sessions involved the discussion of anything more than the involvement of patient/public members.

How do you address the issue of scheduling of inductions and the chairs' availability to attend?

The stage of the guideline development process at which the chairs have their induction is crucial. Ideally there needs to be enough time and resources available for chairs to have access to induction before their first GC meeting. But it may be difficult to arrange induction sessions with enough notice for chairs to attend, and also to convince some of the value of attending an additional meeting. Induction should be arranged at regular intervals to enable groups of newly appointed chairs access as early as possible. Details of these scheduled sessions should be included in recruitment materials in order to give a clear message that they are expected to attend and to allow them to plan. Other options are online training resources and induction sessions via videoconference.

Although chairs should ideally attend an induction session before their first GC meeting, it can be helpful to have people at different stages of the development

process coming at the same time so that they can describe their different issues and experiences. A newly appointed chair might have chaired a previous GC and feel that an induction session would be a waste of time for them. However, because guidelines methodology and political circumstances are constantly changing, they should still be encouraged to attend.

How do you address the need to provide the chairs with ongoing and additional training opportunities throughout the guideline development process?

NICE offers its GC chairs the opportunity to attend a workshop specifically on the health economics aspects of guideline development. Staff supporting each committee also provide training to GC chairs and other GC members on specific methodological issues (for example, systematic reviewing, meta-analyses) as and when required. GC chairs are also offered the opportunity to contact NICE's methodological and patient and public involvement specialists, or members of the technical team, if they have specific questions.

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Appendix 1

Sample guideline committee chairs' induction session—NICE

Guideline Committee Chair Induction

24th Feb 2020

NICE London office, with video link to Manchester office

AGENDA

Time	Item	Presenter/lead
10:00	Arrival & tea/coffee	-
10:20	Welcome and introductions	Technical Advisor, NICE's Centre for Guidelines (CfG)
10:30	Overview of NICE	Senior Public Involvement Adviser, NICE
11:15	Guidance development processes at NICE	Senior Guideline Commissioning Manager, CfG
12:15	Guideline development methodology (evidence reviewing)	Technical Advisor, CfG
12:45	Lunch	-
13:15	Guideline development methodology (health economics)	Technical Advisor (Health Economics), CfG
13:45	Experience as a Guideline Chair (Manchester video link)	Chair, Depression guideline
14:25	Thoughts on effective chairing of Guideline Committees	Senior Public Involvement Adviser, NICE
14:50	Declaring interests	Senior Guideline Commissioning Manager, CfG
15:15	Research recommendations	Technical Analyst, Science Policy & Research, NICE
15:35	Editorial and publishing at NICE	Senior Medical Editor, Publishing, NICE
16:00	Meeting close	-

Appendix 2

Sample guideline committee chairs' induction session slides - NICE

Slide 1 Different expertise - equal status

NICE National Institute for Health and Care Excellence

Slide 2 Desired outcomes

Desired outcomes

✓**A good guideline**

- produced to time and useful to practitioners & people using services

✓**Effective, amicable group working**

- 'different expertise – equal status'
- inclusive – avoiding jargon, explaining necessary terms
- responds to evidence, uses collective experience where appropriate and uses consensus

✓**Needs or problems recognised, tackled early, and resolved**

- members feel able to raise issues – inside and/or outside meetings
- known or 'hidden' disabilities or desired working arrangements are recognised and catered for

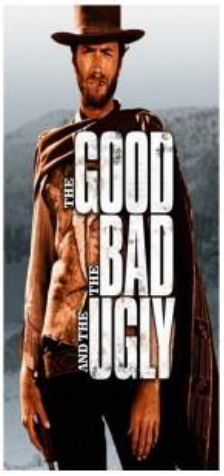
NICE 2

Slide 3 Lay members' feedback

Lay members' feedback

How easy did you find it to contribute to the work of your committee?

- "The Chair always made me feel my contribution was important."
- "I was treated with respect and as an equal member of the group. My views were given equal consideration to others."
- "A lot of medical terminology for a lay person to get used to."
- "I sometimes felt like the views of the lay members weren't taken seriously or given the same 'weight' as the academic or clinical members. This meant that after a while I was reluctant to contribute unless it was something I felt very strongly about."



NICE

4

Slide 4 How lay members on your committee might feel

How lay members on your committee might feel

- The guideline I was involved with covered a lot of very technical discussions about drugs, of which I had limited knowledge. I found it difficult to contribute to these discussions. On other points it was easier to contribute."
- "As I was just a lay member, I felt very positive about each meeting and made to feel I was valued."
- "As a lay member you feel (or at least I do) that you need to have a pretty clear and marshalled argument before you open your mouth. Everyone else in the room has a very clear, gut understanding of diseases and/or how the NHS works - the lay member has neither of these. Consequently, being a lay member requires you to accept that from time to time you may look a fool but that if your point needs to be made that is the risk that you take."

NICE

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Slide 5 How lay members on your committee might feel continued

How lay members on your committee might feel

- "I usually feel able to express my views, even if they differ from expert members. I think it is useful to set aside specific agenda time to ensure lay members are able to have their say - I am happy to interject "as and when" but have been on committees where some members appear a little nervous of having their say."

- "The clinical experts may not have had service user experience however it was still an issue of confidence for me to speak out amongst professors etc. I'm not sure what the solution is but having an agenda item called 'service user concerns' did give us an opportunity but also felt a little patronising, I know this wasn't the intention and I don't how this could be rectified other than the chair having a little more liaison with the service users?"

NICE 6

Slide 6 Working with lay members

NICE

Slide 7 Thoughts on facilitation and enhancing group dynamics

Thoughts on facilitation and enhancing group dynamics

- Preparation
  - clarity about work plan
  - agreeing mode of working with the staff team (and topic lead)
  - managing expectations of different committee members, considering issues which may arise (e.g. from scope)
- Establishing ground rules for working in the committee
  - open, honest communication
  - encouraging members to raise concerns early rather than late
- Observing group dynamics, being alert to problems
- Maintaining participation, managing conflict

NICE 7

Slide 8 Resources

Resources

- 'Good practice in chairing guide' – NICE
- 'A guide to maximising lay input on a committee - NICE
- 'Groups: A guide to small group work in heathcare, management, education, and research' – Elwyn, Greenhalgh & Macfarlane, Radcliffe Publishing, 2001

NICE 8

Patient and public involvement in systematic reviews

Authors: Alex Pollock, Pauline Campbell, Anneliese Synnot, Maureen Smith, Richard Morley

Corresponding author: alex.pollock@gcu.ac.uk

Key messages of this chapter

- Patient and public involvement (PPI) is important to ensure that systematic reviews are relevant and meaningful to people affected by a health condition and people using systematic reviews to inform health policy or practice.
- There is no set formula or single method of involving people in a systematic review, nor is there evidence that any one way of involving people in a review is any more or less impactful.
- Several different factors will influence the decision on the best approach for a specific systematic review, including (but not limited to) the aim of involvement, the people who are being involved, and the resources and time available for this.
- PPI may be useful at any (or all) stages of a systematic review.
- There should always be a clear aim associated with involvement of people within a systematic review. Often this aim will relate to decisions that need to be made within the systematic review process. Depending on the aim of involvement, people may be involved at 1 stage, at 2 or more stages, or they can be involved throughout the whole review.
- Involvement of people in a systematic review can be considered as a continuum, from more involvement and control, to less involvement and control. But there is no evidence of a hierarchical association between level, impact, benefit or success of involvement.
- Different levels and methods of involvement may be useful at different stages in a systematic review.
- PPI in a systematic review should be clearly reported.

Terminology: systematic review

A systematic review is a type of research method that brings together evidence, generally from research studies, to answer a pre-defined research question.

Top Tips

- Plan PPI in a systematic review prior to working on the review protocol. This is because involving patients and the public in the protocol is a good way of making sure your final review addresses what is important to people with lived experience of a health condition.
- Planning should consider the project budget and payment of people's time or expenses, provision of training, and whether ethical approval is required. You should consider the availability of these resources when deciding who you can involve and how.
- Have a clear aim for involvement of patients and the public, and decide in advance what level of control that those involved will have over decision making within the review. Make sure that you communicate this clearly at the outset of the review.
- Good communication is a key to success when involving people in systematic reviews. This means it must be timely, use clear language, and use a method that suits the people involved.
- People can be involved at any (or all) stages in a review. When people are involved will depend on the aim of involvement. Involve people at:
  - the initial stages of the review (that is, protocol), to form the review question and scope
  - during the review, to contribute to searching, study selection, and collecting and analysing data
  - the final stages of the review, to support interpretation of the findings and dissemination of the review.
- Who you involve, and when and how you involve them, should be decided taking into account the topic of the review, the resources available, and the experience of the review team.

- Have a conversation as early as possible with everyone involved about any resources they need, including financial payment for their time.
- For systematic reviews that are being planned and conducted as part of a guideline development, a top and tail approach could potentially fit efficiently within the guideline process.
- Adopting a formal research method or process can be useful when there is a clearly identified role, or aim, for the people involved.
- The ACTIVE framework and the GRIPP2 (Guidance for Reporting Involvement of Patients and Public 2) checklist (Staniskewsa et al. 2017) can be helpful for describing the planned involvement and reporting the actual involvement.

Aims of this chapter

This chapter aims to:

- highlight the importance of planning patient and public involvement (PPI) in a systematic review
- describe who you might involve in your review
- describe the stages when you might involve people
- describe the different levels of involvement you might have
- describe how people can be involved in a systematic review
- provide a framework for describing and reporting how you involved people
- signpost readers to a range of resources for further information.

Planning involvement in a systematic review

PPI and protocol development

A key stage in any systematic review is writing a detailed systematic review protocol. The protocol lays out details of the scope and design of the review, and the methods that will be used to conduct the review. Preferably, a systematic review protocol will be made freely available before the start of the systematic review. This lets people know what you are planning and helps avoid duplication of effort (that is, someone else carrying out the same, or very similar, systematic review).

Ideally, there will be PPI at the protocol development stage for the systematic review. It is good practice to have PPI contributors as core members of the review team. They play a key role in helping to plan how to involve additional PPI contributors throughout the review process.

The systematic review protocol should describe the planned PPI. In particular, the protocol should give details of:

- who will be involved, and how these people will be found or recruited
- when (at what stages) within the review process people will be involved, with a clear aim of the involvement at these stages
- how these people will be involved in order to meet the stated aim(s).

It is important to consider the key principles for good practice in involving people at the planning stage. The following issues are central to PPI in any research activity, including a systematic review:

- supportive and positive relationships
- clear and timely communication
- the roles and expectations of everyone involved, which should be discussed and agreed in advance of any involvement
- skills, knowledge and training (of researchers as well as of the people they involve) needed
- clarity regarding time commitments and requirements.

The project budget and payment for people's time or expenses, provision of training, and whether ethical approval is required must also be considered. The availability of these resources will influence who you can involve and how.

The Cochrane Consumer Network has published a Statement of Principles for Consumer Involvement in Cochrane to guide PPI. It highlights the importance of equity, inclusion and partnership. Communication and organisation are central to successful PPI, and it is important for researchers to consider practical points, such as accessibility (of meetings and materials) and having a clear point of contact for the people who are involved.

Choosing who, when and how for your review

There is no set formula or single method of involving people in a systematic review. Factors that will influence decisions around the best method for a specific systematic review include the:

- Topic of the review, and the people who may be affected by the results of the review.
- Aims of involving people. There may be a very specific aim to be met by involving people, such as informing the review outcomes, or supporting the dissemination of review results.
- Time available to do the review.
- Money available to support the review and involvement of people in the review.

- Expertise of researchers, and their experience of involving people in research.
- Preferences of the individuals involved.
- Desire for review findings to be locally, nationally or internationally generalisable. A review may focus on a topic of national importance, and consequently the methods of involvement could focus on gaining involvement across that individual nation. Alternatively, a review may be internationally relevant, so it may be appropriate to gain international views and opinions.

Although the research team commonly makes the decisions on the plan, there will ideally be PPI in reaching the plan for the methods of involvement in the review. It is essential to consider the views and perspectives of the individual people who get involved, and to be prepared to be flexible and adaptive to the needs and suggestions of the people involved. For example, although you may have pre-planned 1 large workshop to reach decisions on outcomes important to a review, this format may not be accessible to some people and you may need to adapt your plans. If you are asking people to read or comment on written documents it is important to find out whether any of the people involved have specific requirements to facilitate accessibility, such as larger font sizes or audio versions. When seeking people to get involved, you may consider circulating requests for involvement in a variety of formats to promote accessibility. For example, you could circulate an audio description alongside a written description of the project. Being flexible and responsive, and working in partnership with the people who get involved is important to ensure equity and inclusivity.

One review can use a variety of different methods, each of which have a different approach to involvement, with different role classifications, and different levels of involvement. The following sections discuss key things to think about when planning PPI in your systematic review.

Who to involve in a systematic review

It is important to consider who the stakeholders for your systematic review are, and to involve representatives of key groups of people. Key groups to consider include:

- patients and their family members

- carers
- healthcare professionals
- health policy makers
- health funders
- decision makers working in the relevant field.

For a systematic review being conducted as part of a guideline development, the stakeholders for the review may be identical to the stakeholders for the guidelines. However, there may also be some differences. For example, if a systematic review is focused on a specific intervention or a population of people with a particular impairment or activity limitation, then it may be important to consider involving people with relevant specific lived experience.

The 7Ps framework (Concannon et al. 2012), shown in table 1, can be a useful framework for identifying who to involve. Although it has been developed for a US situation, and for involving people in identifying and prioritising outcomes for research on an intervention's effectiveness, the principles can be applied in other parts of the world, and in other types of research.

Table 1 The 7Ps Framework to help identify who to involve in health research (Concannon et al. 2012 edited)

Category	Description
Patients and the public	Current and potential consumers of patient-centred healthcare and population-focused public health, their caregivers, families, and patient and consumer advocacy organisations
Providers	Individuals (for example, nurses, physicians, mental health counsellors, pharmacists, and other providers of care and support services) and organisations (for example, hospitals, clinics, community health centres, community-based organisations, pharmacies, emergency medical services agencies, skilled nursing facilities, schools) that provide care to patients and populations
Purchasers	Employers, the self-insured, government and other entities responsible for underwriting the costs of healthcare
Payers	Insurers, Medicare and Medicaid, state insurance exchanges, individuals with deductibles, and others responsible for reimbursement for interventions and episodes of care
Policy makers	The White House, Department of Health and Human Services, Congress, states, professional associations, intermediaries, and other policy-making entities
Product makers	Drug and device manufacturers
Principal investigators	Other researchers and their funders

In deciding who to involve it is important to consider the aim of the PPI and, therefore, the range of perspectives that are needed to meet that aim. For example, if the aim is to have general oversight of the review conduct, then perhaps, people with a general perspective need to be involved. But if the aim is to identify the outcomes of greatest importance to people with lived experience of a particular health condition, then it will be essential to involve people with relevant lived experience. Often, for PPI, what is of greatest importance is that the people involved have a lived experience of a particular health condition. Generally, knowledge or familiarity with research methods and technical terms is not a requirement for involvement. It is good practice to write a role specification that describes, in plain language, the experience or attributes that people you involve should have. Also consider the potential benefits for people who volunteer to get involved in a systematic review, and make these clear. For example, these could include payment, authorship, acknowledgement, training, or impacting on an area of research that is important to them. The National Institute for Health Research (NIHR) webpage on people in research has examples of descriptions of people sought to involve in health research.

How to recruit people

After identifying the key groups of people to involve, strategies are required to find relevant individuals to approach and invite to get involved. The chapter on how to recruit and support patients and the public, and overcome barriers to their involvement in guideline development highlights different ways of identifying and reaching out to patient and public groups. Two broad strategies commonly used to find people to be involved in systematic reviews are:

- An open recruitment strategy, in which opportunities for involvement are advertised to the general population, and anyone can volunteer to get involved (for example, advertising on the NIHR's People in research webpage). Open strategies can be:
  - Fixed: After a group has been formed, advertising ceases and no new members are added.
  - Flexible: Advertising for new members is ongoing and group membership can fluctuate. This may mean that a series of workshops has different group members, or some group members may attend more than once.
- A closed, or targeted, strategy, in which individual people, or individual groups, are invited to be involved. There are several strategies for recruiting a targeted group:
  - Invitation: People known by name (or reputation) to the researchers will be invited to get involved. This can also be described as 'nomination'.
  - Existing groups: Rather than recruiting specific named individuals, the membership of an existing group is invited to get involved. Because different groups vary in how they operate, this can impact on the membership. In some cases, a group may have closed membership (that is, the same individuals make up the group), and sometimes a group may have open membership (that is, the group membership changes over time).

- Purposive sampling: A qualitative research framework is used for recruitment, generally aimed at getting representation of people with key pre-determined characteristics, experience or expertise. Although this results in a ‘targeted’ group, with closed membership, the strategies for identifying the population from which to sample can be similar to those for open involvement (that is, advertising).

How many people to involve

How many people you involve in your systematic review will depend on several factors. A key factor is the aim of PPI and, linked to the aim, how you are going to involve people (see the section on how to involve people in a systematic review). The factors listed in the section on choosing who, when and how for your review will also influence decisions about how many people to involve. The numbers to involve will also depend on the different groups of people that you want to have represented (see the section on who to involve in a systematic review). Work in partnership with the people you involve to ensure that they are comfortable with the number and range of people involved. When small numbers of people are involved, for example, as members of a steering or advisory group, ask them if they feel they can represent the different viewpoints, or whether additional input is required.

In an exploration of PPI in a range of systematic reviews, Pollock et al. (2018) found that for:

- face-to-face meetings, the number of people involved ranged from 2 to 27
- one-off events, often advertised as open to the general public, the number of people involved ranged from 15 to 81
- involvement that did not require a face-to-face meeting, for example using an electronic Delphi or survey, the numbers invited ranged from 29 to 340 people.

When to involve people in a systematic review

PPI at stages of the systematic review

A systematic review is a process involving a series of different stages. The Cochrane review ecosystem illustrates 11 key stages of a systematic review, from developing the question through to writing and publishing the review. A final, 12th, stage is disseminating the results of the review. People can be involved at any (or all) of these stages. There should always be a clear aim or objective associated with involvement of people within a systematic review. Often the aim will relate to decisions that need to be made within the systematic review process. Depending on the aim of involvement, people may be involved at 1 stage, at 2 or more stages, or they can be involved throughout the whole review.

The Cochrane Involving People learning resource provides examples of systematic reviews that have involved people at the 12 different stages of a review process in order to meet a range of different aims. Table 2 provides some brief examples of PPI at different stages of systematic reviews, taken from the Involving People resource.

Table 2 Examples of involvement of people at different stages of systematic reviews (from the Cochrane Involving People learning resource)

Stage of review	Example review (reference)	Aim of involvement	What happened?
1. Develop question	Edwards et al. (2015)	Clarify the review questions in a systematic review relating to complex mental health needs and services for children and adolescents in the UK	Edwards et al. (2015) used 2 different strategies. In 1 strategy, 6 young people who had been mental health inpatients, were interviewed, individually. The aim was to identify topics for the review to focus on. In the second strategy, healthcare professionals, young people and charity representatives met face to face to generate and rank topics of importance.
2. Plan methods	Pollock et al. (2015)	Clarify methods for a Cochrane review update relating to physiotherapy for people who had experienced a stroke, in particular the categorisation of interventions	Pollock et al. (2015) formed a stakeholder group of patients, carers and healthcare professionals. There were 2 meetings that focused on clarifying methods of the planned review. The stakeholder group's input generated a method for categorising interventions within the review. This method was used to structure the final review and also informed subgroup analyses.
3. Write and publish protocol	Liabo (2013)	Agree the protocol content for a review focused on interventions to support looked-after children in school	Liabo (2013) used a participatory approach to involve a group of young people throughout the review. At one of the meetings, participants were presented with a pre-prepared document with tick-box options for different alternatives within the protocol. The options had been generated from the discussions at previous meetings that focused on the review question. The text included in the final protocol reflected the views that had been collected during the tick-box exercise and associated discussion.
4. Develop search	Rees et al. (2004)	Advise on terminology for the search strategy, for a systematic review relating to HIV-related sexual health for men	Rees et al. (2004) involved a range of people in 3 meetings. In one of the meetings, the group specifically advised on terminology for the search strategy.

Stage of review	Example review (reference)	Aim of involvement	What happened?
5. Run search	Harris et al. (2016)	Help identify unpublished papers, for a realist review relating to community-based peer support	Harris et al. (2016) established an advisory network of stakeholders. Communication with the advisory network occurred through a series of events, as well as less formal communication, including email. Harris et al. report that advisory network members helped to identify relevant unpublished papers during the searching phase.
6. Select studies	Vale et al. (2012)	Provide oversight to a Cochrane review of chemoradiotherapy for cervical cancer	Vale et al. (2012) formed a group of 'patient research partners' who provided continuous oversight for the review. The group was actively involved in several review tasks, including tracing the address details of trial investigators for studies selected for inclusion.
7. Collect data	Bayliss et al. (2016)	Co-produce a coding framework for the qualitative analysis in a qualitative systematic review focused on predictive testing for those at risk of developing a chronic inflammatory disease	Bayliss et al. (2016) had a group of 'patient research partners' who provided continuous oversight for the review. Three of the patient research partners volunteered to be involved in the qualitative analysis. They coded themes for a random selection of 3 papers and contributed to developing a co-produced coding framework in collaboration with the researchers. This was done through email correspondence. Written training documents were developed to support the volunteers with this involvement.
8. Assess risk of bias	-	-	There is little evidence of involvement of stakeholders in the process of assessing risk of bias. Liabo (2013) reported that 'none of the young people were interested in being involved in activities that required them to read the full studies'. As a result of this observation, these stakeholders were involved in 'a general discussion about research quality rather than aiming for them to take an active part in reading the studies and assessing them for quality'.

Stage of review	Example review (reference)	Aim of involvement	What happened?
9. Analyse data	Bayliss et al. (2016)	Consider and comment on the qualitative themes generated for the qualitative synthesis	The patient research partners involved in the review of Bayliss et al. (2016) attended a face-to-face meeting to which all stakeholders were invited. They read all the included papers before the meeting. Bayliss et al. reported that this session aimed to help researchers draw on the perspectives of the patient research partners when interpreting and reflecting upon the data.
10. Interpret findings	Pollock et al. (2014, 2015)	Gain consensus on the clinical implications arising from the review	Pollock et al. (2014, 2015) held a stakeholder meeting at which the draft findings (results of meta-analyses) were presented. Stakeholders were asked to discuss the clinical implications of these findings. Through discussion, the group agreed the wording of a series of statements relating to clinical implications, with anonymous voting used to confirm agreement with the statements. The agreed statements were included with the published review.
11. Write review	Concannon et al. (2014)	Get feedback on drafts of a systematic review of methods of stakeholder engagement in research	Colcannon et al. (2014) held 2 face-to-face meetings with a group of stakeholders, who also participated by email and phone throughout the review process, including commenting on tables, figures and manuscript drafts. Colcannon et al. stated that 'stakeholders [at a second meeting] also helped us identify effective ways to communicate the findings in tables and figures for this manuscript. All stakeholders were invited to participate by email and phone throughout the research, including a review of the manuscript".

