

G-I-N Public Toolkit:

Patient and Public Involvement in Guidelines.

G-I-N PUBLIC Toolkit: Patient and Public Involvement in Guidelines

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Foreword

G-I-N PUBLIC is an international working group of researchers, health professionals and patient/public representatives that supports patient and public involvement in clinical guideline activity around the world. G-I-N PUBLIC was established in 2007, as one of seven working groups of the Guidelines International Network (G-I-N). We are proud to present the ‘G-I-N PUBLIC Toolkit: Patient and Public Involvement in Guidelines’. The toolkit is the result of a series of consultation activities held by G-I-N PUBLIC at international conferences of the Guidelines International Network since 2008. These identified that guideline developers have a need for practical advice on developing effective patient and public involvement programs,¹ clarified needs and expectations regarding such advice² and explored common barriers and practical solutions for effective patient and public involvement in guidelines.³ The knowledge generated by these activities, the work and experience of G-I-N PUBLIC members⁴⁻⁷ and literature on the topic formed the basis for developing the toolkit.

Why involve patients and the public in guideline development, implementation and use?

Guideline developers are increasingly urged to include the perspectives of patients and the public when developing, implementing and using evidence-based health advice. Patient and public involvement (PPI) is advocated by quality standards for guideline development,⁸⁻¹⁰ editorials in medical journals¹¹⁻¹³ and research articles.^{5-7, 14-20}

Various rationales for PPI have been put forward, differing in the contributions, roles and benefits that engagement with the public will bring. We can distinguish several models that advocate for patient and public involvement in health care in the literature.^{16, 21-25} First, the ‘consumerist’ model draws on consumers’ rights and emphasises active and empowered consumers to ensure free and well-informed choice in personalised health care. Second, the ‘democratic’ model draws on the social rights of citizens and taxpayers, insisting public engagement is essential to make health care policy democratic, accountable and in line with public values and interests. Third, the model of ‘expert patient’ emphasises patients’ experiential knowledge (of their own body, illness, life and trajectory through the health care system) can contribute to improvements in the quality of health care. All three models are relevant to PPI in guideline development, as guidelines may be used for decision-making in the care of individual patients, in the design of health care policies and in quality improvement initiatives. PPI in guideline development thus may aim for more patient-centred health care provision, more democratic health care policy-making or quality improvement of care and policy. Being aware of the different rationales for PPI can be helpful to manage divergent expectations that PPI participants may hold.

That being said, this toolkit is not conceived to define, prioritise or evaluate the relative merit of various PPI models. It provides practical advice for the involvement of patients and the public for a variety of reasons, be it well-informed choice, accountability, equality, quality of care or improved implementation. By improving the process of PPI we hope to avoid the tokenistic PPI approach of simply ‘ticking the box’ without ever affecting the participant, the process or the end-product.

Terminology

For the sake of clarity, we consistently refer to ‘patient and public involvement’ (PPI) throughout the toolkit. By choosing this term we purposefully aim to be inclusive. Patients and the public can refer to people with personal experience of a disease, condition or service (patients, consumers, or 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 care services, or whose life is affected directly or indirectly by a guideline (citizens, taxpayers, the public). The term ‘involvement’ may refer to: consultation (gathering information from patients/public through literature, surveys or qualitative research); participation (two-way information exchange between patients/the public and other experts); or communication (tailoring information to patients/the public, for example, patient versions of guidelines or decision aids). Moreover, patients and the public may be involved at any stage of the guideline development and implementation process, including their use in clinical care.

Guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.²⁶ We refer to ‘clinical practice guideline’ (CPG), as it is the most commonly used term and well-known type of evidence-based health advice. We do not exclude guidelines that are used outside clinical practice, for example, by policy makers, or for providing lifestyle advice outside the clinic. We also refer to evidence-based guidelines, as we consider guidelines within the domain of quality improvement tools such as systematic literature reviews, health technology assessments, patient decision aids and quality indicators.

Toolkit objectives

Guideline developers interested in establishing, expanding or improving patient and public involvement activities report a lack of methodological support on how best to do this.¹ This toolkit aims to remedy this gap by providing practical advice based on published literature as well as the authors’ experiences with PPI activities and methods. Its targeted audience is guideline developers and those responsible for the dissemination, implementation and use of guidelines. The toolkit’s chapters:

1. Describe different methods for patient and public involvement in guideline development and use; the pros and cons of these methods; and the circumstances where they are most likely to be useful
2. Provide best practice examples of patient and public involvement methods
3. Describe the resources needed, the pitfalls to avoid, and the main barriers to address in order to support effective patient and public involvement in guideline development and implementation

The toolkit is designed to be a ‘living document’. This means that the methods described in the toolkit may need to be adapted and revised to a specific environment, because social, political, and cultural contexts will affect the success and difficulties of PPI. It also means that the toolkit will be expanded with additional chapters (e.g. literature review of patient views, defining the scope of guidelines). As experience, literature and methodology continue to evolve (especially of the evaluation of PPI²⁷), existing chapters can be updated, and new topics can be added.

Acknowledgements

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members offered guidance and comments on draft chapters. Former members Nancy Huang and Judi Strid contributed to the toolkit proposal. Antoine Boivin, founder of G-I-N PUBLIC, provided vision and leadership throughout the process. We also want to thank G-I-N for financial support, and G-I-N's former Executive Officer Magali Remy-Stockinger for her help in preparing the toolkit's launch at the G-I-N Conference 2012 in Berlin.

August 2012

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Update 2015

In our first foreword, we wrote: “The toolkit is designed to be a ‘living document’. [...] And as experience, literature and methodology continue to evolve, existing chapters can be updated, and new topics can be added.”

Since its launch in 2012, the toolkit has been widely acknowledged and discussed; it has been presented in workshops, webinars and at conferences. The G-I-N PUBLIC steering group has learned from these fruitful discussions that the toolkit met a need by providing international experience and best practice examples to share experience rather than to prescribe what to do. These discussions have also revealed further topics that could be of interest for guideline developers or other toolkit users, like involving vulnerable patient groups or including evidence from qualitative research in guideline development. Furthermore, technical progress has enabled guideline producers to use web-based approaches for guideline development. This has become a major issue for guideline organisations all over the world, even the theme of 2014 G-I-N Conference in Melbourne was “Guidelines in the Digital Age”. These technologies may facilitate involvement of broader patient and/or consumer communities. Moreover, DECIDE, a large, EU-funded project to improve communication of guideline related content to health care professionals and to the public has generated new evidence about how to produce patient version of guidelines. In the past years, involving patients or consumers in other areas of health care research and provision gains more and more acceptance. Many approaches and examples given in the toolkit have proven to be relevant for other research specialists too, as many of them seem to be generalisable.

Therefore, the updated toolkit provides new chapters about these topics that have emerged since its first launch. We do appreciate that the HTAi Group on patient/citizen involvement has been willing to share their experience and resources when involving patients in health technology assessment, thus broaden the focus of the toolkit and offering advice also for other specialties.

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Many people contributed to the relaunch of the toolkit. In the first place, we would like to thank the authors of the new or revised chapters for their time and expertise. G-I-N PUBLIC steering committee members have provided helpful feedback and comments. Jenna McEwan, Administration and Communications Assistant, and Elaine Harrow, Executive Officer, from the G-I-N Secretariat worked exceptionally hard on proofing and editing as well as organising the official relaunch at the Amsterdam conference.

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DISCLAIMER NOTE

The Guidelines International Network (G-I-N) is an international, not-for-profit association of organisations and individuals involved in the development and use of clinical practice guidelines.

G-I-N is a Scottish charity, recognised under Scottish Charity Number SC034047. More information on the network and its activities are available on its website: www.g-i-n.net. This toolkit reflects the views of its authors and the Guidelines International Network is not liable for any use that may be made of the information contained therein.

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G-I-N PUBLIC toolkit introduction (2012)

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One question we often get asked at G-I-N 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 clinical practice 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 Chapter 2 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*. 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 <i>from</i> patients and the public)	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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 	Chapters 1,2
Participation (information is exchanged <i>between</i> the public and other guideline developers)	<ul style="list-style-type: none"> Foster <i>mutual learning</i> and agreement between the public and other experts Facilitate compromise and consensus on collective decisions about guideline recommendations, content, and process 	<ul style="list-style-type: none"> Patient or public participation in guideline development group to foster deliberation with other guideline developers 	Chapters 3, 4,5,6
Communication (information is communicated <i>to</i> patients and the public)	<ul style="list-style-type: none"> Inform patients and the public about professional standards Support individual health care decisions and choices among different health options 	<ul style="list-style-type: none"> Publish patient version of guideline and patient education material Production of patient decision aids 	Chapters 7,8,9

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Chapter 1: How to conduct public and targeted consultation (2012)

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Aims of this chapter

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

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

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

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

Reasons for consultation

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

In its criteria for accrediting producers of clinical guidelines for National Health Service (NHS) Evidence NICE² refers to relevant patient and public groups being included in consultations, and notes that best practice requires a range of patient and public involvement activities in the development of guidelines. The accreditation criteria are based on the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument which was developed to assess the quality of clinical practice guidelines.³

Other key bodies promote public and targeted consultation. For example, in Australia, public consultation on the draft guideline (including relevant professional and patient/consumer organisations) is a requirement for

approval of clinical guidelines by the National Health and Medical Research Council,⁴ and in the USA the Institute of Medicine⁵ promotes this practice in their standards for guideline development.

Some guideline developers have documented their approach to consultation as part of a wider strategy or programme of patient and public involvement in guideline development, for example, NICE,^{6,7} SIGN,^{8,9} and the Spanish national guideline development programme called GuíaSalud.^{10,11}

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

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

Ways of conducting consultation

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

Both open and targeted consultation methods have their advantages as outlined in the following table.

Open or targeted consultation?

OPEN	TARGETED	OPEN AND TARGETED
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	By invitation to all relevant stakeholder organisations, or to groups and individuals with interest, expertise and responsibility	Public posting of draft documents and questions combined with targeted invitations to all relevant stakeholder organisations or groups and individuals with interest, expertise and responsibility
Potential advantages This option has the merit of transparency and in theory opens up the process to all interested parties and viewpoints	Potential advantages Targeting invitations may be more effective in generating responses Where patient/public stakeholders are not known to guideline developers (or key organisations have not registered their interest), a focus on targeted consultation can help developers plan ahead to find individuals or groups and invite them to contribute to the guideline development process The volume of feedback should be manageable	Potential advantages Combines openness and transparency with reaching all relevant stakeholder organisations or targeted groups/individuals
Potential disadvantages Guideline developers may be overwhelmed with the volume of feedback Guideline developers may receive inadequate feedback if publicity is limited and no one feels responsible	Potential disadvantages Important viewpoints may be overlooked or avoided if targeted consultation is not combined with an open invitation to contribute Invited individuals/organisations may not be interested or able to respond in a timely manner	Potential disadvantages Guideline developers may be overwhelmed with the volume of feedback

Consulting patient and public (carer) organisations

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

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

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

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

Identifying and reaching patient and public groups

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

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

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

Consider contacting national and international patient/public groups, as they can be a useful source of contacts and advice as well as an avenue for collaboration. Examples include:

- National groups, such as Consumers United for Evidence-based Practice (CUE) in the USA and Foro Español de Pacientes in Spain
- International groups, such as G-I-N PUBLIC (Guideline International Network's Patient and Public Involvement Working Group), CCNet—the Cochrane Consumer Network, and the Health Technology Assessment international's (HTAi) Interest Sub-group on Patient and Citizen Involvement in HTA (Health Technology Assessment).

Patient and public expert reviewers

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

Consultation at key stages: setting the scope of the guideline

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

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

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

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

- Does the scope take into account issues that are important to patients and members of the public, such as the medicines, treatments, or advice that they think are important?
- Should the guideline include recommendations about treatments that are in current use but may not be considered by patients to be effective, acceptable or tolerable?

- Are there any groups of patients who might need particular consideration given their circumstances (for example, because of particular details of their condition, or because of factors such as their age, disability, culture, ethnicity or gender)?
- Does the scope unfairly exclude any groups of patients (for instance by their age or their general health)?
- Does the scope take into account patients' and public members' needs for information and support specific to the condition?
- Is the wording of the scope respectful of patients, and does it enable a partnership between patient and health care professional?⁷

Impact of patient stakeholders on the scoping stage—case study

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

Consultation at key stages: the draft guideline

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

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

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

- Does the guideline make recommendations about all the issues from the scope that patients and members of the public consider important?
- Do the guideline recommendations reflect what the evidence says about treatment and care?
- Do you know about any important evidence that the guideline has not taken into account?
- Do you agree with the recommendations? If you don't, please explain why.
- Does the guideline recommend treatments and care that patients and the public might consider unacceptable? Your comments could take into account, for example, what you know about the potential benefits and disadvantages (including side effects) of medicines and other treatments.
- Do the recommendations clearly show the need to take into account patients' preferences, for example, if evidence suggests that two treatments may be equally effective?
- Do the recommendations take into account patient and public needs for information and support specific to the condition?

- If appropriate, do the recommendations consider the specific needs of different groups of patients (for example, children or young people, people from specific ethnic groups or cultures)?
- Are the recommendations clear and unambiguous?
- Is the wording respectful to patients and the public?
- Does the wording reflect the importance of partnership between health care professionals and patients?
- Do the research recommendations cover gaps in the evidence about important areas of patient and public experience?⁷

Responding to consultation comments

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

Key guideline bodies promote openness and transparency in the consultation process. The Institute of Medicine (IOM)⁵ advises guideline developers to keep a written record of the rationale for modifying or not modifying a guideline, in response to reviewers' comments. Similarly, as part of Australia's National Health and Medical Research Council's (NHMRC) approval process, guideline developers must provide details of consultation responses and explain why and how the guideline was altered. As part of their desirable criteria for approval, the NHMRC also advocates making a summary of submissions and developers' responses publicly available.⁴ In its accreditation of other guideline producers, NICE² stipulates that if the views of patients are not taken directly into account, the reasons must be explained. For its own guidelines, NICE enters all comments into a table, which includes a 'responses' column for acknowledging and answering each comment, including setting out what changes have been made to the guideline or explaining why no change has been made. The NICE guidelines manual sets out its process for dealing with stakeholder comments.⁶ Other major guideline developers, such as GuíaSalud in Spain, follow a similar open and transparent process for responding to feedback, including making the consultation comments and responses publicly available.

Best practice principles for consultations

- Establish a transparent consultation process
- Identify and involve patients, carers and the public and/or organisations representing their interests at all consultation stages
- Show sensitivity and accommodation for ways that patients and carers may be affected by the specific condition being addressed, for example, different visual, cognitive, or mobility abilities
- Allocate time and resources for consultation in the guideline development process whilst maintaining control of the timetable to ensure the guideline is produced in a timely fashion

- Consider the optimum time period for consultation, balancing the need to produce an up-to-date guideline while taking into account stakeholders' expectations (for example, some organisations consult their constituencies before responding)
- Set up efficient administrative systems for alerting people to consultations and managing responses in a timely manner
- Provide advance notice of consultation dates
- Provide guidance on what respondents could consider commenting on, for example, a list of questions which incorporate patient/public perspectives
- Include equality considerations in the list of questions^a and ensure the method of consultation allows input from the range of patient sub-groups, including vulnerable or under-represented groups
- Ask respondents to give a page/section reference to the draft document where relevant to their comment; providing a standard form for responses can be helpful
- Obtain declarations of interest from any individual expert reviewers, including identification of sources of funding or support in kind for patient organisations
- Ensure that the final decisions in responding to feedback are in accordance with the guideline development group's ongoing decision-making processes
- List comments in a table with guideline developers' responses
- Make comments and responses publicly available, or at least a summary available on request
- Document the consultation process that was followed and make it publicly available
- Consider evaluating whether and how the consultation process adds value to the guideline
- Consider evaluating the particular contribution of patient/public respondents.

Consulting individual patients and members of the public using research techniques

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

- Important gaps in the evidence base
- Insufficient feedback from patient organisations (for example, for some guidelines or topics there may be no patient organisation with a focus on the topic)

^a NICE includes the following equality question in its scoping and draft guideline consultations: 'Do you think this scope/guideline could be changed to better promote equality of opportunity relating to age, disability, gender, gender identity, ethnicity, religion and belief, sexual orientation or socioeconomic status?'

In answering this question, please include details of:

Which particular parts of the scope/guidance you think affect equality of opportunity.

Why and how you think equality of opportunity is affected'.

- Gaps in membership of the guideline development group in terms of patients' perspectives, for example, for guidelines covering children or people with learning (developmental) disabilities
- Information on the perspectives of 'seldom heard' patients who are not part of an organised group or who don't have an organisation to advocate for them, or potentially excluded groups such as people from certain minority cultures or ethnic groups.

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

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

Case Studies

NICE in the UK

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

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

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

^b www.childbirthconnection.org/listeningtomothers/.

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

GuíaSalud in Spain

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

Key messages of this chapter

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

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Chapter 2: How to include qualitative research on patient views in guidelines (2015)

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Aims of this chapter

This chapter discusses how to include *qualitative* evidence within guidelines. Many studies on the views and experiences of patients are based on qualitative research, and including this research is one way for guideline developers to integrate the patient perspective. The chapter provides practical advice on how to conduct a qualitative evidence synthesis as part of the guideline development process. Five steps are covered: 1) establishing a question; 2) searching the literature; 3) quality assessment of studies; 4) synthesising findings; 5) integration into the guideline. The chapter closes with a list of recommended reading.

Introduction

Knowing that an intervention works within the specific context of a highly formalised and randomised controlled trial (RCT) does not automatically translate into effective treatments for real people in actual practice. While RCTs are the ‘gold standard’ to test which interventions are effective, they provide “information on the value of an intervention *shorn of all context*, such as patients’ beliefs and wishes and clinicians’ attitudes and beliefs, despite the fact that such variables may be crucial to determining the success of the intervention” (Black 1996, 1218, my emphasis). In considering whether (and how) the results from RCTs will be reproducible in everyday practice, guideline developers must consider a wide range of additional factors which co-determine how effective, safe or cost-effective interventions ultimately are. For treatments - even those with solid quantitative evidence of effectiveness - to work in the complexity of the ‘real world’, we need to address the potential patient or provider (mis)understandings of the treatment and illness, and a range of legal, financial and organisational factors of distinct health care systems.

Currently, such considerations are usually incorporated implicitly, by relying on the personal experience and expertise of those developing guidelines, including those of wider ‘stakeholders’ such as patient representatives included in the guideline development group (Knaapen, 2013). The incorporation of empirical research on these issues is an additional, and often more transparent and systematic, way of ensuring these contextual factors are included in the guideline development process.

The beliefs, experiences, values and practices of patients are amongst those factors that co-determine the ‘real world’ effectiveness of intervention. The inclusion of research that examines these domains is one of several possible methods to include the patient’s perspective into guidelines (Diaz del Campo, et al, 2010). By examining what problems patients face in their daily lives, research on patients’ views and experiences can be used to establish research questions for a guideline. It may inform a specific sub question, such as what information and support to offer patients, their family and carers. Patient views and experiences may also help policymakers and practitioners to interpret (and implement) evidence of effectiveness, for example

by better understanding the barriers and facilitators for patients following a recommended treatment (See Box 1).

Box 1: Examples of Qualitative Research informing guidelines

The National Institute for Health and Care Excellence (NICE) in the UK has used qualitative research to inform guideline recommendations for a host of topics. For example, for the NICE clinical guideline on Headaches (CG150) a thematic analysis of qualitative studies informed the recommendation on what information to provide to persons with a headache disorder. For the NICE public health guidance on promoting physical activity for children and young people (PH17), a qualitative review was conducted to identify the main barriers and facilitators adolescent girls face to being physically active. Evidence from 15 qualitative studies informed 2 detailed recommendations on supporting girls and young women to be physically active.

Research on patients' perspectives uses diverse methodologies, including quantitative, experimental and qualitative designs (Ryan et al 2001). This chapter focuses on the inclusion of *qualitative* evidence within evidence-based guideline development, as this presents a particular challenge for guideline developers who rarely have been trained in qualitative research. Moreover, qualitative research is not limited to patient views, but can provide valuable knowledge on a range of contextual factors. Guideline developers are interested in including qualitative research results (Zuiderent-Jerak et al. 2012), but express a need for more training in the searching, assessment and synthesis of such research (Tan et al. 2009). Responding to these needs, the aim of this chapter is to provide advice on conducting a qualitative evidence synthesis, a process which can be divided into five steps (with some overlap between the steps to be expected):

- 1) Establishing a review question
- 2) Searching for literature
- 3) Quality assessment of studies
- 4) Synthesising findings
- 5) Integrating qualitative research into the guideline

Syntheses of qualitative health research on specific topics are rapidly multiplying in the published literature (Tong et al. 2012), but no single method or standardised tool has emerged as the 'gold standard' for conducting these steps. To help guideline developers include qualitative evidence, we will provide an overview of the tasks to be completed, discuss available tools, and highlight some limitations for each step. The end of the chapter includes a list of recommended reading for those looking for more in-depth information.

1) Establishing a review question

Before reviewing qualitative research, you must consider the question(s) you seek to answer. Specific questions concerning patients' perspectives may include patient views on a disease or treatment broadly speaking (Campbell et al. 2003, Toye et al 2014); or the factors that influence a patient's treatment decisions, adherence and expectations (Atkins et al. 2008, Pound et al. 2005). Qualitative research also examines behaviours and beliefs of medical professionals (e.g. Blacklock, 2014) and can explore the economic, cultural and practical aspects of a treatment that will determine how successful it ultimately is in practice (Glenton et al. 2013a, Arai et al. 2005).

When devising a question for the qualitative evidence review, consider the various ways in which qualitative evidence can be used during the guideline development process. Depending on the question, a qualitative evidence review can be used to prepare the guideline development process (establishing priorities and determining the guideline's questions). It can also be used throughout the guideline development process,

its findings providing evidence of effectiveness in its own right, or helping explain and interpret quantitative evidence. Or, it can be mobilised after a guideline has been produced, helping to transform general recommendations into specific actions for local practices (Dixon-Woods et al. 2001, 126-128; Ring et al. 2011, 385). The qualitative evidence synthesis therefore may either address its own unique question, or address one or more sub questions of the guideline for which quantitative evidence will also be searched (see also section 5. Integrating qualitative research into the guideline).

2) Searching for literature

Search strategies for qualitative research on people's views or experiences differ from search strategies for quantitative research on effectiveness. When the research question is specific and narrow (i.e. 'In population P, is intervention I more effective than control C, as measured by outcome O?'), an *exhaustive search* strategy is used to locate *all* findings from which to calculate a precise quantitative estimate of a single outcome. When the aim is to examine and map diverse perspectives on (or experiences of) a disease, as in a qualitative review, a *purposive search* can be a more useful and pragmatic strategy (Hannes et al. 2013, 6, Campbell et al. 2011, 35). A search for a purposive sample is completed not when all studies are found, but when additional studies do not add significant new approaches or results, indicating the search has reached "theoretic saturation" or "conceptual robustness" (Ring et al. 2011, 388). To assess if theoretical saturation has been reached, an iterative approach to literature searching, screening and initial analysis of studies, is required. Whether the aim is an exhaustive search or a purposive sampling, to locate the relevant qualitative research requires both automated searches of multiple electronic databases and the hand-searching of other sources.

It has been estimated that a standard 'systematic' search in an electronic database of medical literature (such as Medline) will overlook 30-70% of the relevant research on people's views and experiences (Stansfield et al. 2012, Campbell et al. 2011, 27-35). Much qualitative research is published in non-medical journals and books across a wide variety of disciplines that are not included in databases for medical literature. Additionally, automated searches miss relevant studies because qualitative research on patient perspectives is not as well indexed. Standardised keywords are difficult to identify from qualitative studies that employ a wide number of study designs whose terminology varies within and across disciplines; make use of concepts with multiple interpretations; and rely on more descriptive titles and unstructured abstracts (Evans 2002). For these reasons, locating the relevant qualitative research typically requires searching multiple databases, often across a number of disciplinary domains using discipline-specific search terms and complemented by manual search strategies.

Searching electronic databases

Since searching only Medline or Embase databases may miss much of the relevant qualitative research on patients' views, relevant additional databases to be searched are:

- CINAHL - nursing literature
- PsycINFO - psychology literature
- Applied Social Sciences Index and Abstracts (ASSIA) - social science literature
- Social Science Citation Index (SSCI) - social science literature
- AnthroSource - anthropological literature
- Search platforms (e.g. OVID, Web of Science) include several databases, as well as books and dissertations

To access these databases, and/or the literature contained within, typically requires a paid subscription. Guideline developers working at academic hospitals or universities can usually access them via their institution's subscription.

To help identify studies that use qualitative methods, standard 'methods filters' have been developed for Medline, Embase, CINAHL, PsychINFO, and Ovid databases (see the [InterTASC Information Specialists' Sub-](#)

Group (ISSG) website for a list^c). These can be combined with a search filter designed to identify (quantitative and qualitative) literature on patient perspectives, such as SIGN’s filter^d on ‘patient issues’.

Manual search strategies

Additional search strategies to locate relevant publications include:

- Footnote Chasing (searching footnotes and reference lists for relevant works)
- Forward Citation Searching (searching for relevant work by locating studies that cite earlier key studies)
- Journal Runs (searching select journals that are most likely to publish on the topic)
- Author Searching (searching for all publications by the author of a relevant work)
- Contacting authors and other key informants to provide references

For more details on these techniques, consult Barroso et al. 2003, Stansfield et al. 2012.

3) Quality assessment of studies

The criteria that evaluate the quality of quantitative research cannot be applied wholesale to qualitative research. A host of different quality assessment criteria has been proposed, and discussion is ongoing about which criteria are most useful, and how to assess these criteria in practice (Cohen and Crabtree 2008, Malterud 2001, Spencer et al. 2003). Several tools and forms are available that can help guideline developers assess the quality of qualitative research, and in recent years the majority of qualitative syntheses conduct some type of quality appraisal of included studies (Hannes and Macaitis 2012). After discussing several commonly used tools, we address some general limitations of ‘checklist’ approaches, as a formulaic application of quality assessment instruments can be counter-productive.

Quality Checklists

Several tools and forms are available that can help guideline developers to assess the quality of qualitative research. The advantages and limitations of several commonly used tools are discussed below:

- *Cochrane Manual*

Cochrane uses the work of Lincoln and Guba (1985) to ‘translate’ criteria from quantitative research techniques into qualitative ‘equivalences’ (credibility, transferability, dependability and confirmability). For practical advice on how to operationalise quality criteria in practice, Chapter 20 of the Cochrane methods handbook is useful (<http://handbook.cochrane.org/>), supplemented by more detailed additional chapters (<http://cqim.cochrane.org/supplemental-handbook-guidance>).

- *CASP checklist*

Existing synthesis of qualitative research often use (modified versions of) the CASP checklist, developed by the Critical Appraisal Skills Programme. The original CASP is freely available and covers:

- 2 screening questions to assess whether the study should be further evaluated
- 3 questions how the research design relates to the study’s aim, recruitment and data collection
- And 5 questions on reflexivity; ethics; data analysis; clarity and value of findings (<http://www.casp-uk.net/wp-content/uploads/2011/11/CASP-Qualitative-Research-Checklist-31.05.13.pdf>).

In a comparative study, the CASP was favoured over Spencer’s checklist and JBI-QARI, discussed below (Newton et al. 2012). Figure 1 shows how the results of a CASP quality assessment can be presented (from Blacklock et al. 2014). Campbell (2011) provides a good example of how to use CASP in a literature review of

^c Overview of search filters to locate qualitative research <https://sites.google.com/a/york.ac.uk/issg-search-filters-resource/filters-to-identify-qualitative-research>

^d Search filter to locate research on ‘patient issues’ <http://www.sign.ac.uk/methodology/filters.html#patient>

patient experiences with their modified CASP included in an appendix (on pp. 142-155) (www.journalslibrary.nihr.ac.uk/_data/assets/pdf_file/0008/64736/FullReport-hta15430.pdf).

- *Spencer et al 2003*

Spencer and colleagues (2003) developed quality assessment criteria based on a literature review, interviews and a workshop on existing quality assessment. It includes 18 questions, focusing first on the (analytic) findings, followed by attention to several stages of the research process (design, sampling, data collection, analysis and reporting) and some general features of research (reflexivity and neutrality, ethics and auditability). It is freely available, and each question has instructions on how to apply criteria, and which (if any) methodological techniques might signal good quality. (http://www.civilservice.gov.uk/wp-content/uploads/2011/09/a_quality_framework_tcm6-38740.pdf). This form addresses some of the limitations of quality checklist mentioned below, but Newton et al found it unpractical (Newton et al. 2012).

