

## Chapter 4: How to develop patient versions of guidelines

Author: Corinna Schaefer\*

\*Corresponding author: Schaefer@azq.de

### Aims of the chapter

This chapter describes strategies and methods to communicate clinical practice guidelines (CPGs) to patients. It gives an overview of defined quality criteria for patient information and best practice examples on how best to meet them. Barriers to the production of patient guidelines and suggestions on how to overcome them will also be addressed.

### Why communicate clinical practice guidelines to the public?

Communicating suitable and understandable guideline information is a core strategy to involve patients in health care improvement. Patient and public involvement may occur both:

- At a collective level, defined as involving patients and the public in developing health guidance and/or participating in decision-making within health care systems
- And at a microscopic level, defined as patients taking an active role in their personal process of care, and engaging in shared and informed decision-making regarding diagnostic tests and/or treatment options.

Providing patients and the public with understandable information on diagnostic and/or treatment recommendations which aim to:

- Enable patients to make informed decisions based on the best available evidence
- Support the implementation of CPGs and thus improving health care.

Patient versions of guidelines ‘translate’ guideline recommendations originally formulated for clinicians, to patients and the public. This way, patients can learn about the current standard of care, and how—based on the best available evidence—physicians should treat their condition. Patient versions of guidelines support the trusting relationship between patients and their physicians as both can base their decision on the same body of evidence and standards of care approved by experts in collaboration with patients and/or consumers. Patient versions of guidelines are important tools for shared decision-making and support the implementation of CPGs.

### Which quality demands should patient versions of CPGs meet?

Since the intended purpose of patient guidelines is to support shared decision-making, then it stands to reason that the information within these guidelines should meet special quality demands that have been internationally defined by various institutions and authors.<sup>1-6</sup> Some of these definitions have been further developed, operationalised and validated as instruments for assessing the quality of patient information or patient decision aids.<sup>1-3</sup> These definitions, though varying, all share the same consistent underlying criteria as follows:

1. Patient information should not be influenced by financial or intellectual interest; funding and potential conflicts of interest should be made transparent
2. Patient information should be developed together with patients and/or consumers
3. Patient information should be based on the best available evidence, that is: a systematic literature search and assessment of the existing evidence
4. Patient information should communicate levels of evidence and/or strength of recommendations
5. Patient information should convey a realistic idea of the condition (neither exaggerate nor trivialise)
6. Patient information should describe all treatment options with their risks and benefits; describing the risks and benefits, the information should refer to patient-centred outcomes (mortality, morbidity, quality of life); risks and benefits should be communicated in an understandable way (i.e. no relative risk reduction, absolute numbers)
7. Patient information should address uncertainties like weak or missing evidence
8. Patient information should be easy to read, understandable and accessible.

## **How to assure that patient versions of guidelines meet defined quality standards**

There can be a wide variety of formats and products produced as patient versions of guidelines depending on the target groups, health care systems and the clinical practice guidelines upon which they are based. They can be developed as brochures or short leaflets, web-based documents or web-based applications. Some may be descriptive and provide a broad overview of the condition in question; others may only reflect the CPG content and use algorithms, graphs or tables to illustrate guideline recommendations or pathways. As formats differ, methods may differ as well. Since there is no single prescriptive methodology, the following are suggestions that you may wish to incorporate in developing your own patient version of guidelines:

### **1. Transparency**

The authors and the developing institutions of patient guideline versions should declare their financial and intellectual conflicts of interest (COI). This includes the patient or consumer representatives and their organisations. It should be guaranteed that financing organisations have no influence on the content of the patient guideline and that the authors can act independently. Funding should be made transparent. The same COI declaration forms as for the CPGs may be used, showing that patient versions are linked to the clinical 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.

### **2. Developing information 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. 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 is desirable, it may not always be feasible:

<b>Ways of development</b>	<b>How?</b>	<b>Who?</b>
<i>Joint editing of patients/consumers and clinicians</i>	Patients, clinicians and journalists collaborate during the whole development process of the patient version	Ideally, the patients and physicians that have already been involved in the development of the CPG that is to be 'translated'
<i>Peer review</i>	<p>Patient versions may be produced by clinicians, medical societies or organisations that have developed the CPG</p> <p>The draft is reviewed by patient and/or consumer representatives</p> <p>Patient versions may also be produced by patient or consumer organisations and reviewed by clinicians that have developed the CPG</p>	Ideally, producers and reviewers have already been involved in the development of the CPG

To ensure transparency, the methodology and process of development should be well documented. This can be done either within the patient version itself or it can be made available in an appendix or an extra document (methods report—see section: how to report methods of developing patient versions of CPGs).