Stage of review	Example review (reference)	Aim of involvement	What happened?
12. Publishing the review and disseminating	Hyde et al. (2017)	Plan and contribute to disseminating the results of a review focused on factors affecting shared decision making around prescribing analgesia for musculoskeletal pain	Hyde et al. (2017) held 3 stakeholder meetings at different stages during the review. Group members were involved in 'planning how to share results' and 'agreeing dissemination of the results'. Consequently, 'results were targeted at practitioners, as [stakeholders] felt this was most important'. Hyde et al. reported that group members 'participated in dissemination of the review findings'. They also reported that they 'planned their own roles...including giving presentations and contributing the patient's perspective to discussions at conferences'.

Top and tail approach

Pollock et al. (2019) explored when systematic review authors had PPI in their reviews. They found that people were most commonly involved at the initial stages (stages 1 to 3: framing the question and planning the review) and the final stages (stages 10 to 12: interpretation, publication and dissemination of findings). It was less common for people to be involved during the middle stages (stages 4 to 9: conducting the review). Often people were involved at both the initial and final stages, but not in the middle – this has been termed a 'top and tail' approach (Pollock et al. 2019). A top and tail approach may involve the same group of people at the start and end of the review, or it may involve 2 different sets of people.

For systematic reviews being planned and conducted as part of the development of a guideline, a top and tail approach could potentially fit efficiently within the guideline process. However, there is no evidence to support this as being the 'best' approach, and decisions about when to involve people should be made based on the pre-determined aims of involvement for each individual systematic review.

How to involve people in a systematic review

Approaches to involvement

There is no evidence to show that any one way of involving people in a review is more or less impactful. Several different factors will influence the decision on the best approach for a specific systematic review. These factors may include the topic of the review, time available, resources available, and expertise of the review team.

Two different approaches to involvement have been used for other systematic reviews:

- Continuous involvement – people are involved ‘throughout’ the review process, perhaps as a member of the review author team or an advisory group.
- One-time involvement – people are involved at a specific stage in a review in order to complete a specific task or address a specific aim. For example, a group of people might be involved in discussing and reaching consensus on the question for a review, or people might be involved in order to contribute to the writing a plain language summary.

The aims of the PPI will help determine which approach might be best for a specific review. For example, if a key aim is to ensure that the outcomes included in the review reflect those that matter most to people affected by a particular health condition, then a one-time involvement approach may be more advantageous. This could enable a group of people to come together and reach consensus on the outcomes for the review. However, if the aim of involving people is to provide general oversight to the review process and ensure that all stages of the review process consider the views of patients and the public, then continuous involvement may be more advantageous. Some systematic reviews combine both approaches. For example, they may have PPI input on an advisory group throughout the review process, and then also plan 1 or more one-time events to get additional input into key stages of the review.

Levels of involvement

Involvement of people in a systematic review can be considered as a continuum, from more involvement and control, to less involvement and control. Pollock at al. (2019) explored the different tasks and activities in which patients and the public were involved in a range of systematic reviews. Using an iterative process, they developed a new taxonomy relating to the actions, responsibilities and tasks of those involved, called the 'ACTIVE continuum of involvement'. It describes people as leading, controlling, influencing, contributing or receiving (see table 3).

Table 3 The ACTIVE continuum of involvement (from Pollock et al. 2019)

Level of involvement	Tasks
Leading: Initiating the review; lead responsibility for carrying out and completion of review.	Tasks will include authorship of a review, and may include any activities associated with review completion, including key decisions relating to the methods and execution of the review.
Controlling: Working in partnership with researchers, with varying degrees of control or influence over the review process. Making decisions, controlling, or both, 1 or more aspects of the review process, in collaboration with or under the guidance of the review authors.	Tasks may include defining outcomes of interest, inclusion criteria, key messages arising from review findings and writing a plain language summary. In completing tasks people have control over final decisions, such as application of inclusion criteria, categorisation of interventions, or recommendations for clinical practice.
Influencing: Stating, commenting, advising, ranking, voting, prioritising, or reaching consensus. Providing data or information that should directly influence the review process, but without direct control over decisions or aspects of the review process.	Tasks may include assisting with review tasks, such as hand searching, screening, data extraction and assessment of risk of bias, possibly in a co-reviewer role. Tasks may include peer review, such as commenting on a protocol, systematic review or plain language summary.
Contributing: Providing views, thoughts, feedback, opinions or experiences. Providing data or information that may indirectly influence the review process. People may be participants in a research study (for example, focus groups or interviews).	Tasks may include sharing views or opinions, for example, within a focus group or interview. May include ranking, voting or prioritising as participants in a research study (for example, in a Delphi study).
Receiving: Receiving information about the systematic review, or results of the review.	Tasks may include attending events or reading or listening to information about the review. Although the results of a review may be discussed, these discussions do not influence the review process in any way.

Although the level of involvement of people in a systematic review can be seen as a continuum, there is no evidence of a hierarchical association between level, impact, benefit or success of involvement. Indeed, current evidence and opinion suggests that different levels and methods of involvement may be useful at different stages in a systematic review. What is important is to consider the level of PPI involvement, and their level of control or influence over the process. Decisions about the level of control that people will have at various stages in the review process should be stated in advance, ideally within the systematic review protocol.

Format of involvement

Format of involvement means the ways in which people interact and communicate, such as through face-to-face meetings, events or workshops, individual or group telephone or video-calls, or email and written communication. The format of PPI in a systematic review will depend on several factors. These factors include (but are not limited to) the aim of involvement, the people who are being involved, and the resources and time available for this. In an exploration of the format of involvement adopted in a range of systematic reviews, Pollock et al. (2018) found that direct face-to-face interaction was the most common approach, and that this might comprise a small meeting, a larger workshop or public event, or a combination of these. In most cases, between 1 and 4 meetings or events were held throughout a review, although as many as 20 meetings had been held. Meetings varied in length from 1 hour to half a day. A small number of systematic reviews used electronic or remote methods to involve people. Most commonly, this was an electronic Delphi or survey method, usually involving 2 or 3 rounds of voting.

Research methods and processes

A range of different ways have been used when involving people in a systematic review. Often these methods and processes involve different ways of sharing thoughts and ideas, such as group discussions or written feedback. Several formal research methods have also been used when involving people. Adopting a formal research method or process can be useful when there is a clearly identified role, or aim, for the people involved. For example, the aim might be to reach consensus on the outcomes of relevance to the review, or to agree a way to synthesise the evidence so that it is accessible and understandable.

Formal research methods and processes that have been used when involving people in systematic reviews include:

- Participatory research approaches: Include ‘action research’ and ‘participatory action research’ and are usually considered as ‘approaches’ to research, rather than methods. These approaches integrate PPI with qualitative research, with a joint process of knowledge production by researchers and patients or the public. Participatory research approaches have key tenets: a democratic impulse; iterative data collection and analysis, and simultaneous contributions to science, improvement and change.

Box 1 Example of a participatory research approach

For a realist review of community-based peer support, Harris et al. (2016) used participatory approaches to gain stakeholder involvement throughout the review. An advisory network was formed, comprising a range of different types of stakeholder. Recruitment to the advisory network took place throughout the review, and different individuals had varying levels of involvement, and at different stages. Some members contributed on multiple occasions and others on only a single occasion. A total of 12 meetings were held throughout the review, providing approximately 240 face-to-face contacts with around 120 stakeholders. In addition, there were also email discussions and opportunistic contact with researchers.

- Consensus decision-making techniques: Include using techniques for voting (that is, to make decisions about the review) and ranking (for example, to prioritise domains, such as outcomes, within a review). It also includes the nominal group technique, which involves a structured discussion and rounds of voting to reach consensus on a specific problem or issue, and the Delphi method, which involves several rounds of questionnaires or surveys to achieve consensus.

Box 2 Example of a consensus decision-making process

For an update of a Cochrane review relating to physiotherapy for people who had a stroke, Pollock et al. (2014, 2015) formed a stakeholder group comprising physiotherapists, stroke survivors and carers. During a series of 3 meetings, stakeholders made several decisions relating to the review. Decisions were made using the nominal group technique. In each case, the stakeholder group members first discussed a topic or statement for an agreed amount of time. Then each stakeholder group member individually ranked their agreement with that topic or statement and noted their reasons for this. The 'voting' sheets were anonymous, but were then collected and counted in front of the group members in order to see whether or not there was consensus on a topic. Further rounds of discussion and voting took place when needed.

- Group process: Often the process of involving people within a systematic review entails a group meeting, which may be called a meeting, workshop or conference. These meetings commonly involve discussion and debate, perhaps supplemented with formal methods such as consensus decision-making techniques. The content and processes within these group meetings are often poorly reported. However, evidence suggests that these meetings do often combine careful planning and use of techniques known to enhance the group process. The planning and approach to running group meetings provides a way of addressing many of the general issues identified as important to involvement, such as effective communication, clarity, expectations, respect and trust.

Box 3 Resource on group process

The Agency for Healthcare Research and Quality Practice's Facilitator's Guide to Running Effective Meetings provides a guide to key issues associated with planning and facilitating a group meeting.

- Qualitative research methods: These methods, such as interviews or focus groups, have been used to elicit views and opinions of patients and the public in relation to systematic reviews. The purpose has most commonly been to 'contextualise' the findings of a systematic review to a particular population or area. These data have then been analysed using methods for analysis of qualitative data, such as thematic analysis (Bunn et al. 2015, Martin et al. 2015). In such cases, the involvement of people has occurred after completion of the systematic review. However, it could be argued that the involvement relates to the final stages of a systematic review process (such as dissemination and translation of evidence into practice). The level of involvement is one of 'contribution' and, in these examples, the people involved could arguably be described as 'participants' in research.

Describing and reporting PPI within a systematic review

It is good practice to report who, when and how people have been involved in a systematic review, and to reflect on the impact that this had on decision making and the final outputs of the review. This section presents 2 ways to aid reporting on PPI.

The ACTIVE framework

The ACTIVE framework (Pollock et al. 2019) provides a way of describing how and when people were involved in a systematic review. The framework, mentioned in the section on levels of involvement and shown in table 4, lists a series of framework constructs that should be reported and proposes categories for classifying how people were involved.

Table 4 ACTIVE framework for describing involvement of people in a systematic review (adapted from Pollock et al. 2019)

Framework constructs	Categories	Notes
Who is involved?	• Patients, carers and their families • Patients, carers and their families, and other stakeholders • Other stakeholders only	The ACTIVE framework provides a way of categorising who is involved, using 3 broad categories. A written description should also be provided, giving numbers of people, and key information (for example, length of time with the health condition).
How are people recruited?	• Open, fixed • Open, flexible • Closed, invitation • Closed, existing group • Closed, purposive sampling	The ACTIVE framework provides a way of categorising the way in which people were recruited, using a series of categories based on the method of recruitment. A written description should also be provided, describing the targeted individuals or organisations, as well as where those recruited came from.
When are people involved?	1. Develop question 2. Plan methods 3. Write and publish protocol 4. Develop search 5. Run search 6. Select studies 7. Collect data 8. Assess risk of bias 9. Analyse data 10. Interpret findings 11. Write and publish review 12. Knowledge translation and impact	EACH stage at which people are involved should be clearly stated. The aim of involvement at each stage should be clearly stated.
When are people involved?	Top and tail approach?	If a top and tail approach is used this should be clearly stated, again stating the level of involvement at each point at which people are involved.
How are people involved? Approach?	• One-time involvement • Continuous involvement • Combined involvement (that is, both one time and continuous)	The categorisation of the approach to involvement gives a simple way of summarising what happened in terms of involving people in the review. Further details about what happened at each different stage at which there is involvement should also be provided, as outlined in the row on how people are involved, level of involvement.

Framework constructs	Categories	Notes
How are people involved? Level of involvement?	• Leading • Controlling • Influencing • Contributing • Receiving	For each stage at which people are involved, the level of involvement or control should be stated (see the ACTIVE Continuum in table 3 for definitions of levels and descriptions of tasks completed within each level). The level of involvement may vary at different stages in the review process.
How are people involved? Format and methods?	• Direct interaction • No direct interaction	The categorisation of the **format of involvement** gives a simple way of showing the format of the involvement. It is important to also provide a description of what happened during any interaction. Details of the number and length of the interactions should also be reported. Note whether any **formal research methods and processes** have been used, and if so, what these were.

Several icons have also been developed, which may be useful for ‘labelling’ the PPI within systematic reviews. These icons are shown in table 5.

Table 5 Icons relating to the ACTIVE framework for describing involvement of people in a systematic review

Framework constructs	Categories	Icon
Who is involved?	Patients, carers and their families	
Who is involved?	Patients, carers and their families, and other stakeholders	
Who is involved?	Other stakeholders only	
How are people recruited?	Open, fixed	
How are people recruited?	Open, flexible	
How are people recruited?	Closed, invitation	
How are people recruited?	Closed, existing group	
How are people recruited?	Closed, purposive sampling	
When are people involved?	Top and tail approach?	
How are people involved? Approach?	One-time involvement	
How are people involved? Approach?	Continuous involvement	
How are people involved? Approach?	Combined involvement (that is, both one time and continuous)	
How are people involved? Approach?	Direct interaction	
How are people involved? Format and methods?	No direct interaction	

The GRIPP2 checklist

The GRIPP2 (Guidance for Reporting Involvement of Patients and the Public 2) checklist (Staniszewska et al. 2017) is a guideline for reporting PPI in health and social care research. It is not specific to systematic reviews, and it aims to capture reflections relating to the impact of involvement, in addition to the methods, and other components. There is a long and short-form version. The long form includes 34 items on aims, definitions, concepts and theory, methods, stages and nature of involvement, context, capture or measurement of impact, outcomes, economic assessment, and reflections. It is suitable for studies in which the main focus of the manuscript is PPI. The short form includes 5 items on aims, methods, results, outcomes, and critical perspective and is suitable for studies in which PPI is a secondary focus (for example, to briefly describe the PPI approach used within the manuscript describing the broader study). Although not specific to systematic reviews, the GRIPP2 checklist may provide a helpful guide for reporting the methods and impact of PPI and could be applied to a systematic review.

Resources for planning and conducting PPI in systematic reviews

Cochrane's Involving People

A resource for systematic review editors and authors to support them in getting people involved in producing reviews. It is open access with a free Cochrane account.

Stakeholder Engagement in Evidence Synthesis

Open access resources related to engaging with stakeholders during planning, conducting and communicating evidence syntheses.

Cochrane's Consumer involvement training

A collection of resources for those who want to involve consumers in producing systematic reviews.

Webinars from the International Network for Patient and Public Involvement

A series of open access recordings of webinars about engagement and involvement in an international context, including Stakeholder Involvement in Evidence Synthesis, by Dr Neal Haddaway.

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How to develop information from guidelines for patients and the public

Karen Graham, Corinna Schaefer, Nancy Santesso

Corresponding author: karen.graham2@nhs.scot

Key messages of this chapter

- There are many patient-directed knowledge tools available for presenting recommendations to patients and the public. Guideline developers should consider the purpose of these tools when producing such recommendations. Purposes include informing or educating, providing recommendations, supporting decision making and engaging in shared decision making.
- Involving patients and the public in the development of patient information derived from guidelines (that is, guideline-based information) promotes readability and assures the information is relevant for readers.
- Ensuring high quality of information produced for patients and the public is essential. Tools such as The Patient Education Materials Assessment Tool (PEMAT) and the DISCERN questionnaire can be used to assess various aspects of patient information, such as understandability and actionability of patient information.
- Qualitative research suggests patients and the public want the following information to be available in guideline-based information:
  - Context: who is the information for?
  - Background information about the condition:
    - What are the risk factors?
    - How will the condition progress?
    - How long will the condition last?
    - What is the risk of other problems arising from the condition?
  - Information about how to live with a disease and the treatment interventions:
    - What are the treatments, including the alternatives?
    - What are the risks associated with treatments?
  - What can I do for myself (for example, self-management)?

  - Where can I find more help (for example, phone numbers and websites for sources of support)?
  - How are guidelines produced?
- When prioritising recommendations for inclusion in guideline-based information, it is important to consider the purpose of the information. For example, if the purpose of the information is to promote self-management, recommendations about self-management are the ones to prioritise.
- It is extremely important to communicate the rationale behind guideline recommendations to patients and the public. It is helpful if the strength of recommendations is communicated using both qualitative text and symbols. The use of symbols should be tested with the target audience.
- When presenting information about benefits and harms, evidence shows that people's understanding of risk can be improved by presenting them with absolute numbers rather than words. Even where people say they prefer words, giving them both improves understanding.
- The choice of format for information will depend on the purpose of the information, target audience, the topic, and budget available. If the audience is segmented into different groups, it may be beneficial to have multiple formats to ensure accessibility. Accessibility may mean adapting information (including web-based materials) for people who have low health literacy, translating the information into other languages, as well as making versions available as easy read documents, large print, audio or video.
- People like information presented in layers, which means that they can read as much, or as little as they want. A useful approach is to have short paper versions and longer electronic versions, with the latter in particular using a layered approach.
- Personalisation of guideline-based information, for example 'Who is this information for', is useful because it makes it easier for people to think about how the information is relevant to them.
- Guideline-based information should be easy to find by both healthcare professionals and patients. It may be helpful to provide the patient version along with the guideline itself to ensurethat healthcare professionals who look up the guideline will also find the patient version.

Top tips

- Involve patient and public members of guideline development groups in developing information for the public.
- Include those recommendations in patient information that patients can directly influence or that can empower them to make care and treatment choices.
- Clearly state how the information was produced and by which organisation.
- When developing guideline-based information, consider signposting to other reputable and high-quality sources of information, including organisations and websites.
- The format for patient information should take into account the needs of the target audience. Consider producing multiple formats to promote accessibility.
- Statistical information should be kept simple. Use visuals such as bar graphs, pictograms or tables when possible.
- When summarising evidence on treatment options for patients and the public, simple tabular format (with questions and answers) allows easy comparison and improves comprehension of treatment benefits and harms.
- Use words and symbols to communicate the strength of recommendations to patients and the public.
- Guidelines may use different systems to present uncertainty, and if not intuitive, it may be helpful to include a description of what the system means in information for patients and the public.
- Use colour to distinguish between information from the evidence and information from other sources, for example, patient experience.

Aims of the chapter

This chapter describes strategies and methods to directly communicate all or some of the recommendations contained in guidelines to patients and the public. The guidance in the chapter is based on current best evidence from qualitative research on how to produce useful guideline-based materials for the public and patients, and options for when evidence does not exist. It gives an overview of:

- why producing information for patients and the public may add value to guidelines and foster implementation

- what should be included in guideline-based material for patients and the public
- how to communicate information and strength of recommendations
- how to describe treatment options
- how to ensure material adheres to more general quality criteria for patient and public information.

The chapter also offers best practice examples for developing guideline-based materials for patients and the public.

Communicating guidelines to patients and the public

Many recommendations in guidelines directly affect care for patients and the public. Therefore, efforts should be made to produce knowledge tools for patients (that is, patient-directed knowledge tools) to facilitate patient participation in decision making about care and treatment. There are many ways in which patient-directed knowledge tools can present care and treatment options to patients and the public, including:

- a plain language summary as described in Glenton et al. (2010)
- an interactive summary of findings tables as described in the DECIDE interactive summary of findings table
- a patient version of a guideline, as highlighted in Schafer et al. (2015)
- promotion of single recommendations, as in the Association of the Scientific Medical Societies in Germany (2020)
- interactive patient decision aids, as done by the Ottawa Hospital Research Institute (2020) or 1-page tabular decision aids such as The Dartmouth Institute's Option Grids
- decision boxes, as highlighted in Giguere et al. (2012)
- facts boxes, as shown in Schwartz et al. (2007).

No single approach has proven to work substantially better than another, although interactive and tabular formats have generally been well received, according to DECIDE's work with patients and public. Whichever format is used, it is important to involve people from the target audience for the patient-directed knowledge tool when selecting and developing the tool (DECIDE patients and public, Stacey et al. 2014, Stacey et al. 2019).

Table 1 presents Dreesens et al.'s (2019) framework with the various tools and their purposes. The first part of the framework describes the tools' purposes and the second focuses on the tools' core elements.

Table 1 A conceptual framework for patient-directed knowledge tools to support patient-centred care (based on Dreesens et al. 2019)

Type of tool	Purpose: inform or educate	Purpose: provide recommendations	Purpose: support decision making	Purpose: engage in shared decision making
Patient information and educational material	+	-	-	-
Decision tree	-	+	+	-
Independent or pre- and post-encounter patient decision aid	+	-	+	-
Patient version of clinical practice guideline	+	+	+	-
Encounter patient decision aid	+	-	+	+

Patient decision aids

A Cochrane review on decision aids described them as an intervention designed to support patients' decision making by providing information about treatment or screening options and their associated outcomes compared with usual care and alternative interventions (Stacey et al. 2014). Decision aids inform patients clearly about their options and prepare them to participate in decisions about their care and treatment. Information on shared decision-making tools can be found in the upcoming chapter on guidelines and shared decision making.

Decision aids, such as Option Grids and Facts boxes, are based on the best evidence and input from patients and healthcare professionals. They are easy to

read and use. They can ensure decisions are well informed and made carefully considering patients' views (The Dartmouth Institute, Giguere et al. 2012).

Patient information

Patient information, such as leaflets, can empower patients to ask questions about decisions on diagnostic and treatment interventions. A patient leaflet may include one or a few recommendations from guidelines on a specific topic to help with decision making. Initiatives such as Choosing Wisely, produce materials to promote conversations with healthcare professionals and patients and about what is appropriate and necessary treatment.

Patient versions of guidelines

Patient versions of guidelines are tools that 'translate' guideline recommendations and their rationales so patients and the public can easily understand them. Patient versions of guidelines can support individual decision making and help to foster a trustworthy patient clinician relationship in that they provide understanding about how, based on the evidence, clinicians should treat a condition. In turn, people may feel reassured and confident in their care. In situations where they are not offered care options recommended in a guideline, patients may intervene thus supporting guideline implementation (see the upcoming chapter on dissemination and implementation for further information). Box 1 describes the purposes of patient versions.

Box 1 Purpose of patient versions of guidelines

- Allow priorities to become clear to patients.
- Highlight to patients the benefits and harms of interventions to support decision making.
- Identify interventions for which there is good evidence that harms do outweigh the benefit, potentially reducing the use of or demand for unproven interventions.
- Point out other uncertainties and emphasise when a patient's own values and preferences are especially important for making a treatment choice.

- Identify lifestyle interventions and ways in which the patient can take steps to manage their condition.

It is important that patient versions are derived from guidelines that have recommendations based on a high-quality systematic approach and a formal consensus process. Recommendations for or against interventions will involve the guideline development group's value judgements, which may be the wrong choice for individual patients. Hence, the adequate application of a guideline does not only imply strict adherence to guideline recommendations but also reasonable non-adherence because of a patient's individual preferences or circumstances. It is crucial that guidelines convey this idea to both healthcare professionals and patients, and provide information to facilitate decision making.

Although the word 'translate' suggests using a different language, producing a helpful patient version is about more than tailoring the language to patients and the public. It involves:

- the selection of recommendations and outcomes to present
- how to present the strength of the recommendations and uncertainty in the evidence
- how to present the options available to a patient, and
- decisions about general formatting because patient versions may vary widely in format, length and content.

Ensuring high-quality patient-directed knowledge tools

The quality of materials produced for patients and the public is key to making the information desirable (DECIDE patients and public). Guideline developers therefore require quality criteria to use when developing patient-directed knowledge tools. The International Patient Decision Aid Standards (IPDAS) collaboration has also developed validated quality criteria specific for patient decision aids. One example of national consensus-based quality criteria for development, content and governance of patient-directed knowledge tools is that produced by the National Healthcare Institute of the Netherlands (van der Weijden et al. 2019).