- *Joanna Briggs Institute - QARI*

The quality assessment tool ‘QARI’ developed by the Joanna Briggs Institute (JBI) has been praised for its congruity and coherence, and considered more sensitive to validity than CASP (Hannes et al. 2010). The quality assessment includes 10 questions assessing “congruity” between philosophical perspectives, research objectives, and all steps from methodological design to presentation of findings. Section 20 of JBI’s Reviewer’s Manual provides examples of (in)congruity between philosophies, objectives and methodologies (<http://joannabriggs.org/assets/docs/sumari/SUMARI-V5-User-guide.pdf> pp.83-92). A drawback of QARI is that its quality questions require extensive knowledge of the many philosophical and methodological approaches of current qualitative research. For this reason, Newton et al favoured CASP (2012).

An advantage of “QARI” may be that it is part of JBI’s general software for systematic review of literature (SUMARI). In addition to quality assessment, it includes tools for data extraction and aggregating of findings, allowing for easier integration of qualitative and quantitative studies and ensuring all parts of the evidence synthesis are explicitly documented (<http://www.joannabriggs.org/sumari.html>). Other commonly used software for evidence synthesis (RevMan, GRADE-Pro) do not have specific procedures for qualitative research, so SUMARI might be advantageous for those looking for a single review system for quantitative and qualitative evidence, provided (some of) the reviewers have solid qualitative expertise. Access to all SUMARI evidence appraisal modules costs around \$30 per year (in 2015).

Using the results of a quality assessment

The results of quality assessment can be used in diverse ways. Most quality assessments do not produce numerical scores or thresholds for in/exclusion, but rather display various flaws and strengths of each study (like in Figure 1). Some argue that quality assessment serves only to identify those studies that are “fatally flawed”, excluding them from further analysis (Dixon-Woods et al. 2004; Toye et al. 2014). Others do a full assessment of all studies and subsequently use the quality rating to weigh studies’ contribution to the overall synthesis (Campbell et al. 2011, 37). In addition, the CerQual approach – in analogy with GRADE’s approach to assessing evidence of effectiveness – uses ratings of methodological quality per individual study (along with other factors) to assess confidence in the overall findings of the qualitative review (Glenton et al, 2013b).

Table 2
Quality assessment of included studies (modified from CASP criteria (CASP, 2001)).

Author	Aims clear	Recruitment clear	Data collection			Reflexivity	Ethics committee approval	Analysis described in detail	Description of how themes identified	Deviant case analysis	Triangulation	Respondent validation
			Method clear	Format clear	Saturation discussed							
Aboderin	+	+	+	+	-	+	-	+	+	+	+	-
Grigulis	+	-	-	-	-	-	+	-	-	-	-	-
Hagopian	+	+	+	+	-	+	+	+	-	+	-	-
Nguyen	+	+	+	+	-	-	+	-	-	-	-	-
Oberoi	+	+	+	+	-	+	-	+	+	+	+	-
Owusu-Daaku	+	+	+	+	-	+	-	+	-	+	+	+

Figure 1. Results of a CASP quality assessment, from Blacklock et al. 2014.

The challenge of quality checklists

The use of standardised ‘checklist’ approaches has been strongly critiqued by some commentators, questioning how quality criteria modelled on the principles of positivist science can be applied to non-positivist qualitative research (Cook, 2012). Current tools take research techniques (i.e. methodology) as a straightforward indicator of quality, while an uncritical adoption of “technical fixes” does not, in itself, ensure rigour, validity or quality of findings (Barbour 2001, Dixon-Woods et al. 2004). By limiting criteria to research techniques, current tools fail to assess the *analytic strength* of qualitative research (Eakin and Mykhalovskiy, 2003). By only assessing *reporting*, it does not address potential gaps between conduct and reporting (Newton et al. 2012), nor acknowledge variability in research techniques and terminology across disciplines (Ring et al. 2011, 389). To properly apply quality criteria, quality appraisers need to assess whether techniques are used appropriately, which requires a good understanding of the epistemological principles of qualitative methodology. Such understanding is complicated by the diversity in research paradigms used in qualitative research (e.g. positivist, constructivist, participatory approaches), so that more than one set of quality criteria may be needed (Cook 2012, 649, Dixon-Woods et al. 2004). Current ‘procedural’ checklists require only limited substantive and methodological knowledge of evaluators, which is a major practical advantage of such tools. However, without that knowledge the above limitations are difficult to overcome.

Bearing in mind these limitations, uncritical or formulaic application of checklists can be counter-productive. The creation of new evaluative tools that are both practical and overcome the limitations of existing tools remains a challenge, and current checklists are of practical value to assess the quality of qualitative research.

4) Synthesising findings

The studies that have been identified and appraised for quality, must then be summarised, analysed and synthesised. Summarising studies can be done as part of the quality assessment, noting the participants, settings and main findings or themes. Discrete results extracted from articles are to be synthesised, producing new lists, tables or text describing the main findings, themes or categories. By synthesising the diverse studies we can go beyond the findings of individual papers, drawing broader conclusions and generating new insights.

Aggregative or interpretative synthesis?

Different synthesis methods exist, each with specific characteristics, purposes and limitations (for good overviews see Barnett-Page & Thomas 2009; or Ring et al, 2011). For a synthesis of studies on patients’ perspectives, we can usefully distinguish between aggregative and interpretative approaches (Dixon-Woods et al. 2005, Hansen et al. 2011, Ring et al. 2011). Meta-summary is an aggregative (sometimes called integrative) approach that pools diverse findings to similar research questions. Such a synthesis is largely descriptive. For example, findings can be aggregated/integrated by distinguishing ‘positive and negative experiences’, or by listing ‘barriers and facilitators’ that were discerned in the individual studies.

Often, however, qualitative findings are concepts or themes that cannot be ‘added up’. In these cases, meta-synthesis is an interpretative approach that provides a critical re-interpretation of the primary findings.

Considered to be ‘research of research’, meta-synthesis can generate new findings. Many of the published syntheses of patient perspectives and experiences use a specific subtype of meta-synthesis called ‘meta-ethnography’. This method was originally developed by Noblit & Hare (1998), but Hansen’s (2011) advice is especially relevant for guideline developers, and Toye (2014) discusses specific methodological challenges associated with synthesising patients’ experiences.

Practical tools and software

A synthesis of existing qualitative studies largely requires the same analytical skills, theoretical frameworks and practical tools that qualitative researchers use in the analysis of primary qualitative data. For example, the ‘Framework Approach’ is a highly structured approach to qualitative data analysis that has been adapted to the synthesis of qualitative research (Gale et al, 2013). Computer assisted qualitative data analysis software (CAQDAS) used in primary analysis, such as NVivo, ATLAS.ti or MAXQDA, can also be used in the secondary analysis of qualitative studies. Here, we limit our discussion to tools specifically aimed at synthesis of qualitative health (service) research in the context of evidence synthesis. Both synthesis tools offer a single procedure for quality assessment of studies, extraction of findings and generation of conclusions. Neither provides much detailed guidance on *how* to synthesise, but both primarily provide a framework to report the process to outsiders, such as users of the synthesis or guideline.

- *Joanna Briggs Institute - QARI*

As discussed above, JBI’s QARI software provides an integrated procedure for quality assessment, data extraction and aggregation of findings, including integration with quantitative study synthesis (through use of SUMARI).

- *EPPI-reviewer*

This was developed by the Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI-Centre) in the UK, which aims to provide policy makers and professionals with evidence for practice. EPPI-reviewer is a single software package that guides the entire process of (quantitative and/or qualitative) evidence review. It can produce numerical, narrative or conceptual syntheses and includes tools for statistical meta-analysis, as well as tools for thematic or meta-ethnographic analysis of study findings. The EPPI-reviewer-4 costs about \$17 per month for a single user account (in 2015).

<http://eppi.ioe.ac.uk/cms/Default.aspx?tabid=3396>

The challenge of synthesis

To synthesise studies, we must generalise and abstract, so that findings can be ‘added up’ or compared and contrasted. To make individual studies (appear) comparable, variability between them has to be ignored. The reviewer must disregard at least some of the cultural, organisational or personal contexts that qualitative results were meant to ‘bring back in’. This leads to concern that in synthesising studies we may lose the real value of qualitative research such as “its emphasis on context and holism” (Campbell et al. 2003, 683). The challenge of synthesis is thus to “combine the findings of multiple qualitative studies while preserving and respecting their complexity” (Hansen et al. 2011, 144). Such a process combines the ‘distilling down’ of individual studies (into summaries and evidence tables) to reduce diversity, with the creation of ‘remainders’ where the differences, details and contexts of the original studies is preserved (in appendices and footnotes). Reporting tools (such as the ones above) can help make the connections between the underlying studies and the conclusion more explicit and better documented. However, requiring such a constant ‘audit trail’ also has disadvantages, as cross-connections and abstractions become harder to justify (Colvin 2013).

5) Integrating qualitative research into the guideline

The final phase of *integrating* qualitative research within guideline development is perhaps the most difficult to capture by simple rules or steps. Many agree both qualitative research and patient perspectives are valuable contributions, but no methods exist to include such ‘other knowledge’ in Evidence-Based guidelines (Zuiderent-Jerak et al. 2012). For example, the GRADE process encourages inclusion of ‘judgements’ and

patient values in the development of evidence-based guidelines (Guyatt, et al, 2011), but provides little practical guidance on how to do this well. The integration of different kinds of knowledge largely remains a pragmatic and informal process, often invisible in the final product (Knaapen, 2013).

Some have produced and used syntheses of qualitative health research on patient's views and experiences separately from a guideline. For example, to improve implementation of the recommended interventions (e.g. Glenton et al. 2013a). Publishing such stand-alone documents can make the qualitative evidence more accessible to others. When publishing qualitative evidence syntheses in the peer review literature, you may follow Tong's reporting checklist (Tong et al. 2012). However, separate publication may also hamper the *integration* of the two types of evidence, resulting in a polarised debate between qualitative and quantitative evidence, instead of a constructive dialogue (Hannes et al 2013, 4).

Examples do exist where qualitative and quantitative findings on the same (sub) question are successfully integrated. Qualitative research has been combined with quantitative evidence on patient preferences (Ryan et al 2001). Thomas et al (2004) provides an example where qualitative research helps interpret contradictory evidence on effectiveness. Almost half of the guidelines produced by NICE in the UK (2003-2006) included qualitative research, but did not present it in a uniform way, ranging from narrative descriptions throughout chapters to formal data tables in appendices (Tan, 2009; 171).

To encourage the uptake of qualitative evidence in the guideline, development group members might need to be reminded when the synthesis provides relevant knowledge. While any group member may be expected to read, mobilise, integrate and value its findings, this championing role might more easily be taken up by the producer of the synthesis, the methodologist or patient representatives.

One of the obstacles to the integration of qualitative evidence into evidence-based guidelines, stems from EBM's evidence hierarchy, as "evidence other than that derived from randomised controlled trials (RCTs) is seen as intrinsically less valuable or reliable." (Zuiderent-Jerak et al. 2012, see also Leys, 2003). This affects not just qualitative research, but also other methods of including patient perspectives (such as the inclusion of patient representatives on a guideline panel) (van de Bovenkamp and Zuiderent-Jerak 2013), as well as other types of medical knowledge such as clinical judgment and expertise, evidence from clinical audits and laboratory research. However, the research designs favored by EBM's hierarchy are only 'gold standard' for very specific questions around clinical effectiveness and safety ('*Does an intervention work in controlled circumstances?*') (Cartwright, 2007). Other questions, such as *how* and *if* interventions will work in specific contexts, can better be answered through qualitative research designs, as it requires insight into how context, perceptions and experiences affect processes and outcomes in everyday life.

Following Tonelli, we can reject the notion of 'best evidence' as a single hierarchy and see "other kinds of medical knowledge" such as clinical expertise and patient views and experiences as "different *in kind*, not degree" from statistical and epidemiological knowledge (2006, 249). By providing information that is qualitatively different from (and complementary to) quantitative evidence such as RCTs, it becomes possible for patient perspectives to mediate between quantitative evidence and clinical practice recommendations, by extending, complementing, helping explain, and implementing that evidence. The aim is not to replace or abandon EBM principles, but formalise and legitimise the role 'other considerations' already play in practice (Knaapen 2013, 693). Re-conceptualising the value of diverse medical knowledge does not solve more practical difficulties of integrating patient views into guidelines. The answers to many practical questions remain open to creative experimentation by guideline developers using qualitative research on patient perspectives.

Conclusion

The inclusion of qualitative research in recommendations for practice is becoming more widespread, although some conceptual and practical challenges remain. This chapter acknowledged some of those challenges, and aims to help produce a high quality review of qualitative research on patient views and experiences by providing step by step advice, help navigate practical tools and refer to useful examples so that valid qualitative evidence can be used in guideline development processes.

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Further reading

Short handbooks on qualitative research synthesis for Health Technology Assessment

Swedish Council on Health Technology Assessment (SBU) (2013) *Evaluation and synthesis of studies using qualitative methods of analysis*. Available at : www.sbu.se/handbook (Accessed 16-01-2015)

Ring N, Ritchie K, Mandava L, Jepson R. (2011) *A guide to synthesising qualitative research for researchers undertaking health technology assessments and systematic reviews*. Healthcare Improvement Scotland. Available at : <http://www.healthcareimprovementscotland.org/his/idoc.ashx?docid=04df262c-ec20-40e1-aef7-d2aa3ad03c06&version=-1> (Accessed 16-01-2015)

Practical guidance and resources by the Cochrane Qualitative and Implementation Methods Group

<http://cqim.cochrane.org/welcome>

Detailed textbooks on Qualitative research synthesis in general:

Sandelowski M, Barroso J. (2007) *Handbook for synthesizing qualitative research*. New York: Springer Publishing Company.

Major CH, Savin-Baden M. (2010) *An introduction to qualitative research synthesis: managing the information explosion in social science research*. London: Routledge.

Guidance per step:

Searching for literature

Barroso J, Gollop CJ, Sandelowski M, et al. The challenges of searching for and retrieving qualitative studies. *West J Nurs Res*. 2003;25:153-178.

Quality assessment of studies

Cohen, D. J. & Crabtree, B. F. 2008. Evaluative Criteria for Qualitative Research in Health Care: Controversies and Recommendations. *The Annals of Family Medicine*, 6, 331-339.

Dixon-Woods, M., Shaw, R. L., Agarwal, S. & Smith, J. A. 2004. The problem of appraising qualitative research. *Quality and Safety in Health Care*, 13, 223-225.

Synthesising findings

Overviews of methods for qualitative synthesis:

- Barnett-Page, E. & Thomas, J. 2009. Methods for the synthesis of qualitative research: a critical review. *BMC Med Res Methodol*, 9, 59.
- Hansen, H. P., Draborg, E. & Kristensen, F. B. 2011. Exploring qualitative research synthesis: the role of patients' perspectives in health policy design and decision making. *Patient*, 4, 143-52.
- Ring, N., Jepson, R. & Ritchie, K. 2011. Methods of synthesizing qualitative research studies for health technology assessment. *Int J Technol Assess Health Care*, 27, 384-90.

Examples of integrative synthesis (meta-ethnography):

- Toye, F., Seers, K., Allcock, N., Briggs, M., Carr, E. & Barker, K. 2014. Meta-ethnography 25 years on: challenges and insights for synthesising a large number of qualitative studies. *BMC Med Res Methodol*, 14, 80.
- Campbell, R., Pound, P., Pope, C., Britten, N., Pill, R., Morgan, M. & Donovan, J. 2003. Evaluating meta-ethnography: a synthesis of qualitative research on lay experiences of diabetes and diabetes care. *Soc Sci Med*, 56, 671-84.

Example of aggregate synthesis of qualitative studies.

- Reis, S., Hermoni, D., Van-Raalte, R., Dahan, R. & Borkan, J. M. 2007. Aggregation of qualitative studies--From theory to practice: Patient priorities and family medicine/general practice evaluations. *Patient Educ Couns*, 65, 214-22.

Integrating qualitative and quantitative research

Methodological overview:

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Chapter 3: How to recruit and support patients and the public in guideline development (2012)

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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. This chapter is largely based on experience, expertise and best practice of the National Institute for Health and Clinical Excellence (NICE) in the UK. The chapter consists of three parts. The first part focuses on considering the role patient and public members are expected to fulfil, including considerations of the qualifications, experience and skills expected of such members. The second part focuses on recruitment strategies and addresses advantages and disadvantages of nomination versus open recruitment; and provides practical advice on recruitment methods, applications, interviews and documentation. The third section addresses the support provided, including practical adjustment to the physical environment of the group's meetings, the challenges of providing financial compensation, informal support and training. The chapter ends with considering acknowledgements after finishing the guideline.

1. The role of patient and public member: what are you looking for?

The first stage before recruiting a patient or member of the public or carer to a guideline group is to ensure that the organisation knows what it expects of patient and public members. It is important that organisations have a clear idea about:

- The role of patient and public members
- The skills and experience they need
- The roles that you will be recruiting for
- The difference between 'representing' and 'being a representative'.

The role of patient and public members

Decide in advance whether the patient and public members are undertaking the same role as the health professional, and attending every meeting, or if they are being brought in for specific tasks. It is important to avoid tokenism, by ensuring that this is clear in advance. For example, the NICE in England asks its patient and public members to undertake the same role as health professionals, assessing evidence and drafting recommendations alongside their colleagues. This has allowed an emphasis on patient and public members having the same status in the group, but a different field of expertise. In certain circumstances, however, it is possible to bring in additional patient and public representatives with specific experiences or other contributions as experts for certain topics within guideline development, and to ask them to attend a meeting or contribute to a consultation (see chapter 1 on targeted and public consultation).

Organisations should consider developing a written role and person specification for this role, drawing on the information below.

What experience, knowledge and skills are needed to undertake this role?

The most important attribute that patients and members of the public bring to guideline development is their direct experience of living with a condition, either through personal experience or, if that is not possible, through acting as a carer to someone with the relevant condition or contact with others who have such experience (for example, if a patient and public member is an employee or volunteer with a patient organisation).

Role specifications should be clear, but should not disqualify people who may be able to offer a lot to the group. For example, although it is fair to ask that patient and public members have good communication skills, it may not be useful to ask for set academic levels of attainment. It is also important to think about whether certain knowledge or skills, especially those that are rare in people without medical training, can be gained ‘on the job’. For example, patient and public members may not be familiar with research terminology, but with proper support, this knowledge can be rapidly gained when a person starts working on the guideline. There are specific training programmes for patient and public members in some countries, and free online courses also exist, but these are by no means universally accessible and many very good patient and public members have never had formal training in the role. More important ‘soft’ skills or knowledge which cannot be learned in post should receive greater emphasis, for example, having had contact with a lot of people with the relevant medical condition and being able to reflect their experiences.

NICE looks for the following experience, knowledge and skills from its patient and public members:

- Relevant experience of the condition, and the issues that matter to people with that condition, for example, as a patient or a carer, or as a relevant employee of a patient organisation
- The willingness to reflect the experiences of a wide group of people with a condition, for example, contact with people through patient organisations, forums or self-help groups
- The time and commitment to attend the meetings, do background reading and comment on draft documents
- Good communication and teamwork skills
- The ability to maintain confidentiality
- The ability to work within NICE’s equalities policy and declarations of interest policy.¹

The roles you are recruiting for

In many cases, groups tend to recruit a patient or service user. There are occasions however when this might not be possible, either due to the nature of a condition or because the guideline is aimed at children, in which case recruitment of a carer would be more appropriate. If more than one person is being recruited to a group that will be focusing on a condition where care is complex and extensive, it might be more advantageous to recruit a carer as well as a patient to the group. Wherever possible, more than one member should be recruited to help provide different perspectives and social support for other patient and public members.

The group may also consider an employee or volunteer from a patient or service user organisation to serve on the group even if this person does not have personal experience with the condition. Recruiting this type of member has its advantages because of the extensive work experience the person could bring to the group. In some cases, they may also be more familiar with the research literature or have complementary technical skills, for example, critical appraisal of research.²

Representing, not being a representative

Patients and members of the public on guideline development groups bring a unique perspective, but cannot be expected to speak for everyone with a condition. Bear in mind that there will be a range of different experiences and that issues such as access to services and reactions to side effects vary widely between individuals, and the experiences of patients and members of the public will not always be typical. Remind other members of the group about this, and consider patient experience evidence as part of the group's processes. Patient experiences can come from a range of sources, including qualitative studies, consultations, or patient experience surveys (see chapter 1).

It is also useful to appoint two or more patient and public members to the group. This broadens the experiences available to the group. It also helps each patient have the confidence to speak out, as they are less likely to feel like an isolated individual if there are other non-health professionals in the group. Wherever possible, provide opportunities for patient and public members to prepare for the meeting. This can include offering pre-meetings, supportive phone calls, or asking patient and public members if they would like to exchange contact details with other patient and public members, from this group or previous ones, so that they can share concerns and experiences (never share contact details without express permission).

2. Recruitment

Once you have identified what and who you are looking for, the second stage is recruitment of one or more people to fulfil the role(s). This section provides advice on how to recruit patients and members of the public for guideline development groups.

Nomination or open recruitment?

There are two potential ways to recruit patient and public members to guideline development groups. These are open recruitment or patient nomination. It is also possible to combine elements of both approaches.

In open recruitment, guideline developers advertise the post for a patient and public member, using a role and person specification, and consider applications from anyone who meets that set of criteria. This contrasts with organisations that look for patients or consumers who are already known to the developers, and nominate individuals who they feel would be suitable.

There are advantages and disadvantages to both systems. Open recruitment allows a wider range of people to become involved. It is transparent, and avoids a situation where someone is appointed who is being treated by another member of the group. It also avoids potential biases, by allowing developers to choose between people from different areas of the country, those being treated in different sorts of centres, and those from different groups in society. However, it is time consuming, and requires someone to develop role specifications and administrate the recruitment process. If there are a large number of suitable applicants, this can be costly in terms of staff time. Some people also worry about whether it is fair to ask patients who are very ill to go through a full formal application process.

Nomination, on the other hand, can be more rapid, and there is often a clear idea about the background of the nominee and their ability to participate. However, this process is less transparent and this narrows the pool of potential candidates.

With both approaches, it is important to ensure that the method of selection is clear to other group members and is accepted as legitimate. Both methods can be seen as legitimate, depending on factors including how other categories of group members were selected and what the timescales were.

Additional advantages and disadvantages of each method are shown in table 1.

There is no research into which approach produces the best results. NICE has chosen to openly recruit to its guideline development groups and has found that this approach has led to a wide range of individuals, including many who are not associated with patient organisations, applying for their groups. Other guideline development organisations, such as the Dutch Institute for Healthcare Improvement (CBO) in the Netherlands and the German Agency for Quality in Medicine (ÄZQ) in Germany, have chosen to recruit primarily via (umbrella) patient organisations, and have found it a good way to recruit individuals that are aware of the experiences of other patients in their organisation.

When deciding which approach to use, there are some key elements to consider. These include:

- How are you recruiting health professionals to the group? If some members are nominated, and other members have to compete for a place, this may affect the status of individuals on the group (e.g. if the patient or service user was ‘given’ a place rather than ‘earning’ one). It can also increase a patient and public person’s confidence to know that they were selected from a pool of good quality applicants. Conversely, if health professionals are all nominated then there may be no perceived unfairness in nominating patient and public members
- Who can help? Open recruitment works best when patient organisations or health professional organisations with public involvement functions are able to help publish the vacancy to their members and on their websites, or where there are other chances to make the public aware of vacancies
- Timescales. It takes more time to develop recruitment paperwork, publish it in a place where patients and service users will see it, and process applications than it does to nominate an individual. NICE advertises positions for patients and service users for four weeks to allow patient organisations time to reach their members and for the advertisement to get maximum exposure through websites and other social networks.

[Table 1](#) shows a list of the advantages and disadvantages of each method.

Open recruitment—where

When advertising a vacancy for open recruitment, consider asking national and local charities, patient networks and carer organisations to forward the advertisement to their membership. Health professionals may be able to support this, but bear in mind the likely problems with being honest that may come up if a patient and public person is on the same panel as the health professional who is treating them.

There is a huge potential benefit in using social media, for example, asking charities and patient organisations to use Twitter or Facebook to spread the word about your vacancy. Bear in mind, however, that many people with chronic conditions, or who come from disadvantaged socioeconomic backgrounds, do not have easy access to the Internet, and that this should not be the only method of recruitment.

Table 1—Advantages and disadvantages of open recruitment and nomination as recruitment methods for guideline producing groups

	Open Recruitment	Nomination
Advantages	<ul style="list-style-type: none"> • Allows wider range of people to select from • Allows selection of people who 	<ul style="list-style-type: none"> • Fast • Can use patients with existing relationship with medical professionals on group—group

	<p>are unknown to rest of guideline development group—lower chance of people agreeing with group because they don't want to risk disagreeing with their own doctor</p> <ul style="list-style-type: none"> • Allows phone interviewing and screening against people with narrow perspectives • Wider perspectives—would nomination favour patients at high profile teaching centres rather than those who are attending lower profile general hospitals or who live away from urban centres? • Transparent—can answer questions about why certain people were recruited and demonstrate where procedures have followed equality legislation 	<p>formation may be easier, although this can also lead to power imbalances</p> <ul style="list-style-type: none"> • Can use patients with known background in user-led research • Can use patients with a known ability to work well in committee situations
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	Open Recruitment	Nomination
Disadvantages	<ul style="list-style-type: none"> • More time consuming • Costs of advertising—if paying for advertising to be placed. Rely on people visiting your website? • Costs to management of preparing and processing paperwork and applications • Will you rely on goodwill from charities sending out invitations to people—in which case is this different from nomination? • Risks of a failed recruitment—if condition is rare or patient/service user group is less likely to use recruitment channels like the Internet • Health professionals can worry about disappointment if they persuade a vulnerable person to apply and they are unsuccessful 	<ul style="list-style-type: none"> • Narrower range of patients • May omit patients who have not previously had experience of this sort of work, but may nevertheless be able to make positive contributions • May distort picture of patient experience, as those likely to be nominated may be more likely to be associated with major teaching trusts or campaign organisations, and may have different experiences of care from those in rural areas or general clinics or who have no patient campaign experience • Where health professionals apply and patients are nominated, this can reduce status of patients—they were ‘given’ a place rather than earning one • Risk of narrower patient perspectives through nomination of patients with known background in lobbying on one aspect of a condition • Hard to demonstrate transparent decision-making and how it complies with equality legislation

Documents

When recruiting someone to a guideline development group, you should consider what documents you will need to make public. It will be helpful to publish the job and person specification. Publishing information about the role, either as a detailed advertisement, information for candidates, or an FAQ (frequently asked questions) sheet, will help applicants decide whether the role is right for them. It is also useful to provide a properly structured application form, which will make it easier for people to provide you with the right information to decide who to appoint in a format where applicants’ responses can be directly compared.

It is useful to keep documented evidence of the recruitment process, including the reasons behind your decision who to appoint, to avoid any potential accusations that you have been discriminatory in your practices.

Advertising support

When advertising the role, it is important to state explicitly the kinds of support that will be available for patient and public members of guideline groups. Support includes practical and physical adjustments, financial compensation or reimbursement, informal support or formal training. Many worry about even applying, assuming that adjustments cannot be made, and stating that support is available can encourage better applications. However, be careful not to promise support that you are not able to deliver in practice.

It is especially important to state explicitly that reasonable adjustments will be made for individuals with practical support needs. Patients with direct experience of some conditions will need additional support to participate. Recruiters should offer a chance to discuss what adjustments are possible, and wherever possible practical support needs should be accommodated.

At the recruitment stage it is also important to consider what financial compensation you will offer to patient and public members. Compensation can include reasonable travel expenses, or payment of a fee (either in money, or in the form of payment in kind, e.g. vouchers) for the work done. This is likely to be governed by factors including local and national policies, the impact of paying individuals on their ability to attend, and the consequences for unemployment or sickness benefits if a payment is made.

These, and other kinds of support that may be made available to patient and public members (e.g. mentors, formal training) are discussed in more detail in section three of this chapter on ‘support’.

Interviews and appointments

You should consider whether you are going to interview applicants for the role. Although time consuming, there are significant benefits to interviewing candidates. Interviewing allows you to get a clearer idea about the breadth of the person’s experiences than you can from a paper application. It also allows you to check if someone is likely to find it hard to weigh up evidence objectively or to work well in a group. For example, people who are particularly ideologically opposed to certain kinds of treatment, people who have had very poor experiences of care that they cannot move beyond, or people who are opposed to the methodology behind evidence-based care, may not be good candidates. This is more likely to show up at an interview than at the application stage.

As attending interviews can be difficult for people with chronic conditions and also for people with full time jobs, it may be better to interview over the phone than in person.