### **3. Systematic search and assessment of evidence**

As patient versions are derived from evidence-based guidelines, they can take advantage of the work achieved by the guideline developers who have already performed a systematic literature search and assessment of the evidence. Sometimes, however, the evidence tables of CPGs may not provide all information needed: they may not mention patient-relevant outcomes or absolute numbers, risk reduction or numbers needed to treat/to screen or relevant patient data. In this case, it might be helpful to appraise the original studies, systematic reviews and meta-analyses in order to provide the information necessary for patients to make informed decisions about their treatment. If additional searches are performed, search strategies and results should be documented.

### **4. Communicating levels of evidence/strength of recommendation**

To understand the relevance of guideline recommendations, it is helpful for patients and consumers to have some information about the quality and reliability of studies, reviews and analyses on which recommendations are based. Depending on the information format, this may be achieved in a variety of ways including:

- Patient versions may adopt the wording of the recommendations (e.g. 'should', 'may', 'weak' or 'strong' recommendation) and explain the rationale behind these expressions

- Patient versions may explain the study design and quality for key recommendations in a simple way. This is especially helpful when facing treatment or screening decisions, but it does make the document longer and more complex
- Patient versions may describe evidence in a clear and understandable way (for example, ‘studies of high/modest/poor quality have shown that...’).

### **5. Conveying a realistic idea of the condition**

Patients or consumers should be informed but not manipulated by patient versions of guidelines. Therefore, conditions should be described without threatening or convincing readers, or trivialising the condition. If reliable data on the natural history of the condition is available, it should be communicated. Wording should be as neutral as possible: for example, there is no need to ‘fight’ against a condition or to promise ‘healing’ when healing is not possible—or not necessary. ‘No treatment’ should always be considered and described as an option.

### **6. Describing all options with benefits and risks**

If there are different diagnostic or treatment options, all options should be mentioned. Nevertheless, the patient version should be consistent with the CPG: if options are not recommended or not covered by the CPG due to weak or missing evidence, this should be stated. Risks and benefits of all treatments and/or diagnostic tests should be reported without qualifying these treatments or tests as ‘necessary’ or ‘promising’ or ‘useless’ (or other): it is up to the individual patient to weigh these options against his or her personal needs and concepts—together with his or her physician. On the other hand, it should be made explicit, which treatments or tests are recommended to which group of patients under what conditions and how strong these recommendations are. Furthermore, readers should be able to understand how tests work, what they are able to measure and how interventions are practically performed.

**Example:** For a treatment choice between radiation therapy and brachytherapy for prostate cancer it might be relevant that one treatment is non-invasive and requires several sessions whereas the other one is invasive and performed at a single session.

### **7. Patient-centred outcomes**

Patients should be able to make informed treatment decisions on the basis of information that is relevant to them. To assess benefits and harms of any intervention, they should be able to answer the following questions:

- Will I live longer?
- Will I feel better?
- Are there long-term complications, if any?

Ideally, information should provide data on patient-centred outcomes:

- Mortality
- Morbidity
- Quality of life.

But very often, data on these outcomes—especially on quality of life—is not to be found within the CPG itself. This may be due to studies that test for surrogates rather than for ‘hard’ endpoints. Or guideline authors may not report these outcomes, as their main focus is on generating recommendations. If patient-centred data is missing, all studies and analyses included in the CPG should be searched for concrete data. If no such data is found, another systematic literature search may be performed. If additional data can be found, it should be communicated to the guideline panel to assure that the information given to patients is consistent with the CPG.

## 8. Communicating risks

Risk communication is increasingly recognised as an important topic; not only when informing patients but also when reporting studies.<sup>7-10</sup> It is known, that communicating relative risk reduction leads to the overestimation of treatment or screening effects.<sup>11</sup> Therefore, benefits and harms should be described with absolute numbers rather than with percentages.