The Patient Education Materials Assessment Tool (PEMAT) is a systematic method to evaluate and compare the understandability and actionability of patient education materials (Shoemaker at al. 2013). It is designed as a guide to help determine whether patients will be able to understand and act on information. Separate tools are available for use with print and audiovisual materials.

We have developed a checklist for ensuring good-quality guideline-based information, shown in box 2. The information gives the essential requirements for producing such health information for the public (DISCERN, Shoemaker at al. 2013).

Box 2 Checklist for producing good-quality information for the public

The material:

- Makes its aims and purpose clear.
- Provides details on funding, who produced the information, when it was produced, and what sources were used to compile it.
- Follows a logical format and uses everyday language. Medical terms are defined when used.
- Clearly presents information on treatment options, what will happen if no treatment is used and about the certainty of the evidence. Language reflects potential uncertainty.
- Provides the information in chunks. Uses boxes, tables and bullets to break up text.
- Provides easy to understand numbers.
- Provides visual aids to promote understanding, for example, a picture of a healthy portion size.
- Gives easy to read online information and spoken words can be clearly heard and understood, for example, pace is appropriate. Language is non-directive and non-persuasive.
- Uses an active voice in written and online information.
- Clarifies the actions for people to take.
- Signposts to other sources of information.

Process for developing patient-directed knowledge tools

Ideally, patient-directed knowledge tools should be developed towards the end of the guideline development process, after confirmation of the full set of recommendations and their rationales. Recommendations change throughout the guideline development process and this will avoid having to revise the information each time. Patient-directed knowledge tools should preferably be produced by the patients and healthcare professionals who have already been involved in developing the guideline on which the information is based. During the guideline development process, the group can systematically prioritise situations that require in-depth conversations between healthcare professionals and patients (Association of the Scientific Medical Societies in Germany 2020).

The guideline group can also discuss content beyond that to be included in the guideline, which could or should be covered by patient-directed knowledge tools. So, it is helpful to have the tools in mind when starting the guideline to inform the process of tool development. Patient or consumer organisations may also produce patient-directed knowledge tools, such as educational materials and patient versions of guideines, all of which can then be reviewed by the healthcare professionals and patients who developed the guideline. Developing information for patients and the public together with them helps promote readability and ensures that information is relevant to its readers.

The case study in table 2 shows how the Scottish Intercollegiate Guidelines Network (SIGN) developed the patient version of their guideline on migraine.

There are many ways to ensure that the information in the patient version reflects patients' needs and experiences. Although collaboration of clinicians and patients during the whole development process of the patient version is desirable, it may be more feasible to have collaboration at particular stages of the process, for example at the planning and consultation stages (Schafer et al. 2017).

Table 2 Development of the patient version of the SIGN guideline on migraine

When did SIGN start developing the patient version and what was the timescale?	SIGN started developing the patient version when the guideline was at the editorial stage of the guideline development process. The production process for the patient version took 7 months, including consultation and editorial stages.
Who did SIGN involve in the development process?	Two clinicians and 2 patients from the guideline group were invited to participate in a subgroup responsible for producing the patient version of the guideline. This made it easier to make the guideline and patient version complementary. A volunteer member of the public was also invited to join this group to provide an objective user perspective. Members of the guideline group provided quality assurance checks on the patient version to make sure it accurately reflected recommendations in the guideline.
How were recommendations selected for inclusion in the patient version of the guideline?	The group held face-to-face meetings to select recommendations that patients would find helpful and could influence, for example choice of medication. Patient-important outcomes, patient values and preferences for a recommendation, and the need to consider these in the patient version, were discussed with the full guideline group during development of the guideline. The group agreed how much information on medication and side effects would be useful to help with decisions. The group discussed what other information would be required in the patient version to help with understanding the recommendations.
How did SIGN include information that was important to patients but not recommended in the guideline?	There were a few ideas for content from patients and the member of the public that did not come directly from the guideline. It was decided that these were important to include. So they were presented differently from recommendations, for example, not in recommendation boxes, to make this clear to the information users.
How did SIGN gather feedback on the patient version of the guideline?	The draft patient version was available for consultation for 4 weeks. The full guideline group, voluntary organisations and members of SIGN's patient and public involvement network were invited to provide feedback. Feedback was compiled into a consultation report and shared with the group responsible for developing the patient version. Feedback was used to improve the booklet.

How to select recommendations for inclusion in patient-directed knowledge tools

Patient-directed knowledge tools should prioritise the recommendations that patients can influence or discuss with their healthcare professional. For example, a

recommendation about how a pathologist should prepare a biopsy would not be helpful because patients would never be able to discuss this with the pathologist. Research conducted by DECIDE with patients and the public has shown that people would like recommendations about managing their own care. The challenge with this is finding a sensible way of selecting the recommendations that should be presented in patient-directed knowledge tools. The best way of doing this is to involve patients, their carers and the public in the selection of recommendations, either from within the guideline development group or through a parallel group working on patient-directed knowledge tools (SIGN 100 2019, van der Weijden 2019). Box 3 summarises the questions that can be used to aid selection of recommendations for inclusion in patient-directed knowledge tools. The case study in table 2 shows how recommendations were selected for inclusion in SIGN's guideline on migraine.

Being clear on the intended target group and situation, that is, when patients will receive patient versions of guidelines, is important because this will influence which recommendations should be included and how they should be presented. For example, will they receive it before a hospital appointment? Will they have the opportunity to discuss it with a healthcare professional? If a condition has been diagnosed before they get a patient version, it may not be helpful to include recommendations on diagnostics or risk factors.

Box 3 Questions to ask when choosing recommendations

- Do they highlight options for interventions or care?
- Do they assess harms and benefits of the intervention in question and empower patient to make informed decisions?
- Do they assess harms and benefits of the treatment intervention in question and empower patients to make informed decisions?
- Do they recommend lifestyle interventions and ways in which the patient can take steps to manage their condition?
- Do they identify treatments that have no evidence of benefit?
- Can the recommendations help patients to understand their own condition?

- Do patients and the healthcare professional see a need for intensive conversation?
- Do they address relevant situations of over- or underuse? (this is extremely relevant in the context of diagnostic or screening recommendations)
- Do they address adherence?
- Are there barriers to the implementation of the recommendation, that could be resolved through discussion with the patient (for example, safe use of medicines)?

After the development group has selected recommendations to be included in patient-directed knowledge tools, they should be translated into plain language to allow them to be easily understood by a wide audience. If further information is needed to understand the recommendations (like anatomy, physiology or other information), it should be provided either along with the recommendation or in specific sections or paragraphs.

Content for patient-directed knowledge tools

The information in patient-directed knowledge tools should reflect what is in the guideline. Only diagnostic and care options provided in the guideline should be included (SIGN 100 2019, van der Weijden 2019).

A series of focus groups and other qualitative work with patients and the public (DECIDE patients and public, SIGN 100 2019, Cronin et al. 2018) found that the following issues are considered important when using information from guidelines :

- Context: who is the information for?
- Background information about the condition:
  - What are the risk factors?
  - How will the condition progress?
  - How long will the condition last?
  - What is the risk of other problems arising from the condition?
- Information about the diagnostic and treatment interventions:

  - What are the treatments, including the alternatives?
  - What are the risks associated with treatments?
  - What can I do for myself (that is, self-management)?
- Where can I find more help (for example, phone numbers and websites for sources of support)?
- How are guidelines produced?

Patient-directed knowledge tools, such as patient versions of guidelines, should highlight that there may be other well-known treatment options available but that they are not covered and thus not recommended by the guideline. This may be either because of lack of evidence, lack of resources and prioritisation or because they are outdated. This helps to clarify for patients that there are other options available but they have not been recommended by the guideline because of lack of evidence.

Additional information may be included in patient versions of guidelines if it helps to foster an understanding of the recommendations or supports self-management. Including information not directly linked to recommendations is of value and allows people to participate in shared decision making. If there is content in the patient version that is not in the guideline, this has to be made explicit. Furthermore, the guideline panel should check this type of information for consistency with the guideline. How the information was generated should be documented transparently (for example, based on patient experience, systematic search or qualitative research). The case study in table 2 explains how information that was important to patients but not recommended in SIGN's guideline was included in the patient version.

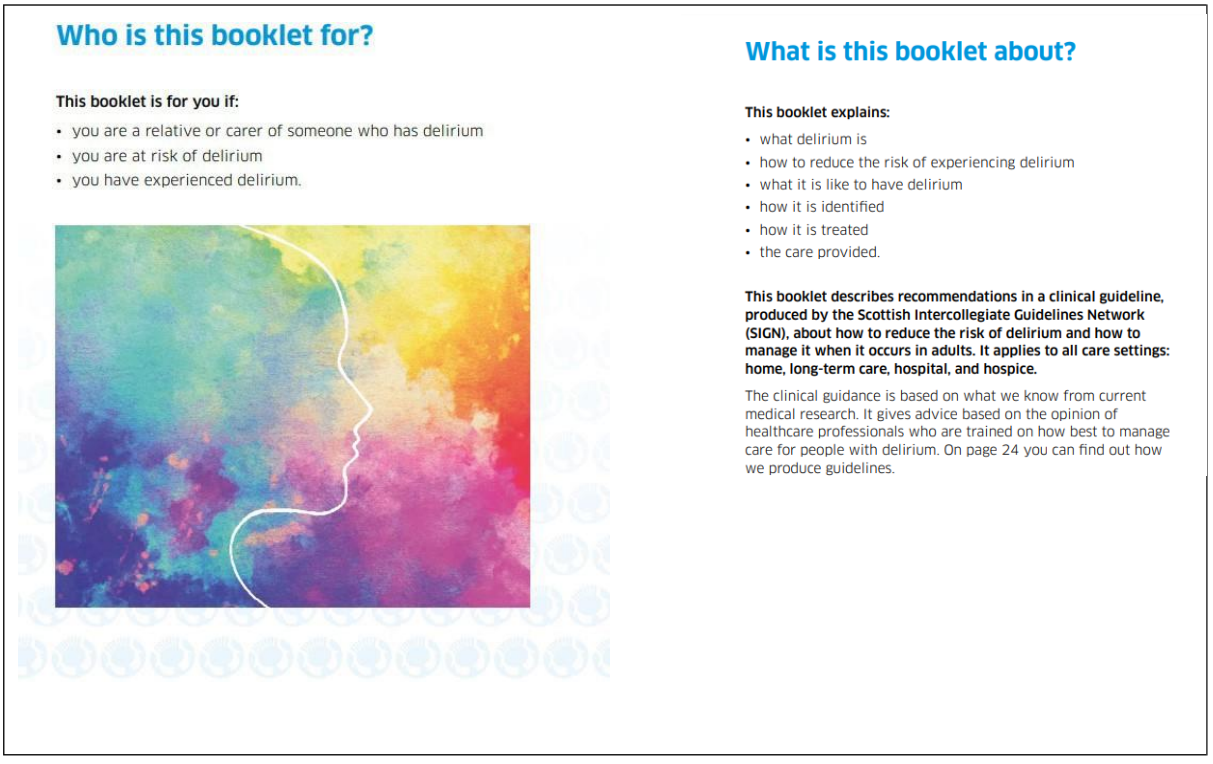
Tick boxes or other interactive tools are useful formats for information not linked to recommendations (DECIDE patients and public). Guideline producers committed to providing patient versions will need to consider each guideline individually to determine the intended purpose of the patient version and then decide on the content (van der Weijden et al. 2019).

Who is this information for?

Research has shown that people will often ignore health information if it does not seem to apply to their individual circumstances. Therefore, patient-directed

knowledge tools, such as patient versions of guidelines, should be clear about who the information is for. Making the applicability of a patient version of a guideline clear, using text such as ‘what does this have to do with me?’, is essential (DECIDE patients and public, Cronin et al. 2018, Loudon 2014, van der Weijden et al. 2019). However, around only half of current patient versions in the English language do this (Santesso et al. 2016). Figure 1 provides a simple example of how this can be done. It shows the information from a patient version in SIGN’s patient booklet on delirium, which explains who the booklet is for and what it is about. The context for using the booklet is clear; the information in the leaflet adds to the information provided by the people involved in a person’s care. Although written for patients, the booklet acknowledges that family members and carers may also read it.

If treatment recommendations apply only to a specific type of disease, it is helpful to make it clear that only patients with this specific diagnosis will benefit from the information. For instance, a guideline for the treatment of exocrine pancreatic cancer will not be relevant to patients diagnosed with endocrine pancreatic cancer, although they themselves will not be aware of this difference. If there are subgroups that have a larger or lesser benefit from interventions, this should also be made clear in the patient version or knowledge tool.



Who is this booklet for?

This booklet is for you if:

- you are a relative or carer of someone who has delirium
- you are at risk of delirium
- you have experienced delirium.

What is this booklet about?

This booklet explains:

- what delirium is
- how to reduce the risk of experiencing delirium
- what it is like to have delirium
- how it is identified
- how it is treated
- the care provided.

This booklet describes recommendations in a clinical guideline, produced by the Scottish Intercollegiate Guidelines Network (SIGN), about how to reduce the risk of delirium and how to manage it when it occurs in adults. It applies to all care settings: home, long-term care, hospital, and hospice.

The clinical guidance is based on what we know from current medical research. It gives advice based on the opinion of healthcare professionals who are trained on how best to manage care for people with delirium. On page 24 you can find out how we produce guidelines.

Figure 1 Information from SIGN's patient version of the guideline on delirium

Downloading material from a guideline developer's website, or using an online tool, supports patients in discussing their care with healthcare professionals (Cronin et al. 2014, Utranker et al. 2018). Guideline producers should consider how the document might be used and word it accordingly.

Background information about the condition

Patients and the public have wider information needs than knowing the treatment options available for a particular condition or problem. When asked, many people thought guidelines could be a simple tool to provide health information, as well as recommendations (DECIDE patients and public). Focus group and user-testing work also found that participants had information needs that were more general than treatment recommendations. These included questions about whether the condition could be prevented, how it would progress, and would it lead to anything else. In particular, knowledge of progress and natural history of a condition may help to assess benefits and harms of different treatment options (DECIDE patients and public). Circumstances of the technical delivery of treatment options may influence the decision-making process (such as, weekly delivery instead of a single intervention, and inpatient instead of outpatient treatment or another arrangement).

Guidelines generally don't provide much of this sort of information as part of the standard guideline production process. For example, the information for the public in the National Institute for Health and Care Excellence (NICE) guideline on depression in adults (CG90 2009) contains little background information on depression. Guideline producers may have to make a choice between not providing information (even though patients and the public may want it) or doing extra work because their standard guideline production process does not routinely generate this information. Taking the former route may lead to information that is less useful than it could be. If taking the latter route, guideline producers may limit the need for extra work by asking patients on the guideline development group what information matters to them, especially those who are representing a wider group of patients. In the NICE depression guideline it was important to describe mild, moderate and severe depression because different recommendations are made for each type of depression. Some of this additional information may be sourced from the appropriate

patient information groups for use in patient-directed knowledge tools. Links to local sources of support for patients and the public can also be provided.

What are the treatments and risks associated with them?

Similar to in the section about background information, guideline producers will need to balance the amount of information to provide and what is available in the original guideline document. Again, producers may consider background information about the treatments or interventions that will assist people in understanding the recommendations and treatment implications (DECIDE patients and public, SIGN 100 2019).

What can I do for myself?

The importance of presenting recommendations that relate to self-management is one of the strongest messages coming from research with patients and the public (DECIDE patients and public). It also emerged in a review of patient and public attitudes to guidelines as one of the purposes of patient versions (Loudon et al. 2014). Relatively few patient versions of guidelines in the English language currently meet this need (Santesso et al. 2016). German patient versions have a mandatory section called living with the disease, in which recommendations for self-management are addressed.

Presenting recommendations linked to self-management are therefore ones to prioritise when deciding which recommendations to cover in guideline-based information. Guideline producers may also want to consider whether to provide additional information about how people could apply the recommendations in their daily lives. When presenting additional information alongside recommendations, it should be clear that this information is not evidence based and is based on patient or expert opinion. The guideline group should check that additional information is consistent with the guideline. However, additional information may be very helpful for other patients if based on patient experience (Schaefer et al. 2015). Guidelines rarely address issues that matter most to patients like treatment burden or the impact that a condition has on daily life and how to deal with that. Information reporting patient experience must be carefully checked to ensure that it contains no effectiveness claims regarding treatments.

The case in table 3 is based on a German guideline on gastric cancer. It shows an example of when patient knowledge and experience led to including additional information in a patient version that was more valuable for users than the guideline recommendations.

Table 3 Integrating patient experience in the German patient guideline on gastric cancer

What kind of patient experience did the patient guideline include?	There was a complete lack of evidence on what patients who had had surgery for gastric cancer should eat. The guideline did not address this question. However, the patient organisation involved stated that, based on their counselling experience, most patients reported that was the most important issue and barrier in their daily life and had much impact on their wellbeing.
How was this experience-based knowledge retrieved?	Based on collective experience retrieved through discussions in self-help groups, feedback from counselling (patient hotlines), and chats in patient forums, a patient group compiled a list of foods that seemed to be beneficial for patients after gastric surgery, and food that might be intolerable. They also provided experience-based strategies on how to start eating after surgery, and how to adapt nutrition to individual needs. This list was forwarded to the nutrition experts involved in developing the clinical practice guideline (CPG) and checked for plausibility.
How was the information presented in the guideline?	The patient version contained a chapter on nutrition. The introduction stated that the following information was not derived from the guideline but from patient experience. Important strategies and the lists of foods were presented. Information specialists checked that the wording was not directive but always reflected that the information was based on experience. For example, instead of writing ‘Do not drink coffee’ they suggested ‘some patients have reported a bad experience with drinking coffee’.
How was this chapter received?	Patients reported that for them, this section contained the most helpful information of the whole patient version. This is especially important because this information was not in the CPG, indicating that information that truly helps patients may partly differ from guideline content.

Where can I find more help?

Many patient-directed knowledge tools provide links or contact information, such as telephone numbers for additional information and support, a need that has been highlighted by patients and the public (DECIDE patients and public). Those

developing guideline-based patient information should consider highlighting other sources of information including:

- contact details of relevant organisations
- relevant websites, including those focusing on financial benefits and returning to work
- other useful publications.

The sites or organisations listed in information should be reputable and assessed as providing high-quality support or information. Tools, such as the DISCERN questionnaire and the PEMAT, are a valid and reliable way for guideline developers to assess the quality of information provided by other organisations (DISCERN, Shoemaker et al. 2013).

Patient versions of guidelines might also provide practical advice, such as what to think of before an appointment with a doctor, or suggest questions to ask when talking to healthcare professionals. Patients involved in developing the patient version can compile their own experiences and offer tips on how to deal with the condition in daily life. For example, a patient version on diabetic foot problems could provide information on what to think of when buying shoes. This is an issue unlikely to be addressed by the guideline but which matters a lot to patients with diabetic foot syndrome. Also, patients involved in developing patient versions, as well as those involved in any wider consultation, can use their own experience and judgement to highlight further information they think would be important to other patients and information that goes beyond the information covered by the guideline. It should be clear in the patient version that further information is based on the experience of patients and not on a systematic search and appraisal of the evidence.

How are guidelines produced?

Patients and the public have very limited awareness of guidelines (Loudon et al. 2014, Sentell et al. 2013). When they are aware of them, they often think they are intended to restrict or ration the care available (van der Weijden at al. 2019). Research shows that some patients worry that guidelines might impair the relationship with their healthcare professionals by suggesting reduced confidence in them (Loudon et al. 2014). A patient version of a guideline is an opportunity to allay

these fears but care is needed to avoid providing too much, complex information about how the guidelines were developed. Some, but not all, people are interested in this information (DECIDE patients and public).

People have found process diagrams, such as the one in figure 2, useful and can help them to understand how information was produced. Although there are some differences in opinion, there is preference for this information to be at the back of the patient version. This is to ensure that the information that most people are interested in comes first, and those who want to can still navigate straight to the information on the guideline process (DECIDE patients and public). Nevertheless, patients taking part in German focus groups expressed a need to have this information at the beginning, because it would allow them to understand the extent to which the information that followed was reliable (Schaefer et al. 2015).

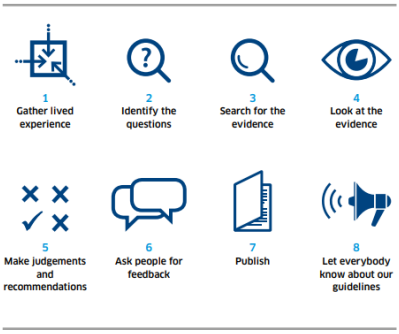


Figure 2 Example of a process diagram used by SIGN

Communicating the strength of a recommendation in patient-directed knowledge tools

Various standards for how to present recommendations advise that the strength of the recommendation and the level of evidence be presented separately (for example, a strong recommendation based on moderate quality evidence). The quality of evidence does, of course, affect the strength of the recommendation.

To enable patients to understand the strength of recommendations in patient versions, we suggest using several strategies, for example, using words and symbols. Some work has also indicated that people want to know why a recommendation is strong or not. Therefore, providing the reasons for a recommendation and what to consider may help.

Conveying the strength of the recommendation in words

Typically, guideline producers will use qualitative text to convey the strength of a recommendation in the original guideline document. For example, strong recommendations may be ‘recommended’ and weaker recommendations may be ‘suggested’. Different guideline producers may use different labels to convey the strength of the recommendation. When using the GRADE approach, recommendations are labelled as ‘strong’, ‘weak’ or ‘conditional’ (Guyatt et al. 2008). It may be helpful, regardless of the system being used, to include a legend in the patient version for the definitions of the terms used (Ottawa Hospital Research Institute 2020).

Research, in particular with healthcare professionals, has indicated that words are interpreted differently (Nast et al. 2013). To minimise misunderstanding, guideline developers should include symbols, other labels and or reasons for the strength of the recommendation. The reasons may be based on the certainty of the evidence, the differences in people’s preferences, resources or other issues, such as feasibility, accessibility or equity.

Using symbols to convey the strength of recommendations

Symbols were used in the WHO’s guideline on health worker roles in maternal and newborn health (see figure 3). The guideline was aimed at a range of stakeholders (although not the public). The symbols were well received.

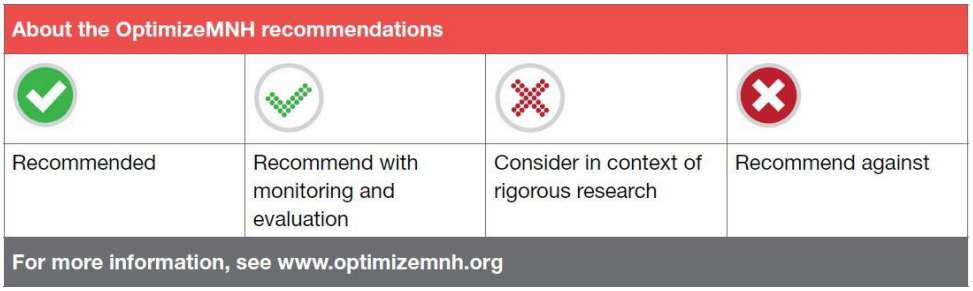


Figure 3 Symbols in WHO's guideline on health worker roles in maternal and newborn health that were tested with the target audience

The solid green ticks are strong recommendations in favour of the intervention, and solid red crosses are strong recommendations against the intervention. The dotted ticks and crosses are weak recommendations for and against the intervention, respectively.