Once a candidate is successful, it is important to notify them in writing and to consider whether you will need a signed declaration of interests from them, and whether you will need them to sign any contracts or agreements. Some organisations designate alternative members in case the appointed member is unwell or their circumstances change, although there can be challenges with availability if people do not know whether or not they are being asked to attend and in some cases it is better to re-advertise or ask for new nominations.

3. Supporting individuals—practical, financial, informal support and training

Practical support

Provision should be made for ‘reasonable adjustments’ to be made to the physical environment of the group’s meetings, the way in which meetings are conducted, and in how communication takes place in the group. In some countries (for example, the USA and countries which are members of the European Union), some aspects of practical support are covered by the laws on disability discrimination or equality.

While not all adjustments will always be possible, patient members should be offered the chance to discuss their practical support needs, and wherever possible they should be accommodated.

Practical support can take a number of forms. Common examples which you can consider include:

- Adjustments for people with sensory impairments, for example, providing large print documents, or microphones in meetings

- Booking meeting rooms large enough for an electric wheelchair to be manoeuvred, and with stair-free access
- Adjustments for people who experience fatigue, such as longer breaks or having a room available in which people can rest
- Adjustments to lighting for people who have lupus
- Providing documents on coloured paper for people who have an autism spectrum condition and who find this helps them
- 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
- Ensuring any food provided meet people's dietary needs.

Once a person has been appointed to a group, provide another opportunity for them to talk about whether or not they need practical support to contribute. Remember that many conditions fluctuate, and someone who did not need support to begin with may develop additional needs.

Valuing members—the problem of payment

As mentioned above, it is important to consider what compensation you will make to patient and public members, and whether payments will include only travel (and other out of pocket) expenses, or also compensation for the work done. There are a number of advantages to compensating patient and public members for their time and effort, and a variety of ways to do so. G-I-N PUBLIC would strongly recommend providing out-of-pocket expenses such as travel costs as a minimum and providing compensation for time and effort where possible, but voluntary participation is preferable to none at all.

According to Involve, a UK based organisation promoting the involvement of patients and the public in research, the advantages of compensation include:³

- Supporting equity of power in groups
- Acknowledging the professionalism and contributions to public service of group members
- Supporting equity of access, by compensating people for lost income if they have to take the day off work, the cost of travelling, access to journals, computers and printers, access to care, personal assistants, childcare and so on
- Clarifying the expectations and responsibilities for individuals.

Smaller organisations may not have a budget for patient involvement, and may rely on volunteers. In this case, you should be clear that you are looking for volunteers at the outset, and be aware that this may affect your ability to recruit people, especially if you are unable to refund travel or other expenses. There may also be policies or laws that govern asking people to work unpaid. It will be worth checking the local context.

NICE pays an attendance fee to patient and public members, as well as travel and subsistence expenses and, where necessary, an overnight hotel. It also contributes to carer costs, both where the patient and public member requires a carer themselves, or has caring responsibilities at home (e.g. childcare). Although health care professionals are able to claim the same travel and subsistence expenses (and General Practitioners may claim costs towards locum cover), they are not paid an attendance fee. This is because a health

professional can generally take part in a guideline development group without taking leave from work or losing paid employment, but patient and public members cannot usually argue that taking time off work to take part is part of their job role. An exception to this is where a patient and public member is taking part in the guideline development group as part of a role as an employee for a patient organisation (for example, if they are a policy officer at a charity). In this case, it is possible to arrange for the attendance fee to be paid to the charity rather than the individual.

In some cases, people who receive state benefits (unemployment or disability payments) can be worried that receiving a payment will qualify as paid work, and that if the payment is high enough, may cause their benefits to be cancelled whilst this is investigated. NICE has also carefully considered how to pay patient and public members who do not work and are reliant on state benefits, so that the payment does not negatively impact on their financial situation. It is important to consider how this will be managed at the recruitment stage, so that you can answer enquiries from potential applicants. It is also important to warn people that any payments may qualify as taxable income.

When expenses are paid, you can avoid some of the pitfalls above by paying for items such as train tickets and hotel rooms from organisational funds. In some countries, this can avoid a person's reimbursements being viewed as taxable income. There may be an organisation in your country who can advise on this.

Informal support

The amount of informal support each person needs will vary. Patient and public members come from a wide range of backgrounds. Some will have a strong background in patient advocacy, and some will have professional experience that, although unrelated to health research, have exposed them to committee work and making decisions as part of a group. For others, this sort of group work will be a completely new experience. Tailoring informal support to the needs of each individual can support people to contribute their best to a group, whilst avoiding providing people with more support than they need.

Make contact with each individual before the group's first meeting. This will allow an opportunity to address any questions about the first meeting that the person has. It is also a good opportunity to talk to the person about if they will need any specific practical support, for example, as a result of a disability.

Provide patient and public members with a named contact person who they know that they can call on if they have any difficulties on the group, either with practicalities or with the personal impact of working on a group. NICE provides a contact person from a dedicated patient and public involvement programme (PPIP) team member. In smaller organisations, this may not be possible. Other potential contacts can be former patient and public members from other groups who are willing to help, or a project manager independent of the group. It is usually advisable to have someone who is not another member of the guidance development group.

It can be easy for health professionals and researchers to underestimate the potential emotional impact of taking part in a guideline development group for individuals. Individuals can sometimes become frustrated if they feel their ideas are not being considered, or can become angry or upset when the group discusses areas such as survival statistics or the advisability of aggressive treatments. This can take the individual by surprise, and can make them worry they are being unprofessional. Unlike health professionals, they rarely have a network of colleagues to discuss their ideas with. It is important to warn patient and public members that these feelings are a possibility (although not universal), are a normal reaction and not unprofessional, and to provide them with someone who they can discuss such feelings with should they arise.

Ideally, the person who is providing support for the new patient and public member should be in contact with them before the first meeting of the group, and may consider attending the first meeting. After that, it is useful to phone or to email periodically to make sure that no problems have arisen.

Training

Patient and public members may benefit from training as well as support. Training could be in technical areas such as how to understand the terminology around medical research or around how to take part in the group effectively (for example, assertiveness).

Training can be in-house, provided out-of-house, or self-directed (for example, online training). Large organisations are better able to provide tailored in-house support. NICE provides a full day training event for new patient and public members, including presentations and group exercises, covering research terminology, what makes a good or bad scientific paper, health economics and a chance to hear previous patient and public members talk about their experiences. This is followed up later in development with a workshop for patient and public members focusing on the end stages of guideline development, publication and support for implementation, (although not all guideline development groups meet for a long enough period of time for attendance to be possible).

In addition to training, or if formal training is not possible, it may be possible to provide networking opportunities for individuals. This can take place before patient and public members start on a group, and could include other patient group members or other patients with the health condition to be considered, allowing for a wider range of viewpoints to be brought to the group. It can also take place once groups are underway. Patient and public members may be willing to support each other, and having someone who has been through the guideline development process to talk to could be a valuable source of help and support. This could be a lunch, a shorter course, or providing people with contact details for other patient and public people developing guidelines. Check what details people are willing to share with strangers and never give out personal details without explicit permission.

In-house training and providing networking opportunities may not be possible in smaller organisations. If there are funding and local opportunities, organisations may choose to use existing external training events or courses on areas such as committee skills or critical appraisal. Some organisations provide training in medical research for consumers. Where this is not possible, there may be free online resources to support self-directed learning. Several organisations offer free online courses to patients and members of the public, such as those offered by the US Cochrane Center⁴ and Project LEAD provided by the National Breast Cancer Coalition in the USA.⁵ Other sources of support can include virtual or online resources, including the HTAi patient glossary on Health Technology Assessment,⁶ the NICE glossary on guidelines,⁷ and the glossary⁸ and series of information resources on evidence-based medicine⁹ from Bandolier.

Supporting Individuals—group dynamics

There is a large body of psychological and sociological research literature around how groups form and work, and the barriers to people effectively taking part in groups. Being aware of group dynamics can help guideline development groups make the most of the experience and insight that patient and public members bring. It is really important to ensure that the Chair of the group is aware of their responsibility to ensure a safe, inclusive atmosphere in the group, and patient and public members are aware of how to contact them with concerns.

In many societies, there is an automatic power difference between doctors (seen as high status), nurses (seen as lower than doctors but higher than patients) and patients. Although few health professionals

consciously act to this stereotype, it can be very intimidating for patient and public members who are asked to speak in guideline development groups, especially if they have to contradict what a health professional is saying.

To overcome this, it is important to publicly stress the importance of patient and public perspectives. Consider delivering a presentation on the importance of patient and public involvement early in the guideline development process. Stress that patient and public members have equal status, that they have essential contributions, and provide examples of where patient and public members have improved a guideline in the past.

Brief the Chair (see chapter 3) to strongly discourage the use of medical and other jargon in meetings, which can exclude patients. Do not allow the use of titles to enforce a status difference; meetings should be conducted on terms of equal respect. You should not allow a meeting where doctors are all addressed as 'Dr X' or 'Professor Y', but the patient and public member is addressed by their personal name ('Dr Smith, this is Sarah' should be unacceptable). It may be possible to have a patient or public moderator Chair the meeting, to ensure that jargon and power imbalances are addressed, but this is not always possible because of the need for specialist chairing skills and, in some cases, the need for a Chair who is an expert on the clinical aspects of the guideline.

Patient and public members should not be seated in an isolated area of the meeting, and should be somewhere where it is easy to get the attention of the Chair and other supportive members of the group. The Chair should be specifically 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 concerns.

Encourage patient and public members to identify potential allies in the group. There may be people on the group who come from a more patient-centred approach than others, or who have agreed with the patient and public member on other points. Helping patient and public members to identify these people and to approach them with ideas at break times can help the patient and public member feel more supported when they raise topics in the main meetings.

4. After the guideline is developed

Patient and public members invest a tremendous amount of time and effort in taking part in guideline development. Acknowledging their input is an important aspect of showing your support and appreciation for their contributions. A consistent and timely 'thank you' process is essential and will help ensure repeat volunteers in the future. A proper thank you campaign may also have the potential to pave the way for volunteers to encourage friends and family to participate in similar guideline development activities.

If guideline development groups are credited as authors on the guideline, patient and public members should receive the same authorship and be credited in the same form as the health professionals.

Patient and public members may be willing to help with the training and support for future patient and public members, for example, by speaking at training or networking events. This can be very valuable to future patient and public members. Keeping records of who is willing to do this is a good way to support new patient and public members.

Further reading

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[Cochrane collaborative consumer online learning.](#)

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- ⁵ <http://www.breastcancerdeadline2020.org/learn/>.
- ⁶ <http://www.htai.org/index.php?id=545>.
- ⁷ <http://www.nice.org.uk/website/glossary/glossary.jsp>.
- ⁸ <http://www.medicine.ox.ac.uk/bandolier/glossary.html>.
- ⁹ <http://www.medicine.ox.ac.uk/bandolier/learnzone.html>.

Chapter 4: How guidelines can involve people facing barriers to participation (2015)

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Aims of the chapter

This chapter provides advice on how to involve people who face barriers to participation in guideline development and related activity. It is designed to be read in conjunction with the other Toolkit chapters about consultation (chapter 1), participation on guideline development groups (chapter 2) and the involvement of patients and the public in dissemination and implementation of guidelines (chapter 5). The aim of this chapter is to show how it is possible to effectively involve people who may face additional barriers to participation, with a particular focus on the examples of children and young people, and adults with mental health and substance use problems. It is also relevant to other groups such as people with a learning (developmental) disability or cognitive impairment, and those who are particularly under-represented in healthcare governance¹, including people from some minority ethnic groups. This chapter is largely based on the experience of the UK's National Institute for Health and Care Excellence (NICE), while also drawing on examples from Norway's Directorate of Health and Centre for Dual Diagnosis. The main part of this chapter focuses on involving people in guideline development, with a smaller section devoted to case studies of involvement in related resources to support use of a guideline.

Involvement in guideline development

To ensure guidelines incorporate the perspectives and priorities of people with the condition and therefore are acceptable and relevant to them, it is important to support effective patient and public involvement in guideline development. For some topics this could involve targeting recruitment to attract a specific group (e.g. young people, people from specific ethnic or cultural groups), making adaptations to the way meetings are run and the nature of the support offered (e.g. people with early stage dementia or a learning (developmental) disability), or it could require a different approach altogether.

The barriers to involvement can be greater for certain groups of people. For example, in our experience at NICE it is not practical for children to be recruited as members of a guideline development group, so other approaches to involving them need to be considered, in addition to recruiting parents or carers to the group.

The same may apply to people with severe cognitive impairment or profound and multiple learning (developmental) disabilities, or people who are acutely or severely ill. However some people who may be considered vulnerable or marginalised have participated as full members of guideline development groups. For example, NICE recruited young adults who grew up in the UK public care system as members of a guideline development group, directly contributing to guidance on promoting the health and wellbeing of 'looked after' children and young people.² In addition, children and young people in public care were consulted on the relevance and acceptability of selected draft guideline recommendations and their views influenced the final recommendations.³ Young people were also involved in producing resources to support guideline implementation (see case study 1 in the box at the end of this chapter). Similarly, guideline developers have reported positively on their experience of involving people with psychotic illnesses or substance use problems throughout the development process. For example, for Norwegian guidelines on these topics, respectively five and four user representatives contributed to guideline development. When asked about their experience of involving patients, the project leaders responded: "How could we have made the guideline without them?" They found that involving people with these conditions was important for both scoping the most important topics and in the process of formulating recommendations. The user representatives, with both their own unique experiences and as representatives of a user organisation, added their experiences to the knowledge base.^{4,5} (See case study 2 in the box at the end of this chapter.)

Involving children and young people

The UN Convention on the Rights of the Child⁶ enshrines the rights of children to be involved in decisions that affect their lives and a requirement that their views are listened to. As a result of this focus on children's rights, 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 are able to give 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 directly mirror those of adults.⁷

The UN Convention on the Rights of the Child defines a child as a person under the age of 18 years, as does UK child protection legislation. However, 16 and 17 year olds in the UK are not considered vulnerable if they are in volunteering or employment situations. For NICE, age 16 is the minimum age for a young person to join a guideline development group, or attend a meeting without needing the consent of an appropriate adult and having to be accompanied by them. If, however, 16 and 17 year olds have a specific vulnerability, such as a learning (developmental) disability, then the need for an appropriate adult would apply.

Definitions of young people also vary. For example, in the UK some policies and services define a young person as aged between 16 and 19; in other settings a young person is defined as someone aged between 16 and 25. Whichever age cut off is used, ‘children and young people’ covers different demographic groups with different needs, especially with regard to ethical and practical considerations that involving children entails, as Bird et al have argued in relation to research with children.⁸

NICE has developed a systematic approach to ensuring that the views of children and young people are included in guideline development for relevant topics, as well as involving parents or other family members. This is reflected in the NICE manual for developing guidelines, published in October 2014,⁹ and is based on a set of principles for involving children and young people.¹⁰ It includes an acknowledgement that the perspectives of parents and carers are important as they bring valuable insight of their own particular experiences and preferences, but they should not be regarded as a proxy for the experiences and views of children and young people. However in practice, parents and carers will continue to act as a proxy voice for babies and infants in guideline development at NICE.

As with adults, it is important to involve children and young people in a meaningful way, setting out clear objectives and clarifying their role. Working with children and young people requires sensitivity and flexibility, especially if the topic itself is sensitive or they are facing serious health problems.

For guidelines affecting children and young people and other groups who may face barriers to participation, we set out below advice and options to consider, based on NICE’s approach.

Starting a new guideline

At the start of planning work for a new guideline, it is important to consider the options for ensuring the perspectives of people with the condition or from the affected population inform its development. This may include identifying resources for any work that may be needed that is not part of the routine development processes.

We recommend you consider the demographics of the population covered by the topic, including the age range, and the implications for recruitment to the guideline development group. For example, for some topics, it may be possible to recruit young people (aged 16-25) to the group, using targeted advertising and social media.

If you plan to involve children or vulnerable adults, it is important to consider ethical issues and measures for protecting the safety and welfare of participants, including following the relevant local ‘safeguarding’ policy.

Organisations that represent or work with your target group may be able to help with recruitment, for example by advising on advertising and using their networks to encourage suitable applicants to apply. In addition they may be able to put forward suitable nominees. (See chapter 2 for further details on open recruitment versus nomination.) Professionals working in the field can also play a role in encouraging suitable applications. This turned out to be a successful route for recruiting young adults (aged under 25) for the NICE ‘looked after children’ guideline development group.

Organisations representing patient, carer and public interests can be a very helpful source of advice on effective ways of involving users of services in new topic areas. For example, NICE sought advice from relevant advocacy and user-led groups for new topics covering health and social care services for people with a learning (developmental) disability. Some stakeholder organisations may also be in a position to support the involvement of people whose voices may not otherwise be heard, perhaps through their own groups or forums. For example, they may be able to work with the people you are interested in engaging to put forward their views on the most important issues for a guideline to cover or on selected draft recommendations. For some topics, a stakeholder organisation may be able to offer practical support to individuals recruited as members of a guideline group. For example, for the NICE guideline on identifying and managing tuberculosis among hard-to-reach groups¹¹, members of the guideline group included people who’d been treated for TB, a number of whom received additional practical support from a homeless charity. This included use of a permanent address for communications as they lived in temporary homeless shelters, and access to a computer for communications between meetings.

To ensure everyone you want to involve can afford to take part, we suggest covering their expenses such as travel costs, and provide compensation for time and effort where possible. If you intend to pay participants, we recommend considering how to do this so that it doesn’t negatively impact on the financial situation of anyone in receipt of state welfare benefits (see chapter 2 for further advice).

Adapting support for members of guideline development groups

As discussed in chapter 2, support for patient and public members of guideline development groups needs to be tailored to their individual needs. In the case of involving a young adult or someone with a memory problem or a person who struggles to organise their time, options such as reminder text messages may be helpful. This could include examples such as texting half an hour before the time of a pre-arranged telephone conversation, or texting to remind the person that support is available should they need it.

When involving people as full members of guideline groups who are not experienced in reading research papers or summaries of research, it is particularly important to offer them training (see chapter 2). It can also be very helpful to highlight to them the most important sections of papers to read or comment on, or

ask them specific questions with a patient or public focus. To minimise bias, this is best done by a neutral support person rather than someone involved in the guideline group's decision-making.

Working with a reference group

When people with the condition or from the affected population are not able to be members of the guideline development group (e.g. children, people with advanced dementia, those with severe autism), parents, carers and advocates will have an important role on the group. In addition, we recommend you consider alternative approaches to involving people with the condition or from the affected population. One option is to have a reference group or panel to help the guideline group identify patients' perspectives and priorities at key stages of guideline development, and beyond to dissemination and implementation. We recommend the panel is supported by people with expertise in facilitation and a track record in working with your target group. For example, for the NICE social care guideline on child abuse and neglect, an external agency with appropriate expertise and experience has been commissioned to convene and support a reference group. This group is being established as an ongoing consultation mechanism to provide up-to-date insight and perspectives from young people who have been affected by child abuse and neglect, and will indirectly strengthen the voices of children and young people in the guideline group's work.

A reference group can also be used in addition to patient and public membership of the guideline group. This could serve to widen the range of patient and carer views available to the guideline development group by including people with different experiences of the condition, treatment and care, or people from a specific ethnic or cultural minority group, or a wider demographic make-up altogether. This may include people who prefer to participate in a peer group or who do not have the confidence or ability to contribute in a multidisciplinary environment.

Below are some issues to consider before setting up a reference group. Some of these issues also apply to other forms of patient and public involvement in guideline work:

- As with any participation initiative, be clear about your objectives – what do you want to achieve by involving people in a reference group?
- At what stage do you want the reference group to become involved? Setting up a group can take many months so build in time for participants to have an induction before commencing the work you want them to do.
- Consider who you want on the group, such as their age, gender, ethnicity or culture, geographical coverage, knowledge of a health condition or intervention.

- Consider ethical issues and protection for the safety and welfare of participants, including following the relevant ‘safeguarding’ policy and legislation for children and vulnerable adults. Guideline developers and those running the reference group have a duty of care to ensure appropriate methods are used to support participants. Only those who are emotionally resilient should be involved and their participation should not compromise their wellbeing.
- Establish criteria for the sort of people you want to recruit in terms of knowledge and understanding. This will help to ensure that only people with the relevant experiences are recruited. In terms of skills, for membership of a guideline development group at NICE we look for people with the ability to contribute in this multidisciplinary setting, though not necessarily prior experience of multidisciplinary groups as this would exclude most young adults and others covered by this chapter. When recruiting a reference group of peers, the ability to contribute in a multidisciplinary setting is not a requirement.
- Consider where your group will meet, how often, how people will travel there, and if there is a need for support from carers, parents or guardians, and for young people, whether meetings are during term time, holidays or near exam time.
- Consider what contact and support will be needed between meetings.
- Consider incentives and reward for participation, particularly when involving young people. This could be a voucher, payment, or treat.
- Plan for feedback to be given to participants at regular stages as to what impact their involvement has had.

Properly supported, a reference group or panel has the potential to provide insight about patient/public perspectives on key questions or issues identified by both the guideline development group and reference group members, at different stages of the process.

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 undertaken by stakeholder organisations. User views and experiences can also be found on the websites of patient groups and other patient-focused websites. For young people’s health topics, Youthhealthtalk - www.healthtalk.org/young-peoples-experiences - is part of a reputable website (Healthtalk) which guideline developers may find useful. The information is based on research with people in the UK, undertaken 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.

Depending on the availability of patient and public evidence, guideline developers may consider seeking additional information from the relevant population group, using methods such as expert testimony or research techniques, which we discuss next.

Patient and public expert testimony

When there are gaps in the information available to the guideline group, it may be appropriate to seek expert testimony from people with the condition or from the affected population (in person, in writing or by video). Relevant stakeholder organisations may be able to support people to provide this type of input. Such expert testimony may be sought once or more during guideline development as the need for expert testimony may only become apparent later in the process.

At NICE there is no minimum age for young people providing expert testimony. If a child or young person under 16, or a vulnerable adult, attends a NICE meeting, they must be accompanied by their parent, carer or other appropriate adult with responsibility for their welfare. Adaptations may be needed to make the meetings accessible for children or for those with cognitive impairments, for example in terms of timing, pace, agenda and language. For some children or vulnerable adults contributing evidence to meetings, special measures may be needed, such as giving testimony via video recording or in a closed, confidential session if meetings are usually held in public.

Consulting a wider group using research techniques

For important gaps in the evidence which are unlikely to be filled through consultation with stakeholder organisations (see chapter 1) or via any of the above approaches, some guideline developers may consider consulting individual patients, relatives, carers or other relevant members of the public, using research techniques. This is an exceptional option requiring additional financial and human resources including access to qualitative research expertise. We recognise that some guideline developers may not have access to such resources, even on an exceptional basis. However, where this is an option, views may be sought, for example, on:

- the scope or specific aspects of the guideline, review questions, or issues raised by the guideline development group that they would like more information on
- the relevance and acceptability of selected draft recommendations

The main types of methods that may be appropriate include:

- group-based methods such as focus groups, participative workshops and ‘virtual’ (electronic) groups
- 1-to-1 or paired in-depth interviews carried out face-to-face, by telephone or electronically
- surveys carried out by telephone, electronically, on paper or by using vote casting or polling

Group-based methods and interviews are best for finding out how people feel and exploring topics in detail.

Consulting people with autism - For the NICE clinical guideline on autism, the National Autistic Society (NAS) consulted people with autism on their views on emerging draft recommendations (developed on the basis of a qualitative literature review) for improving access to and experience of care. The NAS ran focus groups and conducted individual interviews with children and young people on the autistic spectrum. The purpose was to validate findings where appropriate and to allow feedback on areas in which the children and young people felt that the qualitative literature was either not representative of their views or that evidence was missing. This consultation helped inform final guideline recommendations.¹²

We recommend that guideline developers consider the recruitment strategy and choice of methods carefully, in line with the purpose of the consultation, taking into account the topic, the age groups covered by the guideline, the range of views required, and other relevant issues.

When planning a consultation, the life circumstances of the people involved need to be taken into consideration so as not to adversely affect timelines including dates for the consultation and the feasibility of recruiting enough participants. For example, in the case of consulting with children and young people, school holidays and exam schedules would need to be considered.

Techniques for eliciting people’s views need to be tailored to the age, cognitive ability and culture of participants, with materials and activities designed and adjusted to suit them, and taking into account any adaptations needed for people with a physical or sensory impairment. Bear in mind that written methods will not work for people who cannot read or write well, and for some sensitive topics, group based methods may not be appropriate, at least for some participants.

Children’s ability to communicate and express their views in written or verbal form is variable, even within a particular age group. Therefore other media, e.g. visual and performance need to be considered.¹³ When consulting young children, play-based approaches are a good way of communicating with them. With older children and young people, games can work well, along with more conventional qualitative techniques. If questionnaires are used with young people, they should be kept short, taking no longer than 10 minutes to complete. Ideally, young people should be involved in designing both the content and style of the

questionnaire.¹⁴ Digital media is popular with children and young people, but bear in mind that not everyone feels confident with it or has access to it at home.

For a **survey with children in hospital**, guideline developers worked with a children's hospital that had developed a means of obtaining real-time feedback via hand-held touch screen computers which young children find easy to use. Children and young people had contributed to the development of this new data collection system.¹⁵

Consultations should be undertaken by those with relevant expertise and a good track record in working with the relevant population group and using appropriate research techniques. NICE commissions such work using a tender process, including interviewing prospective contractors. Guideline developers with the resources to undertake such activity, need to satisfy themselves that the people doing the consultations have the appropriate expertise, policies and procedures for ensuring the safety and welfare of participants, including following best practice and the country's legal requirements for working with children and vulnerable adults. Consent and other ethical issues need to be considered, including whether formal ethical approval is required from the relevant research governance body.

Whatever the method used to involve people, it is important to give feedback to them on the outcome of the activity, for example the findings of the consultation and how these have been used. We recommend you consider how participants will be acknowledged for their contribution to the guideline. This could be an acknowledgement in the guideline itself, in an accompanying report and on the guideline's website. Seek permission first if you intend to name individuals. Finally, it is important to formally thank participants, for example with a letter or certificate, and where possible and appropriate, a voucher or payment for their time and effort. It may also be possible to accredit certain forms of participation, which could be useful for a person's CV, particularly in the case of young people and others with limited work experience.

Involvement in supporting guideline implementation

Case Studies (see also case studies in chapter 8)

Case study 1 - Involving children and young people

Young people were involved in developing the NICE/SCIE (Social Care Institute for Excellence) guideline on promoting the health and wellbeing of 'looked after' children and young people.¹⁶ They also contributed to two online SCIE resources to support the dissemination and implementation of the guideline. This work included interviewing young people for a film as part of an online package for professionals to support the implementation of the guideline. Young people also helped to develop an online interactive resource, called 'Info 4 Care Kids' – www.info4carekids.org.uk - aimed at children and young people in the UK care system.

This resource includes key messages from the NICE guideline along with further advice and information on the care and support children and young people can expect, the choices they have, and who they can approach if they don't believe they are experiencing the standard of care recommended by NICE.

Case study 2 - Involving people with mental health and substance use problems ('dual diagnosis')

In March 2012, the Norwegian Directorate of Health launched a national guideline for 'dual diagnosis'.¹⁷ In parallel to the development of the guideline, the Centre for Dual Diagnosis worked closely with user organisations in the substance abuse and mental health field to prepare for its implementation. This 'prioritisation and input' working group consisted of representatives from 10 service user and other interest groups, along with representatives from the four main professional organisations (doctor, social worker, nurse and psychologist). Their primary purpose was to assist the Centre in planning and developing various measures to implement the guideline. The representatives of user organisations were paid for their participation, as well as having their travel expenses covered. This collaboration resulted in several implementation tools.

Each user organisation from the 'prioritisation and input' group selected a priority recommendation for implementation in practice. Information focusing on "10 recommendations you should know" was developed for people using services, carers and support services staff. Further information was included on which support services personnel are responsible for following each recommendation. Current issues and questions that users, relatives or carers might want to ask staff in support services were also included. On reflection the Centre deemed the information too detailed for some people with a dual diagnosis and so developed information specifically for this group. Recommendation cards consisting of just the 10 recommendations were produced to be handed out by staff working closely with this group of patients.

The online version of the information – www.ropbruker.no – is accompanied by an interactive question and answer facility. Employees who work with people with a dual diagnosis also have access to an online resource page – www.snakkomrus.no. This includes filmed interviews with representatives from user organisations in the 'prioritisation and input' group sharing their experiences of issues related to being dependent on alcohol and/or drugs, as well as their reflections and feedback to support services staff.