**Example:** *‘Breast cancer screening reduces breast cancer specific mortality by 25%’ gives little idea of the possible benefit for a woman facing a screening decision. A clearer statement is ‘one woman out of 2.000 who have had mammography every two years for over ten years is saved from death due to breast cancer’.*<sup>12</sup>

Communicating ‘numbers needed to treat’ (to screen, to harm) may help patients to understand the relation between risks and benefits. For example, describing 5- or 10-year survival rates in order to point out the benefits of screening tests may be misleading if screening leads to an earlier diagnosis.

It may be helpful to illustrate numbers with graphs. In order to avoid biased reporting, comparative graphs should show the same scale types and risks and benefits, and alternative treatment options should be reported with the same reference parameters.

## 9. Uncertainties

Results of qualitative research has shown, that many patients prefer clear recommendations on what to do. But sometimes, evidence is weak or missing and studies are of poor quality or results not comparable. Patients, though expecting recommendations, seem to trust in information that addresses these uncertainties. If no data on outcomes is available, this should be made clear. If effects of interventions are unknown, if results are heterogeneous or even contradictory, this should at least be stated. To what extent the details of uncertainties should be addressed is itself uncertain. A balance needs to be found by the developers to reveal uncertainties, but without providing information that is of no help to patients.

**Example:** *Sentences like ‘Perforation has been seen in 2 to 45 in a hundred patients treated with gastrectomy’ might not be really useful for patients, as this information does not communicate the actual risk a patient might face with the procedure. At best, this information emphasises that the risk of perforation is unclear.*

## 10. Understandability and accessibility

Patient versions of guidelines should be easy to find and easy to read. It should be tailored to patients’ needs 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.

**Example:** Using terms like ‘lymphadenctomy’ will make a leaflet or a brochure difficult to understand. On the other hand, these are the expressions patients will hear during their consultations and process of care. Therefore, there may be some value in using these terms in a brochure and defining them in an understandable way.

Depending on the format of the information, a glossary might explain technical terms and specific expressions to assure understandability.

It may be helpful to collaborate with professional writers or health education specialists in order to achieve an ‘easy-to-read’ text. Health literacy is varying among people, showing that it depends especially on socioeconomic status and education and that lower levels of health literacy are associated with poorer outcomes.<sup>13,14</sup> So, it certainly is necessary to publish patient versions in plain language. An elaborate version could be just as important, as potential readers might consider plain language not suitable for themselves. To foster accessibility for immigrants, translations in additional languages may be made available.

Distribution techniques are discussed and depend on the target population. It is important that patient versions of guidelines are accessible for free, which is easily achieved by providing a PDF document on a website. Not everybody can easily access the Internet, so a printed version should be made available as well. Web applications may be interesting to web-savvy patients and consumers.

## What other information may patient versions of CPGs provide?

Patients and the public are likely to want to know more about their condition, to contact other patients and want help answering further questions. Patient versions of CPGs may therefore provide a list with information sites or brochures, how to contact patient organisations or other information centres. It 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 the physician. If patients are involved in the development of the patient version, they could compile their own experience and offer tips on how to deal with the condition in daily life.

**Example:** A brochure on diabetic foot syndrome could provide information on what to think of when buying shoes—an issue that would never be addressed by the CPG but matters a lot to patients.

It is helpful to ask the patients involved which further information they think would be important to other patients—beyond facts and recommendations on diagnosis and treatment covered by the CPG.

## How to evaluate patient versions of CPGs

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 had helped their patients.

## How to report methods of developing patient versions of CPGs

The guideline development process may be well described in a methods report thus demonstrating transparency and is publicly accessible. It may provide information on:

- Aims
- Funding and responsibilities
- Recruitment of authors
- Search strategies, results and references
- Consensus process
- Author's contributions
- External comments/consultation.

**Example:** Table of contents for a patient version of a CPG on major depression:

- What this information is about
  - What is depression?
  - *How is depression diagnosed?*
  - *Severity*
  - *How is depression treated?*
  - Who might be involved with treating depression?
  - What you can do yourself
  - Help in case of emergency
  - What relatives should know
  - Where to find further help and support
  - How to find a psychotherapist
  - Glossary
- } *Guideline recommendations*

## References

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<sup>2</sup> <http://www.discern-genetics.org/>.

<sup>3</sup> <http://www.ipdasi.org/>.

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