Having learned from work with patients and the public (Ottawa Hospital Research Institute 2020), SIGN uses a system of icons with text to flag recommendations and their evidence level. The symbols in figure 4 were adopted for SIGN's autism booklet for patients, carers and families of children and young people, which is the public version of the autism guideline.

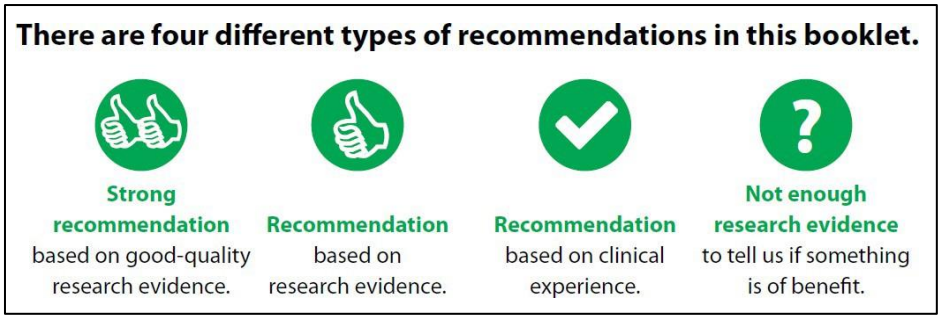


Figure 4 symbols tested with parents and carers for SIGN's autism booklet

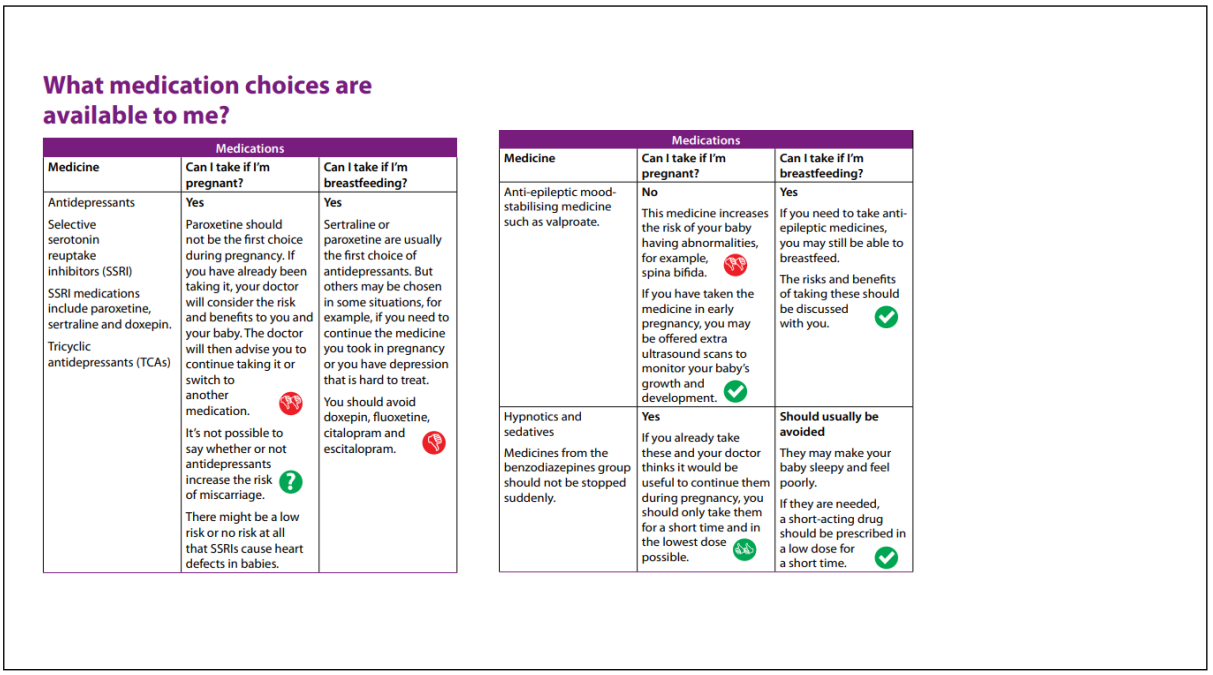
Use of symbols to express strength of evidence needs to be tested with the target audience. For example, parents and carers taking part in user testing of the symbols in figure 4, found the thumbs up, tick and question mark symbols clear and easy to understand. However, the response to the underlying 4 levels of evidence was mixed. Some parents appreciated the level of detail offered by the grades of evidence and recommendations, and others thought it would be sufficient simply to

know that SIGN recommended an intervention (DECIDE patients and public). The parents understood the essential message of the evidence levels, which is that one intervention is strongly recommended and another one less strongly recommended. But most did not understand why it is necessary to have these different levels of recommendation. Similarly parents found the not enough evidence icon disconcerting. Although they understood that the question mark and text was meant to convey uncertainty, they did not like this message, or understand why guideline producers would need to use it (DECIDE patients and public).

Presenting treatment options and communicating their risks and harms in patient-directed knowledge tools

Structuring the presentation

Structured presentations (especially with question and answer approaches) for presenting treatment options were well received and understood in work with patients and the public (DECIDE patients and public, Santesso et al. 2015). When summarising evidence on treatment options for patients and the public, a simple tabular format, as shown in figure 5, allows easy comparison and improves comprehension of treatment benefits and harms (DECIDE patients and public, Glenton et al. 2010, Loudon et al. 2014, Santesso et al. 2015, Santesso et al. 2016). ‘No treatment’ (doing nothing) should be considered and presented as an option to help people understand the benefits and risks of interventions. Presenting the benefits and harms for each option allows patients and the public to weigh these options against their personal values and preferences and can support conversations with healthcare professionals, something patients and the public have asked for (Santesso et al. 2016). It should be clear that information presented on the benefits and harms of treatment options is based on a systematic search and appraisal of the evidence.



What medication choices are available to me?

Medications		
Medicine	**Can I take if I'm pregnant?**	**Can I take if I'm breastfeeding?**
Antidepressants Selective serotonin reuptake inhibitors (SSRI) SSRI medications include paroxetine, sertraline and doxepin. Tricyclic antidepressants (TCAs)	**Yes** Paroxetine should not be the first choice during pregnancy. If you have already been taking it, your doctor will consider the risk and benefits to you and your baby. The doctor will then advise you to continue taking it or switch to another medication. It's not possible to say whether or not antidepressants increase the risk of miscarriage. There might be a low risk or no risk at all that SSRIs cause heart defects in babies.	**Yes** Sertraline or paroxetine are usually the first choice of antidepressants. But others may be chosen in some situations, for example, if you need to continue the medicine you took in pregnancy or you have depression that is hard to treat. You should avoid doxepin, fluoxetine, citalopram and escitalopram.
Anti-epileptic mood-stabilising medicine such as valproate.	**No** This medicine increases the risk of your baby having abnormalities, for example, spina bifida. If you have taken the medicine in early pregnancy, you may be offered extra ultrasound scans to monitor your baby's growth and development.	**Yes** If you need to take anti-epileptic medicines, you may still be able to breastfeed. The risks and benefits of taking these should be discussed with you.
Hypnotics and sedatives Medicines from the benzodiazepines group should not be stopped suddenly.	**Yes** If you already take these and your doctor thinks it would be useful to continue them during pregnancy, you should only take them for a short time and in the lowest dose possible.	**Should usually be avoided** They may make your baby sleepy and feel poorly. If they are needed, a short-acting drug should be prescribed in a low dose for a short time.

Figure 5 Example of presenting treatment options in SIGN's patient version of mood disorders in pregnancy

Using qualitative and quantitative statements about benefits and harms

Existing patient versions in the English language generally say little about potential benefits and harms of treatment options, and very few provide numerical information (Santesso et al. 2016). There is evidence that people's understanding of risk can be improved by presenting them with numbers rather than words and even when people say they prefer words, giving them both improves their understanding (Büchter et al. 2014, Knapp et al. 2014, Natter and Berry 2005). For numerical information, using absolute numbers, rather than relative numbers, and natural frequencies (for example, '50 of 100 people') are easiest to understand and are less confusing (Büchter et al. 2014, DECIDE patients and public, Knapp et al. 2014, Natter and Berry 2005). Evidence shows that patients and consumers overestimate risks when probabilities are presented in verbal terms. Using numbers results in more accurate estimates of risk (Büchter et al. 2014, Knapp et al. 2014, Natter and Berry 2005, Santesso et al. 2015, Trevana et al. 2013). There is good evidence, that presenting relative risk reduction alone leads to overestimation of treatment effects, so this should be avoided (Trevena et al. 2013). Although there is currently no certain way to present numerical information from guidelines to patients and the public, we

recommend guideline producers present information on benefits and harms and consider adding numerical information. Many people, although not all, would like to see such information on benefits and harms. Numerical information presented as a statement has been found to be more helpful than pictograms, but any numerical information should be tested with the target audience (Ottawa Hospital Research Institute 2020).

For qualitative text statements, standard text such as that shown in figure 6 provides consistency and includes both the size of the effect (for example, will not decrease, will decrease, probably decreases, may decrease, will not lead to more side effects) and the certainty and quality of the evidence (Büchter et al. 2014, Knapp et al. 2014, Natter and Berry 2005, Santesso 2015).

What happens to people who take vitamin C

This table provides more detail about what happens to people who take vitamin C. These numbers are based on the results of the research, when available. The quality of the evidence is either ranked as high, moderate, low or very low. The higher the quality, the more certain we are about what will happen.

What happens	Not taking Vitamin C	Taking Vitamin C (1 to 2 g per day)	Quality of evidence
Probably will not decrease how long the cold lasts if vitamin C taken as soon as the cold starts	The cold lasts **84 hours or 3 ½ days**	The cold lasts **2 fewer hours** (9 fewer to 4 more hours) *	⊕⊕⊕◯ Moderate
Will decrease how long the cold lasts if vitamin C taken before the cold	People at normal risk The cold lasts **84 hours or 3 ½ days**	The cold lasts **7 fewer hours** (3 to 11 fewer hours)	⊕⊕⊕⊕ High
Probably decreases how long the cold lasts if vitamin C taken before the cold	People at high risk The cold lasts **134 hours or 6 days**	The cold lasts **19 fewer hours** (8 to 30 fewer hours)	⊕⊕⊕◯ Moderate
Will not decrease the chance of catching a cold	People at normal risk **50 per 100 people**	**49 per 100 people** (48 to 50 per 100)	⊕⊕⊕⊕ High
May decrease the chance of catching a cold	People at high risk **70 per 100 people**	**35 per 100 people** (27 to 46 per 100)	⊕⊕◯◯ Low
Will not lead to more side effects	**6 per 100 people**	**6 per 100 people**	⊕⊕⊕⊕ High

Quality of evidence: The quality of the evidence is either ranked as high, moderate, low or very low. The higher the quality, the more certain we are about what will happen.
*The numbers in brackets show the range where the actual effect may be.

Figure 6 Format for presenting information from a Cochrane review of the effect of Vitamin C on the common cold in plain language (Hemillä et al. 2007)

Information about benefits and harms should refer to patient-relevant outcomes. Reporting on benefits could include controlling or getting rid of symptoms, prevention of recurrence, and eliminating the condition both short term and long term. Reporting on risks could include side effects, complications and adverse reactions to treatment, both short term and long term. Note that the harms of an option extend beyond clinical risks. For example, to make a treatment choice between radiation therapy and brachytherapy for prostate cancer, it may be important for some people that one

treatment is non-invasive and requires several sessions whereas the other is invasive and performed at a single session. If the effect of treatments on morbidity or mortality is unknown, this should be stated.

Presenting uncertainty

Patients and the public do want to know about uncertainty (Knapp et al. 2009). For example, how sure are we that X in 100 of those affected will have pain? This information can be understood if well presented. Most guideline producers will have a system to evaluate the quality or certainty of the evidence. Different systems such as symbols, words and letters may be used, and if not intuitive, it may be helpful to include a description of what the system means in the patient version.

In addition, if reference is made to treatments for which there is no or very low quality research, this should be made clear. It should not be confused with a treatment in which evidence has shown that the treatment has little to no effect. Figure 7 is an example of how SIGN has presented such information.

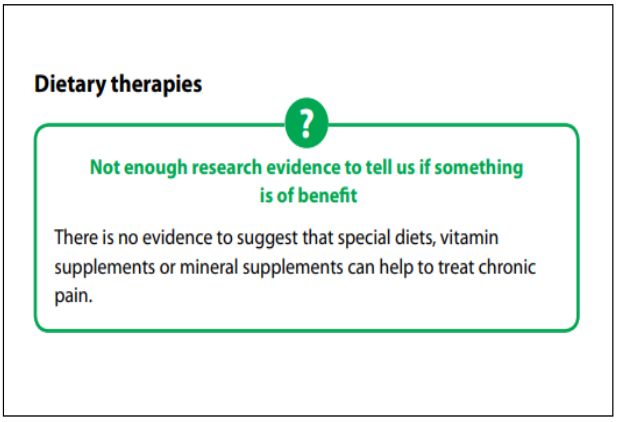


Figure 7 Example from SIGN on presenting information about a treatment which is not supported by the evidence

Using graphical approaches to present information

Focus groups and user testing with patients and the public found that patients and the public liked graphics to break up the text, but that graphics and charts should be kept simple (DECIDE patients and public). Those who used numerical information to increase their understanding of the risks and benefits indicated a preference for the

information to be presented in pie charts. Evidence from a low-quality randomised controlled trial suggests that bars, pictographs and tables tend to be efficient tools to present numerical information (Trevena et al. 2013). The authors found that information seemed clearer when presented in this format. Simple bar charts were easily understood although they don't convey uncertainty. Graphs should present benefits and harms on the same scale and alternative treatment options should be reported for the same outcomes.

Formatting and style of patient-directed knowledge tools

There are many potential formats for patient information derived from guidelines and the format used should take account of the target audience. In addition to this, the choice of format will depend on the topic and budget available.

There is no one-size-fits-all approach to developing guideline-based patient information (DECIDE patients and public). But consider the information in the sections on using a layered approach, personalisation, accessibility, and colour, fonts and graphics.

Using a layered approach for presentation of information

The length of patient versions produced by different organisations varies, with them ranging from 2 to 3 pages to 40 or more pages. Patients and the public accessing information in guidelines don't want to be overwhelmed by the amount of information (Cronin et al. 2018, DECIDE patients and public, Loudon et al. 2014, Utrankar et al. 2018). A German qualitative study on a plain language version of a breast cancer screening guideline found that people consider a brochure of 15 or more pages as 'long' and that it makes no difference for readers if this 'long' brochure has 15 or 150 pages (Frauenselbsthilfe nach Krebs [Womens Health Coalition] 2012). People like information presented in layers, which means that they can read as much or as little as they want. A useful approach is to have short paper versions and longer electronic versions, with the latter in particular using a layered approach (Ottawa Hospital Research Institute 2020). However, people with chronic conditions may appreciate longer booklets that can be read and reread time after time, thereby accompanying them through the whole process of care (Frauenselbsthilfe nach Krebs [Womens Health Coalition] 2012). Exactly how much information should be

provided depends on the target group and may be discussed early in the development process.

The concept of layered presentation, that is, the most important information in the first layer, less important in the next layer, is one of the strongest findings on work with patients and the public (DECIDE patients and public). For paper documents, patients and the public could select the recommendations for inclusion in the document. In the German National Disease Management Guidelines Program, the most important information is presented in a short information 2-page leaflet. The leaflet then refers to a comprehensive brochure that provides in-depth information. An example is their patient-information.de portal webpage on coronary heart disease. If necessary, more than 1 leaflet on different topics can be derived from a sinlge guideline. For example, SIGN's patient publications on the management of asthma present information from the guideline in various booklets, including a smaller booklet specifically on asthma in pregnancy. The flow of information in digital documents can be controlled by asking readers, who want more information on a topic, to click on text that has a link to another webpage or website.

Personalising the information

Many patient versions attempt to personalise the information provided. Participants in UK focus groups and user testing found personalisation useful because it makes it easier to think how the information is relevant to them. The same has been found in other fields (DECIDE patients and public, Glenton et al. 2010). The degree of personalisation that is possible and appropriate will be context specific.

The simplest personalisation is to have a statement at the beginning of the patient version saying to whom the information applies (see the section who this information is for). Some patient versions use the words 'you' or 'I' in text or headings to refer directly to the reader. For example, a heading could be 'What you need to know', or 'How much fibre do I need?'

Other ways to personalise information include personal stories, or narratives, of people with the same problem (Hartling et al. 2010). But, personal stories are not without problems, particularly regarding how to select stories for inclusion. For example, should the aim be to provide balance, to downplay problems, or to

emphasise benefits? Selection of patient stories has proved difficult in decision-support work (Winterbottom et al. 2008). Evidence also suggests that personal stories may influence risk perception and lead to over or underestimation of treatment effects (Betsch et al. 2011, Betsch et al 2013, Winterbottom et al. 2008). So, if treatment or test options are presented in personal stories, it may be important to select the number of stories in proportion to their potential benefit. Furthermore, highly emotional narratives seem to have a greater impact on the perceived risk (Winterbottom et al. 2008).

In reality, it may be difficult to find the best story but readers do need to be able to connect with how information in patient versions affects them. Online websites focusing on patient views have been increasingly accessed and it might be helpful for guideline developers to signpost readers to popular websites, such as healthtalk.org or patientslikeme. These websites could provide personal stories for patient versions of guidelines.

Using quotations from people who have the condition may also be a useful way to personalise the information in patient versions and to engage readers (Loudon et al. 2014). Work with patients and the public highlights that patients find quotations useful, helping them to relate to the material (DECIDE patients and public). The use of quotations has the same challenge as using patient stories in terms of deciding which quotes to select. It may be difficult to find quotations that are consistent with the evidence base presented within the patient version. Figure 8 provides an example of quotations that SIGN used to personalise information in its guideline on managing diabetes.

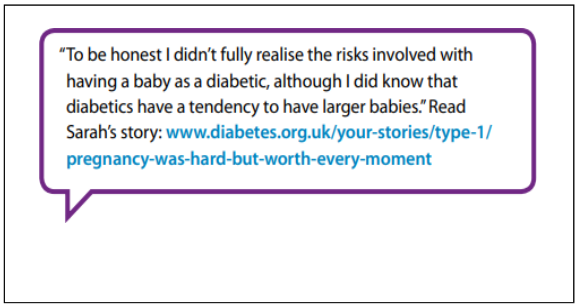


Figure 8 Quotation to personalise information in SIGN's guideline on managinging diabetes

Ensuring accessibility

If the audience is segmented into different groups, it may be beneficial to have multiple formats to maximise accessibility and findability. This includes the availability of hard copies as well as online versions of the material, such as access through mobile phone application, patient portal and access, and social media (Cronin et al. 2018, DECIDE patients and public, Utrankar et al. 2018). More and more patients, including older people, search for health information on the internet.

It has also been suggested that information for patients and the public linked to guidelines could be embedded within the guideline itself. This would allow healthcare professionals to more easily access it when having conversations with their patients (DECIDE patients and public).

According to Santesso et al. (2016), about half of existing patient versions are intended to be printed (although they are also available as pdfs) and half are intended to be read on-screen (although they can also be printed). Increasing accessibility of these may mean translating the patient version into other languages, as well as making versions available in large print, as audio or video. For example, SIGN produced information from a guideline on perinatal exposure to alcohol in the form of a booklet for parents andcarers and a YouTube video animation for young people on perinatal exposure to alcohol.

Guideline developers providing information in the form of web-based materials should ensure they are accessible for all. Careful consideration should be given to colour contrasts and making text clearer. Adding descriptions to images, which screen readers can then interpret, can give people access to all the information from guidelines. By adding descriptions to different command buttons, patients can more easily navigate the online information.

Patient information derived from guidelines should be easy to find. In Santesso et al.'s review (2016), the easiest patient versions to find were ones from a guideline organisation that also had a dedicated patient website. Of course not all guideline

producers can have a whole website, although it is still possible to make it easy to find patient versions. For example, by having a dedicated section of the guideline producer's website to list patient versions of guidelines. If the patient version is on another organisation's website, it should be easy for people to find it when searching for help on their condition. For example, NHS Inform (Scotland's single source of quality-assured health information) provides links to patient versions of guidelines on their website to help people to find them when searching for information on conditions. Evaluation of German patient versions has suggested that patients wanted healthcare professionals to forward the patient version to them (Schaefer et al. 2015).

If the patient version is designed for healthcare professionals to use in their conversations with patients, or to hand a printed copy to them, then it should also be simple for healthcare professionals to access. Therefore, it may be helpful to provide the patient version along with the guideline itself to ensure that healthcare professionals who look up the guideline will also find the patient version. Incentives for healthcare professionals to provide the patient version of the guideline may foster implementation. For example, a German survey found that most patients learned about patient versions of guidelines from their physicians (Schaefer et al. 2015).

Patients and the public have very low awareness of guidelines (Loudon et al 2014, Utramker et al. 2018), so it is likely that most people will not be looking specifically for guideline-related material when using, for example, internet search engines to find materials. Guideline producers may need to get professional help to assist them in getting 'hits' so that they reach their target audiences, and to ensure that the patient versions are indexed to their best advantage to allow search engines to find them. Patient organisations and other voluntary organisations should also be encouraged to promote patient versions of guidelines on their websites.

Patient information derived from guidelines should also be easy to read. Easy read is one form of accessible information. They use short, simple sentences and pictures to explain topics. For example, easy read documents provided by Mencap on keeping clean and handwashing help explain guidance during the Covid-19 outbreak.

The amount and level of technical terms that people are confronted with in patient versions of guidelines should be carefully considered (DECIDE patients and public) Health literacy varies and depends especially on socioeconomic status, education and ability to speak the language the patient version is written in, with lower levels of health literacy being associated with poorer health outcomes (Berry et al. 2010, Wolf et al. 2005). Plain language should be used, unless it is absolutely essential to use specialist language, so as to not exclude some of your audience. Using terms like 'lymphadenctomy' or 'types of pharmacological treatments' will make a leaflet or a brochure difficult to understand for many (perhaps most) of the people expected to read the material. On the other hand, these are the expressions patients may hear during their conversations with healthcare professionals. Health forums may also provide some indication of words that are presently being used by patients and the public. Current patient versions have provided terms and defined them in an understandable way, for example, in brackets after the term, separately in a box, or as part of a short glossary at the end of the document (both NICE and the German National Disease Management Guidelines Program do the latter for their guidelines).

Colour, fonts and graphics

The text size and colours used in graphics must be appropriate for the target audience (DECIDE patients and public).

Colours

Poor choice of colours can make a document hard to read; avoid using light text on light backgrounds and dark text on dark backgrounds. Some colour combinations may work better (or worse) on computer screens than in print.

Colour blindness affects about 1 in 8 men and 1 in 200 women, so should be considered when selecting colours for use in patient versions. Common types of colour blindness are:

- red/green colour blindness
- blue/yellow colour blindness

Avoid using these combinations of colours together. Similarly, the use of pale pastel colours is not helpful for people with visual impairments (DECIDE patients and public).

The use of colour can also convey meaning, which may not be what is intended. Black can sometimes be associated with death and red can be seen as highlighting danger (DECIDE patients and public). Inconsistent use of colour in documents can be confusing (DECIDE 2011 – 2015). Colour coding recommendations can be problematic and are required to take into account people's pre-existing associations with colour, for example, red for stop, green for go (DECIDE patients and public). The way that colour is used to differentiate between recommendations needs to be clear in patient versions of guidelines (DECIDE patients and public).

Fonts

A font with a clear design should be used to ensure accessibility. Use a minimum font size of 12 pt for standard versions and a minimum font size of 16 pt or larger for large print.