Conclusion

People who face barriers to participation can be meaningfully involved in the development of guidelines and related activity. This requires early and careful planning, and clarity on objectives, which groups to involve, ethical and practical considerations, and the most appropriate methods to use. It requires access to relevant

expertise and in some cases substantial additional resources. In this chapter, we have also emphasised that those working with children and vulnerable adults have a special responsibility for their wellbeing. The examples from the UK and Norway indicate that involving people who face barriers to participation can be rewarding for them and those they work with, and make a real difference to the guideline and related resources to support its implementation.

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Chapter 5: The role of the Chair in patient and public involvement: training and support (2012)

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Aims of the chapter

This chapter describes the method for selecting and supporting the Chairs of clinical guideline development groups (GDGs), developed over recent years for the National Institute for Health and Clinical Excellence (NICE) in the UK. The model places particular emphasis on involving and engaging with patient and public members of GDGs as an integral part of the overall responsibilities of group Chairs. Interactive discussions throughout a day's induction session take account of this aspect of the Chair's role, alongside other elements which NICE feels are important for those undertaking the Chair's role. The approach described has been developed over time, specifically tailored to the needs of the Chairs of NICE guideline development groups. Elements of the model will be generalisable to other organisations, even where the NICE guideline development 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.¹ This is a very specific form of 'multi-disciplinary' working, which may not be familiar to those who develop guidance without such involvement. Where this is the case, other chapters in this toolkit will help readers identify key elements for such work.

For the purposes of this chapter the terms 'patient and public members' will be used throughout. The patient and public members of NICE's guideline development groups are recruited as individuals with a breadth of knowledge and experience about a particular clinical area, topic, 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 and public member' refers to patient, unpaid carer, service user, consumer, user representative and/or patient representative.

A key message of this chapter is that if the Chair of a guideline development group is properly supported and trained in facilitative and inclusive skills then this results in successful patient and public participation in the guideline's development. In other words, a skilled Chair can improve group dynamics by empowering patient and public members who then, in turn, contribute more meaningfully.

Readers of this chapter should gain an understanding of:

- Key issues for inducting and supporting Chairs of guideline development groups
- One sample mechanism for identifying and selecting guideline development group Chairs
- The inherent value in providing formal and structured induction for Chairs of guideline development groups
- Particular issues for Chairs of groups with patient and public members

- Organisational and resource implications for adequately supporting and inducting guideline development group Chairs
- The barriers to effective chairing, and some potential solutions for overcoming them.

Best practice information

NICE's approach to inducting and supporting guideline development group Chairs

Background

In May 2006, the World Health Organisation (WHO) conducted a review of NICE's clinical guidelines development programme,² making a number of recommendations for improvement and refinement. One recommendation was that Chairs of guideline development groups (GDGs) should be recruited through a standard process, preferably through open advertising, and that NICE should develop standardised training for GDG Chairs. The first of these points was quickly adopted (see discussion below).

In terms of the standardised training of GDG Chairs, NICE derived a one-day 'induction' programme, discussed more fully below, which seeks to address issues about the participation of patient and public members of the group, alongside other relevant matters for NICE GDG Chairs. This approach reflects the results of an evaluation carried out by NICE's Patient and Public Involvement Programme (PPIP) in 2004,³ (repeated in 2008⁴), which identified the role of the Chairs of GDGs as crucial to the success of: a) the way the GDGs functioned, and b) how well GDG patient and public members felt integrated into the group and its workings. GDG patient and public members variously described characteristics of 'good' Chairs as:

- 'Inclusive'
- 'Skilled'
- 'Open'
- 'Honest'
- 'Able to influence'
- 'Encouraging healthy rivalry'.

One 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 and public members were on an equal footing to the professionals' and another said 'The Chairman was very accommodating to the patient and 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 PPIP's evaluations revealed that the patient and public members felt that the Chairs could either be 'weak' or 'skilled' depending on how well they managed their guideline group and how well they offered appropriate support to the patient and public members of the group.

As is found in studies of different types of small group work,⁵ the PPIP's evaluations identified a relationship between the skills of the Chair and the success of the group. The role of a guideline development group Chair is clearly a key element determining how well a group functions; success or otherwise of a group rests on the skills of the Chair.

NICE's Chairs' induction programme

As a consequence of the WHO report and the subsequent evaluations described above, a programme for inducting NICE's guideline development group Chairs was developed jointly by NICE's Centre for Clinical Practice and its Patient and Public Involvement Programme. As stated above, it is specifically tailored to NICE's needs and the context in which NICE works. NICE operates a mixed model of guideline development where most of its guidelines are developed by external contractor organisations (known as National Collaborating Centres or NCCs), according to methods and processes set out in a publicly-available manual.⁶ A new Chair is recruited for the GDG which addresses each new guideline topic. A guideline development group is a multi-disciplinary group comprising health care professionals (both specialists in the topic and generalists), patients and/or members of the public, and a technical team (systematic reviewer, information specialist, health economist).

Alongside the work contracted to NCCs, some of NICE's guideline development work is undertaken 'in-house'. These guidelines are developed by GDGs with 'standing' Chairs who oversee the development of guidelines on different topics. Both newly recruited GDG Chairs and standing Chairs are invited to attend induction sessions.

The induction process for NICE's guideline development group Chairs is under constant review and refinement, reflecting accumulated experience of GDGs and their Chairs, GDG members and, importantly, change and refinement in methods and processes for developing NICE clinical guidelines.

The role of a guideline development group 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. NICE's GDG Chairs are responsible for running independent groups, but knowledge of the methodological and process expectations of the organisation is crucial in ensuring the Chairs can run a group charged with delivering a clinical guideline on behalf of its commissioning organisation. It is key for the Chairs to focus on their main objective, which is to deliver a high-quality guideline, within the resource and time constraints allowed. It should be acknowledged that a reliance on explicit methods and processes may not apply in every location or organisation where guidelines are being developed.

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

At NICE, the Chair's role in supporting the patient and public members of the guideline development group is part of the overall induction programme, and references to and discussion about this are woven into the different sessions of the day. This emphasises that patient and public member involvement is an integral part of the guideline development process, and of the workings of the guideline development group. If there were a separate section of the induction programme, specifically focusing on patient and public involvement, an impression might be given (however subliminally) that patient and public member involvement is an 'added extra' and not an integral—and essential—part of the guideline development process.

The day-long programme comprises a mix of presentations, discussions and interactive sessions, intended to introduce Chairs to the NICE methods and processes⁶ which govern the development of NICE clinical guidelines, and also covering practical issues in running guideline development groups such as regular and full declaration of interests, good facilitation skills, and the importance of NICE's duties regarding equalities legislation (see NICE Revised Equality Scheme 2010-2013⁷), and issues arising from the NICE policy on participation of patient and public members of GDGs. Presentations are delivered both by methodological

and process specialists from within NICE Centre for Clinical Practice (NICE CCP), and specialists in patient and public involvement from within PPIP, further emphasising the importance of an inclusive approach to guideline development. Overall objectives of the day are to:

- Provide a specific opportunity for GDG Chairs and NICE staff to meet, share experience and discuss the work of the institute in context
- Provide an overview of key NICE processes, procedures and methods
- Identify key references 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 guidance development ‘professionals’ within NICE.

Additional resources

General information about the role of Chairs in running groups on which patient and public members sit can be found in two key additional reference resources:

- Patient and Public Involvement Toolkit,⁸ Chapter 4 Building Relationships
- Patient and Public Involvement in Research Groups—Guidance for Chairs.⁹

Resource and planning requirements

There are significant resource implications for supporting and inducting Chairs of guideline development groups, mirroring, but not necessarily equivalent to, the specific and targeted resources needed for support of patient and public members of the groups. Some of these resource implications are financial but the main call on resources is that of ensuring adequate staff time to deliver appropriate induction and support. Some of these implications are outlined below.

Recruitment of Chairs

To ensure transparency, it is essential to have an open recruitment process, whereby anyone with an interest can apply to Chair a group. NICE has developed a formal corporate recruitment policy to support this. Potential Chairs must submit an application (as they would for a position of employment) and a formal process for selection and recruitment follows. Applications are assessed against formal criteria in a ‘role description’, and then short-listed. Short-listed candidates are invited to attend an interview with a panel comprising senior members of NICE staff and members of its board. Further information on vacancies for Chairs of NICE groups can be found on the NICE website—www.nice.org.uk/getinvolved/joinnwc/join_a_nice_committee_or_working_group.jsp.

This process, although transparent, carries a significant administrative burden, including the staff resources involved in drafting recruitment paperwork, the time taken to short-list the applicants, and the interview process with senior members of staff.

Organisation of induction

Guideline development group Chairs are most often health professionals with extensive commitments. Given the large number of guideline topics which NICE is handling at any one time, it can be difficult to identify suitable times and dates for induction sessions. In this context, and because of the complexities inherent in running induction programmes of this nature, NICE has found it essential to have a dedicated

person within the Centre for Clinical Practice to act as the strategic and operational lead on the Chairs' induction work.

Financial commitment

Although guideline development organisations may differ on their policies for remunerating their guideline development group Chairs, within NICE, the Chairs' employing organisations are reimbursed for the time they spend working on the guideline group. This is at a rate of two working days per guideline development group meeting, which approximates to 2 days per calendar month. In addition, Chairs' travel and subsistence expenses are met by the NCCs, according to NICE's policy. It is a requirement for all GDG Chairs to attend the induction session (see Guideline Methods manual, section 3.3.1). Consideration needs to be given as to whether the reimbursement of the Chairs by their employers to attend the induction would encourage them to attend. This is not something currently offered by NICE, but other guidance development organisations might wish to consider offering this.

Barriers—and strategies to address them

This section outlines some of the key barriers to appropriately supporting and inducting guideline development group Chairs, and some proposed solutions, based on the NICE model. It is important to point out that these barriers and solutions do not necessarily relate solely to chairing multi-disciplinary groups which include patient and public members. To be of most practical use to the readers of the chapter, this section is presented as a series of questions and answers.

What is the relationship between a guideline development group Chair's facilitation skills and their clinical expertise? Is there a potential for tension between these two functions?

While there are clear advantages in recruiting guideline development group Chairs with highly developed facilitation skills, NICE recognises that these can sometimes go hand in hand with clinical expertise in a particular topic area. NICE has two different approaches: some groups have a Chair with specific clinical expertise in the guideline topic area; in contrast, some groups have a 'generic' Chair (who may or may not have specific topic expertise) recruited for their facilitation skills, who works alongside a clinical lead who provides topic expertise.

The key to identifying an appropriate approach is to be clear about the role of the Chair in running the guideline development group. There may need to be strategies in place for managing any conflicts which arise for a 'topic expert' Chair, as the goals for facilitating discussion and debate on the evidence within the group may not always coincide with the desire for a particular clinical approach to the guideline topic.

Should induction for guideline development group Chairs be compulsory?

NICE's experience is that induction for guideline development group Chairs can be advantageous in the running of functional and successful groups, but compulsion may be difficult when dealing with busy health professionals. The 2009 NICE guidelines manual states 'Everyone who is appointed as a GDG Chair is required to attend one of these induction sessions'. In addition, having a strong recommendation from a senior member of the guideline organisation's staff about the value of induction can be influential in encouraging newly recruited Chairs to attend induction sessions.

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

Induction programmes for Chairs need to be tailored to the particular methods and processes of the guidance-producing organisation. One model would not necessarily be appropriate for all organisations.

Induction programmes also need to be constantly refined and modified in light of evolving external influences (e.g. changing political priorities and legislation), organisational changes, developments in guideline methods and processes, and in response to feedback and evaluation from participants. We suggest, though, that where there is patient and public membership of such groups, there are common themes which may well apply across differing processes for guideline development. See, for instance, the generic resources in references 5, 8 and 9.

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

The NICE model also allows for a considerable amount of discussion during each session. Leading questions for these discussions invite participants to think about the generic topics being covered in relation to NICE and its guideline development methodology, and their particular topic. For instance, in the presentation about NICE guideline methodology, the first section on scoping concludes with a pause for discussion, which invites participants to reflect on and discuss themes relevant for their particular guideline topic:

- Each topic has unique characteristics
 - Do you anticipate issues in managing the expectations of GDG members regarding 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 which might need specific consideration?

Will someone who is a good committee Chair automatically be a good guideline development group Chair?

Not necessarily! The skills in chairing a formal committee are very different from those involved in chairing and facilitating a dynamic, reactive, and discursive guideline development group. A skilled guideline group Chair will be expected to run the practical aspects of the group (keeping to time and process, etc.) and is also expected to foster debate and discussion among group members, and 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 guideline development group processes and methodologies?

The guideline development group Chair needs to familiarise themselves with the 'rules' (of methodology and both organisational and group processes). Induction sessions are an ideal opportunity for these rules and expectations to be clearly outlined to the newly-recruited Chairs. In order to deliver a good clinical guideline, the guideline development group Chair needs to embrace these rules, and be a champion for them during

group discussions and deliberations. The induction session also allows Chairs time with staff members from the guidance-producing organisation, which can be helpful in terms of their orientation.

How do those providing induction address the issue that Chairs might find the concept that they need induction to be patronising?

It needs to be frankly acknowledged by those delivering training and induction to Chairs that the Chairs can find the concept of how to be a ‘good Chair’ patronising. However the importance of the skills needed to successfully work within a small group and within a specific methodology cannot be over-emphasised. The presence of patient and public members on GDGs is just one example of a difference between routine committee chairing and guideline group chairing which can be used to illustrate the importance of attendance at an induction session.

How do you address the fact that the guideline development group Chairs may or may not be used to working with patient and public members?

As part of the induction there needs to be an exploration of the Chairs’ experience in working with multi-disciplinary groups comprising patient and public members. One of the key advantages of delivering formal induction to new Chairs is that the programme allows for issues and concerns in this area to be addressed and shared in a safe environment, with support from the guidance-producing organisation.

Providing the Chairs with good practice examples (such as those cited in this chapter^{8,9}) can provide them with additional practical information to help them support the patient and public members of the guideline group. In addition, it is important to raise awareness of the need to recognise and support the differences between the individual patient and public members of their GDG, who may range from highly experienced people with specialist knowledge of a small topic area, to people for whom working on a committee at a national level may be a new experience.

How do you ensure that the guideline development group Chairs get the best possible experience from the induction?

One of the key things that NICE has identified as enriching the induction experience for guideline development group 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 continue to share as they move into the guideline development phase.

In theory, in terms of patient and public member involvement, it should be possible for a number of guideline development organisations to pool resources for Chairs’ induction sessions, but care would be needed to take account of different methodologies across organisations if such sessions were to range more widely than looking at techniques of engaging with and the involvement of patient and public members.

How do you address the issue of the scheduling of inductions and 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 guideline development group meeting. However as has been discussed previously in this chapter, it is often difficult to arrange induction sessions with enough notice for Chairs to attend, and sometimes to persuade Chairs of the value of their attending an additional meeting. Induction should be arranged at regular intervals to enable groups of newly-appointed Chairs access at the earliest possible time. Details of these scheduled sessions could be included in recruitment materials to: a) give a clear message about the expectation that Chairs will attend and b) allow for the applicants to plan their availability.

Although the ideal model is to induct the Chairs before their first GDG meeting, there can be advantages in people at different stages of the development process being inducted at the same time. This allows them to share their different issues and experiences with one another. In addition, a newly-appointed Chair may well have chaired a previous GDG and feel that an induction session would be a waste of time for them. However, as guidelines methodology and political circumstances are constantly changing, it is helpful to identify these as drivers for them 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 guideline development group Chairs the opportunity to attend a workshop specifically on the health economics aspects of guideline development. The NCCs also provide training to GDG Chairs and GDGs on specific methodological issues (e.g. on systematic reviewing, meta-analyses, etc.) as and when required. They are also offered the opportunity to contact NICE's methodological and patient involvement specialists or members of the NCC technical team if they have specific questions.

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Appendix 5.1

Sample guideline development group Chairs' induction session—NICE



Email: nice@nice.org.uk

www.nice.org.uk

NICE Guideline Development Group Chairs' induction session

Agenda

Time	Item
09:45	Refreshments
10:00	Welcome and introductions
10:15	Overview of NICE
10:30	Developing NICE clinical guidelines
	To include overview of health economics considerations
12:00	Editorial and publishing at NICE
12:45	Lunch
13:30	Chairs' roles and responsibilities
14:00	Effective chairing
14:40	Managing declaration of interests and equalities
15:30	Evaluation, close

Appendix 5.2

Sample guideline development group Chairs' induction session slides—NICE

Paper 5 v12/03

Different expertise – equal status The key role of Chairs in supporting effective GDGs

Barbara Meredith, Project Manager
Patient and Public Involvement Programme

NHS
National Institute for Health and Clinical Excellence

Desired outcomes

- A good guideline
 - produced to time
 - useful to NHS and patients
- Effective, amicable group working
 - 'different expertise – equal status'
 - inclusive – avoiding unnecessary jargon: pausing to explain necessary terms
 - responds to evidence, uses collective experience where appropriate
 - uses consensus
- Problems recognised, tackled early, and resolved
 - members feel able to raise issues – inside and/or outside meetings

2

NHS
National Institute for Health and Clinical Excellence

Some issues for chairs and members

- Working within the NICE development process and within the constraints of the scope
- Limited evidence in many areas
- Objectivity vs personal experience
- Health ethics – challenge of proposing *stopping* doing some things vs perceptions on rationing
- Broad view of economics vs own specialist area
- Importing/accepting recommendations from other NICE centres (TA, IP, CPHE) and following previous/defined methodologies
- Where appropriate, considering NICE legal obligations for equal opportunities
- Editing process

NHS
National Institute for
Health and Clinical Excellence

Working with patients and carers

- Bearing in mind – responding to patient/carer member needs potentially benefits all group members
- Being inclusive but not patronising, avoiding tokenism
- Recognising and responding to fears and concerns
 - feelings of inadequacy because of lack of research skills or training
 - ‘fear of the unknown’
 - time commitment: volume of reading and the need to be selective
 - handling patient/carer input sensitively
 - considering standing agenda item on patient/carer concerns
 - using PPIP as a resource when needed
- Ensuring timely access to papers and admin support
- Ensuring audibility in meetings

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Health and Clinical Excellence

Some thoughts for facilitation of the GDG and enhancing group dynamics

- Preparation
 - clarity about workplan
 - agreeing mode of working with NCC, clinical lead
 - managing expectations of different GDG members, considering issues which may arise (e.g. from scope)
 - anticipating 'sticking points'
- Establishing 'ground rules' for working in the group
 - open, honest communication
 - encouraging members to raise concerns early rather than late
- Observing group dynamics, being alert to problems
- Maintaining participation, managing conflict

'Groups. A guide to small group work in healthcare, management, education and research' Elwyn & Greenhalgh, Fraser Macfarlane. Radcliffe Medical Press, Oxford, 2001

Chapter 6: How web-based technologies can support patient and public involvement – a best practice example from Australia (2015)

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Aims of the chapter

Over the past decade, many guideline developers worldwide have started to explore and introduce web-based technologies for guideline development and publication. The reasons were to overcome the main challenge of keeping guidelines and systematic reviews current and improve information management and overall workflow. Some examples of initiatives by guideline developers are GradePro Guideline Development Toolⁱ, MAGICAPPⁱⁱ, Cancer Council Australia's Cancer Guidelines Wikiⁱⁱⁱ and CPG development portal^{iv}. These systems have translated guideline development processes, methodologies and workflows into a web-based environment. The underlying data is stored in a structured machine-readable format, linkable and easily shared and can be integrated into other systems.

This transition to electronic guidelines raises questions with regards to ongoing stakeholder engagement and peer review processes, such as: What does public consultation on electronic guidelines in the information age look like? How will consultation be managed when 'living' guidelines are subject to frequent and rapid updates across multiple platforms (such as mobile/tablet devices, desktop, e-book, apps, clinical decision systems)? With patients and the public as a critical stakeholder group, an important question is how can guideline developers ensure that we continue to capture patient and public perspectives while moving into the age of 'living guidelines'.

In this context, it is of interest to analyse and explore how new technological developments and web-based social tools can be used to facilitate active consumer involvement and provide the required transparency for the guideline development.

This chapter describes how guideline developer Cancer Council Australia has translated the public consultation process into their wiki-based guideline development approach with consumers and the public being an important stakeholder group. The organisation's approach, resource and planning requirements are described. Barriers and challenges are outlined with strategies on how these have been addressed.

The chapter concludes with future directions to enable ongoing consumer involvement in living guidelines and what would support and maximise consumer input in the transition to continuous publishing models. Since many guideline developers are moving towards online guideline development and continuous updating models, this example may be useful to other developers and inform their digital PPI approach.

Applying web-based tools to support guideline development, publication, review and updating

Before focusing on how Cancer Council Australia used web-based tools to support the public consultation process, it is useful to get an introduction about what the transition to online guideline development and continuous updating entailed.

In 2008, Cancer Council Australia started to investigate web-based technologies and publication tools to support their clinical practice guideline program^v with the objective to overcome the challenges of currency and process inefficiencies experienced with developing print-based guidelines. As a not-for-profit

organisation with no in-house software development team and limited resources available, we tested the feasibility of open-source wiki⁵ software for guideline development and intended to make use of existing plug-ins⁶ as much as possible to save costs and development time.

In 2010, Cancer Council Australia implemented a wiki platform for guideline development. We translated the key guideline development steps and processes based on the NHMRC guideline development methodology into an online environment^{vi}. Compared to print-based clinical practice guidelines that were typically developed as comprehensive, carefully crafted, desktop-published documents, the information needed to be structured to suit the online medium. The information was broken down into smaller, succinct data pieces (i.e. the clinical question in PICO⁷ format with its resulting recommendations/practice points). The data was structured via semantic software.

Different information views relevant to different user groups, including patients and the public, are automatically generated and updated with semantic data queries⁸. Examples for automatically produced summary views are:

- the summary of recommendations (see Figure 1)
- a landing page organised by topics or PICO questions
- a landing page displaying the guideline information sorted by specific disease stages and population groups

Each clinical question page stands on its own and is linked back to the guideline as well as the technical documentation, the underlying evidence base and additional resources (see Figure 2).

Figure 1: Screenshot excerpt summary of recommendations

How effective is endoscopic management compared with surgical management for high grade dysplasia in patients with BO?

+ Recommendation	Grade
It is recommended that patients with high grade dysplasia in Barrett's Oesophagus be managed in centres with high volume experience of the condition. The treatment and follow-up should occur in those specialist centres.	C

✓ Practice point(s)
<p>Patients with high grade dysplasia in Barrett's Oesophagus can be discussed at a multidisciplinary team meeting at a specialist centre.</p> <p>Endoscopic treatment will be the first line treatment option for the majority of patients with high grade dysplasia in Barrett's Oesophagus. There will be a group of patients for whom endoscopic treatment is not appropriate or successful and will be best treated with surgery in a specialist centre.</p>

⁵ Wiki is a collaborative Web site set up to allow user editing and adding of content. (wiki. Dictionary.com. Dictionary.com's 21st Century Lexicon. Dictionary.com, LLC. <http://dictionary.reference.com/browse/wiki> (accessed: June 27, 2015).)

⁶ A plug-in is a software component that adds a specific functionality to an existing software.

⁷ PICO stands for: (P) patient problem or population, (I) intervention, (C) comparison and (O) outcome(s).

⁸ An advantage of structured information is that it is possible to develop new and additional views as required.

Figure 2: Screenshot clinical question page

Does complete mediastinal lymph node dissection improve overall survival compared to mediastinal lymph node staging in stage I NSCLC?

Clinical practice guidelines for the treatment of lung cancer > Clinical question

Information on authorship and revision

Last modified:
16 September 2014 00:17:00

Author(s):

- Associate Professor Gavin Wright MD FRACS — Author
- Cancer Council Australia Lung Cancer Guidelines Working Party — Co-author

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5 Further resources

Introduction

Mediastinal lymph node staging, either by pre-operative (mediastinoscopy, endobronchial ultrasound FNA) or intra-operative sampling is an integral part of surgical resection of NSCLC. Besides the prognostic value of proper staging, the current evidence base for adjuvant chemotherapy shows a survival advantage for patients receiving chemotherapy if any nodes are found to be positive. Whilst accurate lymph node staging should be standard practice, the evidence to date has been unclear as to when a complete mediastinal lymph node dissection is indicated, if at all.



Comments



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Cancer Council Australia's wiki platform is used for guideline development, publication, review (including expert stakeholder and consumer consultation) and ongoing updates. Part of the initial platform launch in 2010 were workflows to support online quality assessment of the included studies, guideline publication with in-built version history as well as internal review and online patient and public consultation (see [[inset cross-reference to next chapter]]). Since then, the platform has been further developed and refined and some features and workflows specific to guideline development, i.e. citation screening or generating recommendations according to the NHMRC methodology, had to be custom-developed. The wiki platform is also a responsive site, which means the content display adjusts depending on the device that is used (mobile, tablet or desktop) to optimise the user experience.

The following sections focus on how the public consultation process has been integrated in this online environment.

As described in chapter 1 of the toolkit, there is a long history of public consultation on draft guidelines involving professional and patient/consumer organisations as well as individual stakeholders in Australia (see chapter 1). Therefore, Cancer Council Australia has also been focusing on translating this process into the web environment in order to continue to facilitate and maximise consumer and other stakeholder involvement. Since the organisation had to address many functional requirements overall with transitioning

guideline development into an online environment, the organisation chose to pilot existing commenting plug-ins and approaches where possible and continuously iterated rather than undertaking extensive stakeholder research at the start and custom-building a new software feature. Guideline developers with internal IT and PPI staff may choose a less experimental and agile approach.

Stages to translate the stakeholder consultation process into the wiki platform environment

Step 1: Enabling online commenting to conduct public consultations on draft guidelines

As a first step, the existing printed feedback form that was used for public consultation, was translated into a simple online form (see Figure 2). A plug-in was installed to enable users to post comments online. Instead of asking stakeholder groups to submit their feedback on the draft guidelines document during the consultation period using a word form and submitting the document via email, stakeholders were asked to submit their feedback using the online form.

Figure 2: Screenshot of online commenting to conduct public consultation on draft guidelines

The screenshot shows a wiki page titled "DOSE OF RADIOTHERAPY".

Evidence summary:

Evidence summary		[edit]
In patients with locoregional inoperable NSCLC and with good performance status, higher doses of radiotherapy are associated with better response and possibly survival.		Level
		II
		28,31

Recommendation:

Recommendation		[edit]	Grade
Doses in the vicinity of 60Gy in six weeks are recommended because they are safe and give the highest response rates.			B

Comment on this guideline section:

A modal window titled "Comment: Dose of Radiotherapy" is open. It contains a text area for input, a "Save page" button, and a "Cancel | Editing help (opens in new window)" link.

This new method of making a submission on draft guidelines content was well received by our stakeholders, including consumers, based on survey feedback that was collected. It was also more efficient for our project team and guideline working party to consolidate and reconcile the comments, since automatic notifications were received when a new comment was posted. Also, a comment summary of all submitted comments could be automatically generated in real time. This comment summary was used during the face-to-face post consultation meeting with the working party to ensure all submissions had been sufficiently addressed. The

working party responses to the comments were posted directly under each stakeholder submission by the lead authors themselves.

Figure 3 provides a wide range of consumer submission examples including lead author responses. Consumer representatives successfully used the commenting technology and lead authors have assessed and responded to their feedback. Past submissions and comment replies stay available as part of the audit trail for subsequent consumer and stakeholder groups.

Figure 3 Examples of consumer online submissions and responses

Submission: [Personal experience](#)

personal experience

History Summarize

▼

I can only comment from personal experience... 2 attempts were made to obtain adequate amounts of tissue to test for EGFR mutation genes on my Mother without success. Both attempts resulting in pneumothorax and not enough tissue obtained. After first round chemo and no significant change to tumor size her oncologist suggested trying Erlotinib. Within 2 weeks her cough was gone and within 6 weeks her "snowstorm" and all tumors had shrunk resulting in 80% cancer reduction. My Mother survived another 15 months with good QOL. She would not have had this "extra" time without the use of Erlotinib. Her EGFR status was never known.

118.210.27.52 18:44, 21 May 2012

Actions ▾

▼

Obtaining enough tissue in order to test for the presence of an activating EGFR gene mutation is often difficult and fraught with risk of complications as unfortunately your mother seems to have suffered. It is only worth pursuing upfront where patients insist on knowing in order to avoid initial chemotherapy. As your mother's case highlights, patients can start with chemotherapy then switch to receive erlotinib later and still obtain substantial benefit. This is why there is a practice point indicating consideration of obtaining adequate tumour tissue be undertaken "where possible".... It is up to the individual patient doctor and patient to weigh up the risks of going for more tissue versus being treated without knowing EGFR status. Fortunately there are new biopsy techniques that can minimise risk (Eg EBUS).

Assoc. Prof. Nick Pavlakis 05:22, 15 August 2012

Parent Actions ▾

Submission: [Advance care planning](#)

discuss advance care plans

From Clinical question comments:What is the role of advance care planning and timing of referral for patients with lung cancer?/Recommendations

Perhaps using the term "offer to discuss advance" rather than "discuss" is softer language and more patient-centered. Note inconsistency "advance care planning" vs "advanced care planning"-should be advance care planning

Willem Landman 11:59, 30 May 2012

Actions ▾

Thanks. will fix typo. I agree. A difficult debate between ACP being offered as standard care to all vs. the concept of assessing readiness for ACP. I favour the latter and will amend

Dr Natasha Michael MBChB MRCP MRCGP MSC 12:49, 1 June 2012

Parent Actions ▾

Submission: [Constipation](#)

constipation

History Summarize

▼

methylnaltrexone is not available in New Zealand, for purposes of Australasian guidelines

210.54.1.137 11:48, 30 May 2012

Actions ▾

▼

Hopefully this guideline may change that!

Professor David Ball MB BS, MD, FRANCZP 18:54, 30 May 2012

Parent Actions ▾

▼

Guidelines are written based on best available evidence and the evidence for methylnaltrexone is compelling. I do however take your point and we are very aware re the differences in opioid / drugs availability between countries

Dr Natasha Michael MBChB MRCP MRCGP MSC 12:37, 1 June 2012

Parent Actions ▾

Submission: [Palliative care & Lung Cancer](#)

Palliative care & Lung Cancer

History Summarize

▼

Palliative Care,in terms of symptom management, and advance care planning, is not only relevant to Stage IV Disease-it needs to be available for all patients with incurable disease, who have burdensome symptoms, including psychological distress. There are no details for Small cell Lung cancer- again, palliative Care needs to be a prominent recommendation.

203.10.55.11 16:03, 16 May 2012

Actions ▾

▼

Thank you for your comments that are very appropriate. This is primarily an error of formatting and we will be altering the table of contents as we feel that it sits in an inappropriate place at present suggesting that it should only be available for stage IV.

Dr Natasha Michael MBChB MRCP MRCGP MSC 17:21, 23 May 2012

Parent Actions ▾

Submission: [Treatment of NSCLC](#)

treatment of NSCLC

History Summarize

▼

No mention of Palliative Care in stage 3A/B in the treatment of NSCLC. five year survival rates are 14% and 4% respectively.

152.76.1.244 14:50, 2 May 2012

Actions ▾

▼

Happy to add a practice point stating that given symptomatology experienced by these patients and their poor survival outcomes, referral to palliative care should be considered.

Dr Margot Lehman MBBS FRANZCR GDP 17:15, 22 May 2012

Parent Actions ▾

▼

That would be excellent. Thank you

Rebecca 10:16, 23 May 2012

Parent Actions ▾

Identified barriers and improvement strategies

During our first two online consultations on wiki-based clinical practice guidelines, we received one or two submissions via email, mainly from professional colleges. The online public consultation presented a barrier to them, since these organisations were used in consulting with their members and developing a document submission that a Project Delegate would submit on behalf of the committee via email. In these instances, we asked the submitters if it was possible to create a user account for their organisation on the wiki and post the submission online on their behalf. In all cases, this suggestion was accepted. For subsequent guideline consultations, these stakeholder organisations have been posting their submissions online.

In Australia, internet access and connectivity is still restricted in some rural areas and online consultation presents a participation barrier for stakeholders with limited access. Therefore, we continue to support offline channels until Australian communication infrastructure enables the rural population to participate more actively online. Cancer Council Australia's approach is to be inclusive and support stakeholders as well as possible in the transition to online consultation. We encourage and support everyone's participation in the online consultation process, but continue to accept submissions in other formats if it is difficult for them to participate otherwise.

The working group members also experienced some challenges with this new online consultation process. The lead authors of each clinical question were encouraged to take ownership of their allocated guideline section and post the agreed responses to public submissions themselves. Some of the clinical experts found this task challenging. They did not know that they had to log in with their details first before being able to

post a response and were generally unsure how to respond to comments, particularly consumer submissions. As a solution, our Project Team provided phone-based support and training on how to use the tool. For example authors were encouraged to thank the person submitting and then provide a response. As quality control, the dedicated Project Officer was responsible for monitoring all comments and would remind authors who had not provided timely responses.

The above challenges illustrate that guideline developers transitioning to online consultation would need to allocate resources to support all stakeholder groups to overcome these initial difficulties and maximise outcomes.

Step 2: Enabling ongoing public consultation and submission of new evidence

As the next step, we undertook some modifications to our online public consultation settings with the aim of improving the currency and accuracy of previously launched online guidelines.

Firstly, instead of limiting the public consultation to a specific time period on the draft guidelines, we left the commenting function enabled even after the guidelines had been finalised and launched online. This means that stakeholders are able to continuously comment on content and notify us about changes in the area of any published guideline as well as errors. This enables us, the guideline developer, to promptly initiate a discussion with the guideline working party if an important aspect has been missed and should be integrated or if an update for a guideline is warranted and instantly correct any errors.

Secondly, we implemented a “Submit new evidence” feature (see Figure 4). This feature is a separate button where all stakeholders can submit a reference if they notice important evidence had been missed in the systematic review or new evidence has emerged. We wanted to encourage stakeholders, who become aware of any important and new literature to be able to notify us as soon as possible. Once a literature submission is lodged by a user, the designated Systematic Review Project Officer receives an automatic submission alert. The suggested paper is then assessed against the inclusion and exclusion criteria according to the systematic review protocol:

- a) If the submitted paper does not meet the criteria, a response is posted and the submitters are able to access the outcome of his submission by accessing a permalink⁹.
- b) If the submission does meet the inclusion and exclusion criteria, the submission is processed further. The paper is critically appraised, data extracted and added to the body of evidence, draft content and evidence statements as applicable. The submitters are able to track their submissions via the permalink and also able to browse the associated critical appraisal and guideline content.

⁹ a permanent URL that points to a specific webpage

Figure 4: Screenshot “Submit new evidence”-feature

Submit new evidence

Step 1: Identify the evidence you wish to submit

Please fill in **one** of the following fields. They are approximately in order of our preference

1) PubMed ID

If your evidence is listed on PubMed, please provide the PubMed ID, and go to [step 2](#)

2) Abstract Link

If your evidence is not on PubMed, but it is on the web, please provide a URL to the abstract here and go to [step 2](#)

3) Citation

If your evidence is not available on the web, please provide a full citation in this box. Please specify enough information that we can find your literature submission

Step 2: Tell us about your reference

Comments

(Optional): If you have any comments about your evidence, please provide them here

As a result of these new features, we were able to incorporate quite a few important pieces of evidence into guideline content as well as correct content mistakes, such as linking to an incorrect reference.

Identified barriers and improvement strategies

For an external stakeholder (consumer or expert), the change to ongoing public consultation can be a difficult concept to grasp. We have received questions around the general process and regarding the processing of the submissions on already launched, “finalised” guidelines. In this case, the stakeholders are guided to read our [guidelines development handbook](#). The handbook explains that the small group of question authors reviews changes before they are made. If there is a major change, such as a change in recommendation for a question, the whole working party has to review and approve before an update is actioned. All changes are reviewed annually by the working party and it is also discussed if any new area has emerged that needs to be covered in the guideline. In addition, stakeholders also receive an automatic notification as soon as a response to their submission has been posted.

The example demonstrates that clear processes and guidelines are very helpful for stakeholders in order to understand how ongoing public consultation is approached and submissions are processed.

Step 3: Implementing section-based, structured commenting and integrating new evidence submission into commenting

The most recent adjustment to our public consultation setting has been through investing in an upgrade of the commenting system itself. The decision to conduct this upgrade was informed by general advancements

in commenting systems by community-driven websites¹⁰ who put a lot of resources into user research.

When we started to transition to online public consultation, there was only one comment page set up for each content page with a topic that corresponded to each content section. After conducting two online consultations with this simple set up and assessing the performance of the online commenting feature itself as well as user feedback, it became clear that users were looking for more opportunities to comment and a more user-friendly set up. From an information management and software architect perspective, it also made sense to optimise the commenting system and put more structure in place. The comment plug-in was upgraded and a talk-page is now automatically generated for each section (see Figure 5). Stakeholders are now able to comment more often and either start a new topic for discussion or reply to an existing one. The upgrade resulted in a clearer user interface. The new set up also meant that different matters were separated under subheadings rather than having one long comment thread with different levels of replies. From a data perspective, each talk-page has a link in place and is associated with the applicable section. Based on this new structured set up, additional user facing features can easily be implemented in future.

Figure 5: Screenshot section-based commenting

Vecht et al [4][5] randomly assigned 63 patients at multiple institutions in the Netherlands with single brain metastases from various primary sites (33 with NSCLC) to surgery plus 40Gy WBRT versus WBRT alone. Overall median survival (6 vs. 10 months, [p=0.04]); and functional independent survival (FIS) (3.5 versus 7.5 months [p=0.06], reaching statistical significance in the stratum with stable extra cranial disease [p=0.01]) favoured addition of surgery in a clinically significant manner. Of note in the stratum with progressive extra cranial disease there was no significant difference in FIS and absolute values were similarly poor in each arm.

Mintz et al [6] randomly assigned 84 patients at multiple institutions in Canada with single brain metastases from various primary sites (45 with NSCLC) to surgery plus 30Gy WBRT versus WBRT alone. The study was powered to detect a 50% increase in overall survival with 80% chance. Overall median survival and QOL did not differ in a clinically or statistically significant manner between the groups.



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Clinical benefit of surgery plus WBRT compared to WBRT alone: Meta analysis

A meta analysis by Hart et al [1] identified the above 3 RCTs enrolling 195 patients in total. No significant difference in survival was found (HR = 0.72, 95% CI 0.34 to 1.55, P = 0.40). Reduction in the risk of death due to neurological cause with surgery and WBRT approached significance (RR = 0.68, 95% CI: 0.43 - 1.09, [P = 0.11]). The risk of adverse events was not statistically different between arms. The authors concluded that surgery and WBRT may reduce the proportion of deaths due to neurological cause and may improve FIS but not overall survival.

There was substantial heterogeneity between the trials ($I^2 = 83\%$). Both trials that implied improved survival after surgery reported better survival in those undergoing surgery and WBRT whilst that implying equivalence of the treatments reported better survival in patients receiving only WBRT. Indeed the Mintz trial enrolled patients with poorer performance status and higher burden of extra cranial disease. It may be therefore that the youngest and fittest patients with control of their extra cranial disease benefit from resection as it is the intra cranial disease that will be their life limiting pathology and as such improved local control may prolong both their quantity and quality of life.

No randomised evidence is available to guide addition of surgery to WBRT in the case of multiple metastases.



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In addition, the evidence submission feature was improved. Instead of having a separate button to submit a reference for assessment, we integrated the functionality into the comment submission workflow. It became clear that the current set up, where the comment was separated from the literature submission, was not very intuitive. Sometimes, users would include a reference as part of their narrative comment and not use the “Submit new evidence” button. This was not ideal from a Project Management perspective, since the Project Officer was then required to formally enter the reference into the literature submission form, in

¹⁰ We looked at discussion feature development and approaches followed by jive, lithium and wikipedia.

order for it to go through the workflow set up for processing the literature submission. We assumed that if we integrated the “Submit new evidence” feature into the commenting, similar to what users are used to when attaching a photo to an email or text message, we would be able to improve the functionality and outcomes of this feature (see Figure 6).

Figure 6:



Identified barriers and improvement strategies

The move to section-based commenting has improved participation as stakeholders have the opportunity to comment directly below each section rather than having to scroll down the page before being able to comment. Therefore, this feature update lessened the barrier for participation.

However, some minor usability issues were noted after we implemented the integrated evidence submission feature. To date, 10 literature submissions have been received via the integrated new evidence submission feature, from consumers¹¹ as well as expert stakeholders. One out of the 10 literature submissions was incomplete where the submitter referred to the paper only stating the main author and year. In order to complete the missing information, the Technical Team confirmed the reference with the submitter, filled in the missing information and then processed the submission through the system workflow. With a few small improvements on the form by implementing error notifications, users would be supported to provide complete submissions of reference information.

During our last online public consultation, we also received a few longer and complex submissions. We noted that the references in these long submissions had not been attached using the new evidence submission feature. Instead, reference lists were included as part of the comment narrative. This indicates that it might be challenging for users to take the time and attach many references associated with longer complex submissions. For these submissions the allocated Project Staff added the references retrospectively, so the custom-designed online workflow could be used for processing and the complete reference information was stored on the wiki. A solution to overcome this barrier would be to develop applications to support bulk reference uploading, similar to what users know from photo album uploading applications.

For these latest feature innovations usability and uptake are continuously monitored to evaluate how well they perform for stakeholders. In general, an agile feature development approach has been followed throughout all stages of development by Cancer Council Australia with the aim to learn and improve stakeholder input for electronic guidelines.

¹¹ individual consumers as well as consumer stakeholder organisations

Summary of resources and planning requirements

Resources and planning requirements are summarised below based on the Cancer Council Australia example.

Resource and planning requirements

Skills:

An experienced consultant with high level expertise in implementing online engagement solutions as well as a skilled Product Manager with expertise in Change and Stakeholder Management were engaged. High level support for this initiative and continuous involvement was provided by the Senior Project Sponsor (CEO), the Clinical Guideline Network Manager as well as other key stakeholders.

Time:

Initial comment implementation: ca. 3 hours consultant time, 3 hours Product Management time, 1 hour training

Implementation of initial new evidence submission feature and workflow: ca 3 hours Product Management time, 16 hours consultant time, 2 hours testing and bug fixing, 1 hour training

Upgrading commenting function and enabling section-based commenting: 3 hours Product management time, 40 hours development time, 2 days Guidelines Team involvement in setting up section-based commenting for all existing online guidelines, 1 day initial testing and bug fixing, 1 hour training

Integration of new evidence submission workflow into commenting

3 hours Product management time, 24 hours development time, 0.5 day initial testing and bug fixing, 1 hour training

Money:

Initial implementation and new evidence submission workflow: No specific extra costs required for the commenting plug-in as we used an existing, freely available open source product.

Please note: if it was required to custom-build a commenting plug in from scratch and no existing code was used, it would be a significant engineering effort.

Upgrading commenting function and enabling section-based commenting: No specific extra costs required as our developer customised the existing, freely available open source commenting plug-in.

Please note: Due to the customisation, developer time is now required for ongoing maintenance in case of general system upgrades to ensure compatibility of the customised commenting plug-in with the overall wiki set up.

Practical considerations:

It is important to note that community facilitation is required to successfully transfer public consultation into an online environment. In particular, senior stakeholders who might have high level clinical expertise, but are less experienced to use digital tools, as well as consumers⁴ that are unfamiliar with these web-based participatory technologies, will need to be adequately supported by the Guidelines Project Team.

Traditionally, guideline development is undertaken by a multi-disciplinary working party including consumers as well as a project team consisting of a technical team specialised in guideline methodology as well as project and content managers. In the digital age, it will be important to widen the circle and also involve

digital experts (i.e. Product Managers, Information Architects, Business Analysts, User Interface and SEO experts) in the guideline development process, so effective digital solutions for guideline development and stakeholder engagement can be developed. It is extremely helpful to consider technical perspectives and data requirements from the start when considering process and methodology changes in guideline development.

Future directions

While Cancer Council Australia is moving further towards realising a portfolio of “living” guidelines that are continually updated as new evidence is published, the organisation aims to optimise the consultation process further and apply technological solutions to maximise stakeholder engagement.

One assumption is that it might be very challenging for stakeholders that are interested in a particular guideline or section of a guideline, to actively participate in an ongoing revision process and keep track of the changes, especially, if updates are integrated in an asynchronous fashion. It would be easy for stakeholders to miss a content update in a particular section if they are not notified and invited to comment.

So how can we keep stakeholders engaged and providing feedback if updates are going to be conducted in an asynchronous manner?

As a first step, it is intended to develop an efficient and intuitive notification and monitoring system for stakeholders to ensure that they can easily monitor, contribute and engage with all guideline areas of interest and keep track of content updates. A wiki offers users the ability to ‘watch’ activities of specific pages by default. However, the usability of this feature needs to be improved, so stakeholders can easily subscribe to a guideline or specific PICO question page and receive custom notifications about any changes, including an invitation to provide feedback. In addition, it is critical to implement targeted consultations on major content updates (i.e. any change in evidence base and recommendation) to ensure wide consumer and expert feedback is sought to help maintain the high quality of the guideline product over time.

Conclusion

Many guideline developers are currently transitioning into producing online clinical practice guidelines and applying web-based technologies to improve efficiency and information management. In parallel, guideline developers are also working on optimising their processes to enable rapid systematic review updates and ensure currency of recommendations based on integration of the latest evidence. A best practice standard on stakeholder consultation and peer review processes using web-based technologies for living guidelines has not yet been established.

This chapter, described how guideline developer, Cancer Council Australia, has applied a staged approach to integrate the stakeholder consultation process into their wiki-based guideline development environment. The different implementation stages of applying web-based technologies for consultation, barriers and approaches on how to overcome these barriers have been outlined. Resourcing and planning requirements that might be able to assist other guideline developers with similar projects are specified. Public consultation submissions were included as examples to demonstrate the type of online engagement with consumer stakeholders. Future directions with regards to transitioning to a “living” guidelines portfolio have been discussed. An agile, user-centric approach and active involvement of consumers in the development and testing of web-based technologies are considered as invaluable by Cancer Council Australia. Where possible, small scale user testing was incorporated. User testing on a larger scale as conducted by professional software companies would be extremely valuable, however, this would require additional funding and resources.

Overall, web-based technologies have huge potential to support ongoing consumer engagement. The general rise of social media and crowd-sourcing initiatives to support science projects give an indication of what is possible. Therefore, it is important for developers to continue to explore the potential of new technologies for guideline development and allocate resources to this area.

Acknowledgements:

Thank you to Prof Ian Olver, Natalia Jerzmanowska and Andrew Garrett for reviewing this manuscript and providing useful feedback.

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Chapter 7: How to develop patient versions of guidelines (updated 2015)

Authors: Karen Graham, Shaun Treweek, Nancy Santesso, Corinna Schaefer

Aims of the chapter

This chapter describes strategies and methods to communicate all or some of the recommendations contained in guidelines directly to patients and the public. The guidance is based on current best evidence from qualitative research for how to produce useful guideline-derived materials for the public and patients and options for when evidence does not exist. It gives an overview of why doing this may add value to guidelines and foster implementation, what should be in guideline-derived material for patients and the public, how to communicate information and strength of recommendations, how to describe treatment options and how to ensure material adheres to more general quality criteria for patient and public information. It also offers examples.

1. Why communicate clinical practice guidelines direct to patients and the public?

Clinical Practice Guidelines are statements that include recommendations intended to optimise patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. They are different from other sources of health information because they present recommendations about what should or should not be provided or done, something that other sources of information do not generally do. Since many of these recommendations will directly affect the care received by patients and the public, it seems natural that efforts should be made to produce guideline-derived materials that are meant to be used by patients and the public to support their health care decisions.

What are patient versions of guidelines?

Guideline-derived material for patients and the public (which, for brevity, will now be referred to as ‘patient versions’) are documents that ‘translate’ guideline recommendations and their rationales originally produced for health professionals into a form that is more easily understood and used by patients and the public. Patient versions can be used for multiple purposes and guideline producers should consider their desired purpose. For example, patient versions 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. In addition, patient versions of guidelines can:

- 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/demand for unproven interventions
- Identify interventions for which there is no or only low level evidence communicating uncertainty regarding their harms and benefits
- Point out other uncertainties and emphasise when a patient's own values and preferences are especially important when 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 based on guidelines that have recommendations based on high quality evidence and a formal consensus process. Guidelines produced without robust methodology may potentially lead to a negative health outcome for patients.

Recommendations for or against interventions will involve value judgements from the guideline development group 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 due to a patient's individual preferences or circumstances. It is crucial that guidelines convey this idea to both physicians 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 and covers the selection of recommendations and outcomes to present, how to present strength of the recommendations and uncertainty in the evidence, how to present the options available to a patient, as well as general formatting and language.

2. When to start developing the patient version

Ideally, the patient version(s) should be developed towards the end of the guideline development process once a full set of recommendations and their rationales are confirmed. Recommendations change throughout the guideline development process and this will avoid revising the patient version each time. It is helpful to have a sub-group of the clinical guideline group produce the patient version to ensure a close link between the clinical guideline and the patient version. Key reasons to develop the patient version with members of the guideline group are:

- It will be easier to make the guideline and patient version(s) complementary
- Decisions about which recommendations to put into patient versions can be discussed with the guideline development group. Additional information to help patients and the public understand the recommendations can be discussed and/or identified with the guideline development group
- Patient important outcomes, patient values and preferences for a recommendation, and the need to consider these in the patient version, can be discussed with the full guideline panel

3. Developing the patient version together with patients and/or consumers

Developing patient versions together with patients and/or consumers helps promote readability and assures that information is relevant to its readers. Ideally, patient versions are produced by the patients and healthcare professionals that have already been involved in the development of the guideline that is to be ‘translated’. Patient versions may also be produced by patient or consumer organisations and reviewed by people that have developed the guideline.

There are many ways to assure that patients’ needs and experiences are reflected by the information. 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.

Asking a wider group of patients and public for feedback on the patient version can help ensure that the version is accessible to the target audience. 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 via links to sources of further information and support
- Is seen as relevant to patients and consumers
- Has a sensible 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 while 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/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 that 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 4.1. To ensure transparency, the methodology and process of development should be well documented. An example of a document used to record the development of a patient version is included in Appendix 4.2.

4. How to select the recommendations to be included in the patient version

Guidelines often have dozens of recommendations and not all of these are required to go into patient versions. Patient versions should prioritise the recommendations that patients can influence or discuss with their clinician. For example, a recommendation about how a Pathologist should prepare a biopsy would not be helpful as patients would never be able to discuss this with the Pathologist. Research has shown that people would like recommendations about managing their own care.¹ The challenge with this is finding a sensible way of selecting the recommendations that should be presented in the patient version. The best way of doing this is to involve patients, their carers and/or the public in the selection of recommendations for the patient version, either from within the guideline development group or through a parallel group working on the patient version.

Being clear on the intended target group and situation, i.e. when patients will receive patient versions of guidelines, is important as 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 prior to receiving a patient version, it may not be helpful to include recommendations on diagnostics or risk factors.

To help patients and members of the public decide which recommendations are helpful the following questions may be asked:

- Do they highlight options for treatment or care?
- Do they assess harms and benefits of the 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?

Once the development group has selected recommendations to be included in the patient version, they should be translated into lay terms 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), it should be provided either along with the recommendation or in specific chapters or paragraphs.

5. What should be in a patient version of a guideline?

Patient versions should reflect what is in the guideline and only options included in the guideline should be included in the patient version. However, patient versions 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 due to 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 due to lack of evidence.

Since guidelines include recommendations about what should or should not be provided or done, the recommendations should not be lost when producing patient versions. Additional information may be included if it helps to foster an understanding of the recommendations or support self management. 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 content¹.

A series of focus groups and other qualitative work with patients and the public found that the following issues are considered important when using guidelines ²:

- 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 treatments/interventions: What are the treatments, including the alternatives? What are the risks associated with treatments? What can I do for myself (i.e. self-management)?
- Where can I find more help (e.g. phone numbers and website for sources of support)?

- How are guidelines produced?

These issues are discussed in more detail in sections 6.1 – 6.5.

The challenge when producing patient versions of guidelines is presenting information on benefits and harms in a way that is easy to read and not too complex. Alternatively, this information can be provided in other formats like decision aids. Although patients may not want too much information about the research evidence, it must be presented in a way that is easily understood and can enable patients to make informed choices. This is discussed in section 9.

Other things to consider:

- Presenting information that appears prescriptive can give the impression that guidelines are sets of rules for treatment meaning that individual patients have no choice. Information should be presented in a way that clearly highlights the patient choices.
- It is helpful for patients to know how guidelines are produced but care should be taken not to provide too much complex information.² Figure 1 is an example of information on how guidelines are produced which was tested with patients taking part in DECIDE Glaucoma user testing. Patients understood and found this to be helpful.

WHAT IS SIGN?

The Scottish Intercollegiate Guideline Network (SIGN) writes guidelines which give advice for healthcare professionals, patients and carers about the best treatments that are available. We write these guidelines by working with healthcare professionals, other NHS staff, patients, carers and members of the public.

How are SIGN guidelines produced?

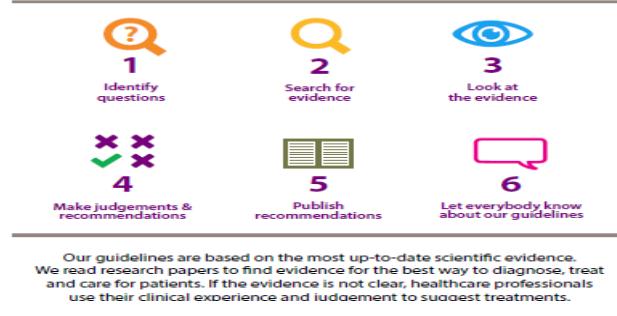


Figure 1 Example of explanation on how guidelines are produced

- The need for presenting information on cost effectiveness may vary depending on the health system, with interest being greater in health systems with larger out-of-pocket health costs for patients.

Not all of the information that patients and the public find useful is routinely generated as part of the guideline production process. A crucial question for a guideline producer is how far to go in generating this information, for example, background information about the condition may be rather limited in a guideline intended for health professionals and guideline producers may consider providing this information or providing links to this information or local sources of support for patients and the public.

6.1 Context: who is this information for?

Research is showing that people will often ignore health information if it does not appear to apply to their individual circumstances. Patient versions should therefore be clear about who the information is for. Making clear the applicability of a patient version of a guideline - ‘what does this have to do with me?’ - is essential¹ although around only half of current patient versions in the English language do this.³ For a simple example of how this can be done, Figure 2 shows the opening paragraph of a patient version produced by the Scottish Intercollegiate Guidelines Network on schizophrenia which explains who the booklet is for and what it is about. www.sign.ac.uk/patients/publications/131/index.html.⁴ The context for the use of this 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 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.

Downloading a document from a website, or using an online tool, does not allow an immediate conversation though it may support a later one. Guideline producers should give thought to how the document might be used and word it accordingly.

This booklet is for you if:

- ★ you think you may be having psychotic experiences;
- ★ you think a family member or friend may be having psychotic experiences;
- ★ you work with people who may be having psychotic experiences;
- ★ you have been diagnosed with schizophrenia; or
- ★ a family member or friend has been diagnosed with schizophrenia.

This booklet aims to make adult patients and their families aware of the treatment and care they should expect to receive when they are experiencing psychosis or when they have been diagnosed with schizophrenia. Most parts of the booklet are for patients but we acknowledge that family members and carers will also read this.

The booklet explains:

- ★ psychotic experiences;
- ★ what schizophrenia is;
- ★ what may happen when you first become unwell;
- ★ what treatment choices are available;
- ★ what you can expect from treatment; and
- ★ how you can help yourself to stay well.

The booklet does not cover diagnosis, but your health-care professionals can answer any questions you may have. The information in this booklet adds to the information and advice given to you by the people involved in your care.

Figure 2 opening paragraph of SIGN patient version of schizophrenia guideline

6.2 Background to 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.² Focus group and user-testing work also found that participants had information needs that were more general than treatment recommendations: i.e. can the condition be prevented, how will it progress, will 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.²

Guidelines generally don't provide much of this sort of information as part of the standard guideline production process. The NICE guideline on depression in adults (<http://www.nice.org.uk/Guidance/CG90/InformationForPublic>, for example, contains little background information on depression.⁵ 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. 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.

6.3 Information about treatments (interventions)?

Similar to 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/interventions that will assist people in understanding the recommendations and treatment implications.

6.4 What can I do for myself?

The importance of presenting recommendations that relate to self-management was one of the strongest messages coming from DECIDE's focus group and user-testing work with patients and the public.² It also emerged in a review of patient and public attitudes to guidelines as one of the purposes of patient versions.

¹ Relatively few patient versions in the English language currently meet this need.³

Presenting recommendations linked to self-management are therefore ones to prioritise when deciding which recommendations to cover in a patient version of a guideline. 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 Scottish Dental Clinical Effectiveness programme chose to present three recommendations in its patient version, all linked to self-management which is shown in figure 3. More information on selection of recommendations is given in section 4.