Graphics

Give careful thought to the use of graphics. Patients and the public like the text to be broken up (DECIDE patients and public), but the graphic should carry useful information, not simply be a decorative element.

The way information is presented can affect perceptions of its trustworthiness. Using cartoons in a physical activity patient version, for example, meant that people had less trust in the information it contained; indeed it led people to question whether adults were the target audience at all (Berry et al. 2010, Loudon et al. 2014). However, cartoons have been helpful when addressing people with learning disabilities. Logos can help if these are a recognised 'brand' for patients and the public, but too many becomes overwhelming and may be counter productive (DECIDE patients and public).

Table 4 provides some tips for using graphics.

Table 4Tips for using graphics in patient versions

Use	Avoid
• Graphics relevant to the topic to illustrate what the patient version is about • Annotated diagrams to explain conditions • Images to break up the text to make the patient version patient friendly • Metaphorical images such as a blocked pipe to illustrate blood clot	• Graphics that may be upsetting or patronising • Complex, technical diagrams • Cartoons, because these are difficult for patients to identify with • Too many logos, which can be confusing for patients and distracting

Ensuring transparency in patient-directed knowledge tools

The authors and organisations producing patient-directed knowledge tools should declare their financial and intellectual conflicts of interest (COI). This includes patient or consumer representatives and their organisations. It should be clear what influence, if any, individuals and organisations had, or could be perceived to have had, on the content of the patient version. The same COI declaration forms as used for guideline development groups may be used, showing that patient versions are linked to the guideline not only in terms of content but also in terms of methods and transparency. If all authors of the patient version have already been part of the guideline panel, a new declaration of COI might not be necessary.

Evaluating patient-directed knowledge tools

Users of patient-directed knowledge tools should be encouraged to provide feedback on the information. Feedback should be collected and considered when updating the information. Ways to collect feedback may include a structured questionnaire at the end of the information, tests with focus groups, or surveys. It can also be useful to ask for feedback from other stakeholder groups, because they might be able to assess the extent to which the patient-directed knowledge tool helped their patients who are members.

Getting feedback on patient versions of guidelines

Asking a wider group of patients and public for input and feedback on the patient version can help ensure it is accessible to the target audience (SIGN 2019, van der

Weijden et al. 2019). The chapter on how to conduct public and targeted consultation provides more details. The purpose of collecting feedback is to ensure the patient version:

- Provides useful information that helps patients make decisions.
- Provides patients with further experience and support regarding coping strategies or other issues that are not covered by the guidelines, but may matter to patients in their daily life. These can be provided directly in the patient version or indirectly through links to sources of further information and support.
- Is seen as relevant to patients and consumers.
- Has a useful layout that patients can effectively navigate.
- Uses appropriate language, fonts and graphics.

Various methods can be used to obtain feedback, depending on the intended audience and the intended goals. For example, an open consultation can help to foster ownership and transparency, whereas workshops can help to obtain specific feedback on relevance to readers and their level of understanding. Other methods include:

- Circulation of the document to guideline developers' own patient or consumer networks and voluntary organisations for written comment.
- Use of discussion groups to provide feedback, for example a discussion group with children and young people may be more effective than written consultation.
- Consulting patient organisations who have broad experience with patient counselling and collect data on individual experiences.

An example of questions guideline developers may want to ask patients and consumers is given in appendix 6.1. To ensure transparency, the methodology and process of development should be well documented. The case study in table 2 shows how SIGN gathered feedback on their patient version of the migraine guideline.

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Resources: appendix 6.1

Consultation on patient version of guideline on xxxxxxxx

Name:

Job title (if applicable):

City/Town:

Presentation (Please tell us what you think of the way the booklet is presented)

Is the layout easy to read?

Are the images and diagrams appropriate and meaningful?

Writing Style (please tell us what you think of the way the booklet is written)

Do you think that the language and tone is appropriate?

Content (please tell us what you think of the content)

How useful is the content?

Does the content help patients and carers understand what the latest evidence supports around:

- diagnosis
- treatment
- self-care

How to foster shared decision making through guidelines

Corinna Schaefer, Andy Hutchinson

Corresponding author: schaefer@azq.de

Key messages of this chapter

- Healthcare professionals (HCP) have the responsibility of enabling shared decision making (SDM). Guidelines guide HCPs to make clinical decisions. To foster shared SDM in clinical practice, guidelines have to reflect this concept in their structure, wording, content and tools.
- For a patient-centered guideline approach, it may be helpful to combine goal setting, goal-based SDM, the consideration of contextual factors, and the continuous evaluation of treatment goals, treatment burden, and barriers to adherence.
- Strategies to enable SDM through guidelines include:
  - use of wording that supports discussion between the patient or service user and health or social care professional about their care
  - presentation of options and their harms and benefits in a way that enables risk communication and discussion of options
  - systematic identification and prioritisation of recommendations and clinical situations that are most relevant to SDM
  - provision of a generic chapter on SDM
  - provision of guideline-based decision tools
  - integrating SDM aspects and decision aids into the guideline, recommendations and algorithms.

Top tips

- Implementing SDM-enhancing strategies in guidelines needs strategic planning from the very beginning, including scoping, formulation of review questions, and

evidence selection or interpretation. A clear responsibility within the guideline production team for including SDM is helpful.

- The guideline team may not have all the expertise needed, or at its disposal, for implementing SDM-enhancing strategies (for example, medical writers or information specialists to design decision support tools for patients). Check beforehand what expertise might be needed and seek collaboration.
- If resources are scarce, it is helpful to prioritise clinical situations or recommendations in which SDM is of high importance when creating additional tools for decision support.
- The guideline group should review and approve all additional tools (patient information or decision support tools) to ensure consistency with the recommendations.

Aims of this chapter

This chapter provides a rationale for harmonising guidelines with shared decision making (SDM) and discusses strategies for fostering SDM through guidelines. It does not discuss the concept of SDM, the underlying evidence or the different types of decision aids in use, nor does it provide evidence on their effects and how these can be measured. Information on these topics can be found elsewhere, for example National Institute for Health and Care (2021a) and Stacey et al. (2017). Instead, this chapter focuses on the guideline developer's perspective and aims to provide practical support that is mostly based on experience from various guideline development processes.

Rationale: SDM and guidelines

Theory and practice: definition of clinical practice guidelines

Guidelines can be understood as tools to support clinical decision making. In its 2011 standard reference work, 'Clinical practice guidelines we can trust', the US Institute of Medicine (2011) states:

'Rather than dictating a one-size-fits-all approach to patient care, [clinical practice guidelines] should aid clinician and patient decision-making by clearly describing and appraising the evidence and reasoning regarding the likely benefits and harms related to specific clinical recommendations.'

SDM is a key element of the clinical encounter as reflected in patients' views. Its importance, and the need for input from healthcare professionals (HCPs) when making a treatment choice, were recurrent findings in DECIDE research (Fearns et al. 2016). The Institute of Medicine's definition emphasises that guidelines can support HCPs in guiding patients through the SDM process.

However, some considerations and insights from guideline research suggest that clinicians' misconception of the underlying evidence, the format of many guidelines, and the wording of their recommendations might be a barrier to individual SDM:

- Evidence from a large sample of various guideline groups and a review of qualitative evidence (Carlsen et al. 2007) suggest that some clinicians may

misinterpret guideline recommendations as absolute do's or don'ts that are opposed to SDM. This seems to apply especially to recommendations in favour of interventions.

- The development of guideline-based performance measures and pay-for-performance models may plausibly lead to clinicians following recommendations rather than discussing options with their patients, especially when these impact on either certificates or reimbursement (Legaré and Witteman 2013). The same may apply to the increasing role that guidelines have in legal contexts, that is, malpractice claims (Mackey and Liang 2011).
- A survey among physicians indicated that stronger and weaker guideline recommendations may be perceived as equally binding (Nast et al. 2013).
- In the literature, guidelines have been largely criticised for not providing guidance for individual situations that may need to go beyond the generalisation of a given guideline recommendation. This may be especially so when patients have comorbidities or multimorbidity (Elwyn et al. 2016; Young et al. 2015).

Key to success: harmonising guidelines with SDM

Guidelines, in a widely cited definition (Institute of Medicine 2011), are described as facilitators of clinical decision making. However, their potential to impede patient-centred decision making has to be taken into account.

In their Guidance manual, the German Association of the Scientific Medical Societies addressed this issue by explicitly stating:

'Guidelines can be understood as "treatment and decision corridors" which can or should be deviated from in justified cases. The applicability of a guideline or individual guideline recommendations should be reviewed in individual situations in the individual encounter according to the principles of shared decision-making.' (German Association of the Scientific Medical Societies 2012)

Therefore, guideline adherence truly means meticulously considering whether to deviate from a recommendation in the care of an individual person and discussing this with them (Kühlein and Schaefer 2020). To support clinicians in doing so, it is most important to integrate tools and elements into the guideline that facilitate talking about these options and SDM. This is why guidelines and decision tools have been

stated as maintaining an ‘inevitable relationship’ (van der Weijden et al. 2012). Such a relationship seems crucial, because the format of many guidelines does not provide even basic elements that enable HCPs to present options and their probabilities to patients (Morgott et al. 2019).

The patients’ view seems to support this. Qualitative evidence from the DECIDE project indicated that patients need health information that enables them to choose between treatment options, including information about harms (Fearns et al. 2016). They would like help with making such choices from HCPs, especially general practitioners. Hence, guidelines have an important role here because they are mainly aimed at HCPs.

The following sections provide some guidance about different tools and strategies guideline that developers may use to enable and support SDM through guidelines.

Strength of the recommendation – a trigger for SDM?

Before presenting different enablers for SDM in guidelines, we will discuss whether or not SDM is more applicable for some recommendations than others. We will also discuss whether the strength of a recommendation has a role in deciding this.

Some models that assess the potential for SDM in guidelines suggest that weak recommendations are most appropriate for sharing decisions. This applies especially to the GRADE framework: ‘*When a recommendation is weak, clinicians and other health care providers need to devote more time to the process of shared decision-making by which they ensure that the informed choice reflects individual values and preferences.’* (Andrews et al. 2013)

However, in their DECIDE work, Fearns et al. found that weak recommendations triggered strong negative reactions from members of the public (2016). Although they understood that a weak recommendation was less strongly endorsed, they often interpreted it as the intervention not being effective.

Weak recommendations are made when there are different options, including no intervention, that are equally sensible and choices may differ largely among individual patients depending on their individual situations. Therefore, without any

question, SDM applies here. However, SDM may be equally important in relation to strong recommendations, if the situation is appropriate (that is, it is not an emergency situation). It is assumed for strong recommendations that most informed people would decide in favour of the recommendation. But this raises the question of who makes that assumption. The experience, concerns and preferences of the guideline developers may not be shared by all patients. Several people may decide differently, in the context of their particular circumstances. These circumstances are characterised by the International classification of functioning, disability and health's (ICF) contextual factors and may present good reasons for deciding against a well-established, evidence-based intervention (World Health Organization [WHO] 2001).

These contextual factors include:

- environmental factors: factors that are not within the person's control, such as family, work, government agencies, laws, and cultural beliefs
- personal factors: factors such as race, gender, age, educational level, coping styles, health status, and risk attitudes, which vary widely among individuals and cultures.

Offering SDM enables patients to make a decision that best suits their individual and environmental conditions. Box 1 provides an example of a guideline panel deciding to provide a decision aid for a strong recommendation.

Box 1 Case study of decision support for a decision on taking statins for coronary artery disease in the German national disease management guideline on chronic coronary artery disease (Bundesärztekammer 2019)

Background

High grade evidence for statins in patients with coronary artery disease (CAD) shows consistent effects on mortality and morbidity and only rare adverse events. However, myalgia has often been reported under statin use, although randomised control trials showed no difference between intervention and control groups therefore suggesting a nocebo effect. Most

guidelines give a strong recommendation in favour of statins for patients with CAD.

Rationale

Based on clinical experience, the large multidisciplinary guideline panel identified that the decision to start or continue statins was a key situation for SDM, mainly for 2 reasons:

- they assumed there was considerable overtreatment in older patients on polypharmacy, and
- according to their clinical experience, some patients refuse to take statins because of the false belief that these caused muscle pain.

Intervention

A decision support tool was designed, based on the results of the systematic review for the guideline, that provided a drugs fact box for statins and additional plain language information, which clearly explained why myalgia was most probably not caused by the medication. It was formatted so that it could be printed and handed out to patients (as a short leaflet) as well as being used online. The tool underwent formal consensus and was integrated into and published with the guideline. It was provided to clinicians (through the guideline and the webpage for physicians), but was directly and freely accessible for patients (though the patient webpage). Evaluation showed that physicians thought such tools were helpful in the clinical encounter and that most would use them with their patients (Schwarz et al. 2019).

Preference sensitivity

It is widely recognised that SDM is a concept to tackle preference sensitive decisions (Elwyn et al. 2009). As indicated by the above ‘GRADE’ definition, a considerable group of guideline developers and methodologists assume that weak recommendations indicate such preference sensitive decisions. However, not all guideline groups are consistent in their choice of the grade of recommendation for

identical clinical questions. Every recommendation is not only based on the underlying evidence but on the collective value judgement of a specific group, influenced by, among others, their experience, academic interests and professional background. Hence, although there is some overlap between preference sensitive situations and situations where guideline panels make weak recommendations, they are not totally congruent. The concept of preference sensitivity needs to be operationalised to help identify situations where SDM is most appropriate. An example of operationalisation is shown in box 2.

Box 2 Case study on operationalisation of 'preference sensitivity' to guide the development of decision support tools for guideline developers

The National Institute for Health and Care Excellence (NICE) uses an operationalised concept of preference sensitivity in its process guide for decision aids. The concept is used to determine whether or not a decision point in a guideline needs more support to enable SDM, and has characterised those decisions as follows:

'Preference-sensitive decision points are points where the person's values and preferences are particularly important. They occur when either:

- There are 2 or more options for investigation, treatment or care that deliver similar outcomes but:
  - they have different types of harms and benefits which people may value differently, or
  - the likelihood of the harms or benefits may differ, or
  - the practicalities of the options are different (for example, the choice is between medicine and surgery, or the requirements for monitoring differ), or
  - people may consider the overall risks of harms for any of the options outweigh the overall benefits compared with no treatment or
- The choice between an investigation, treatment or care option and the option of 'no treatment' is finely balanced.' (NICE 2018c)

Strong recommendations against interventions – providing rationales, not options

Strong recommendations against interventions are rare and usually made when a panel is sure that an intervention provides no benefit but substantial harm. It is hard to imagine that any reasonable and informed person would choose an option that does them no good, but instead, puts them at risk of serious harm. SDM requires commitment from patients and for some it may even be hard work discussing options with their doctor, reading, understanding the evidence, weighing up the benefits and harms, and making a decision. It is reasonable to ask whether the commitment, time and resources are necessary when there is no sensible alternative, and if patients and HCPs might rather need another type of information in these situations, that is, information that explains and supports a recommendation instead of offering options. Evidence from DECIDE indicates that when making a decision, patients want an honest explanation of the rationale behind such a recommendation (Fearns et al. 2016).

For example, imaging for low back pain is not recommended in the absence of red flags indicating a serious condition. Evidence has shown that imaging does not lead to better outcomes but may cause unnecessary treatment and increase the risk of the problem becoming chronic (Chou et al. 2011). Most guideline panels make a strong recommendation against imaging for low back pain. However, research indicates that patient expectation may be a driver of unnecessary testing because of the false belief that imaging is beneficial, and because patients may feel uncomfortable and not acknowledged when not getting a test or a treatment (Warner et al. 2016, Parmar 2016, Pathirana et al. 2017).

The idea that recommendations against interventions need transparent communication is reflected in the concept of ‘Choosing Wisely’. In the US, the Choosing Wisely programme is collaborating with Consumer Reports to provide patient leaflets for all Choosing Wisely recommendations. However, these recommendations seem to not have been implemented very well (Hong et al. 2012). They have also been shown to not adhere to international quality standards (Legaré et al. 2016). This indicates that information supporting negative recommendations:

- needs to be provided to patients and physicians at the same time, and
- has to be designed carefully and respect patients' autonomy.

In the NICE guideline on dementia (NG97; NICE 2018a) a strong recommendation is made against routine enteral feeding for people living with severe dementia. A decision support tool on enteral (tube) feeding for people living with severe dementia was developed to guide discussions between HCPs and patients, their carers and relatives (NICE 2018b). Although being called a decision aid, the tool clearly explains the certainty of the evidence regarding harms and the lack of evidence for any benefit, thereby being strongly supportive of the recommendation.

In conclusion, we strongly suggest that:

- strong recommendations **in favour of interventions** (if not addressing emergency situations) be carefully considered for SDM with decision tools provided
- strong recommendations **against interventions** need careful discussion with the patient, supported by information that explains the rationale rather than offering options.

Strategies to foster SDM in guidelines

In the following paragraphs, we present some strategies that might help to harmonise guideline recommendations with SDM. However, developing a guideline in a way that enables and promotes SDM will require strategic planning by a guideline team who is committed to this concept, oversees the whole guideline production process, and creates a guideline format that is most appropriate to enable SDM for the specific condition or topic in question.

Strategic planning and the provision of additional guideline-based knowledge and decision tools also need resources and expertise. Not every guideline group will be able to adopt all the strategies suggested in this section and they will not be suitable for every recommendation in a guideline. Therefore, the group will need to prioritise which strategies to use and which recommendations to choose. Some suggestions on how to identify such recommendations are given at the end of this chapter.

Based on qualitative interviews with guideline and SDM experts and group discussions with international participants, a team of experts developed a framework of suggestions on how guidelines could be adapted to enable SDM. They characterised these strategies as those:

- aimed at HCPs or patients, or
- generic or aimed at a specific recommendation (see table 1; van der Weijden et al. 2013).

Table 1 Strategies for implementing SDM in guidelines (adapted from van der Weijden et al. 2013)

Strategies within the guideline, aimed at the HCP	**Strategies within the guideline, aimed at the HCP**	**Strategies linked to or within the guideline, aimed at the patient**	**Strategies linked to or within the guideline, aimed at the patient**
Generic strategies	*Recommendation-specific strategies*	*Generic strategy*	*Recommendation-specific strategies*
• Separate chapter on SDM • Language that involves patients	• Cluster 1: Structuring options to increase option awareness • Cluster 2: Structuring the deliberation process	• Patient version of a guideline	• Cluster 3: Providing patient support tools linked to or within the guideline

Some of the suggested elements have generally been shown to be effective, such as decision aids (Stacey et al. 2017); others lack direct evidence and are based on reasoning, experience and expert opinion. The list of strategies is not complete and they should be understood as suggestions that have been found to be helpful and feasible, based on experience in various guideline groups.

In the following sections, we discuss generic strategies and then move on to those aiming at a specific recommendation or topic.

Changing the wording in recommendations

A very simple strategy that highlights the importance of patient-HCP interaction is using wording that encourages discussion and engagement in SDM. For example, using ‘offer’ or ‘recommend’ instead of ‘perform’, and ‘discuss with the patient’ instead of ‘do’. Currently, it seems that several guidelines have adopted this wording, as shown in an investigation of 2 national guideline programmes in Germany (Schaefer et al. 2015).

The GRADE wording of ‘we recommend’ and ‘we suggest’ reflects this idea, although some guideline groups were not altogether comfortable with ‘suggest’ always indicating a weak recommendation. This might not offer enough guidance, because it does not allow differentiation between options that are poorly investigated, and options that have high-grade evidence showing benefit outweighing harms, but with a risk profile or treatment burden such that individual choices are likely to be highly preference sensitive.

Presenting options and their benefit–harm profile in the guideline

This strategy aims to present the options discussed in the guideline in a way that enables HCPs to adequately discuss them with patients. The presentation should also include evidence-based options that may be viewed as second best by professionals (for example, because they are deemed to be less effective), but that may be embraced by patients (for example, because of less intense side effects).

It seems a promising strategy because evidence suggests that some physicians have difficulties in understanding relative risks and adequately communicating those (Wegwarth et al. 2012). It includes:

- listing all the options including no intervention in a comparable format, ideally in tables or graphs
- providing the benefit–risk profile with important outcomes, including treatment burden (Dobler et al. 2018) that allows comparisons of options by:
  - providing absolute effect sizes rather than relative reductions
  - using the same framing for all options and outcomes presented

- avoiding wording that suggests a value judgement (such as ‘dramatic reduction’ or ‘minimal increase’)
- highlighting uncertainty (in wording and effect size, with confidence intervals).

For evidence on some of these options see the systematic reviews in Lühnen et al. (2017).

However, a study investigating international guidelines on cardiovascular disease and diabetes found that the vast majority did not provide absolute risk reductions or the numbers needed to treat for interventions (Morgott et al. 2019). Therefore, they did not allow HCPs to grasp the relevance and effect size of the options in question and compare them.

Providing a generic chapter on SDM in guidelines or developing a guideline on this topic

The rationale for a generic chapter on SDM in guidelines is that it could potentially raise awareness of SDM among HCPs, address perceived enablers and barriers to SDM expressed by HCPs, and offer solutions (van der Weijden et al. 2013). There are different examples of such chapters in various guidelines, and they differ in length, content and format. To our knowledge, to date, none of these chapters has been evaluated or tested with guideline users. Therefore, their impact on guideline users remains unclear. Potential downsides of this approach are that:

- its impact may be limited if it is not referred to in the diagnostic and treatment recommendations
- it may easily be ignored by guideline users if it stands separately, and
- it may only be read carefully by those who are already aware of the importance of SDM.

We suggest that if this strategy is adopted, the chapter should not be designed as a textbook. Instead, it should offer practical examples on how to integrate SDM and patient centeredness into treatment planning and evaluation and the examples should be referred to in all relevant recommendations. Discussing treatment goals and planning or evaluating treatment is a core principle of health care provision. Therefore, the concept of goal-based SDM may provide a valuable link between

guideline structure and SDM (Elwyn et al. 2020). Box 3 provides an example of a comprehensive generic SDM chapter and its content.

Box 3 Case study on a generic chapter on SDM and treatment planning in the German national disease management guideline on the treatment of type-2 diabetes (Bundesarztekammer 2021b)

Background: Among specialty societies, such as the American Diabetes Association (2020), it is largely accepted that optimal treatment of diabetes requires discussion of individualised disease-specific treatment goals (HbA1c, blood pressure, cholesterol), and continuous evaluation and adjustment of treatment strategies and goals. The German national disease management guideline (GNDMG) on type-2 diabetes provides, to our knowledge, the first model on how to integrate treatment planning and SDM in a guideline.

Content: The chapter was structured to highlight the close relationship between goal setting, SDM and evaluation. The guideline panel made consensus-based recommendations and offered practical advice on the following topics:

- Agreement on and continuous evaluation of treatment goals:
  - considering and prioritising fundamental, functional and disease-specific goals (Elwyn 2020).
- Risk communication on diagnostic and treatment options:
  - principles of adequate risk communication in the context of the clinical encounter (Elwyn et al. 2006, German Network for Evidence-based Medicine 2015).
- SDM:
  - presentation of the SDM-Model and suggestion of questions and phrases to enable HCPs' engagement in SDM (Bieber et al. 2016, Elwyn et al. 2017).
- Assessment of contextual factors that may influence prognosis, goals, treatment burden and adherence:

  - before prioritising goals and planning therapy, assess and consider contextual personal and environmental factors (WHO 2001).
- Continuous evaluation of goals, treatment burden and adherence:
  - if goals are not met, before changing treatment strategies:
    - ◊ assess contextual factors as potential reasons and offer solutions, and
    - ◊ evaluate if individual goals are still valid, and if not, agree new goals.