Recommendation 1

Brush your teeth regularly and effectively

Improving your oral hygiene reverses the early stages of gum disease. Your dentist or hygienist can help by showing you how to brush your teeth in the most effective way.

Recommendation 2

Have a plan of when you will brush your teeth

Having a firm plan will help you remember to brush your teeth. For example, you could plan to always brush first thing in the morning when you get up and last thing at night when getting ready for bed.

Recommendation 3

Use an ordinary toothbrush or a rechargeable powered toothbrush and fluoride toothpaste

Rechargeable powered toothbrushes may remove more plaque than ordinary toothbrushes. However, both types of toothbrush are good for removing plaque if they are used properly.

ness

Figure 3 recommendations in patient version of dental guideline

6.5 Where can I find more help (e.g. phone numbers and websites for sources of support)?

Many patient versions provide links or contact information such as telephone numbers for additional information and support³ and this was a need that came out in the DECIDE focus groups and user testing.² How far a guideline producer goes in listing additional sources of support is a similar problem to the one raised in sections 6.2 and 6.3. Patients and the public may find the information helpful, especially for lifestyle change self-management recommendations, but generating it may not be part of the routine guideline production process. Patients and the public may also want to know more about their condition, how to contact other patients and may want help answering further questions which patient versions may be unable to answer. Those developing patient versions should consider highlighting other sources of information including:

- Contact details of relevant organisations

- Relevant websites
- Other useful publications

The sites or organisations mentioned in patient versions should be reputable and assessed as high quality.

Tools such as DISCERN is a valid and reliable way for guideline developers to assess the quality of information provided by other organisations.⁶

The patient version 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 health professionals. Patients involved in the development of 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 - an issue unlikely to be addressed by the guideline but which matters a lot to patients with diabetic foot syndrome. Patients involved with the development of patient versions, as well as those involved in any wider consultation, can use their own experience and judgement to highlight which further information they think would be important to other patients and which 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. For example, a phrase introducing such paragraphs could state that 'The following information is additional to the guideline and based on patient experience'.

6.6 How are guidelines produced?

Patients and the public have very limited awareness of guidelines. When they are aware of them, they often think they are intended to restrict or ration the care available.¹ Research shows that some patients worry that guidelines might impair the relationship with their health professionals by suggesting reduced confidence in them.¹ A patient version is an opportunity to allay these fears but care is needed to avoid providing too much information about how the guidelines were developed: some, but not all, people are interested in this information.² An example summary of the guideline process produced by the DECIDE project is shown in Figure 1 (see page 94). There was some differences of opinion, but overall, the DECIDE user testing suggested that this information should be at back of the patient. This is to ensure that what the majority of patients are most interested in comes first, and those that want to can still flick (or navigate) straight to the information on the guideline process. Nevertheless, patients taking part in German focus expressed a need to have this information rather at the beginning which would enable them to understand to which degree the information following was reliable.²⁵

7. Communicating the strength of a recommendation

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

It seems reasonable then that patient versions should also provide an indication of the strength of a recommendation, although there are presently few examples in patient versions.

To enable patients to understand the strength of recommendations, we suggest using a number of 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.

7.1 Convey the strength of the recommendation in words

Different guideline producers may use different labels to convey the strength of the recommendation. When using the GRADE approach⁷, recommendations are labelled as ‘strong’, ‘weak’ or ‘conditional’. Research is pending on the understanding of these terms, but in the meantime 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.

7.2 Symbols may help although these have to be intuitive (and tested with your audience)

Symbols were used with a WHO guideline on health worker roles in maternal and newborn health (<http://optimizemnh.org/intervention.php>), which was aimed at a range of stakeholders (though not the public). The symbols were well received (see figure 5). The solid green ticks are strong recommendations in favour of the intervention; solid red crosses are strong recommendations against the intervention. The dotted ticks and crosses are weak recommendations for and against the intervention, respectively. Use of symbols to express strength of evidence would need to be tested with the target audience.

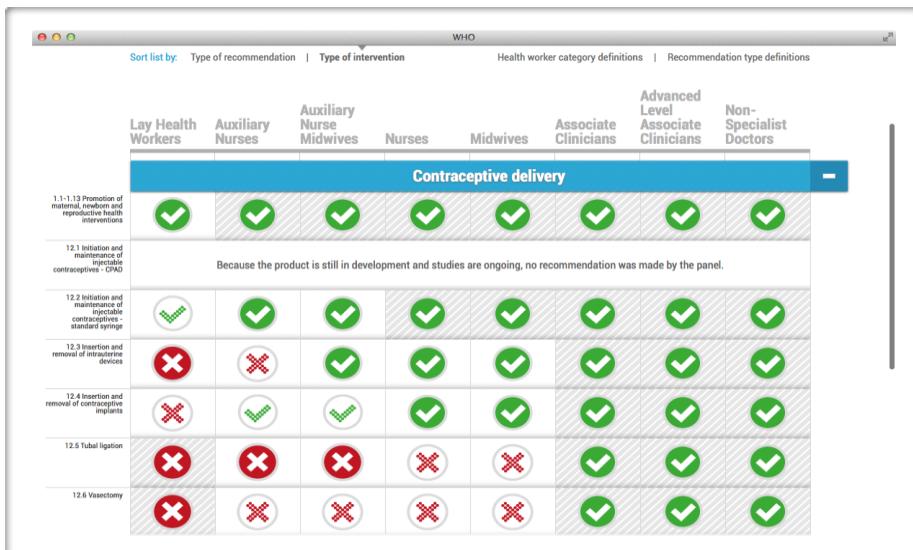


Figure [x] Symbols may be helpful to communicate information about strength of evidence but need to be tested with the target audience.

Having learned from the DECIDE project, SIGN adopted the use of the following symbols to convey the strength of recommendations in a guideline on glaucoma to patients:

	Strong recommendation based on research evidence
	Recommendation based on the considered opinion of the guideline developing group
	There is not enough research evidence to tell us if something is of benefit

Figure 6 symbols tested with patients

Before using these symbols to convey the strength of the evidence, they were tested with patients as part of the DECIDE project. Patients found these clear and they understood how the recommendations were different to each other.²

7.3 Using qualitative text to present strength of a recommendation

Typically guideline producers will use 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’. Research, in particular with health care professionals, has indicated that words are interpreted differently. To minimise misunderstanding, 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. The example in Figure 5 above (the one with strong, and hopefully the weak icon) indicate that 'most women ...would want ...' and 'the majority of people...would want... but many would not'. The example shown in Figure 3 from the Scottish Dental Effectiveness Programme (SDCEP) provides the recommendation but also a summary of the reasons related to the certainty of the evidence. In the SDCEP example, recommendations 1 and 2 are strong and recommendation 3 is weak.

8. Describing treatment options

Patient versions should be consistent with the guideline upon which they are based. If options are not recommended or not covered by the guideline due to weak or missing evidence, this should be stated in the patient version. 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.

The benefits and harms for all treatments and/or diagnostic test options presented in the patient version should be reported (see section 9) and in a way that allows direct comparison. 'No treatment' 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 health professionals, something patients and the public have asked for.³

There are many ways in which options can be presented, including a Plain Language Summary⁸, interactive Summary of Findings tables⁹ and Option Grids (<http://www.optiongrid.org>).¹⁰ (See Appendix 4.3) The DECIDE focus group and user-testing work has not found a single approach that works substantially better than another, although tabular formats have generally been well received. Whichever format is used, it is important to involve people from the target audience for the patient version in its selection and development.

9. Communicating information about treatment effects 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.³ Although there may be concerns about whether patients and the public can understand detailed information about benefits and harms, when efforts are made to do this well it is possible to achieve decent levels of overall understanding.³ There is evidence that people's understanding of risk can be improved by presenting them with numbers rather than

words and even where people say they prefer words, numerical information improves understanding⁸. Explaining risks associated with interventions in terms of natural frequencies (events per 100 or 1000) are a less confusing way of presenting risk information to patients and consumers and can help to increase overall understanding.^{11, 12, 13} There is evidence that patients and consumers overestimate risks when probabilities are presented in verbal terms. The use of numbers results in more accurate estimates of risk.^{12,13}

While 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 since many people, though not all, would like to see it. Patients taking part in DECIDE Glaucoma user-testing found numerical information presented as a statement more helpful than a pictogram for example:



Figure 7 example of numerical information presented as a statement

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. The benefits and harms of no treatment (i.e. doing nothing) should also be presented. Surrogates like progression free survival in chemotherapy should be avoided. If the guideline or the trials included do not provide such data, it should be stated that treatment effect on morbidity and/or mortality is unknown. For example, many new anti

diabetic agents have shown to influence HbA1c, but it is unknown whether they have the potential to reduce diabetes complications like micro or macro vascular complications.

Some general guidance on presenting benefits and harms is given in the following sections 9.1 - 9.5

9.1 Use a structured presentation

Structured presentations (especially with question and answer approaches) were well understood in work with patients and the public.^{2, 12} Presenting options in a table with benefits and harms highlighted, is a useful method for highlighting options and allows a comparison.^{8, 12}

What are the medication choices available during pregnancy and when breastfeeding my baby?

Medications			Medications		
Medicine	Can I take if I'm pregnant?	Can I take if I'm breast feeding?	Medicine	Can I take if I'm pregnant?	Can I take if I'm breast feeding?
Antidepressants selective serotonin reuptake inhibitors (SSRI), and tricyclic antidepressants (TCA))	<p>Yes</p> <p>Paroxetine should not be the first treatment choice during pregnancy. If you have already been taking this, your doctor will consider the risk and benefits to you and your baby before advising you to continue taking this or switching to another medication.</p> <p>It is not possible to say whether or not antidepressants increase the risk of miscarriage.</p> <p>It is possible that there may be a low risk or no risk at all that SSRIs cause heart defects in babies.</p> <p>Babies exposed to antidepressants during pregnancy may show signs such as agitation, irritability and, in rare cases, seizures. This is unusual, is not normally harmful and does not last for long.</p>	<p>Yes</p> <p>Sertraline or paroxetine are usually the first choice of antidepressants, but others may be chosen in certain situations, for example, if you need to continue the medicine you took in pregnancy or if you have depression which is difficult to treat.</p> <p>You should avoid doxepin.</p>	<p>Anti-epileptic mood-stabilising drug (for example valproate)</p> <p>Benzodiazepines should not be stopped suddenly.</p>	<p>No</p> <p>This medicine increases the risk of your baby having fetal abnormalities for example, spina bifida</p> <p>You may have extra ultrasound scans to monitor your baby's growth and development.</p>	<p>Yes</p> <p>If you need to take anti-epileptic medicines, it may still be possible to breastfeed. The risks and benefits of taking these should be discussed with you.</p>
Lithium Lithium should not be stopped suddenly	<p>Yes</p> <p>There may be a risk of birth defects so you may have extra ultrasound scans to monitor your baby's growth and development.</p> <p>Babies exposed to lithium around the time of birth have increased risk of poor temperature control, floppiness, breathing problems and thyroid problems. They may need to stay in hospital longer.</p>	<p>Not recommended</p> <p>Lithium can affect your baby's thyroid and kidney function. If you choose to breast feed, your baby will need to be closely monitored.</p>	<p>Antipsychotics (medication used to treat types of mental disorder such as schizophrenia and bipolar disorder)</p> <p>Alternative medicines (for example St John's Wort)</p>	<p>Yes</p> <p>It is not possible to say whether or not antipsychotics increase the risk of complications during your pregnancy. You may have extra ultrasound scans to monitor your baby's growth and development.</p>	<p>Should usually be avoided.</p> <p>They may make your baby sleepy and feed poorly.</p> <p>If they are needed a short-acting drug should be prescribed in a low dose for a short time.</p> <p>Yes</p> <p>It is not possible to say whether or not antipsychotics pose a risk to your baby.</p> <p>You should avoid clozapine.</p>

Figure 8 example of benefits and harms table from SIGN post natal depression patient version

9.2 Use qualitative and quantitative statements about effects and harms

Some people prefer words, some prefer numbers; giving both leads to greater understanding.^{12, 13} For numerical information, use of absolute numbers, rather than relative, and natural frequencies (e.g. '50 of 100 people') are easiest to understand.² There is good evidence, that presenting relative risk reduction alone leads to overestimation of treatment effects, so this should be avoided.¹⁴ For qualitative text statements, the standard text shown in the table in Figure 9 will provide consistency and include both the size of the effect (e.g. improvement, slight improvement, or no improvement) and the certainty of the evidence.⁸

	Important benefit/harm	Less important benefit/harm	No important benefit/harm or null effect
High quality evidence	Will improve/ decrease/ prevent/ lead to fewer (more) [outcome]	will improve slightly/ decrease slightly/ lead to slightly fewer (more) [outcome]	will not improve/ will lead to little or no difference in [outcome]
Moderate quality evidence	probably improves/ decreases/ prevents/ leads to fewer (more) [outcome]	probably improves slightly/ probably decreases slightly/ probably leads to slightly fewer (more) [outcome]	probably will not improve/ probably leads to little or no difference in [outcome]
Low quality evidence	may improve/ decrease/ prevent/ lead to fewer (more) [outcome]	may improve slightly/ may decrease slightly/ may lead to slightly fewer (more) [outcome]	may not improve/ may not lead to any difference in [outcome]
Very low quality evidence	We are very uncertain whether [intervention] improves [outcome]		
No events or rare events	Use comments in a plainer language or summarise results		
No studies found or reported	No studies found/reported [outcome]		

Figure 9 Structured text statements used by the Cochrane Collaboration to present uncertainty information in a consistent way.

9.3 Use a layered approach

Think carefully about the order in which information is presented. The concept of layered presentation of information - most important first, less important later - is one of the strongest findings coming out of the DECIDE project.¹⁵ In paper documents this could be done by selection (e.g. the Scottish Dental Clinical Effectiveness Programme periodontal patient version only present three recommendations (Figure 3) by order of presentation, boxes or other formatting approaches. Another approach is to offer different formats and link them to each other. For example, in the German National Disease Management Guidelines Program, the most important information is presented in a short information leaflet of two pages. It refers to a comprehensive brochure that provides in depth information. If necessary, more than one leaflet on different topics are derived from one guideline. Electronic documents could have ‘Click here for more’ or similar approaches to control the flow of information.

9.4 Consider graphical approaches

Focus groups and user-testing found that patients and the public liked graphics to break up the text but that graphics and charts should be kept simple.² 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 low quality randomised controlled trial suggests that bars, pictographs and tables tend to be efficient tools to present numerical information. They suggested that information was 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.¹⁶

9.5 Present uncertainty

Patients and the public do want to know about uncertainty.¹ For example, how sure are we that X in 100 of those affected will have pain. This information can be understood if presented well.¹² Most guideline producers will have a system to evaluate the quality or certainty of the evidence. Different symbols, words, letters, etc 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 where there is no research or very low quality research, this should be made clear and not confused with a treatment in which evidence has shown that the treatment has little to no effect.

There is no research evidence to tell us how useful self-help support groups are as a treatment for people with depression. This does not mean that there has not been success for some people but that at present there is not enough research evidence to say whether self-help groups are more likely to be successful than they are to be unsuccessful.

Figure 10 example of how to be clear what is meant when saying that a treatment is not supported by research evidence

10 Formatting and style of patient versions

Formatting is important. There are many potential formats for patient versions and the format used should take account of the target audience. Focus group and user testing work has consistently found that patients and the public like something they can read on paper, especially older people.² Nevertheless, more and more patients, even older people, search for health information on the internet³⁰. Young people are much more open to electronic formats² and a suggestion coming out of workshops with patients and people who

write for the public at the DECIDE International Conference (<http://www.decide-collaboration.eu/decide-international-conference>) was to have short paper documents with longer, more interactive electronic versions or resources linked to it. It has also been suggested that information for patients and the public linked to guidelines could be embedded within the guideline itself so that health professionals can more easily access it when having conversations with their patients.¹⁸ About half of existing patient versions are intended to be printed (though also available as pdfs) and half are intended to be read on-screen (though they can also be printed).³

There is no one-size-fits-all approach to developing a patient version² but information in sections 10.1 – 10.6 should be considered:

10.1 Personalisation

Many patient versions attempt to personalise the information provided. Participants in focus groups and user-testing in the UK found personalisation useful because it makes it easier to think how the information is relevant to them² something that has been found in other fields.¹⁹ The degree or personalisation that is a) possible and b) 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 section 6.1). 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?’ Another approach is to provide background statements that readers might be able to relate to personally such as the example shown in Figure 11.

Tiredness and a lack of energy are often described, and may mean you are doing a lot less than you used to (sometimes this may be due to the side effects of medication).

Figure 11 Example of personalisation from a Scottish Intercollegiate Guidelines Network (SIGN) patient version on managing schizophrenia.

Other ways to personalise information include personal stories of real people with the same problem. These are not widely used at present³ and many people ask for them as a way of making it easier to relate to the information.¹ Personal stories are not without problems, particularly with regards to how to select stories for inclusion (e.g. 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.²⁰ Evidence also suggests that personal stories (narratives) may influence risk perception and lead to over or underestimation of treatment

effects.^{21, 22} 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.²²

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 like www.healthtalkonline.org or www.patientslikeme.com. These websites could provide personal stories for patient versions of clinical practice guidelines.

The use of quotations from real patients who have the condition may also be a useful way to personalise the information in patient versions and to engage readers.¹ DECIDE user testing findings highlight that patients find quotations useful, helping them to relate to the material. The use of quotations has the same challenge as the use of patient stories in terms of deciding which quotes to select, and it may be difficult to stay true to the story when bound by the evidence base presented within the patient version.²³ The following quote from a real patient is used in a patient version of SIGN's Glaucoma guideline which was tested with patients as part of the DECIDE project (Glaucoma user testing). It helps patients to relate to a particular recommendation and increases understanding of the importance of doing what is recommended i.e. having your eyes tested every two years if there is family history of glaucoma:

"Following diagnosis I discovered that it was a hereditary disease and that all the family knew about our risk except me. My brother and my sister had been having regular tests for some time". **Roy, age 78**

Figure 12 example of personalising information

10.2 Easy to find, easy to read

Patient versions of guidelines should be easy to find and easy to read. In the review by Santesso and colleagues³ 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, SIGN has a dedicated section of their website which lists all the patient versions of guidelines. If the patient version is on a 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.²⁴

Similarly, if the patient version is designed for health professionals to use in their conversations with patients, or to hand a printed copy to them, then it should also be simple for health professionals to access. Therefore, it may be helpful to provide the patient version along with the guideline itself to assure that health professionals who look up the guideline will also find the patient version. Incentives for health 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 physicians²⁵.

Patients and the public have very low awareness of guidelines¹ 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. In other words, make sure your patient version is easy for search engines to find. 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. Patient organisations and other voluntary organisations should also be encouraged to promote patient versions of guidelines on their websites.

As mentioned earlier, patient versions should be tailored to the needs of the people you expect to read them and formats may differ depending on the target population. The amount and level of technical terms that patients are confronted with should be carefully considered.² Health literacy varies and it 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 outcomes.^{26,27} 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 ‘lymphadenectomy’ 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 health 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 (the latter is done for guidelines produced by the National Institute for Health and Care Excellence or by the German National Disease Management Guidelines Program).

The way information is presented can affect how trustworthy the information is perceived to be. 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.^{1,28} Logos can help if these are a recognised ‘brand’ for patients and the public but too many becomes overwhelming and may be counter-productive.²

10.3 Length of the patient version

Producers of patient versions are currently publishing patient versions in different lengths (2-3 pages and 40 and greater). Patients and the public don’t want to be overwhelmed by information.^{1,2} A German qualitative study about a lay version of a guideline on breast cancer screening found that people consider a brochure of 15 pages or more as “long” and that it makes no difference for readers if this “long” brochure has 15 or 150 pages²⁹. People like information presented in layers which means that they can read as much, or as little as they want. One suggestion from DECIDE conference workshops is to have short paper versions and longer electronic versions, with the latter in particular using a layered approach.¹⁸ People with chronic conditions may however appreciate longer booklets that can be read and reread time after time, thus accompanying the patient through the whole process of care.²⁵ Exactly how much information should be provided depends on the target group and may be discussed early in the development process.

10.4 Fonts and graphics

A font with a clear design should be used to ensure accessibility. A minimum font size of 12pt should be used for standard versions and a minimum of font size 16pt or larger for large print. Careful thought should be given to the use of graphics in patient versions. Patients and the public like the text to be broken up² but the graphic should carry useful information, not simply be a decorative element. Some tips for using graphics are given in Figure 13.

Use	Avoid
<ul style="list-style-type: none"> • Graphics relevant to the topic to illustrate what the patient version is about <ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Graphics which may be upsetting or patronising (such as images of obese people) • Complex, technical diagrams • Cartoons as these are difficult for patients to identify with • Too many logos which can be confusing for patients and distracting

Figure 13 Tips for using graphics in patient versions

10.5 Colour

Good use of colour can make things easier to read but colour can also convey meaning, which may not be what is intended. User-testing work in DECIDE found that black was sometimes associated with death and that red was linked to danger.² Inconsistent use of colour was confusing.² User-testing with health professionals in DECIDE also found that colour coding recommendations was problematic if people saw that colour was being used to differentiate items but it was not clear how it was being used. Poor choice of colours can make a document hard to read; light text on light backgrounds and dark text on dark backgrounds should be avoided. 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

Using these combinations of colours together should be avoided. Similarly, the use of pale pastel colours are not helpful for people with visual impairment.²

10.6 Other formats

Accessibility may mean translating the patient version into other languages, as well as making versions available in large print, as audio or video.

11. Transparency

The authors and organisations behind patient versions should declare their financial and intellectual conflicts of interest (COI). This includes the 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 conflict of interest (COI) might not be necessary.

12. Evaluation of patient versions

Readers 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 physicians and clinicians, as they might assess to what extent the patient version has helped their patients. An example questionnaire to collect feedback is given in Appendix 4.4.

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Chapter 8: How to involve patients and the public in dissemination and implementation of guidelines (2012)

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Aims of the chapter

This chapter provides guideline developers with advice on how to involve patients and the public in guideline dissemination and implementation. It is based on current practice from guideline developers, primarily the Scottish Intercollegiate Guidelines Network (SIGN), and suggests a wealth of examples of possible ways to involve patient groups in the dissemination and implementation of guidelines. It also provides information on the recruitment, skills, training and expected role of patients, carers and members of the public when participating in guideline dissemination and implementation activities.

Introduction

Involving patients and/or members of the public in the development of guidelines allows their views and experiences to complement the evidence and experience of health care professionals. When patients, carers or members of the public have been involved with the development of a guideline, they are in a good position to serve as informed advocates to communicate to others the importance of the evidence and the significant role that guidelines can play in making decisions about one's own health care. Involving patients, public and carers in guideline dissemination is an additional critical step in successfully implementing clinical practice guidelines. Their input can be crucial in increasing awareness of the guideline, not only among patients and the public, but also among health care professionals. Their input is valuable to develop education materials, online resources and implementation tools that public and professionals audiences find useful, understandable and convincing. For clarity, we here present the role of patients and the public in three domains: 1. *dissemination* and 2. *implementation* of specific guidelines, and 3. *raising awareness* of guideline development *in general*. In practice, these three roles are best combined and intertwined, not kept separate.

Dissemination of guidelines

Dissemination of guidelines is about raising awareness about the existence and content of the guideline, to the public, patients and professionals. Patient organisations and charities are in a good position to promote guidelines at annual conferences and other regional and local events. For example, a patient organisation can promote a new guideline in their newsletter and at their annual member meeting, and provide the guideline on their website. Many patient organisations, charities and their networks include close connections with many health care professionals in their disease area. They can thus promote the guideline to professionals at events that are attended by both professionals and patient organisations.

Dissemination to the public

Involving individual patients and carers in media releases provides the best platform for their personal stories and can help to raise awareness of guideline recommendations. SIGN regularly involves patients and

carers who have helped develop guidelines in media releases to highlight the importance of making diagnosis and treatment decisions based on the latest evidence.

Dissemination to patients

Patient organisations and charities can promote the guideline (and its patient version) in their newsletter, host it on their website and include it in the information packages provided to their members. At information sessions organised for patients and the public, they can distribute the patient version of the guideline and discuss how patients can use it to help them make treatment choices.

Dissemination to professionals

Patient organisations and charities also attend conferences aimed at (and organised by) health care professionals, to promote their own organisation and learn about new developments concerning their condition. In turn, many of the events and meetings organised by patient or user groups are frequently attended by health care professionals.

For example, the guideline on management of perinatal mood disorders (and its patient version) was launched at the Scottish Perinatal Mental Health Forum. This conference was organised by the Mental Health Network, a service user led organisation in the greater Glasgow area, and attended by service users and their families as well as (mental) health care professionals.

Box 1. Patient organisation disseminating guideline to patients and professionals

Psoriasis Scotland Arthritis Link Volunteers (PSALV)

The Scottish charity Psoriasis Scotland Arthritis Link Volunteers (PSALV) provides the SIGN guideline on Psoriasis and Psoriatic Arthritis to its patient members. They promoted the guideline (and its patient version) on their newsletter, host it on their website and include it in the information packages provided to their members. At information sessions organised for patients and the public, they distribute the patient version of the guideline and discuss how patients can use it to help them make treatment choices.

PSALV also attends conferences aimed at (and organised by) health care professionals, such as the Scottish Dermatology Nurses annual conference. There, they raise awareness of the support and information their own organisation offers to patients and carers, but also distribute the SIGN guideline on management of Psoriasis and Psoriatic Arthritis. <http://www.psoriasisscotland.org.uk/>

Implementation of guidelines

Implementation of guidelines includes developing additional tools, documents or campaigns to encourage awareness and use of the guidelines. These tools can be designed either for the public/patients, or for professionals, and patients and public members can be involved in both the design and the promotion of such implementation tools. This can include web-based resources for health care professionals or patients to help disseminate and implement the guideline recommendations, for example, podcasts and video presentations. Or it can include the development of more- or less-extensive public awareness campaigns and strategies. Patients and the public can also be involved in developing patient versions of guidelines (see chapter 4) and the development of decision-making tools (see chapter 6). Once dissemination/implementation tools have been developed, patient and public members and organisations can help promote and distribute these tools, usually along side the dissemination of the guideline itself, using dissemination strategies such as those described above.

Patient versions of guidelines

Patient versions of guidelines give patients, carers and members of the public access to recommendations in guidelines. They can help people to understand the care and treatment choices available and allow them to play an active role in decisions regarding their own health. Patient versions of guidelines help patients to evaluate their own care, as they can monitor whether their own care is in line with the guidelines, and gives them the opportunity to discuss with health care professionals if they are not being offered recommended treatments. Providing patients with this information can help to change the behaviour of the health professionals caring for them. For example, the National Centre for Clinical Excellence in Norway produced a ‘recommendation card’ for patients that highlighted the ten most important recommendations so that patients and relatives had increased knowledge of what kind of assessment, treatment and follow-up to expect from their health care professionals. Such information is usually developed with the involvement of patients. For more information, see chapter 4.

Development of web-based resources

Often web-based resources are developed for health care professionals and patients to help with implementation of guideline recommendations. There are many examples of patients and public members being involved in the development of such implementation materials.

- The New Zealand Guidelines Group (NZGG) involved members from patient groups and lay members from NZGG’s Implementation Advisory Group in the development a web service to help with the recognition and early referral of autism spectrum disorder (ASD). They reviewed materials and provided input on design, and some of the video material is presented by a person with ASD, or their family and carers. <http://www.asdguideline.com/community>
- To help with implementation of the National Institute for Health and Clinical Excellence (NICE) guideline on self-harm, a podcast for patients and the public was developed. Within the podcast, a service user explains their experience of self-harm, access to services and harm minimisation. <http://guidance.nice.org.uk/CG133>
- As part of the NICE guideline on medicines adherence, a poster to inform patients and the public for use in waiting rooms and other health settings was developed. The poster provides a general template with the key messages from NICE in a clear and accessible format, which can be adapted for local use. The two patient/public representatives, who had been involved in developing the guideline, were also involved in developing this template. <http://guidance.nice.org.uk/index.jsp?action=download&o=43740>

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, and ensuring physicians treat patients in accordance with the (new) guidelines. In addition to being organised or co-developed by patient or charity organisations, patients can be involved in delivering and executing such education programmes. [Box 2](#) provides an example of a successful patient-mediated education campaign based on a guideline.

The Breakthrough Breast Cancer Campaign is a non-profit charity organisation that developed guides to raise awareness and improve the availability of services for women at increased risk of breast cancer due to their

family history. Based on NICE and SIGN guidelines, they develop guides for women on breast cancer diagnosis and treatment in the UK. www.breakthrough.org.uk

Box 2. Patient-mediated awareness campaign

Heart Heroes promoting the Community Heart Check

Individual patients can become involved in developing and delivering implementation support tools such as education programmes. The New Zealand's Pharmaceutical Management Agency (PHARMAC) undertook a comprehensive project to implement the Cardiovascular (CVD) Risk Assessment Guidelines that were revised in 2009.

A small number of 'Heart Heroes' were selected to work with PHARMAC. These heroes were Maori men with heart conditions who were making lifestyle changes to better manage their heart disease. Their role was to talk about their personal journeys to other Maori men and to encourage others to learn more about their risk of heart disease. The 'Heart Heroes' attended local events such as sports or cultural events where 'Community Heart Checks' were set up that offered people free comprehensive cardiovascular risk assessments. The aim of the heart checks intervention was to create interest in heart health; inform people about their options for caring for their heart; empower people to start conversations with their doctors and nurses about heart health and to ask for regular heart checks; to create a 'buzz' within families and social groups to make having heart checks an easy and non-threatening thing to do.

Feedback received via the consumer survey indicated that reactions of people who had a Community Heart Check were positive and encouraging, indicating that people were interested and engaged in finding out about their level of heart health and what they could do for themselves and their families, including 82% who felt they would tell their friends to have a heart check. <http://www.oneheartmanylives.co.nz/tane-stories.html>

Raising awareness of guideline development (organisations) in general

SIGN also has established a group of patient and public representatives known as 'Awareness Volunteers', who help raise awareness of SIGN and their guidelines in more general terms. Their roles are diverse and include:

Contribute to advertising materials

- For example leaflets and posters, or media releases

Help SIGN exhibit at events, hospitals and conferences

- An information stand at the Royal Infirmary of Edinburgh was visited by approximately 200 people, mostly staff, who appreciated the volunteers' presence and SIGN's publications
- The Bipolar Scotland conference, attended by 100 delegates was useful to get patients involved in SIGN's work because it provided good networking opportunities and raised awareness of SIGN.

Give talks to patient groups and health care professionals

- Awareness volunteers provided an overview of SIGN and patient involvement to third year nursing students the University of Abertay who appreciated hearing the information from patients in their own words and liked the informal setting.

Encourage other groups to be aware of, and get involved in, SIGN's work

- For example, community and user groups, such as Gartnavel diabetes support group where 20 members considered the talk worthwhile as most had not heard of SIGN, but now are interested in SIGN's publications.

How to improve PPI in dissemination and implementation

SIGN takes a proactive role in supporting the implementation of its guidelines and in improving the implementability of its recommendations. Equipping patient and public members with the right knowledge at the onset empowers them to become effective partners in the dissemination and implementation process. SIGN has identified several areas where patient groups would have the biggest impact on guideline dissemination and implementation including publicising, monitoring, raising awareness, campaigning for change, and ensuring health care professionals are following guideline recommendations.

Recruitment

Patients and public members to participate in dissemination and implementation activities can be recruited in a variety of ways. First of all, patient and carer representatives who have participated in developing the guideline can continue to be involved in the next steps when the dissemination and implementation strategy and tools are developed. When patients, carers or members of the public have been involved in the development of a guideline, they are in a good position to serve as informed advocates to communicate to others the importance of the evidence and the significant role that guidelines can play in making decisions about one's own health care. For more advice on their recruitment, see chapter 2 of this toolkit.

Additionally, permanent groups, networks or 'panels' of patient and public members can be established to recruit from. In addition to the previously mentioned 'Awareness Volunteers' group, SIGN has a well-established Patient Network which is a virtual network of patient groups, charities and voluntary organisations who are committed to assisting us with guideline dissemination and implementation activities. SIGN's Patient Network members are alerted when new guidelines and patient versions are published and are asked if they can raise awareness of them and disseminate them through the various methods mentioned above, with the goal of reaching health care professionals, patients and members of the public in their networks. Members for these groups or networks can be recruited via patient groups, charities, voluntary organisations and volunteer centres. Such groups should include diverse members, including those from equality and diversity groups, and various geographical regions.

Informing patient and public participants about guidelines and their development

To ensure patients and public groups are well-informed before participating, they are informed about guidelines and the role public and patient group members play in the development, implementation and dissemination of guidelines. Starting with the most basic information, we explain the role of the Scottish Intercollegiate Guidelines Network (SIGN) in writing guidelines that give advice about the best treatments that are available. We also explain that the guidelines are written in collaboration with doctors, nurses and other National Health Service (NHS) staff, and with patients, carers and members of the public. It is at this introductory point when we drive home the fact that our guidelines are based on the most up-to-date medical evidence written for NHS staff and patients to help make important decisions about health care; to make sure patients get the best care available, no matter where they live; and to improve health care across Scotland.

Clarifying expectations

It is important to provide as much detailed information as possible about the specific role of the patient, carer or member of the public. Expectations should be explicitly addressed in a formal recruitment packet. It is helpful to inform volunteers up front of the time commitment required as participants of a guideline dissemination/implementation team. It is good practice to offer potential volunteers the opportunity to attend an informal drop-in session to find out more about the role. In addition, a contact name and phone number could be provided for the volunteer to call when questions arise. An example recruitment poster is provided in this toolkit as appendix 5.1. Potential volunteers can complete an application form that allows them to share with guideline developers their reasons for wishing to join a dissemination group and to describe their relevant experiences for this type of work. An example application form is provided as appendix 5.2 in this toolkit. Potential volunteers should be asked to attend an informal interview with patient involvement staff to discuss how they might go about carrying out their role and to decide if they are suitable. An example set of interview questions is included in the toolkit as appendix 5.3. It is good practice to offer unsuccessful individuals feedback from the interview process and to make them aware of other patient involvement opportunities within the organisation that may be more suited for them, for example, reviewing draft guidelines.

Skills required to join dissemination groups

Patients, carers and members of the public should be fully trained to carry out their assigned role. The following characteristics however should be apparent in the individuals you interview including:

- Enthusiasm
- Time to commit to the work of the group (e.g. identify awareness-raising opportunities, preparing for and participating in awareness-raising activities)
- Good communication, presentation and teamwork skills.

Training and support

Patients and members of the public should receive full training to allow them to successfully undertake their role in dissemination groups. This can include:

- Information on the guideline development process and methodologies
- Practical tasks to develop communication skills and presentation skills
- Individuals should be given a named contact who can support them via email, telephone or face-to-face
- The opportunity to meet with patient involvement staff should be made available at various times of the year
- Individuals who are new to this role can be assigned a ‘buddy’ (a patient or member of the public already carrying out this role) to help them carry out their role in dissemination activities.

Resources

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

- Staff time to recruit, train and supervise patient and public members

- Sufficient finances to reimburse out-of-pocket expenses including travel expenses, child care expenses and carer allowance
- Sufficient finances for publicity materials
- Possibly, financial compensation for patient and public representatives' time and work. See chapter 1, 'Valuing members—the problem of payment' for a discussion of the importance and challenges of providing such compensation.

Conclusion

In conclusion patients and members of the public play an active role in guideline dissemination and implementation activities. Patient and public engagement ranges from involving them in the development of educational materials and implementation tools to raising awareness of guidelines with various stakeholders. The examples given in this chapter demonstrate how involving patients and the public has been successful and provides a useful guide to involving patients and the public in future dissemination and implementation activities.

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Appendix 8.1



Would you like to volunteer to work with SIGN to help them to get the latest up-to-date evidence-based health information to patients, carers and members of the public?

SIGN writes clinical guidelines for all NHS staff—including doctors, nurses, dentists, physiotherapists, occupational therapists—and also for patients. SIGN guidelines give advice on the best treatments that are available. We write them by working with NHS staff as well as with patients, carers and members of the public. The guidelines are based on the most up-to-date medical research evidence.

Patients, carers and members of the public play an important role in our work. Involving patients and carers in the development of our guidelines allows their views and their experiences to complement the evidence and the knowledge and experience of health care professionals.

SIGN has begun to produce patient information booklets which are based on our clinical guidelines. These booklets explain the recommendations in the clinical guideline; and help to make patients aware of the tests and treatments they should expect to receive from the NHS. We want to make sure that patients, carers and members of the public know about this resource and we need your help to do it!

We believe that patient, carer and public involvement at SIGN shouldn't end when our guidelines are published. We are looking for (lay) volunteers to help raise awareness of SIGN's work and patient involvement opportunities within their own communities/locality.

What would we ask you to do?

You would be a member of a group of 10-12 people. Tasks may include:

1. Actively identifying awareness-raising opportunities and advising the Patient Involvement Officer at SIGN of these
2. Helping SIGN to exhibit at events, giving talks to patient groups
3. Contacting local groups and clubs to encourage them to host awareness talks to help raise awareness of SIGN's work (for example, Community Health Partnerships, community and user groups)
4. Identifying groups to distribute guidelines, patient booklets and information leaflets to and help them distribute to relevant groups they are involved with
5. Contributing to advertising materials such as leaflets and posters
6. Highlighting patient issues of concern which arise from awareness-raising activities.

You may also be asked to support lay representatives on guideline development groups who become involved in awareness-raising activities.

How much of your time do we ask for?

You are free to give as much time as you wish to SIGN. We do ask you to make sure you have the time to commit to at least two awareness-raising activities per year and a few hours per month.

What skills are required?

We are not asking for specific skills or knowledge as you will be fully trained to carry out this role. It will however help if you have some of the following:

- Enthusiasm
- Time to commit to the work of the group (e.g. identify awareness-raising opportunities, preparing for and participating in awareness-raising activities)
- Good communication, presentation and teamwork skills.

Expenses

We can't pay you a salary but all travel expenses and other out-of-pocket expenses will be reimbursed, for example:

- Costs of travel to and from meetings
- Parking charges
- Child care.

What can you expect from SIGN?

- Appreciation and respect
- Safe working conditions
- Support
- Relevant information and training opportunities
- Information in a format that is suitable (e.g. large print, Braille or another language).

What training and support will you receive?

All Awareness Volunteers will be asked to attend a full-day induction and training day. The interactive training day aims to equip volunteers with the knowledge and skills necessary to carry out this role.

The Patient Involvement Officer will provide email and telephone support to members of the patient dissemination group. The group will meet with the Patient Involvement Officer and the Implementation Advisor at least once a year to identify problems, good practice and possible improvements.

A number of SIGN buddies are available to meet and support new patient, carer and public representatives who become involved with SIGN. They are available to meet face-to-face, by email or by telephone.

Declaration of interests and confidentiality

We ask everyone involved with SIGN to sign a declaration of interests form. This asks you about your personal and non-personal interests in commercial companies that might be, for example, involved in producing new drugs. We ask everyone involved in SIGN's work to act as independently as possible. If you have significant personal interests that may conflict with SIGN's work then we may ask you to withdraw from your work with SIGN. We also ask everyone to sign a confidentiality agreement to make sure they do not make any work of SIGN public until consultations and launches.

How should you apply?

You should complete the application form and provide a short personal statement detailing your reasons for wishing to become a SIGN Awareness Volunteer. You should also highlight any relevant skills and experience.

SIGN is committed to equality of opportunity and encouraging a diverse range of applicants. We ask applicants to complete an equalities monitoring return so that we can identify any equality groups that we have not reached. This is separate from your application and is not considered in the recruitment process.

All applications will be considered by SIGN's Senior Management Team and the Patient Involvement Officer. Short-listed nominees will be invited to an informal interview on 3rd/4th October in Edinburgh or Glasgow with Patient Involvement staff.

We will be holding drop-in information sessions in Edinburgh and Glasgow to give you the opportunity to find out more about the role by speaking to staff and volunteers:

- Edinburgh, 6th September 2011 (1:30–3:30)
- Glasgow, 7th September 2011 (1:30–3:30).

If you would like more information or would like this information in another format, please get in touch with Karen Graham, Patient Involvement Officer, by phone at 0131 623 4740 or by email at karen.graham2@nhs.net.

Completed nomination forms and personal statements should be returned to Karen Graham at the address above by **Monday 19th September**.

Appendix 8.2



Application for SIGN Awareness Volunteer

Please complete this form to apply to be a SIGN awareness volunteer. If you have any questions or concerns about the form, please call Karen Graham, Patient Involvement Officer at 0131 623 4740 or email her at karen.graham2@nhs.net.

Contact details

Full name:

Telephone number (home):

Telephone number (mobile):

Email address:

Nominating organisation (if applicable):

Named contact from nominating organisation:

Address:

Telephone Number:

Email address:

Please return your completed nomination form to Karen Graham, Patient Involvement Officer, SIGN Executive, Elliott House, 8-10 Hillside Crescent, Edinburgh, EH7 5EA or to karen.graham2@nhs.net by **Monday 19th September**.

Volunteering with SIGN

Training

To become an Awareness Volunteer with SIGN, you must be prepared to attend a full day induction and training day on **Thursday 20th October 2011**. Please tick the box to indicate that you are willing to attend training.

Which areas would you be able to volunteer in? (please tick all that apply)

- Within 20 miles of my home address only
- Scotland wide
- Ayrshire and Arran
- Borders
- Dumfries and Galloway
- Fife
- Forth valley
- Grampian
- Greater Glasgow and Clyde
- Highland
- Lanarkshire
- Lothian
- Orkney
- Shetland
- Tayside
- Western Isles

Please return your completed nomination form to Karen Graham, Patient Involvement Officer, SIGN Executive, Elliott House, 8-10 Hillside Crescent, Edinburgh, EH7 5EA or to karen.graham2@nhs.net by **Monday 19th September**.

Personal statement

(Please detail your reasons for wishing to become a volunteer and list any relevant skills or experience.)

Thank you for applying to be a SIGN awareness volunteer.

Please return your completed nomination form to Karen Graham, Patient Involvement Officer, SIGN Executive, Elliott House, 8-10 Hillside Crescent, Edinburgh, EH7 5EA or to karen.graham2@nhs.net by **Monday 19th September**.

Appendix 8.3

Awareness Volunteer Questionnaire (SIGN)

Candidate name:

Vacancy reference:

Panels:

Personal Awareness

1. Tell us a little bit about yourself and your reasons for applying for this position.

2. From the role description what do you understand the role of the Awareness Volunteer to be and what personal qualities and skills do you have to bring to the role?

Communication

3. Within this post you would be expected to communicate with a variety of individuals varying from health care professional level to members of the public and patients. What experience do you have of working with a range of individuals?

4. As part of an awareness-raising visit you may find yourself in some challenging situations, for example, patients and the public often find it difficult to accept SIGN's methodology. Can you tell us about a time when you had to use your communication and diplomacy skills to resolve a difficult situation?

Working with others/networking

5. Team work—Being able to work as part of a team is important for this role. What qualities do you have that you would consider contribute to being an effective team member. Can you give us a positive example of being part of a team?

6. Networking ability—If a new guideline or patient version was launched there may be a requirement to increase the networks/sources of patients that these should be disseminated to. How would you go about creating a new network of contacts in these circumstances?

7. Engagement skills—Tell me about the steps you would take to make sure there is full participation and commitment from the right people to become involved in SIGN guidelines.

Judgement and decision-making

- 8. You may be faced with situations which are quite emotive while visiting patient support groups or projects. Often patients find it difficult to accept why their particular issue has not been addressed in the guideline. How will you deal with a difficult audience and how will you ensure that you keep to the facts and apply objectivity?**

INVITE QUESTIONS FROM THE CANDIDATE

0 - Inadequate	1 - Weak	2 - Acceptable	3 - Strong	4 - Exceptional
Much less than acceptable performance	Less than acceptable performance	Performance of a standard to do the job	More than acceptable performance	Outstanding performance

Behaviour	Question	Score	Comments
Personal awareness	1		
	2		
Communication	3		
	4		
Working with others/networking	5		
	6		
	7		
Judgement and decision-making	8		
Total	/32		
	%		

Interview Record

Title: **Post Ref.:**

Candidate: **Candidate. No.:**

Date: **Time:**

PANEL DECISION: **OFFER** **HOLD** **REGRET**

Signature:

Date:

Chapter 9: How guidelines can support patient involvement in the clinic (2012)

Authors: Trudy van der Weijden,* Marije Koelewijn-van Loon, Loes Knaapen and Antoine Boivin

*Corresponding author: Trudy.vanderWeijden@MaastrichtUniversity.nl

Aims of the chapter

Clinical practice guidelines (CPG) can be adapted for patient use providing a greater opportunity for patients to become active participants in the medical decision-making process of their own health care (or of a family member). For example, patient-adapted guidelines provide more clarity around treatment options that may exist while emphasising the benefits and risks of those options. With the adapted guideline, patients can have an informed discussion with their physicians about risks and benefits. These discussions form the basis of shared decision-making.

This chapter will focus on the importance of patient decision aids in the shared decision-making process. Shared decision-making is a model for clinical practice describing three key steps: choice talk, option talk and decision talk where the clinician supports deliberation throughout the process.⁸ This is a collaborative venture between the patient (and sometimes a family member/carer) and their health care professional.

Summary and visualisation of the model: choice talk, option talk and preference talk⁸

Choice talk

- Step back
- Offer choice
- Justify choice—preferences matter
- Check reaction
- Defer closure.

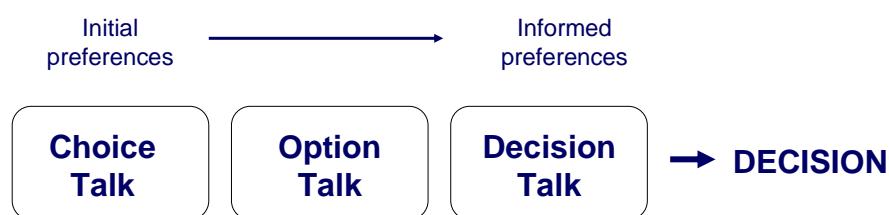
Option talk

- Check knowledge
- List options
- Describe options—explore preferences
- Discuss harms and benefits
- Provide patient decision support
- Summarise.

Preference talk

- Focus on preferences
- Elicit preferences
- Move to a decision
- Offer review.

DELIBERATION



Decision support may be needed in the option talk phase and can be designed in two formats: 1) brief enough to be used by patient and clinician together, and 2) more extensive, designed to be used by patients either before or after clinical encounters. ‘Patient decision aids’ is a term commonly used to refer to paper, digital, web-based, passive or interactive interventions that provide support for patients who are facing tough decisions about their health care options. Patient decision aids have been defined as decision support interventions that help people think about the choices they face: they describe where and why choices exist and they provide information about options, including, where reasonable, the option of taking no action (or ‘watchful waiting’).

To facilitate this next step in guideline development, we aim to present the results of an explorative study on strategies for the adaptation of guidelines, to better support both professionals and patients in shared decision-making in clinical practice.

This explorative chapter presents ideas that, to the best of our knowledge, have not yet been implemented systematically among guideline development groups. Until more literature evolves in this area we are unable to provide concrete information or insight at this time into available resource for successful planning strategies or ways to identify and overcome potential barriers.

Best practice information, from the literature; from guideline developers, users, and evaluators; and/or from author’s experience

What is the relationship between clinical practice guidelines and patient decision aids?

Although both CPGs and patient decision aids support decision-making, the conceptual roots of these tools differ. CPGs arise from the evidence-based medicine movement, aiming at synthesising and disseminating ‘the best available evidence’. In health care practice however, careful exploration of an individual patient’s values and preferences are needed, a function that CPGs cannot fulfil because their recommendations are usually based on population estimates. Although patient decision aids also follow the principles of evidence-based medicine, they fill this gap by also prioritising individual patients’ preferences and patient choice.² CPGs are often developed by professional or governmental organisations, and have, until recently, hardly

acknowledged the issue of individual patient preferences. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group has made this issue more explicit. Consideration of patient preferences is made possible by distinguishing between ‘strong’ and ‘conditional’ (also known as ‘weak’) recommendations. The strength of recommendations may be affected by factors such as variability in patient preferences and values, as well as the quality of the evidence, the balance between desirable and undesirable effects, and considerations of resource use.⁸ Strong recommendations are inappropriate in so-called preference-sensitive decisions.

The difficulty of translating evidence to an individual patient is challenging, particularly in so-called grey zone-, preference- or option-sensitive situations where tradeoffs between options are involved that depend on patient preferences. Decisions are preference-sensitive when:¹

- Options have very different implications for patients, in terms of delivery mode or side effects, that leads to large inter-individual variability in terms of preferences regarding the trade-off between benefits and harms
- More than one relevant treatment option exists, options are in balance in terms of their attractiveness or when the outcomes are more or less equally desirable, but different individuals may value these outcomes differently
- There is insufficient or conflicting evidence about the risks and benefits of an option
- There is an impressive number needed to harm, even though the number needed to treat is very good
- The effect of the intervention depends on the patient’s collaboration or if the decision intervenes with the patient’s lifestyle.

Examples include decisions about major surgery, medications that must be taken for the rest of one’s life, and screening and diagnostic tests that can trigger cascades of serious and stressful interventions.

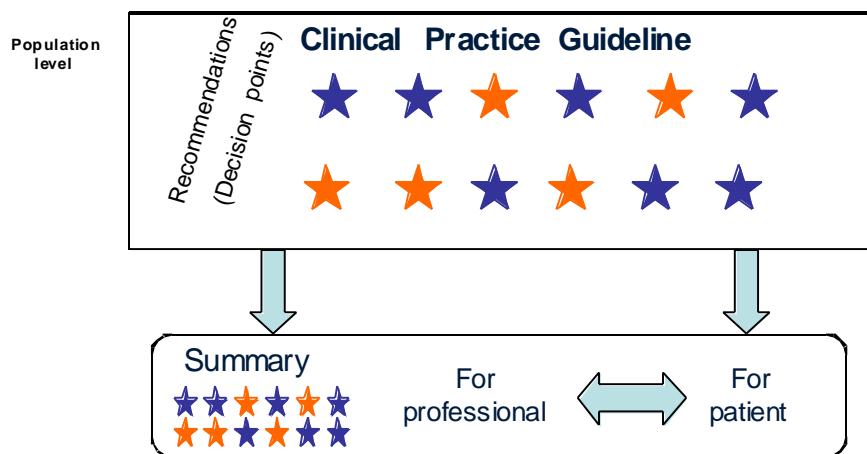
We thus contend that stronger relationships between CPGs and patient decision aids can help translate population-based recommendations to individual patients. Such integration is however not straightforward and can raise tension between recommendations applicable to ‘average’ patients and how best to consider individual patients’ values and preferences.³

The tendency to call all patient-oriented materials *patient decision aids* and all professional-oriented material *guidelines* adds to the confusion, as it fails to distinguish recommendations about a single best option from those that aim to support a dialogue about the pros and cons of different options.⁴ Patient decision aids help people to deliberate, independently or in collaboration with others (family, carers, or health care providers), about options, by considering relevant attributes; they support people in forecasting how they might feel about short-, medium- and long-term outcomes which have relevant consequences, in ways which help the process of constructing preferences and eventually making a decision that is appropriate to their individual situation.⁴

The printed version of a complete guideline document may run to over 100 pages, and is organised around a large number of decision points. In the following figure these decision points are symbolised as stars; blue for strong recommendations and orange stars for preference-sensitive recommendations. These may be related to issues such as screening, diagnosis, treatment, and referral related to one disease or symptom complex. In practice, professionals often only use summarised versions describing the key practice recommendations. Patient versions of guidelines, either in print or digital versions, are often a summary of

the complete document explaining recommendations in plain language. The summary of the CPG is crucial in clinical practice; this often is the only document that health care providers are actually using. It seems of crucial importance to have a patient version of this professionals' summary, to support the patient in having an easy overview of what the CPG is about.

Figure 1: Relationship between full clinical practice guideline and its summaries for patients (or patient versions of guidelines)

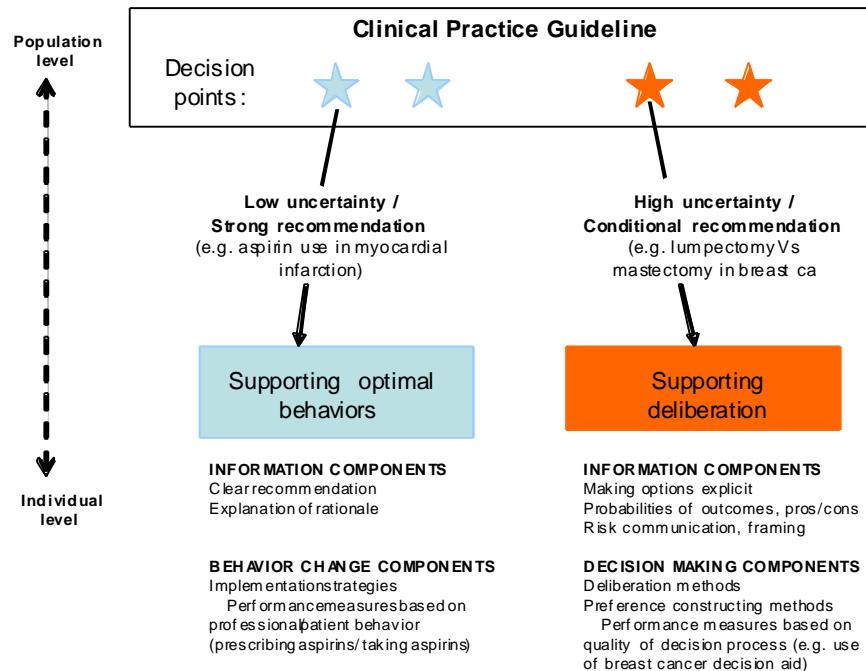


Patient decision aids are usually organised around one decision point. The format may range from printed fact sheets to be discussed during a consultation to tools that patients need to study before the consultation, such as paper booklets, computerised CD-ROMs, videos, or interactive websites.

We recommend a sequential order for collaborative development of CPGs and patient decision aids.⁷ CPGs have been placed at the top of the following figure, as they can be considered precursors of patient decision aids. The work of a CPG panel must take place before developing a patient decision aid (orange square) and becomes a sensible exercise, because the information in the CPG should be translated to individual patients. Recommendations with high uncertainty call for tools that support the professional and patient deliberation process, the careful weighing of arguments for and against some proposition.

Relationship between complete guidelines and patient decision-support tools or aids

Decision-support tools focus on a single decision point addressed by the full guideline document. Decision-support tools can either aim at supporting patient's behaviours toward a single recommended 'best course of action', or support deliberation between different options.



How can clinical practice guidelines support shared decision-making?

Supporting deliberation can be organised by connecting a full-blown patient decision aid to a CPG.⁶ Intermediate strategies may be more feasible and may also facilitate shared decision-making to a certain extent. Proposed strategies related to a specific recommendation can be categorised into three clusters:

1. Increasing option awareness of health care providers through improving the representation of options within a guideline recommendation
2. Improving the deliberation about options through describing the deliberation process for a preference-sensitive recommendation, and
3. Provision of patient decision aids related to a specific recommendation, to support the patients' option awareness, elicitation of preferences and/or deliberation.

Strategies to facilitate shared decision-making may not be related to one specific recommendation.

Examples of strategies not related to a specific recommendation are:

- a) The addition of a separate chapter to the clinical practice guideline
- b) A change in the language used throughout the whole guideline document.

a) First, in a separate chapter the professional can be alerted to the importance of involving the patient in decision-making, e.g. through describing the value of shared decision-making and patient centeredness. This may include provision of relevant variables about reasons for adherence and non-adherence to recommendations and their correlation to personal characteristics (age, sex, history of the disease, comorbidity), social aspects (socioeconomic status, educational level, family environment, culture and religion), and the health system context. A second strategy involves the provision of the necessary and facilitating conditions for shared decision-making at the micro (interaction professional—patient), meso (health care team), and macro (organisation) level. For example, at the micro level, explain that discussing patients' preferences should be done in a timely manner, tailored to the patient's characteristics (e.g. to the literacy and numeracy level of the patient, and illness perceptions), and that a follow-up consultation should

be offered where desired. A third strategy involves support for the professional in eliciting the patient's preferences by suggesting some examples of patient-centred questions, e.g. 'How can I help you to improve your quality of life?', 'What is important to you?', or 'How do you see this decision?'

b) Regarding language used, CPGs could use wording that makes the involvement of patients in decision-making explicit, e.g. by indicating 'offer the patient a statin prescription' instead of 'prescribe statins to the patient'. Another strategy is to encourage professionals to use the same simple language in both communication to colleagues (referral letters) and in communication to patients.

Further reading

Raats CJ, van Veenendaal H, Versluijs MM, Burgers JS: A generic tool for development of decision aids based on clinical practice guidelines. *Patient Educ Couns* 2008, 73:413-7.