The guideline underwent public consultation. Comments on the SDM chapter highlighted its importance and that it was very helpful. However, others indicated that they felt that, although helpful, it was too complex. (Bundesärztekammer 2021b)

Recently, the NICE guideline on shared decision making (NG197; NICE 2021) issued the first ever, to our knowledge, clinical practice guideline on SDM (see box 4). Many of the advantages and limitations discussed earlier may apply equally to this guideline. However, it has already demonstrated its potential to raise awareness and it is unique in addressing system-related factors that may enable or hinder SDM in practice, referring to the concept of organisational health literacy.

Box 4 Case study on development of a specific guideline on SDM (NICE, NG197, 2021)

Background: Every NICE guideline includes a statement emphasising that it is not mandatory to apply the recommendations and that, although professionals and practitioners should take the guideline fully into account, they should also consider individual's needs, preferences and values, and make decisions in consultation with them and their families and carers or guardian. NICE has also recommended SDM in several general guidelines, such as on patient experience in adult NHS services (CG138, NICE 2012), medicines optimisation (NG5, NICE 2015) and multimorbidity (NG56, NICE 2016). Topic-specific guidance also often explicitly recommends SDM for

specific decisions. But because SDM is not yet routinely practised in the National Health Service (NHS), NICE was asked to produce guidance about facilitating SDM and embedding it in everyday practice.

Content: The NICE guideline on shared decision making (2021a) addresses the 'three legged stool' of the implementation challenge for SDM: engaging and empowering patients and people who use services; engaging and supporting individual HCPs; and engaging senior managers to embed SDM into healthcare organisations and systems. The guideline covers:

- Embedding SDM at an organisational level, including:
  - making a senior leader accountable for embedding SDM within healthcare organisations
  - identifying senior HCPs and service users as champions for SDM
  - developing an organisation-wide improvement plan to put SDM into practice
  - ensuring that training and development for HCPs in SDM includes specific components
  - promoting SDM to people who use services.
- Putting SDM into practice, including:
  - supporting SDM by offering interventions at different stages, including before, during and after interactions in which a healthcare decision might be made.
  - giving guidance on what that support should include.
- Patient decision aids (PDAs), including:
  - how HCPs can make best use of PDAs
  - how organisations can facilitate use of PDAs by HCPs.
- Communicating risks and benefits, including
  - discussing consequences in the context of each person's life and what matters to them
  - giving specific recommendations on how to discuss numerical information with service users.

The guideline generated a large number (more than 1,100) of comments at public consultation. These were generally supportive. Regarding the development of the guideline, NHS England and NHS Improvement commissioned the development of the NICE Standards framework for shared-decision-making support tools, including PDAs (NICE 2021c). This will help users assess the usefulness and quality of a PDA and help PDA developers conduct a self-assessment of the quality of their tools and processes. To support implementation of the guideline, Keele University and NICE worked in partnership to develop a free online SDM learning package (NICE 2021b).

Systematically identifying and prioritising situations needing SDM support in the guideline

Some clinical situations described in a guideline will be essential for supporting SDM, but others may be of lesser importance. It may be helpful to systematically identify and prioritise such situations. This helps with structuring the guideline process, raising the guideline groups' awareness of emphasising SDM in the guideline, and assigning resources to the clinical situations that are key for decision support. The aim is to highlight throughout the guideline those recommendations that are most important when providing recommendation-specific decision support tools.

For setting up a structured process, it is important that a guideline group includes HCPs and patients or lay persons. It may be achieved through a criteria-based group rating or other consultation methods (see the chapter on how to conduct public and targeted consultation). For example, the German Association of the Scientific Medical Societies has systematically developed a very elaborate process to identify recommendations suitable for Choosing Wisely, based on rating criteria with a 4-point Likert scale (German Association of the Scientific Medical Societies 2020). This process can easily be adapted to identify SDM-priority recommendations. Nevertheless, simple surveys among the guideline group or other consultation methods can be equally helpful.

Developing guideline-based patient-directed knowledge or decision tools

When a situation with specific need for decision support has been identified, respective tools should be provided. Van der Weijden et al. (2013) suggested a patient version of the guideline, although awareness of other information formats for patients that may accompany a guideline has increased over time. For more information on patient versions of guidelines, see chapter on how to develop information from guidelines for patients and the public.

However, the concept of patient versions of guidelines is not well implemented. For example, a structured analysis of the German Guideline registry indicated that only 35% of all guidelines provided patient versions (Ollenschläger 2018). Furthermore, many providers use patient versions to give specific information in an easy-to-read manner rather than as a tool that the patient and health care provider can use through an SDM process.

A group of researchers recently presented a framework to characterise and categorise the various patient-directed knowledge tools, including those that may be suitable to supporting clinical decisions (Dreesens et al. 2019). For a detailed description of this framework, see the chapter on how to develop information from guidelines for patients and the public.

Furthermore, quality criteria regarding the production of guideline-based patient-directed knowledge tools have been formulated (van der Weijden et al. 2019). They should inform the development process

Among the suggested formats to support decision making, the framework presented by Dreesens et al. (2019) lists decision trees, pre- or post-encounter patient decision aids, patient versions of guidelines, and encounter decision aids (see table 2). But only encounter decision aids are labelled as engaging SDM, based on the existing evidence (Coleywright et al. 2014, Wyatt et al. 2014):

Table 2 Patient-directed knowledge tool types (adapted from Dreesens et al. 2019)

Purpose	Patient information and educational material	Decision tree	Independent/ pre- & post-encounter PDA	Patient version of guideline	Encounter-PDA
To inform or to educate	+	-	+	+	+
To provide recommendation(s)	-	+	-	+	-
To support decision-making	-	+	+	+	+
To engage in SDM	-	-	-	-	+

Encounter decision aids are short tools designed to be used during consultation ('point of care' tools). They may vary in format and may be presented, for example, as Option Grid decision aids, drug facts boxes (Schwartz and Woloshin 2013), or interactive online tools, such as tools for GPs.

The International Patient Decision Aid Standard (IPDAS) Collaboration and NICE (2021c) have published advice and quality criteria for SDM support tools, including PDAs.

Decision aids have proven to be effective. A Cochrane review found high to moderate quality evidence that decision aids improved a variety of outcomes, such as knowledge or risk perception and reduced decisional conflicts (Stacey et al. 2017). However, a follow-up study of this review showed that many of the decision aids included in the Cochrane review, that had been rigorously developed, tested and proven to be effective, were not implemented in routine care (Stacey et al. 2019). The most commonly reported barriers were lack of funding, outdated PDAs, and clinicians disagreeing with use of the PDA. Enablers included design for and integration into the care process. The authors suggested that '*to improve subsequent use, researchers should codesign decision aids with end users to ensure fit with clinical practice.'* (Stacey et al. 2019). This shows how involving the guideline panel may be helpful in the development of decision aids. The panel would be able to provide a broad range of clinical expertise and practical experience from different

health care professions and patients. This would ensure that the guideline and the decision support tools are consistent and complement one another, and encourage uptake of both.

There are several ways to provide decision support tools alongside a guideline. Some possible approaches are described here.

Check out what already is out there

For some situations, high quality decision tools may exist. For example, see the Ottawa Hospital Research Institute's repository for English language decision aids and the Option Grids decision aids list. If there is consensus, a guideline panel can recommend suitable decision tools and provide a link to them instead of producing new ones.

Production by an external team

A team of information specialists, researchers and patients can develop decision tools for prioritised situations after the guideline has been published, using its systematic searches and evidence tables as basis for the decision tools. Ideally, members of the guideline group should review the draft for consistency with the guideline and the underlying evidence. The tools should be available for patients but also for HCPs, and be linked to the guideline documents (NICE 2018c).

Content management system-based semi-automated production

Guideline development tools and content management systems, such as MAGICapp or GRADE Pro, enable guideline groups to produce semi-automated electronic decision aids for use in the clinical encounter (Agoritsas et al. 2015, Vandvik et al. 2013). These are produced directly from the datasets of the systematic review and critical appraisal for each guideline recommendation or the underlying clinical question and are available directly through the app or other front ends, and so are linked to the guideline itself. Although representing a helpful tool to support the discussion between patient and clinician, a patient decision aid also needs input from patients or patient representatives, because they can shape the value elicitation statements or narratives that are needed to turn it into a decision support tool.

Production during the guideline development process

After having identified relevant situations for SDM, guideline groups can develop decision tools for the guideline. They can be published as print, PDF, and web- or app-based or interactive online tools.

An advantage of these decision tools is that they are directly linked to the guideline and use the same body of evidence. However, they remain separate tools with additional features for interested guideline users, and do not necessarily raise awareness of SDM among guideline users in general. Only if integrated into and referred to by the guideline itself, do these tools gain importance and awareness, as explained in the next section).

Integration of SDM and decision aids in guideline algorithms and recommendations and provision of SDM tools as part of the guideline

Probably the best way to harmonise guidelines with SDM is to integrate all processes and develop a product that reflects the need for clinical guidance as well as the need for sharing decisions. This means integrating SDM in guideline recommendations and algorithms and putting decision tools at the heart of the guideline itself.

Integrating decision tools into the guideline

Decision tools for clinical encounters can be integrated into the guideline by:

- publishing them as integral part of the guideline rather than separately (for example, as an appendix or supplement)
- cross-referencing and referring to the decision tools in the context of the recommendations in question (either in the recommendation itself or the background information)
- a formal consensus process for all decision tools, indicating formal approval of the guideline panel and therefore the same level of credibility and relevance as recommendations or other guideline elements.

Recommending the use of decision aids

Guidelines make recommendations for HCPs. In clinical situations with high relevance, the use of decision aids can be part of a recommendation. For example, based on expert consensus, the GNDMG on CAD recommends:

'Before receiving cardiac catheterisation, we strongly recommend the use of the respective patient decision aid (see annex). The consultation and use of the decision aid has to be documented.' (Bundesärztekammer 2019)

An encounter decision aid was developed for this recommendation, presenting the risks and benefits of all treatment options (medical treatment, stenting, coronary artery bypass grafting) in the form of an option grid. The decision, aid as well as the recommendation, underwent formal consensus. This recommendation was reflected and referred to in the treatment algorithm.

Similarly, in its guideline on urinary incontinence and pelvic organ prolapse in women, NICE (2019a, 2019b) recommends:

'If a woman is thinking about a surgical procedure for stress urinary incontinence, use the NICE patient decision aid on surgery for stress urinary incontinence to promote informed preference and shared decision making.'

The PDA referred to is a longer format PDA because of the complexity of the decision. It was developed by members of the guideline committee (including patient members) and PDA specialists and was formally consulted on.

Other recommendations that include the use of a decision aid might cover issues such as agreeing on individual treatment goals or evaluating treatment strategies.

Algorithms or decision trees

Algorithms provide a concise and dense overview of clinical decisions on the diagnosis or treatment of a condition. They are among the most cited and best implemented elements of clinical practice guidelines (Vader et al. 2020). The GNDMG on type-2 diabetes (Bundesärztekammer 2021a) provides a treatment algorithm that asks for SDM and the evaluation treatment goals before initiating and before modifying treatment (see figure 1). This is expressed through the symbol of

speech bubbles indicating: '*agreement on treatment goals and therapy strategy using shared decision-making'*.

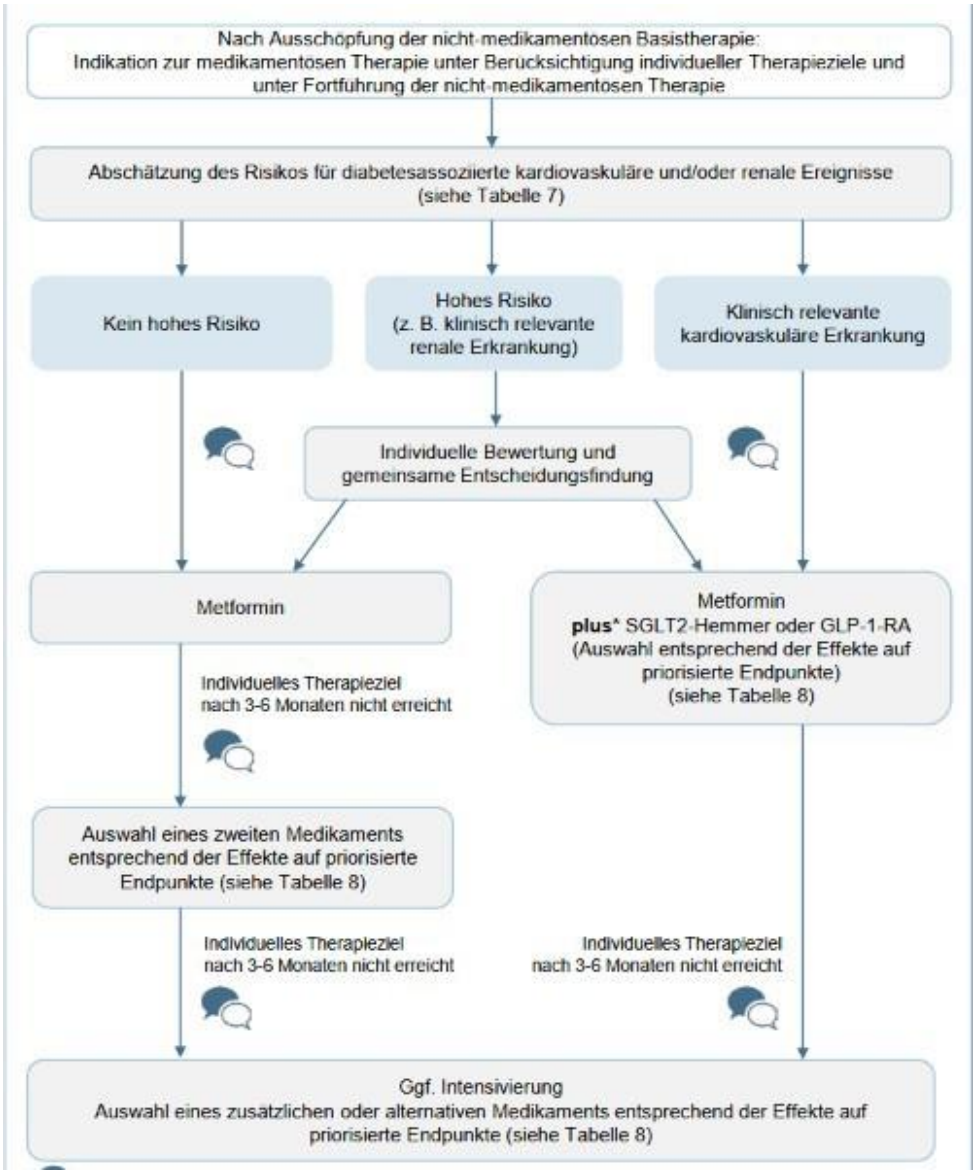

Figure 1 Treatment algorithm for type-2 diabetes based on SDM (Bundesärztekammer 2021a)

Shaping guidelines as unique tools to enable SDM – going beyond recommendations

The Canadian PEER initiative proposes an even more radical approach: They advise the use of so called 'simplified guidelines' that do not offer treatment recommendations. Instead, they suggest thresholds for discussing different treatment options with patients, therefore being designed to guide the patient-

clinician encounter rather than providing guidance for clinicians only (Allen et al. 2017). So far, guidelines for lipid management in primary care, management of opioid use disorder, and prescription of cannabis in primary care have been developed. The idea that guidelines do not provide general guidance but enable individual conversations challenges the concept of guidelines as understood by most guideline developers and users. Giving it serious consideration might pave the way for future patient-clinician decision support tools that could address some shortcomings of actual guideline development. However, these tools may not be appropriate for all clinical situations and conditions. There will be some indications for which more concrete guidance is needed, and other situations in which enabling discussion is more than adequate.

Conclusion

So far, robust evidence on which strategies are most effective in supporting SDM through guidelines is lacking. Therefore, the content of this chapter is mostly based on experience and expert opinion. To the best of our knowledge, there are no experimental studies on the performance of SDM in practice, in which a guideline with SDM strategies is compared with a guideline with ‘classic’ recommendations. However, because SDM is widely regarded as an ethical obligation to assure patient autonomy (Steckelberg et al. 2011), we strongly recommend the use of practices supporting SDM that align with a guideline developer’s resources and goals.

SDM for individual patients can be promoted through population-level guidelines using a broad range of methods. These comprise interventions aimed at patients (providing decision support tools) and at HCPs (increasing awareness, encouraging engagement in SDM, enabling adequate communication). Some of the strategies are rather simple and do not require much planning or resources (consider wording that encourages discussion); some are moderately resource demanding (presenting information on options, developing generic chapters, highlighting situations with specific demand for SDM, production of semi-automated decision aids); but some entail a lot of additional work (producing decision tools for the guideline and assuring their visibility in the whole guideline context, formulating recommendations on the use of decision aids, on SDM and goal setting). Guidelines are produced in various settings. Some are very constrained, others have broad opportunities and resources.

See table 3 for a summary of the strategies to encourage SDM that are presented in this chapter.

Therefore, not every intervention presented in this chapter will be helpful in all settings. However, even small changes in guideline production may contribute to the aim of enabling SDM through guidelines.

Table 3 Summary of proposed strategies to encourage SDM

Intervention	When	Who	Resource demanding
Revise wording of recommendations	During guideline production	Guideline group	–
Present options and their benefit–harm profile in the guideline	During guideline production	Guideline Group, content management system support possible	+/-
Identify and systematically prioritise clinical situations needing SDM support	During guideline production	Guideline group	+
Provide either a generic chapter on SDM in guidelines or a specific SDM-guideline	Before or during guideline production	Guideline group or former guideline groups	+/++
Provide guideline-based decision support tools	During production or after publication	External teams, information specialists and medical writers, guideline group	+/++
Integrate SDM and decision aids into guideline algorithms and recommendations and provide SDM-tools as an integral part of the guideline	During guideline production	Guideline group, possibly supported by medical writers or others	++

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Involving patients and the public in guideline dissemination and implementation

Authors: Karen Graham, Anne Hilde Rosvik

Corresponding author: karen.graham2@nhs.scot

Key messages of this chapter

- Patient and public involvement in dissemination strategies is valuable for developing educational materials, online resources and implementation tools that public and professional audiences find useful, understandable and convincing.
- A combination of strategies for involving patents and the public is essential when disseminating guideline recommendations to patients and the public. This includes media releases, digital tools, distributing patient versions of guidelines, and appointing community champions.
- Patient organisations and charities can promote the guideline (and its patient version) to patients and the public through various routes. These include social media, their newsletter, at conferences, by hosting it on their website, and including it in the information packages provided to their members.
- Providing patients and the public with information about conditions or procedures recommended in guidelines can help them to understand the care and treatment choices available to them based on the evidence. It can also support shared decision making about their own health. This can help with implementing guideline recommendations.
- Patient organisations and charities can promote guideline recommendations to professionals through educational materials, educational meetings such as conferences, and mass media information.
- Attitudes of healthcare professionals and lack of agreement with recommendations can act as barriers to implementation. Patients, the public, and patient organisations can play a key role in addressing these problems by becoming involved with implementation strategies.

Top tips

- Patients and the public may have conflicting views about recommendations, and these need to be understood and resolved during the guideline development process.
- Think about how patients and the public can be involved in dissemination and implementation plans during the development of guidelines and not at the end of the process.
- Focus on developing implementation strategies in which patients and the public can play an active role.
- Provide patients and the public with access to guideline recommendations and their rationales by using patient versions of guidelines and other decision-making tools to promote awareness of them and encourage their use in people's own care.
- Encourage and support patients to become involved in developing dissemination and implementation strategies for self-management recommendations.
- Raise awareness of tools with patients and the public to promote decision making about care and treatment, thereby helping with implementation of guideline recommendations.
- Patient and public members of guideline groups who become involved with dissemination and implementation strategies should be trained and supported.
- Provide a named contact for patients, the public, and organisations to contact.

Aims of this chapter

This chapter focuses on ways in which recommendations from guidelines can be promoted to maximise impact on patient care. It describes ways that patients, the public and organisations can be involved in guideline dissemination and implementation strategies. It aims to describe who to involve in this process and how they can be involved in planning and delivery of dissemination and implementation strategies. It does not give guidance or advice on how to implement guidelines.

The chapter highlights a wealth of examples from guideline developers and other organisations on involving patients and the public in the dissemination and implementation of guidelines.

Dissemination of guidelines

Dissemination of guidelines is about raising awareness among the public, patients and professionals of the existence and content of the guideline. Dissemination plans are ideally developed in parallel with developing recommendations (SIGN 2019). Dissemination plans are needed to clarify at the start of the guideline development process the target audience, which will determine the scope, objectives, format, style and wording of the recommendations as well as the tools for dissemination (NICE 2020, Schipper et al. 2016, Armstrong et al. 2018).

Patient and public involvement in dissemination strategies is valuable to develop educational materials, online resources and implementation tools that public and professional audiences find useful, understandable and convincing. This is demonstrated in case studies 1 and 2.

Case study 1

On publication of their epidermolysis bullosa (EB) psychosocial guideline in 2019, DEBRA International circulated the news to:

- 45 member patient support groups
- 3,422 social media followers

- 400 members of the DEBRA International Research Involvement Network
- 530 members of the international EB clinical network (EB-CLINET), and
- 407 members of the clinical practice guideline network.

DEBRA International also gave presentations on the guideline at the annual congress in Switzerland (2018) and the first EB World Congress 'EB 2020' (2020), attended by 690 delegates representing 215 organisations from 54 countries.

Patient support groups involved with DEBRA International are patient-founded and led (many people within the clinical practice guideline network are also affiliated with these groups). They further supported dissemination in the following ways:

- recirculating news about the guideline to their members and signposting to the document hosted on the DEBRA International website
- hosting the guideline on their own websites
- presenting the guideline at events, such as national patient and clinical meetings, study days, and forums
- presenting real-life patient stories to complement the guideline content
- liaising with organisers of other groups to promote it, for example, following discussions with DEBRA Norway, it was included in the programme of the European Rare Disease Day (2019).

At EB 2020, DEBRA International launched 3 patient versions of the guideline to support adults with EB, parents of children with EB, and both caregivers and patients in understanding the multidisciplinary team involved in their care processes. These are hosted on the DEBRA International website, circulated by the same means, and freely available. Currently, DEBRA Belgium is translating these into Dutch, and there have been requests for Turkish versions.

DEBRA International started a programme to develop EB infographics for low-resource countries to help EB patients, their families, and doctors in

countries without a DEBRA group. EB infographics are more pictorial ensuring key guideline recommendations remain consistent no matter where people live. For the EB Psychosocial guideline, the 'Healthy mind and control' EB infographics are currently being developed.

Case study 2

The Scottish Intercollegiate Guidelines Network (SIGN) produced the first UK guideline on children and young people exposed prenatally to alcohol. The guideline is also accompanied by downloadable information for individuals having assessment for fetal alcohol spectrum disorder (FASD) and information for clinicians to support individuals and their carers before, during and after the assessment process. To raise awareness of the guideline, there was extensive coverage on social media with retweets from various charities including NOFASD-UK, Scottish Drugs Forum, Alcohol Awareness, FASD Network UK, and Adoption UK. This was to endorse the impact of the SIGN guideline on patients and carers in Scotland. SIGN involved a young person living with FASD in the production of a YouTube video animation on FASD that used their story to increase awareness of the condition and the guideline recommendations with both professionals and the public. This was a different approach, which suited audiences with different learning styles and allowed access to new audiences on a wider platform. The video received 930 views within the first 6 months of publication and supported social media promotion of the guideline recommendations.

Strategies for disseminating guidelines to patients and the public

To ensure patients and the public are aware of guideline recommendations, a combination of strategies is essential (Schipper et al. 2016). One strategy is to disseminate guideline recommendations and their rationales using patient and public versions of guidelines in various formats and other decision-making tools (DECIDE

patients and public, Schaefer et al. 2015, Santesso et al. 2016, Utrankar et al. 2018). Details on the development of these and how patients and the public are involved in the process is provided in the chapter on how to develop information from guidelines for patients and the public.

When disseminating guideline recommendations through patient and public versions of guidelines, the involvement of patients and the public in multiple dissemination strategies outlined below have been found to be effective (Schipper et al 2016). These include:

- media releases involving patients and the public
- digital tools, such as websites and apps
- providing copies of the patient and public version to public places such as libraries
- using community champions to disseminate patient versions of guidelines to patients.

Media releases

Involving individual patients, the public, and carers in media releases provides a useful platform to highlight their personal stories and can help to raise awareness of guideline recommendations. Patients, carers and members of the public, who have helped develop guidelines, should be supported to be involved in media releases to highlight the importance of making diagnosis and treatment decisions based on the latest evidence. Patients and the public can also help promote awareness that patients helped develop the guideline to ensure that the needs of users shaped the recommendations. Consent should be collected from the patient, carer or member of the public to share personal experiences of care in media releases. The individual's contact details should not be shared, and comments should be sent to the guideline organisation. Any criticism should be responded to directly by the guideline organisation. Media releases shared via social media should be shared from the guideline organisation's social media account.

Digital tools

The use of digital tools, such as apps and websites, can help to raise awareness of guideline recommendations. Web-based self-management programmes can serve

as a tool for healthcare professionals to share evidence-based information to help patients to successfully manage their conditions (Brosseau et al. 2012).

Community champions

People living with particular conditions have expert knowledge to become community champions, and it is both feasible and effective to involve them in adaptation of information from guidelines for patients, for example self-management guides (Campbell at al. 2018). Patient, public, and carer members of guideline development groups can act as champions for change. Together with other patient champions, they are in a good position to communicate to others the importance of the evidence when making decisions about their own care.

Providing support and training for patients and members of the public to become community champions is one approach that guideline developers can take to disseminate patient versions of guidelines to patients and the public. This is highlighted in SIGN 50's guideline developers handbook. Community champions educate and raise awareness of guidelines by organising stalls, talks and presentations at various places where patients and the public are likely to be. Examples include health conferences, community groups and local festivals. Patients and members of the public can also be supported to participate in virtual events, such as conferences and webinars, to raise awareness of guideline recommendations. Case study 3 highlights how patient and public members of guideline groups can be trained and supported to become community champions to assist with dissemination of guidelines.

Case study 3

SIGN appointed patient members of guideline groups and members of the public to become Awareness Volunteers (Community Champions). In addition to patients who were members of guideline development groups, others were recruited through patient groups, charities, voluntary organisations and volunteer centres.

Expectations of the role were clarified. The role included contributing to advertising materials, exhibiting at events, conferences and community

hospitals, and delivering talks to patient and community groups about SIGN and patient versions of guidelines. In addition to this, Awareness Volunteers delivered talks to student nurses to raise awareness of guidelines and patient versions of guidelines.

SIGN provided training and support, which included:

- training on guideline development processes
- practical tasks to develop communication and presentation skills
- a named contact for individuals, who could support them in their role
- availability of a buddy for people new to the role.

Resources at the organisational level needed to successfully involve patients and members of the public in dissemination groups included:

- staff time to recruit, train and supervise patient and public members (see the chapter on recruitment)
- sufficient finances to reimburse out-of-pocket expenses, including travel expenses, childcare expenses and carer allowance (see the chapter on recruitment)
- sufficient finances for publicity materials
- possibly, financial compensation for patient and public representatives' time and work.

Patient organisations and networks of patients

Patient organisations and charities can promote the guideline (and its patient version) through social media, in their newsletter, at their annual conference, hosting it on their website (see case study 4), and including it in the information packages provided to their members.

The benefits of organisations and charities promoting guidelines include that:

- they have an established and engaged membership base

- patients and the public may be more likely to access information through their channels when searching for information
- they are a trusted source of information for the public, and
- their knowledge of the patient and public group can enable them to pick out and phrase the most relevant recommendations for their audience.

Patient organisations can organise events where people share their experiences and take part in training and education (Schipper et al. 2016). Recommendations from guidelines can be disseminated at these events organised for patients and the public, for example, through posters, pocket cards, handouts and summaries. Discussions can take place on how patients can use them to help them take part in shared decision making (see the chapter on how to develop information from guidelines for patients and the public). Patient organisations may also provide telephone advice based on guideline recommendations.

Networks or 'virtual panels' of patients and the public can aid the dissemination of recommendations from guidelines as shown in SIGN 100's handbook for patient and carer representatives. SIGN's Patient Network members are alerted when new guidelines or patient versions of guidelines are published. Network members can raise awareness of them by circulating them to patients and other patient organisations.

Case study 4

Patient organisations promoting NICE guidelines:

Mind provides links to NICE guidance in their treatment and support sections of topics. For example, in schizoaffective disorder.

The MND Association created patient friendly resources to support the NICE guideline on motor neurone disease (NG42 2016). These include a pocket guide containing a summary of what you should expect from your care and an animated video setting out key aspects of the guideline.

Strategies for disseminating guidelines to professionals

The involvement of patients and the public in dissemination plans can be crucial in increasing awareness of the guideline, not only among patients and the public, but also among healthcare professionals. Various strategies exist for disseminating guidelines to professionals, including educational materials, educational meetings such as conferences, and mass media information. Evidence shows that when multiple strategies for dissemination and implementation of guidelines are used, significant improvements in knowledge, practice and patient outcomes are likely (Fischer et al. 2016, Schipper et al. 2016).

Many patient organisations, charities and their networks include close connections with health and social care professionals in their disease area. They can thus promote the guideline to professionals through social media, on their websites, and at events and workshops that are attended by both professionals and patient organisations. Patient organisations and charities also send members to attend conferences aimed at (and organised by) healthcare professionals, to promote their own organisations and learn about new developments concerning their condition. Patient and public representatives from guideline groups can also be trained and supported by guideline organisations to speak at relevant conferences to raise awareness of the guideline with healthcare professionals. Case study 3 provides details of support and training for this role.

Patients and the public who have been involved with the development of guidelines can be supported to take part in media releases aimed at professionals to raise awareness of guideline recommendations (see case study 5).

Case study 5

SIGN published its guideline on risk reduction and management of delirium on World Delirium Awareness Day. To help raise awareness of the guideline, the patient representative from the guideline development group was involved in a media release. They were supported to share their experience of delirium and how the guideline could improve care in a blog and video.

Recruiting patients and members of the public as community champions can also help to raise awareness of guidelines with health and social care professionals (see case study 3).

Implementation of guidelines

Barriers to implementation of guidelines by healthcare professionals include lack of awareness and lack of familiarity with the guideline and its recommendations. Attitudes of healthcare professionals and lack of agreement with recommendations can also act as barriers to implementation (Fischer et al. 2016). Patients and patient organisations can play a key role in addressing this problem by becoming involved with implementation strategies (SIGN 2019). Structured implementation can improve adherence to guideline recommendations.

Implementation of guidelines includes developing additional tools, documents or campaigns to encourage awareness and use of the guidelines. These can be designed either for patients and the public, or for professionals. Patients and public members of guideline development groups can be involved in both the design, testing and promotion of such implementation strategies.

After implementation tools have been developed, patient and public members and organisations can help promote and distribute these tools. This is usually alongside the dissemination of the guideline itself, using dissemination strategies such as those described in this chapter.

Implementation tools can include web-based resources for health and social care professionals or patients to help implement the guideline recommendations, for example, podcasts and video presentations. They can also include the development of more- or less-extensive public awareness campaigns and strategies. Case studies 6, 7, 8, 9, 10 and 11 demonstrate the various strategies and tools that can support implementation of guideline recommendations.

Case study 6

> As part of implementation of the SIGN glaucoma guideline a poster was created highlighting key recommendations for use with community

optometrists. A patient representative on the guideline group was involved with the design of these and dissemination.

Case study 7

Patient organisations can promote guidelines in their training for patients and professionals to encourage a change in practice. To help with implementing SIGN's guideline on children and young people exposed prenatally to alcohol (SIGN156), Adoption UK Scotland highlights recommendations from the guideline in training they provide for professionals to help support families.

Information from guidelines for patients and the public

Information for patients and the public, such as patient versions of guidelines and plain language summaries, give patients, carers and members of the public access to recommendations in guidelines. This can help with implementation (see the chapter on how to develop information from guidelines for patients and the public). Patient information about conditions or procedures can help people to understand the care and treatment choices available to them based on the evidence and can support shared decision making about their own health (Bradley et al. 2019). Information from guidelines can help patients to evaluate their own care because they can monitor whether their own care is in line with options recommended in guidelines. It allows patients to discuss recommended treatment options with healthcare professionals and to find out why they are not being offered recommended treatments. Providing patients with this information can help to change the behaviour of the healthcare professionals caring for them. Case study 8 demonstrates this.

Case study 8

The National competence service for simultaneous substance misuse and mental illness in Norway has produced a wide range of resources for patients and professionals, which they publish on their website. These resources include a 'recommendation card' for patients that highlights the 10 most important recommendations so that patients and relatives have increased knowledge of what kind of assessment, treatment and follow-up to expect from their healthcare professionals.

Example

The Norwegian guideline for assessment, treatment and follow-up of people with substance abuse and mental illness was developed by the Norwegian National Directorate of Health, medical associations, the Knowledge center for dual diagnosis and 10 user organisations. A user version of the guideline was developed by the Knowledge center for dual diagnosis in collaboration with several user and relatives organisations. They have also developed and published several other resources:

- Video collection of examples on how assessment tools and motivational interviews can be used in clinical work, as well as videos with representatives from user organisations that address several important topics.
- Web page with an introduction to motivational interview (MI), with clinical examples of how the various MI techniques can be used, as well as videos that show how the method can be used in clinical work. Care givers and patients can order free cards on assessment of drug use and MIs.
- Dual-diagnosis TV consisting of continuous lectures, interviews and other short snippets.
- Contact information for the Expert Council, a group where the National knowledge center for dual diagnosis, user organisations, social entrepreneurs, and professional organisations share experiences and

discuss key topics within the drug or substance misuse and mental health field.

A web resource for users with:

- information about follow-up and treatment
- guideline and guidance documents from the authorities
- links to all user organisations, foundations, and social entrepreneurs in the area of substance abuse and mental health
- user rights
- digital self-help programmes or guidance
- helplines and humanitarian organisations to contact for practical help.

In addition to equipping patients with information about treatment options, raising awareness of guideline recommendations can promote their involvement in other areas, such as implementation of recommendations in relation to healthcare-associated infections. Raising patient's self-awareness on the risks and transmission of infections is one method to promote their involvement in infection prevention and control interventions. Involving patients as partners can promote conversations with professionals about infection control, for example, the patient can remind healthcare professionals to wash their hands (Fernandes Agreli et al. 2019).

Self-management tools

Self-management is an important component of care for patients with chronic conditions. Research shows that patients view guidelines as potential sources of self-management support (DECIDE patients and the public, Vernooij et al. 2016). It is therefore crucial that every effort is made to develop implementation strategies in which patients can play an active role. One example is online education tools that promote shared decision making. Brosseau et al. 2012 found that an online evidence-based educational programme delivered through Facebook could improve the knowledge, skills, and self-efficacy of patients with arthritis in relation to evidence-based self-management rehabilitation interventions. Facebook offers a way

for healthcare professionals to interact with their patients and share guideline recommendations to promote shared decision making.

Involvement of patients in innovative implementation strategies for self-management recommendations can increase their feeling of having control over their life. For example, self-monitoring, the use of short message services (SMS), diaries, reminders and action plans can serve as tools to support self-management for patients with conditions, such as cancer pain, asthma and diabetes. In patients with cancer pain, SMS alerts and interactive voice response (through a mobile phone) can be used to report and assess pain, allowing patients to be more involved with their pain management. In patients with asthma, action plans can encourage patients to be in more control of their asthma. The use of such tools may be a way to encourage patient empowerment because the patient's role in managing their condition becomes more active, thus aiding the implementation of self-management recommendations (te Boveldt et al. 2012, Vernooij et al. 2016). Case study 9 provides an example of how patient organisations can support implementation of self-management recommendations.

Case study 9

A UK patient organisation, the National Rheumatoid Arthritis Society, developed a framework of supported self-management for people with newly diagnosed rheumatoid arthritis with the aim of improving patient outcomes. The Right Start service and resources supports the implementation of recommendations on self-management in the NICE guideline on rheumatoid arthritis in adults: management (NG100 2018) and related quality standard (QS33 2013). Right Start outcomes are being independently evaluated as part of a quality improvement programme and national audit.

Development of apps and web-based resources

Often apps and web-based resources are developed for health and social care professionals and patients to help with implementing guideline recommendations.

Examples of patients and public members being involved in developing such implementation materials are highlighted in case studies 10 and 11.

Case study 10

To help with implementation of the NICE guidelines, patients or service users were involved in developing podcasts.

NICE has worked with patient organisations, such as the British Lung Foundation, Prostate Cancer UK and the British Skin Foundation, to develop podcasts. Examples include:

- Why you should get the flu jab – with the British Lung Foundation
- How is prostate cancer managed and treated? - with Prostate Cancer UK
- What is melanoma and how can I prevent it? – with the British Skin Foundation and a patient.

Individual patients or service users were also involved in developing the following podcasts:

- Care of women and their babies during labour and birth
- Which contraceptive method is best for me?

Case study 11

To help with implementing the guideline developed by SIGN, NICE and Royal College of GPs on managing the long-term effects of COVID-19 (2020), an app is in development for patients and the public. A patient who was involved in developing the guideline was involved with this at both the planning stage and early user testing stage of the app development. Interactive content is being developed to support self-management. Further user testing with patients and the public is planned.

Public awareness-raising campaigns

Patient organisations and charities can be involved in using a guideline to develop education programmes for patients or people at high risk of a condition. Informing patients and the public about a condition and how best to prevent, diagnose and treat it can support the implementation of a guideline by encouraging patients to seek care in accordance with the guideline. It also ensures that professionals treat conditions in patients in accordance with the new, updated or existing guidelines. In addition to being organised or co-developed by patient organisations or charities, patients can be involved in delivering such education programmes.

Individual patients and members of the public can be involved in raising awareness of public health messages, based on evidence. Case study12 provides an example of this.

Case study 12

World Antibiotic Awareness Week (WAAW) is a global campaign held each year in mid-November. The Scottish Antimicrobial Prescribing Group (SAGP) and Health Scotland lead activities in Scotland to support WAAW and work closely with colleagues in Public Health England and professional groups to coordinate activities and share feedback. The aim is to raise awareness among health and social care staff, patients and the public about the need to use antibiotics more wisely to stop antimicrobial resistance. Since 2019, the campaign slogan has been ‘Keep Antibiotics Working’ and SAPG has promoted key messages using social media, the SAPG website, and radio adverts. Health Scotland has supported the campaign using posters in community pharmacies, GP practices and other community settings. Antimicrobial Management Teams in Scotland lead their Health Board campaign and local activities are supported by SAPG communications and resources. Public partners (volunteers) play an important role in these local activities through promoting the key messages and engaging healthcare staff and members of the public in discussions about the campaign.

Evaluating service provision and commissioning

Patient organisations and charities can evaluate the quality and provision of services using guidelines as a measure. They can develop research projects and frame questions about the availability and quality of provision to evaluate if services and experiences are aligned with published guidance.

Patient organisations and charities can then use guidelines to develop or scrutinise service improvement plans, to ensure they align with the evidence of what is effective and good value care. Case studies 13 and 14 provide examples.

Case study 13

Healthwatch Bucks in England wanted to find out about the experiences of people treated in the hospital emergency department after a self-harm injury. They wanted to see if the NICE clinical guideline on self-harm in over 8s (CG16 2004) was being followed. They worked with a mental health charity, Buckinghamshire MIND, who carried out interviews with service users. As a result of the project, Healthwatch Bucks made recommendations aimed at supporting implementation of the NICE guideline. Local health service organisations responded by producing a joint action plan that implemented several recommendations, including those around privacy and consent.

Case study 14

Pancreatic Cancer UK worked with University Hospital Birmingham to develop a project to deliver fast track pancreatic cancer surgery.

The patient organisation worked in partnership with the hospital to implement NICE guideline recommendations to improve access to services and reduce waiting times. The project enabled patients to have surgery in 16 days rather than 65 days, increased the number of those having surgery

by more than a fifth, and achieved a cost–saving benefit of £3,200 per patient.

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Beyond guidelines – tools to support patient involvement in health technology assessment

Authors: Ann Single and Karen Facey, on behalf of the HTAi Patient and Citizen Involvement in HTA Interest Group

Corresponding author: ann.single@patientvoiceinitiative.org.au

Key messages of this chapter

- Health technology assessment (HTA) considers patient involvement as both patient participation (such as committee membership and submissions) and research into patient aspects (such as patients' needs, preferences, expectations and experiences) using robust scientific methods. This is similar to patient involvement in clinical guideline development.
- As in clinical guideline development, patient involvement in HTA plays an essential role with patient input and research into patient aspects helping to identify what the traditional scientific evidence means for patient communities. It can also address gaps and uncertainties in that evidence.
- Choosing the approach to patient involvement and tools to use depends on the goal for involvement and context of implementation.

Top tips

- Start with a clear goal(s) agreed by guideline developers, staff within the organisation and patient groups, communities and key patients.
- In patient involvement, earlier is better, so begin by developing involvement processes with patient groups, communities and key patients.
- Manage expectations about what can and can't be achieved with patient involvement – explaining the purpose of the process and how decisions are made.
- Consider the ethical consequences – including harm and burden to patients and their representatives – and develop strategies with patient groups to manage them.
- Develop values and quality standards for patient involvement in guidelines internationally and encourage GIN members to adopt and enact them.

- Learn from the experiences of others and document and share your own experiences.

Aims of this chapter

This chapter gives an overview of tools to support patient involvement in health technology assessment (HTA). It begins by explaining the parallels and differences between HTA and clinical guideline development. It then discusses the barriers to patient involvement in HTA, outlines how patients participate in the HTA process, and how patient-based evidence is used. It presents tools developed to support patient involvement in HTA that may be adapted to suit the needs of clinical guideline development.

The HTA context

HTA can be defined as

'a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.' (O'Rourke et al. 2020.)

HTA is deployed in more than 30 countries, using robust scientific evidence and deliberation to guide policy decisions about medicines, devices, interventions, procedures, and other health technologies. HTA often seeks to determine the value of a new health technology based on clinical and cost effectiveness evidence. However, when HTA was first described by the US Office of Technology Assessment in 1976 it was envisioned as a means of considering all the implications of introducing a new health technology. As such, wider societal aspects – including the impact for patients and their families, legal and ethical issues, and the environment – were considered essential to any assessment of the consequences of the way a health technology was or was not used. In some HTAs, this wider consideration of consequences continues to inform the determination of value and has important implications for the evidence considered and deliberative frameworks used.

One of the accompanying footnotes to O'Rourke at al.'s definition of HTA, Note 3, recognises that value has many dimensions and the overall value of a health technology 'may vary depending on the perspective taken, the stakeholders involved, and the decision context' (2020). As such, it appears to support a view that the evidence base for HTA is robust but not neutral. Determining value depends on your perspective, which shapes the questions you ask in an HTA, the evidence you consider, and how you interpret it. This understanding of value determination has implications for the goals of patient involvement and subsequent use of research into patient aspects (known as patient-based evidence) and approach to patient participation. For example, patient-based evidence and participation may be used in recognition that traditional scientific evidence (such as randomised controlled trials) may not capture the outcomes that are most important to patients. It needs to be interpreted in the light of patients' needs, preferences, expectations and experiences, especially for application in the local healthcare context. As such, it often provides an important opportunity for those with lived experience of a condition to challenge assumptions made about patients and to direct inquiry to more relevant issues. Thus, patient involvement in HTA can be viewed as a means to patient-centred healthcare policy, 'ensuring fair and transparent allocation of resources informed by the needs, preferences and experiences of patients' (Facey et al. 2018).

There are many parallels between clinical guideline development and HTA in terms of scientific rigour and fair processes to translate international evidence into improvements in healthcare at a national or regional level. However, there is a difference in the way the evidence flows into decision making. Although clinical guidelines inform improvement in the whole care pathway and are focused on informing clinicians of best practice (provider decision making), HTA focuses more on decisions about a specific item in the care pathway and may be linked directly to reimbursement (payer decision making). HTA is often described in 3 steps:

- Assessment: critical review of published or submitted evidence about the clinical effectiveness or cost effectiveness of a health intervention.
- Appraisal: wider consideration of the evidence in the local context with value judgements about value and appropriate use.

- Decision making: decisions about whether health interventions are made available, and to whom, in a health system - access or reimbursement decisions. (Garrido et al. 2008.)

Bodies that undertake HTA vary widely and may be responsible for assessment, appraisal or both, but all seek to inform decision making in some way. Furthermore, many of the HTA bodies are part of larger organisations that undertake a range of evidence-based work in the health system and this often includes clinical guideline development. Hence sharing approaches, while recognising differences, seems appropriate.

As HTA has become increasingly associated with treatment reimbursement and access issues, it has become more contentious. In some countries this has resulted in strong patient advocacy challenges and political drives to involve patients in the processes. Some HTA bodies have responded by creating transparent processes for patient participation in the HTA process and developing approaches for obtaining patients' needs, preferences, expectations and experiences (Facey et al. 2010). However, this involvement is not widespread or consistent. Some HTA bodies are reticent about involving patients or including their perspectives, especially when a health technology's value is seen as scientifically determined and patient involvement considered a source of bias rather than evidence and perspective. If such concerns are not satisfactorily explored and resolved within an HTA body (and its stakeholders), patient involvement is unlikely, or may at best be tokenistic because of its perceived threat to the credibility and legitimacy of HTA rather than improving the robustness of HTA. Without careful consideration of an HTA body's beliefs and norms before committing to shared goals for patient involvement, HTA bodies risk setting up unrealistic expectations for patient communities. As a result, patient input and patient-based evidence will be perceived to have little or no consequence because of implicit or explicit barriers.

Hence guidance was needed to provide practical ways in which patients could contribute to HTA and decision making with credibility and legitimacy (Boivin et al. 2014). Clarification was also needed about the complementary but different roles for evidence generated from research into patients' needs, preferences and experiences using robust, scientific methodology and insights gained from patient participation in

HTA processes. Such participation includes patient input from written submissions and committee membership.

Barriers to patient involvement in the HTA process

Beyond organisational beliefs about HTA and patient involvement, a variety of barriers to involvement need consideration to operationalise it and avoid the features of tokenism, such as lack of transparency in decision making, lack of influence, and lack of inclusivity. In 2005, Hailey identified common themes that had been reported about consumer (patient and public) involvement in health research relevant to HTA. Facey updated this table in 2017 (Chapter 5). Table 1 presents a summarised version of Hailey and Facey's work. with some recent literature additions.