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Chapter 10: Beyond guidelines - tools to support patient involvement in Health Technology Assessment (2015)

Authors: Karen Facey and Tania Stafinski on behalf of the HTAi Interest Sub-Group for Patient/Citizen Involvement in HTA

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1. Aims of this chapter

This chapter gives an overview of tools to support patient involvement in health technology assessment (HTA). The chapter begins by explaining the parallels and differences between HTA and clinical guideline development. It then discusses the barriers to patient involvement in HTA and outlines work by HTA International (HTAi) to identify good practice in patient involvement in HTA. It presents tools developed to support patient involvement in HTA that may be adapted to suit the needs of clinical guideline development.

2. The HTA context

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. Whilst clinical guidelines inform improvement in the whole care pathway and are focussed 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 into reimbursement (payer decision making). HTA is often described in three steps:

- Assessment: critical review of published or submitted evidence about clinical and/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/reimbursement decisions

HTA organisations vary widely and may be responsible for assessment, or appraisal, but all seek to inform decision-making in some way. Furthermore many HTA organisations are part of larger bodies that undertake a range of evidence-based work in the health system and this often includes clinical guideline development. Hence sharing approaches, whilst recognising differences, seems appropriate.

Over the past decade as HTA has become more 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 drivers to involve patients in the processes. This has led some HTA organisations to create transparent processes for patient participation in the HTA process and develop methods for obtaining patients' perspectives¹. However, this involvement is not widespread or consistent and there is reticence amongst some HTA organisations to involve patients or include their perspectives in what is seen as a scientific process. There is also concern about potential bias resulting from industry funding of patient

organisations. Hence guidance is needed to provide practical ways in which patients can contribute to HTA and decision-making.

3. Barriers to patient involvement in the HTA process

In 2005, Hailey² identified common themes that had been reported about consumer (patient and public) involvement in health research, which he thought were relevant to HTA. A summarised version of the sub-themes is presented in Table 1.

Table 1. Challenges in consumer participation

Theme	Summarised sub-themes
Interaction of consumers and researchers	Time needed to develop a trusting, productive relationship.
Availability of resources	Administrative, financial, staff support.
Identifying a reasonable consumer position	Recognising that there are differing values, expectations, environment, culture, genetics, experience of the health system etc, but that it is not possible to canvass all.
Technical demands	Lack of knowledge/power/credentials/skills in scientific process and health care policy options.
Training and education	Lack of education and training that has been developed specifically for consumers.
Nature and extent of consumer representation	Difficulty defining which consumers should be involved, lack of representation, difficulty reaching marginalised populations.
Time demands and remuneration	Time commitments, working to tight timetables, whether and how much consumers should be paid.
Matching consumer information and information from researchers and the literature	Lack of concordance between issues that consumers 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 how credible evidence of patients' perspectives is in the scientific context.
Consumer impact on discussion and decisions	Concerns by researchers/clinicians that the optimal process for inclusion of lay perspectives is unclear and might soften scientific debate, be an inefficient use of committee's time, inappropriately impact funding decisions and be tokenistic. Concerns by patient groups about how evidence from different sources is weighed and valued and about greater influence of professional participants. Absence of good quality research to show impact of consumer participation.

Although this research is over a decade old, many of these barriers still exist and are probably still applicable not only to HTA, but also to clinical guideline development. Further to this work, Hailey worked with the International Network of Agencies for HTA (INAHTA) to undertake surveys with its members about consumer involvement in HTA³. In the latest survey in 2010, 33 HTA organisations (63%) responded to the survey and of these 67% stated that consumers were involved in their HTA processes. Of the 22 HTA organisations that involved consumers, 95% involved consumer organisations and about 35% routinely involved patients in the provision of evidence, interpretation of evidence and review of draft reports. Only 19% had evaluated the consumer involvement.

In 2010-2011 the European Patients' Forum (EPF), undertook separate surveys with different stakeholders about patient involvement in HTA with 40 responses from HTA organisations, 18 from decision-makers and 23 from patient organisations in Europe⁴. They noted that the type and level of patient involvement in HTA varies widely, reflecting the different rationale, motivation and approach applied in each country. They confirmed that few HTA organisations and decision-making bodies involve and integrate patients' perspectives in their reports and 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 are perceived to be the lack of capacity, time and good methodologies to involve patients. They noted that HTA organisations and decision-makers need to improve their means of facilitating patient involvement, such as education and training programmes and holding public conferences, seminars and workshops.

The EPF report ended with a list of recommendations to and from HTA organisations, decision-makers and patient organisations to foster patient involvement in HTA. All stakeholders suggest that patient organisations need to start by understanding the principles of HTA and then being pro-active to identify ways and means to get involved. HTA organisations also need to involve patients in a systematic, comprehensive and meaningful way. In their recommendations to HTA organisations and decision-makers EPF suggests the following items are needed:

- Capacity building
- Better and timely communication with patient organisations
- Transparency
- Policies and guidelines on patient involvement in HTA
- Partnership with patient organisations
- Assessment of the impact of patient involvement

4. HTAi capacity building for patient involvement

HTAi is the global scientific and professional society for all those who produce, use, or encounter HTA. It has members from over 65 countries and seeks to embrace all stakeholders, including researchers, HTA organisations, policy makers, industry, academia, health service providers, and patients. In 2005, HTAi established an Interest Sub-Group for Patient/Citizen Involvement in HTA (PCISG). This interdisciplinary group advocates that those living with a particular condition or disease and their informal care-givers offer unique insights into the impact of a condition on daily life, the benefit and the burden of current treatments, the most important elements that should be present in a new treatment and what side effects can be tolerated. The PCISG advocates that such input is needed to fully understand the value of different technologies.

To improve patient involvement in HTA, the PCISG collects experiences of patient involvement in HTA, shares good practice and promotes fair and robust processes for patient involvement in HTA.

PCISG has two major audiences for its work: patient organisations and HTA organisations. It seeks to build capacity in patient organisations to help them understand HTA processes and how they can best contribute. With HTA organisations, it seeks to promote methods for patient involvement that build on good practice and are practicable in rapid processes that seek to inform reimbursement decisions. To do this, tools have been developed via the international network that could be adapted for use in clinical guideline development. Some of the key tools are described in this chapter – more information can be found here <http://www.htai.org/interest-groups/patient-and-citizen-involvement/resources.html>.

5. Key initiatives from HTA organisations to involve patients

PCISG has developed a template for HTA organisations to describe how they involve patients and citizens in their processes. The template is presented in Annex 1 (or can be found at http://www.htai.org/fileadmin/HTAi_Files/ISG/PatientInvolvement/v2_files/Resource/PCISG-Resource-Patient_Submission_Collation_Template_30-May14.doc).

At February 2015, eleven HTA organisations had completed the template and these are posted on the HTAi website <http://www.htai.org/interest-groups/patient-and-citizen-involvement/resources/for-hta-agencies-and-policy-makers.html>. Seven were from Europe - Basque Country (Spain), Catalonia (Spain), England and Wales (UK), Germany, the Netherlands, Poland, Scotland (UK) and one each from Israel, Australia, Taiwan and Canada.

Twenty percent is a fairly small return from the 55 organisations in the International Network of Agencies for HTA and it is likely that returns are from organisations that do include patients. Despite this, the information provides useful case studies of how patient involvement is being undertaken and for a patient organisation seeking to engage in a specific country it outlines how they might get involved and a key contact. With these caveats, the following section provides an overview of some of the responses according to two themes that have may have particular relevance for clinical guideline processes, namely topic selection and patient evidence.

5.1 Identifying and selecting technologies for HTA

Most HTA organisations established to inform reimbursement/coverage recommendations review all new drugs and therefore do not have a need for processes for identifying and selecting technologies for assessment. However, for most HTA organisations that have a mandate including non-drug technologies, such processes are needed.

While some, including the Pharmaceutical Benefits Advisory Scheme in Australia and the National Institute for Health and Care Excellence (NICE) accept HTA requests from the public and patients, none have developed approaches that actively seek the views of patients to identify possible technologies for assessment. In general, technologies for assessment are proposed by a broad range of stakeholders who submit requests online through an HTA organisation's website.

Patient involvement in the selection of a list of potential technologies for assessment has focussed on the appointment of patient representatives to multi-stakeholder selection committees/panels convened by HTA organisations, such as NICE. However, not all HTA organisations have selection committees and not all selection committees include patient representatives. Therefore, other opportunities for patient input into decisions around which technologies to assess are needed. They may include the engagement of patients and families in the development of criteria used to select technologies for HTA.

(It is known that organisations with remits for comparative effectiveness research in the UK⁵, and USA⁶ have developed interesting approaches to engage patients fully in the topic identification and selection processes and in the project monitoring phases, but these experiences are not captured in the HTAi Agency Good Practice Examples.)

5.2 Patient evidence

HTA reports contain synthesised information on several aspects of a technology, including the burden and severity of the condition/illness and experiences with current treatments (the comparators), its clinical effectiveness, its economic implications (in some cases, cost-effectiveness and budget impact), and its

broader ethical, organisational, legal and social (including patient) issues. Traditionally, this information has come from published literature and/or submissions provided by health technology manufacturers. As a result, the extent to which different aspects of a technology are described and discussed in a HTA report has, for the most part, been dependent on the evidence available from scientific or administrative sources. With increased recognition of the limitations of these approaches and the importance of addressing any clear evidence gaps, particularly related to disease burden, clinical effectiveness and the interpretation of ‘meaningful benefit’, most HTA organisations have established other mechanisms for gathering this evidence. They include seeking input from patients and families.

HTA organisations that perform their own literature reviews, may undertake specific literature searches to determine patients issues, using iterative processes to identify the issues that are important to patients and then searching to identify literature (often qualitative research studies) that describe patients’ perspectives and experiences about those issues. Systematic processes can be used to critically appraise such qualitative research and synthesise it using methodologies from social and humanistic research⁷. If evidence is lacking, primary research can be commissioned and reported as part of the HTA⁸. In such processes, patient groups or patient experts can also provide helpful input to the protocol that defines the research questions, identifying outcomes that matter most to patients and provide important consultation comments on the draft guideline and recommendations.

When HTA reports are produced using submissions from manufacturers as the basis of the evidence, patient organisations may be invited to contribute patients’ views, perspectives and experiences in the following ways:

- 1) Providing input into the assessment scope and protocol
- 2) Completing patient group submissions, which contain information 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 received the technology being assessed
- 3) Nominating an individual patient to give expert testimony and answer questions at the appraisal committee
- 4) Providing feedback on the HTA report during stakeholder consultations as a member of a patient group or as an individual in a public consultation

Of the countries examined, only NICE uses all four approaches, so these processes are by no means standard practice.

Patient group submission processes may be compared on the basis of the following key elements/questions:

- a) Who can make a patient submission?

Previously, in most HTA organisations, opportunities to complete a submission were limited to patient organisations. However, a growing number are now accepting input from individual patients or exploring ways of accomplishing this, recognising that many diseases, especially those that are rare, do not have patient organisations. While NICE has already established an approach, the Canadian Agency for Drugs and Technologies in Health (CADTH) is piloting an individual patient submission process.

- b) How much time is allowed to complete the submission?

Most HTA organisations have explicit timeframes for completing patient submissions that fit in with their HTA processes. For example, CADTH allows a total of 35 business days for preparing and submitting patient input⁹. Manufacturers are required to provide CADTH with notification of a pending submission before

formally filing it. Calls for patient input and the respective deadline are posted on the “Open Calls for Patient Input” website page, 20 business days in advance of the applicant’s anticipated date of filing.

c) What information is contained in the submission?

HTA organisations with patient submission processes have developed templates to be completed by patient organisations. Across the templates, the types and sources of information requested are broadly similar. In general, information sought relates to:

- Physical and mental impact of the condition on patients, families and informal care-givers
- Experiences with current treatments, including the burden of treatment and how well they feel their condition or illness is managed
- Expectations of and experiences with the technology being assessed from the perspectives of patients, families and informal care-givers

The importance of illustrative quotes from patients and families/carers supporting all three aspects is highlighted, along with the need to capture a range of views in a concise and balanced way.

d) How is patient information used in HTA?

In HTAs that do not undertake their own systematic review, submissions of evidence from manufacturers are generally critically reviewed in an assessment phase. Whereas patient group submissions tend to inform the scoping of the assessment and are given prominence in the appraisal phase, when value judgements are applied. In the past year, HTA organisations that take submissions from patient groups have moved to creating a separate section in their reports that summarises the key points from patient input (SMC, CADTH) and some HTA organisations provide the full submissions on their website (NICE), alongside input from other stakeholders. There is still concern about how the evidence from patients is weighed alongside the scientific evidence and this will continue to be an area of debate. It is important to explain how the evidence has been reviewed and how it influenced HTA recommendations.

e) Is feedback on the submission provided to patients?

In general, feedback from HTA organisations to patient organisations on their submissions is limited (SMC provides verbal feedback to those that request it, whilst CADTH has a new system of written feedback). However, most HTA organisations have acknowledged the need to incorporate such a step into their processes in order to optimise both the impact of future submissions and the legitimacy of HTA decisions.

f) What is the impact of patient submissions?

There are arguments as to whether the impact of patient submissions (and patient involvement more widely) should be measured. Some support measurement of the impact of patient involvement. Others note that patient input is one part of the multi-factorial, multi-stakeholder engagement that is part of the deliberative discussion, so it should not be judged separately. It is clear that some case studies of impact would be helpful training tools and that more needs to be done to consider this issue.

6. HTAi Patient group submissions templates

The PCISG has worked with HTA organisations and patient organisations to review patient group submission forms and develop a standard submission template, which has been consulted upon internationally. This has led to one HTAi patient group submission template for medicine's HTA and one for non-medicine's HTA (any health technology that is not a medicine – device, education programme, psychological service etc). As diagnostics are somewhat different to other technologies, a specific template for patient group submissions to HTA of diagnostic technologies is being developed.

The template for patient group submissions to non-medicine's HTA is presented in Annex 2. This is accompanied by a cover note for HTA organisations, which stresses their need to take the template and adapt it to their own circumstances and processes and to the technology being assessed. For the medicine's HTA cover note and template, see:

http://www.htai.org/fileadmin/HTAi_Files/ISG/PatientInvolvement/v2_files/Resource/PCISG-Resource-MedsHTAI_Patient_Submission_Template_COVER_v1.1_Jun15.doc and

http://www.htai.org/fileadmin/HTAi_Files/ISG/PatientInvolvement/v2_files/Resource/PCISG-Resource-HTAi_Patient_Submission_Template_v1_30-May14.doc

This template has also proved to be a useful tool in training sessions with patient groups to help them understand what information is needed by decision makers and consider how they might gather it.

To ensure that patient submissions contain information that is most useful to decision-makers, HTA organisations have developed training sessions and tutorials for patient organisations. In addition, some have dedicated staff who provide support to patient organisations during the completion of submissions. The PCISG has also adapted a guide used by the pan-Canadian Oncology Drug Review that helps patients complete a patient group input submission template. It 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. This can be found via the following link:

http://www.htai.org/fileadmin/HTAi_Files/ISG/PatientInvolvement/v2_files/Resource/PCISG-Resource-GuidanceandChecklist-Dec14.docx

This is currently being piloted but has been welcomed by patient groups and could be of help to those contributing to guideline processes.

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 PCISG developed values and quality standards for patient involvement in HTA which can be seen here: (http://www.htai.org/fileadmin/HTAi_Files/ISG/PatientInvolvement/v2_files/Info/PCISG-Info-PosterValuesandStandards-30-Jun14.pdf)

These resulted from an 18-month research process that included:

- An evidence review of principles for HTA and patient/public participation in decision making processes and health research
- An HTA and patient leader expert workshop, which used the nominal group technique to identify principles for patient involvement in HTA
- Development of the principles into draft values that underpin the ethos of patient involvement and quality standards that are the practical steps that can be taken to implement patient involvement in HTA
- A three round international Delphi consensus process, including 150 respondents from 39 countries to agree the final values and quality standards

This resulted in the following values and quality standards for patient involvement in HTA that were launched in June 2014 and could be applied or developed to suit the clinical guideline setting.

7.1 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.

7.2 Quality Standards

In addition to the five values, 10 quality standards are specified, five of which represent overarching statements that apply to HTA-informed decision-making, in general.

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.

Individual HTAs

The remaining 5 standards apply to specific steps followed during the assessment and formulation of a recommendation/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, it has been stressed that patient involvement is seen as a journey. Every HTA organisation starts in a different place and the high requirements of the values and quality standards should not be seen as off-putting. The aim is to encourage every HTA organisation to take a step on the journey to involve patients in their processes and, for those that already do, to evaluate what they do and improve it. HTAi is developing initiatives to support the implementation of these values and quality standards, including an annual award for improvement in the values and quality standards and a patient charter based on the values and quality standards, indicating what patient groups can expect from HTA organisations.

7. Application of HTA tools to support patient involvement in HTA to clinical guideline development

The template used to capture HTA organisation experiences of patient involvement, the patient group submission's template for non-medicine's HTA and the values and quality standards for patient involvement in HTA could be adapted for use in clinical guideline development.

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9. Canadian Agency for Drugs and Therapeutics in Healthcare. Patient Input. <https://www.cadth.ca/cdr/patient-input> (accessed 13 May 2015)

Appendix 10.1

HTAi template for HTA organisations to determine how patients and citizens are involved in HTA

Your name & position			
Date		Email address	
Country		Organisation	
Purpose & work of your organisation			
Type(s) of health technologies assessed by your organisation			
Purpose of your organisation's patient involvement			
How are individual patients and/or carers involved in your HTAs (e.g. submissions, participating on committees, etc)?			
How are organisations representing the views of patients and/or carers involved in your HTAs?			
How do you involve citizens?			
What processes or tools are used by the individual patients, carers, organisations and/or citizens to provide input (e.g. completing templates on website, verbal presentations, etc)?			

What support do you provide patients, carers, citizens and organisations to enable them to participate?	
How do you measure or evaluate the impact of the involvement?	
What are the main impacts of involvement in HTA witnessed by your organisation?	
How do you provide feedback to the patients, carers, citizens and/or organisations on how their input was used and its value to the HTA?	
Tips for others	
Other	

Do you give permission for HTAi to place this information on its website?

<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Other:
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Please **email** this form to: Ann Single, Patient Involvement and Education Working Group Co-ordinator, singlehaworth@gmail.com.

Appendix 10.2

HTAi Patient group submission template for non-medicines' HTA

<HTA committee name>
Health Technology Assessment (HTA) on
<Name of Health Intervention in Condition X>

1. Overview of this form

What is the purpose of this form?

This submission form has been created to help patient groups provide clear, comprehensive information to organisations that do health technology assessment (HTA) in order to make decisions about the reimbursement or recommendations for use relating to a health intervention. This form is specifically designed for HTAs of health interventions that are not medicines, which we call non-medicine health technologies.

The form includes prompts or suggestions to draw out the unique knowledge and perspectives of patients that are most likely to inform decisions made in HTA. This will help in the assessment of the value of a health technology and in making recommendations or decisions about its availability in the health service.

This form is intended to help patient groups present the range of experiences and views of patients with the disease/condition for which the health intervention is being assessed. It is not intended for use by individual patients.

What information do we value from patient groups?

We recognise that patients and those who support them have unique knowledge about what it is like to live with a specific disease or medical condition. We believe patient groups can help us understand patients' unique perspectives by collecting and presenting patients' and carers/care-givers' views and experiences by engaging with a wide range of patients. They can describe advantages and disadvantages of health interventions based on patients' experiences and what patients value from a new intervention.

Layout of this form

- Section 2 explains how you should complete this submission form.
- Section 3 asks you for some background information about your patient group.
- Sections 4-8 are the main parts of the submission form for you to complete, describing the views and experiences of patients and their care-givers/carers.

Our commitment to you

We recognise that completing this submission may require substantial resources, so we commit to making these submissions available to everyone involved in the appraisal process, particularly HTA reviewers and committee members. Furthermore, our reports will document how the information from patient groups was used in developing our conclusions/recommendations.

If requested, we will provide you with further feedback about how the submission from your patient group was used and contributed to the decision.

2. How to complete this form

In the main sections of this form, you are asked to describe the:

- challenges patients face in living with the condition being assessed
- experiences of using health interventions that are currently available
- expectations and potential benefits/drawbacks concerning the health intervention being assessed

Each question has a series of prompts or suggestions (in the boxes) that are intended to assist you in providing information that will help HTA reviewers and committees to better understand the impact of the condition, unmet needs and the impact of interventions that are currently available. Please address any of the prompts that your group feels are important and describe any other relevant issues that are not captured in the list of prompts. You may find it helpful to collaborate with other patient groups to complete the form, ask local clinicians for assistance, or contact [*at this HTA organisation at email address*].

What do we mean by patient and carer/care-giver?

In all parts of this form the term “patient” refers to anyone living with, or who has lived with, or has a high risk of the condition, for which the health intervention is indicated. “Carer/care-giver” refers to anyone who assists a patient in an informal or unpaid capacity – such as a family member or friend. It does not include those paid to give care, such as doctors or nurses.

What information is most helpful?

Please provide clear facts, information and summaries of experiences that give a concise, accurate and balanced overview of a range of patients’ and care-givers/carers’ perspectives/views. Describe experiences at different stages of the disease with a particular focus on symptoms – their impact and how well they are currently managed with existing therapies. State the source of your information (e.g. web survey, helpline analysis, social networking, focus group, patients’ records, one-to-one conversations with those who have experience of an intervention, patient stories, research studies, etc).

HTAi is developing guidance on [methods patient groups can use to collect information for medicines HTA](#) and this may be helpful to you.

There is no need to send us published clinical trials, as we already have access to such studies. However, if you have views about the interpretation of a particular study, such as the relevance of reported outcomes or importance of effect, we would be happy to hear them.

In any of the sections in this form, if there are groups of patients who should have special consideration, please indicate the specific needs of that group (e.g. children, women/men, ethnic groups, those living in a particular location, people with other disabilities, and particular patients with the disease or sub-types).

Need help?

If you require help in understanding HTA related terms, please refer to the [HTAi glossary](#) for patients or visit the training resources on the [HTAi website](#).

If you have any questions when completing this form, please contact:
<NAME, PHONE, EMAIL – Contact person from HTA organisation>

3. Information about your patient group and this submission**Name of patient group:****Condition(s) represented by your group:****Name of person completing this form:****Role in the organisation:****Email:****Phone:****Postal address:****Website address:****Type of group (tick all that apply):**

- | | |
|--------------------------------|--------------------------|
| Registered charity/association | <input type="checkbox"/> |
| Fellowship | <input type="checkbox"/> |
| Informal self-help group | <input type="checkbox"/> |
| Unincorporated organisation | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |

Please specify _____

Membership of your group:

- | | |
|---------------|--------------------------|
| International | <input type="checkbox"/> |
| National | <input type="checkbox"/> |
| Regional | <input type="checkbox"/> |
| Local | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |

Please specify _____

Purposes of group (tick all that apply):

- | | |
|---------------------|--------------------------|
| Advocacy | <input type="checkbox"/> |
| Education | <input type="checkbox"/> |
| Campaigning | <input type="checkbox"/> |
| Providing a service | <input type="checkbox"/> |
| Research | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |

Please specify _____

What is the source of the information about patients' and carers/care-givers' experiences and needs that are presented in this submission?**Items to cover:**

- *Source – such as individual patient stories, review of patient group helpline queries, surveys, social media, one to one discussions with patients, focus groups, interviews, documentation of clinic visits, published or unpublished research*

- *Strength – how many patients and methods for each source*
- *Breadth – how representative are your findings compared with the views of the many patients that might be treated with this technology – did you approach patients that are seldom heard?*

In line with all stakeholders participating in this HTA, we ask you to complete our declaration of interests form.

Are you willing for this submission to be shared on our website after removal of any financial or personal information that could identify patients?

YES / NO

We may invite you to a meeting where this HTA is to be discussed. Would you or a member of your group be willing to attend such a meeting to answer questions or provide clarifications?

YES / NO

4. Impact of condition

How does the condition or disease for which the health intervention is being assessed affect patients?

Issues you could consider in your response:

- *Aspects of the condition that are most difficult/distressing at different stages of the disease such as specific symptoms; difficulty in activities of daily living (dressing, eating, socialising, intimacy; loss of ability to work/go to school; social exclusion)*
- *Activities that patients find difficult or are unable to do such as engaging in sports and physical activities, housework, shopping*
- *Emotional and psychological impacts such as fear, anxiety, uncertainty, stigma, embarrassment*
- *Impacts of illness on family life*
- *Financial implications such as cost of aids/interventions/support to control symptoms, manage disease, loss of income*

How does the condition or disease affect carers/unpaid care-givers?

Issues you could consider in your response:

- *Challenges faced by family and friends who support a patient to manage the condition/access the service such as disruption of usual daily routines*
- *Pressures on carers/care-givers daily life such as emotional/psychological issues, relationship challenges, organisation of care, fatigue, stress, anxiety, depression, physical challenges, financial issues*

Are there groups of patients that have particular issues in managing their condition?

Issues you could consider in your response:

- *For example groups such as men, women, children, young adults, older people, those with disability, ethnic groups, those in deprived areas, other minority groups, those with a particular genotype*
- *Issues they face (such as looking after family, managing this condition alongside other conditions, access to treatment, social stigma)*

5. Experiences with currently available health interventions

How well do currently available health interventions work?

Issues you could consider in your response:

- *Main health interventions currently used by patients for this condition, or if there are none, please state that*
- *Extent to which currently available health interventions control or reduce the most difficult/distressing aspects of the condition or cure it (e.g. reduction in symptoms; ability to dress, work, go to school, socialise; improve breathing, swallowing, walking)*
- *The most important benefits of currently available interventions*
- *The burden of currently available health interventions on daily life (e.g. difficulty in using the interventions, challenges in recovering after treatment, need for rehabilitation, special clinic visits for treatments and examinations)*
- *Side effects associated with currently available health interventions that are distressing or difficult to tolerate*
- *Financial implications to the patient and his/her family such as costs of purchasing the intervention, travelling costs, administration costs*
- *Implications for carers/care-givers such as vulnerability to risk of infection, inflicting pain on loved one when using the intervention*
- *Areas the current health interventions do not address*

Are there groups of patients that have particular issues using the currently available health interventions?

Issues you could consider in your response:

- *Those who find it difficult to operate the device (e.g. children, older people, those with a disability, those with breathing difficulties)*
- *Those who need to use a device, which has poor social acceptability, in a public place*
- *Those with a particular form of disease for which there is currently no treatment*

6. Experiences with, and expectations of, the health intervention being assessed

For those with experience of this health intervention, what difference did it make to their lives?

Issues you could consider in your response:

- *Main reasons for use of this health intervention*
- *State any objectives set when starting the health intervention and whether they were achieved*
- *Reasons patients do or don't like the health intervention being assessed compared with other health interventions*
- *Extent to which the health intervention controls or reduces the most difficult aspects of the condition, or resolves it (e.g. reduction in symptoms, ability to dress, work, go to school, socialise, improve breathing, swallowing, walking)*
- *Symptoms that have changed and impact on daily life and quality of life such as less pain, less fatigue, improved continence, less nausea, increased mobility, less time linked to assistive device (e.g. oxygen, dialysis, etc)*
- *Limitations of the health intervention*
- *Unwanted outcomes (e.g. side effects) that are difficult to tolerate and those that patients are willing to tolerate*
- *The burden of the health intervention on daily life (for example ease of use, challenges in recovering after treatment, need for recalibration, special clinic visits for treatments and examinations)*
- *Financial implications to patients and their families (e.g. costs of purchasing the intervention, travelling costs, administration costs)*
- *Impact on use of healthcare services, such as fewer visits to clinic*
- *Impact of intervention on carers/care-givers*
- *Any aspects of the health intervention that patients would like to change*

For those without experience of the health intervention being assessed, what are the expectations of using it?

Issues you could consider in your response:

- *Whether the clinical studies have studied outcomes that are important to patients (e.g. symptoms that limit activities)*
- *Minimum level of improvement of the most important symptoms that patients would like to see*
- *What patients would most like to see from the intervention being assessed (e.g. improved daily life, ability to work, improved mobility, greater symptom control, easier use, less intrusive application)*
- *Main reasons why the health intervention being assessed may not be used*
- *Perceived advantages and disadvantages*
- *Financial implications to patients and their families (e.g. costs of purchasing the intervention, travelling costs, administration costs)*
- *Impact of health intervention on carers/care-givers*

Which groups of patients might benefit most from health intervention being assessed?

Issues you could consider in your response:

- *Groups that currently have very limited treatment options or who find current interventions difficult to administer*

7. Additional information

Please include any additional information you believe would be helpful to the HTA reviewers and committee (e.g. ethical or social issues, information needs about the health intervention).

8. Key messages

In up to five statements, please list the most important points in your submission.

For example:

- *The biggest challenges of living with this condition are...*
- *Current health interventions are inadequate because...*
- *This intervention being assessed will be beneficial because....*

Contact:

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