Table 1 Barriers to patient participation in HTA (adapted from Hailey [2005] and Facey [2017])

Challenge	Issues
Interaction of patients and researchers	• Time needed to develop a trusting, productive relationship
Resources	• Administrative, financial, staff support
Mechanisms of participation	• Lack of a comprehensive approach that sets the goals of participation for each stage of HTA (Gauvin et al. 2015) • Often chosen by the decision maker, who shapes it in a specific manner and so has control over the participation (Boivin et al. 2014)
Identifying a 'patient position'	• Recognising that there are differing values, expectations, environment, culture, genetics, and experience of the health system, and that it is not possible to canvass all
Nature and extent of patient representation	• Difficulty defining which patients should be involved • Questions about representativeness • Concerns about conflicts of interest and influence of health technology developers • Difficulty reaching marginalised populations
Technical demands	• Lack of knowledge, power, credentials or skills in scientific process and health care policy options
Training and education	• Lack of education and training developed specifically for consumers
Time demands and remuneration	• Time commitments, working to tight timetables, payments that should be made to patients
Balancing information from researchers, the literature, and patients	• Lack of concordance between issues that patients regard as important and those in which research has been conducted • Concern about methodology to balance qualitative and quantitative evidence and the role of costs, including questions about credibility of patient-based evidence • Devaluing patient-based evidence in evidence hierarchies (Gauvin et al. 2015)

Challenge	Issues
Use of patient input	• Unsure what to do with patients or how to involve them • Concern of tokenism • Impact on timelines • Poorly moderated discussions preventing patient contribution (Facey et al. 2010) • Researchers' or clinicians' concerns that scientific debate is softened by including patient perspectives • Possible distortion of funding decisions because of patients' biases • Selection bias – processes may be inaccessible to many patients and ignore, or aim to eliminate bias, rather than valuing the unique perspective of individual patient participants and developing more accessible and appealing processes (Vanstone et al. 2019) • Patient group concerns about how evidence from different sources is handled, weighed and valued, and that others have more influence • Power differences between patients and professionals (Boivin et al. 2014) – processes value clinical and economic evidence over lived experience and patient-based evidence (Vanstone et al. 2019)
Lack of awareness of HTA processes	• The implications of HTA processes for healthcare systems (including beyond yes or no funding decisions) are not understood • Patients do not know how HTA is used or how to participate
Few evaluations of patient input	• Absence of good quality research to show that patient involvement makes a difference • No demonstration that patient involvement improves quality of assessments
Burden, benefit or risk	• Poor consideration of the impact on patients or patient groups of involvement, including poor management of expectations • Benefit (for example, capacity building, learning, system change) should outweigh risk (for example, physical, emotional, spiritual, economic harm; Vanstone et al. 2019)

Although the research reflected in table 1 was initially done in the first decade of this millennium, many of these barriers still exist. They are probably applicable not only to HTA, but also to clinical guideline development.

Similarly, the variation in type and level of patient involvement in HTA identified by a European Patients' Forum (EPF) survey in 2011 remains a feature in this field. It

reflects the different rationale, motivation and approach applied in each country. The EPF confirmed that few HTA bodies and decision-making bodies involve and integrate patients' perspectives in their reports or conduct formal evaluation of the impact of patient involvement in HTA. Moreover, when there is some form of patient involvement this is often not done in a systematic, comprehensive and meaningful way. Apart from financial resource constraints, the main challenges were perceived to be the lack of capacity, time and good methodologies to involve patients. (EPF 2013.)

The first book in this field, Patient involvement in health technology assessment (Facey et al. 2017), sought to address the need for information about good methodologies and approaches to patient involvement in HTA. It drew on the expertise and experience of 80 authors from around the globe. In addition to providing case studies, the book aimed to be a cohesive guide to the field. It set out the rationale and detailed recognised approaches to participation and evaluation, and appropriate scientific methodologies for research into patients' needs preferences and experiences. The latter included the use of qualitative evidence synthesis, discrete choice experiments (DCEs), analytical hierarchy process (AHP), patient-reported and relevant outcome measures, ethnography field work, deliberative methods, and social media analysis.

Importantly, the book also sought to clarify issues that had arisen because of inconsistent terminology in the field and the resulting inappropriate use and treatment of patient involvement in HTA. Building on the work of the Health Technology Assessment international (HTAi) Patient and Citizen Involvement in HTA Interest Group (PCIG) in 2010, which described the 2 distinct but complementary approaches of patient involvement, that is, participation and robust evidence about patients' perspectives (Facey et al. 2010), the book expanded on the different roles and considerations for each. Participation was defined as a form of dialogue for shared learning and problem solving that can aid value judgements throughout the HTA process. Described as a mosaic of approaches selected according to the goal(s), participation is often sought to address gaps and uncertainty in the evidence and recognised for its role in interpreting evidence for real-world implementation. It commonly takes the form of patient input, such as written submissions and

committee membership, which is characterised by its source (patients and patient groups gathering and presenting information to aid decision making). Whereas evidence about patients' perspectives, known as patient-based evidence, is intended to provide evidence of patients' needs, preferences and experiences in a form that can be critically assessed, as are other forms of scientific evidence. Table 2, by Staniszewska and Werkö (2017), summarises key differences between the 2 approaches.

Table 2 Summary of the differences between patient-based evidence and input from patient participation in the HTA process (Staniszewska and Werkö 2017)

Patient-based evidence	Patient participation in the HTA process
Produced through research, generally published in peer-reviewed journals	Originates in perspectives of individuals, groups of patients or organisations
Draws on a range of methodologies	Does not necessarily use or need a specific methodology
Draws on robust scientific methods whose strengths and limitations are known, and provides a robust conclusion that can be clearly interpreted	The quality of the methods used to gather inputs may be unclear or not considered as important
Depends on appraisal of quality, including formal critical assessment and peer review	The concept of quality may depend on factors such as authenticity or diversity of perspectives
Research is based on research genres and specific research questions, and takes time to generate from either primary or secondary research	Patient participation can be used at any point in the HTA process, and may be in the form of a dialogue to enable immediate reaction to an emerging issue
May be more limited in accounting for context of the HTA, depending on whether studies have considered context	Can consider the context of the HTA question
Can be based on a synthesis of studies, which means a comprehensive, unbiased view of a patient issue can be summarised very effectively	Provides a selection of perspectives that may not be comprehensive but are informative
Research directly addresses questions of bias and balance, which provides some assurance of quality	Bias in relation to patient input is a complex concept that requires exploration in the future

In addition to clarifying these distinctions and describing appropriate methodologies and approaches, Facey at al. (2017) drew on the work of Abelson et al. (2016) and the OHTAC Public Engagement Subcommittee (2015) to suggest that patient involvement begins with defining the goals for involvement, which should then guide

decisions about approaches, methods and evaluation within the framework of the HTAi Values and Quality Standards for Patient Involvement in HTAi (see the section on HTAi Values and Quality Standards for Patient Involvement in HTA for more information). These goals may be instrumental, democratic, scientific or developmental (OHTAC Public Engagement Subcommittee 2015).

The editors and many of the authors of the book were active members of the HTAi PCIG. This interdisciplinary group, formed in 2005, promotes awareness of patient and citizen involvement, encourages methodological development, shares best practice, and supports jurisdictions seeking to introduce or develop involvement. PCIG has been active in developing tools for HTA bodies and patient groups to adapt for local involvement activities. Some of these tools may be suitable for adaptation for clinical guideline development. Key tools are described in the next section and further tools can be found on PCIG's web pages.

HTAi Values and Quality Standards for Patient Involvement in HTA

Increased awareness of and interest in patient involvement in HTA has led to calls for guidance around 'best practice' from many stakeholder communities, including those comprising patients and families. In response, the PCIG produced HTAi Values and Quality Standards for Patient Involvement in HTA. These values and standards, shown in table 3, were developed through an international 3-round Delphi process. They can be applied or developed to suit the clinical guideline setting.

Table 3 HTAi Values and Quality Standards for Patient Involvement in HTA (2014)

Values	• Relevance: Relevance refers to the fact that patients and families hold important knowledge and a unique perspective, which can only be obtained through 'lived' experiences with a particular disease or condition. Both are essential to the generation of HTA evidence that is comprehensive and captures the value of a technology to those directly affected by its use. • Fairness: Fairness relates to the need to create opportunities for patients to be engaged in the HTA process that are equivalent to those already available to other stakeholder communities, such as healthcare providers and industry. Therefore, patient involvement is

	viewed as a basic 'right' of patients and families affected by HTA-informed decisions. • Equity: Equity is often defined as the absence of avoidable differences among groups within a population. Patient involvement in HTA helps to ensure that HTA evidence reflects an in-depth understanding of the diverse needs of various groups of patients. This information can reduce the risk of creating inequities in health status when healthcare systems are required to distribute health resources fairly among all users. • Legitimacy: Legitimacy refers to the acceptance of HTA-informed recommendations or decisions by affected individuals through appropriate patient involvement. Engagement of patients and families in HTA contributes to the transparency, accountability, and credibility of HTA-informed decision-making processes, which, in turn, enhances their legitimacy. • Capacity building: In general, adoption of formal mechanisms for involving patients in HTA not only addresses existing barriers to their engagement, but also provides an opportunity to build capacity for patients, families and HTA organisations to work together in a productive way.
Quality Standards: **General HTA process**	1. HTA organisations have a strategy that outlines the processes and responsibilities for those working in HTA and serving on HTA committees to effectively involve patients. 2. HTA organisations designate appropriate resources to ensure and support effective patient involvement in HTA. 3. HTA participants (including researchers, staff, HTA reviewers and committee members) receive training about appropriate involvement of patients and consideration of patients' perspectives through the HTA process. 4. Patients and patient organisations are given the opportunity to participate in training to empower them so that they can best contribute to HTA. 5. Patient involvement processes in HTA are regularly reflected on and reviewed, taking account of the experiences of all those involved, with the intent to continuously improve them.

Quality Standards: Individual HTAs	The remaining 5 standards apply to specific steps followed during the assessment and formulation of a recommendation or decision about a particular health technology. 6. Proactive communication strategies are used to effectively reach, inform, and enable a wide range of patients to participate fully in each HTA. 7. Clear timelines are established for each HTA with advance notice of deadlines to ensure that appropriate input from a wide range of patients can be obtained. 8. For each HTA, HTA organisations identify a staff member whose role is to support patients to contribute effectively to HTA. 9. In each HTA, patients' perspectives and experiences are documented and the influence of patient contributions on conclusions and decisions are reported. 10. Feedback is given to patient organisations who have contributed to an HTA, to share what contributions were most helpful and provide suggestions to assist their future involvement.

In developing these values and quality standards, the PCIG stressed that patient involvement should be seen as a journey. Every HTA body starts in a different place and the high requirements of the values and quality standards are intended to encourage them to take a step on the journey to involve patients in their processes. Those who already do, should evaluate what they do and make improvements. Since their publication in 2014, several HTA bodies have endorsed the Values and Quality Standards and used them to review their own processes. For example, CADTH has used it for their Framework for patient engagement in health technology assessment (2019).

Participation throughout the HTA process

Technology or topic selection

Most HTA bodies established to inform reimbursement or coverage recommendations review all new drugs and therefore do not need processes for identifying and selecting technologies for assessment. However, some jurisdictions require a sponsor to make a submission to trigger the assessment. Usually, the manufacturer is the sponsor. But when manufacturers do not submit a drug for assessment, other stakeholders, such as patient groups, may seek to make a submission so that patients can access the drug. Some HTA bodies, such as the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia, accept

submissions from the public and patient groups. In practice this is rare because of the complexity of the technical process, but PBAC has supported and considered 1 submission from a patient group, Rare Cancers Australia.

However, HTA bodies with a mandate for assessing non-drug technologies do need processes for identifying and selecting technologies for assessment. For example, the Swedish Agency for HTA and Assessment of Social Services (SBU) and the Scottish Health Technologies Group (SHTG) accept topic proposals from patient groups and other stakeholders. Patient organisations have the right to request Germany's Joint Federal Committee (G-BA) for a decision on non-medicine technologies. This means that not only can they propose a topic, but a request must be discussed, and if it meets the conditions for an HTA, G-BA must conduct the HTA. Instead of using a form, a specialist team, available to patient organisations regardless of funding, skills or size, helps with drafting the request (Haefner and Danner 2017).

Additionally, IQWiG (Germany's Institute for Quality and Efficiency in Healthcare programme) ThemenCheck Medizin (TopicsCheck Medicine) allows anyone to propose a topic for an HTA. IQWiG uses a 2-stage selection process to determine up to 5 citizen proposed topics each year. Usually completing proposal forms can be challenging for any stakeholder even with support from the HTA body. However, IQWiG has developed a simple online process designed to enable people without medical or research knowledge submit a question.

In terms of prioritisation of work, SBU has involved patients and carers in prioritisation methods. Its process is based on work by the James Lind Alliance and is used to identify the 10 most important uncertainties for condition areas with many uncertainties (Werkö and Andersson 2017).

However, most HTA bodies need to develop opportunities for patient input into decisions around which technologies to assess. This may include the participation of patients and their families in the development of criteria used to select technologies for HTA.

Scoping

Patients and patient groups may be involved in scoping, which generally uses the PICO (population, intervention, comparator, outcome) framework. For example, the National Institute for Health and Care Excellence (NICE) elicits patient input by publishing its draft scoping documents for comment and then publishes all the comments and the new scope. An examination of the NICE's public involvement webpage reveals patient groups provide important input, particularly about patient subgroups, comparators and outcomes that matter.

Another example may be found in Australia's Medical Services Advisory Committee's (MSAC) PICO Advisory Sub-Committee. This group circulates the scope and a consultation survey to targeted patient groups.

EUnetHTA is a network of European agencies that collaborate in the joint production of HTA reports. The network uses the HTAi template (described in the section on HTA tools for patient input) to involve patients in EUnetHTA's patient input in Relative Effectiveness Assessments (reports that assess clinical effectiveness). The intention is to gain patient input to inform the development of the PICO table and provide the assessment team with insights into patient experiences.

Patient input at scoping has been shown to be valuable for highlighting outcomes that matter to patients and identifying appropriate comparators for HTA submissions.

HTA tools for patient input

With the adoption of more rapid HTAs, especially for drugs, many HTA bodies began accepting submissions in the form of a written template. Some, for example the Centre for Drug Evaluation (Taiwan), the National Committee for Health Technology Incorporation (CONITEC, Brazil), and PBAC and MSAC (Australia), accept submissions from any member of the public, including patient groups. Whereas others, such as NICE (England and Wales), the Scottish Medicines Consortium (SMC) and CADTH (Canada), apply criteria that usually limit submissions to patient groups and include a declaration of funding basis. Submissions contain insights from the lived experiences of patients and their families that may challenge assumptions or address gaps and uncertainties. Templates generally ask questions about the daily lives of patients and families affected by the particular condition or illness,

current treatment options and their impact, as well as the experiences of those who have had the technology being assessed.

The PCIG has worked with HTA bodies and patient organisations to review patient group submission forms. They have developed 3 standardised HTAi patient group submission templates for medicines, non-medicines and diagnostics. These tools have been consulted upon internationally and translated from English into French, Spanish and Mandarin. The template for patient group submissions to the non-medicine's HTA could be adapted for clinical guidelines. This is accompanied by a cover note for HTA bodies, which stresses the need to adapt the template to suit their own circumstances, processes and the technology being assessed. In 2021, the EC-funded IMPACT HTA project used the HTAi work to develop a new patient group submission template for re-appraisal after data collection. This aims to document patients' experiences during the data collection period and identify unexpected effects not captured in the clinical evidence.

The HTAi templates highlight the information that is valued by decision makers but patients need to be well supported by training, guidance and feedback to realise their value. This is because patients may not know which areas of their lived experience knowledge are being assumed, misunderstood or missing in the evidence. Some HTA bodies have dedicated staff who provide support to patient organisations during the completion of submissions. SMC, for example, provides feedback on draft submissions and CADTH gives feedback in a letter after the assessment.

The PCIG has adapted a guide developed by CADTH's pan-Canadian Oncology Drug Review that helps patients complete a patient group input submission template. The HTAi's guidance for providing patient input using the templates helps patient groups understand what kind of information will have most impact and gives guidance on how to undertake surveys and conduct interviews with patients and report findings. Recognising that patient groups usually conduct this work without an ethics committee review, the PCIG also developed an HTAi short guide and a long guide on ethical issues for patient groups to consider when collecting and reporting information for HTA submissions.

Additionally, in 2020 the PCIG released a Summary of Information for Patients template and guidance based on a research project and SMC's experience in providing information to patient groups from the sponsors about the medicine being assessed. The rationale for the template is that people, especially those in smaller or less HTA-experienced patient groups, require information about the product being assessed to target their input. The PCIG intends that HTA bodies will adapt the template.

Patient input in submissions has helped HTA bodies understand:

- the trade-offs patients might make
- the consequences of variations in service provision
- the potential real-world value of small clinical benefits to patients
- the consequences of treatment pathways
- how a treatment is administered for patient subgroups not identified in clinical trials.

Berglas et al. (2016) studied how patient input was integrated in 30 assessments by CADTH's Common Drug Review. They found that CADTH reviewers used patient insights about health status achieved, progress of recovery, and longer-term consequences of illness and treatment to frame the assessment. The CADTH Canadian Drug Expert Committee uses these insights to aid the interpretation of evidence. They also found patient input identified outcomes that are important to patients, but which may not be measured in clinical trials.

Committee membership

Patients and their representatives may be included on advisory and appraisal committees. To overcome ongoing confusion about the roles of patient and public members, Street et al. (2020) found identifying members by the interest and values they are tasked to represent provided clarity. They defined a patient member as someone 'who has been selected to support the inclusion of the interests of patients in HTA processes on a committee', whereas a public member 'supports the inclusion of the interests of the society at large'. Patient members may be nominated for a committee to give specific expertise based on their lived experience. As committee members, they can also present the wider experiences and perspectives of their

patient communities on a particular condition or issue. Furthermore, patient and public members play an important role in ensuring that patient involvement processes are appropriately enacted, can reflect on improvements, and provide training to those providing patient input. G-BA appraisal committees are an example of HTA bodies using this approach. They include patient representatives throughout the appraisal process and in all sessions of the committee.

Hearings

Australia's PBAC conducts consumer hearings when there is greater uncertainty in interpreting benefit and harm evidence, such as some medicines for rare diseases. In Brazil, public hearings are legally provided for and the first hearing took place in March 2021. It was for spinal muscular atrophy. The intention is that public hearings be held before the final decision is taken for cases in which the secretary of the Ministry of Health's Secretariat of Science, Technology and Strategic Inputs determines that the relevance of the matter justifies a hearing. The hearings are envisaged as a face-to-face consultative mechanism open to anyone and participants will have the opportunity to speak. (Silva et al. 2019.)

Consultation

Several HTA bodies, including the Italian National Agency for Regional Healthcare Services (AGENAS), CONITEC (Brazil) and NICE (England and Wales), publish consultation reports to seek feedback from a wider range of stakeholders, including patients and patient groups. Because these reports can be quite technical, patient involvement is better supported if patient-friendly versions are prepared and workshops or meetings are held to discuss the issues with relevant patient communities.

Dissemination

HTA bodies use patient-friendly versions of HTA reports and recommendations to communicate how recommendations were formed and what this means for patients. For example, working with Health Improvement Scotland's public partners and drawing on the guidance from the DECIDE project, the SHTG produced a patient guide to its HTA on wound dressings.

Beyond individual HTAs

The use of patient participation beyond individual HTAs is less described in the literature. Examples include the formation of advisory groups at SMC, NICE and Health Technology Wales who involve patients in developing and reviewing patient involvement processes. Another example is CADTH's involvement of patients in shaping and contributing to the agenda of its key capacity building activity, that is, its annual symposium. PCIG is currently undertaking a study to describe patient participation at the organisational level and may develop tools to support this area if a need is identified.

PCIG's resources to involve patient groups and individual patients in HTA, include the HTAi Online Resource Directory. The directory aims to make it easier to locate useful resources shared by HTA bodies, not-for-profit organisations and other relevant organisations.

Use of patient-based evidence

HTA bodies that perform their own literature reviews, such as SBU, DEFACTUM (part of Corporate Quality in Central Denmark Region), AGENAS, CADTH, RedETS (the Spanish Network of Health Technology Assessment Agencies and Benefits of the National Health System) and SHTG, may undertake specific literature searches to determine patient issues. They use iterative processes to identify issues of importance to patients, and then search for literature (often qualitative research studies) that describes patients' perspectives and experiences about those issues. Such studies provide evidence of how people, including patients, carers and family members, perceive and experience a condition and its treatment. They are in a form that can be critically reviewed and is explicit about the strengths, limitations and bias of its methods. Systematic processes, such as qualitative evidence synthesis, can be used to critically appraise such qualitative research and synthesise it using methodologies from social and humanistic research (Swedish Council on HTA 2013). If evidence is lacking, primary research can be commissioned and reported as part of the HTA (Danish National Board of Health 2007).

EUnetHTA's HTA Core Model Online (2017) includes a patient and social aspects domain that focuses on patients' and their significant others' considerations, worries

and experiences before, during and after the implementation of the technology. The EUnetHTA HTA Core Model Handbook provides guidance on conducting research into patients' perspectives that could be used for a variety of needs. In such processes, patient groups or patient experts can also:

- provide helpful input to the protocol that defines the research questions
- identify outcomes that matter most to patients
- provide important consultation comments on the draft guideline and recommendations.

In recognition of the increasing use of rapid assessments, Health Improvement Scotland has produced 3 resources, which they are trialling. See the HTAi website for the guide to conducting rapid qualitative evidence synthesis for HTA, the methodology and the coding template.

In addition to qualitative research, patient preference methodologies, such as DCEs and AHPs, may provide a useful additional source of evidence to inform HTA recommendations. Some HTA bodies are exploring these methodologies. Patient preference research may be especially useful when a technology is being compared with a standard treatment that has different features, such as mode, ease of administration, side effects, and the risk of serious side effects (Bouvy et al. 2020). However, further research is needed to ascertain its optimal use in HTA and the health technology development lifecycle (Danner and Gerber-Grote 2017). Limitations associated with stated preference methods, such as participant innumeracy, hypothetical bias, variation among subgroups, and inert or flexible preferences need to be considered. A PCIG project subcommittee is investigating these issues.

IQWiG conducted 2 preference elicitation studies – one using DCE and one using AHP - in which patients valued the importance of treatment outcomes in different indications. It found the studies had potential to generate weights or prioritise outcome-specific HTA results. The AHP study demonstrated that patients valued different outcomes to clinicians and the DCE study in lung cancer identified important alternative endpoints (Egbrink and IJzerman 2014).

Impact

Inconsistent terminology, limited goal descriptions, and poor documentation of patient involvement's use and influence have made it challenging to evaluate their impact. Despite this, the need to evaluate the impact of patient involvement is increasingly recognised, especially to improve practice. Evaluation has been used to determine if and how patient insights were integrated into assessment reports, and if the presence of written patient statements are associated with positive reimbursement decisions. It has also been used to assess the impact of written statements (Mason et al. 2020). The number of sources of evidence and variables in an HTA make such evaluations problematic. An alternative approach to understanding the impact of patient involvement in HTA is case studies in the form of stories (for example, as described by Single et al. 2019). The PCIG has developed this work using their Patient Involvement Impact Perspectives template (see Stakeholders perspectives of impact of patient involvement in HTA (Impact Project)) to collect further case studies or stakeholders' experiences of patient involvement in HTA. Such information could provide reflections on the perceived impact of patient involvement from the perspective of anyone involved in an HTA, including patients and people working in HTA or industry.

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