G-I-N PUBLIC Toolkit:

Patient and Public Involvement in Guidelines

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

Contents

Notes on contributors

Antoine Boivin is a practicing family physician and assistant professor at the department of family practice, Université de Sherbrooke, Canada. He completed his PhD degree on patient and public involvement in health care improvement at the Scientific Institute for Quality of Healthcare (the Netherlands). He co-founded the Guideline International Network Patient and Public Involvement Working Group in 2007. He has published a number of research articles and given courses and conferences on patient and public involvement in guideline development and implementation.

Sarah Chalmers Page is currently programme manager for the Medical Technologies Evaluation Programme at the National Institute for Health and Clinical Excellence (NICE) in the UK. Her work in public involvement started as an assistant psychologist in local government, and has formed a common thread in her career through general National Health Service (NHS) management and several years as a patient and public involvement project manager in NICE, including leading training events for prospective patient and public members for guidance development and for guidance-developing managers and clinicians. She holds an MA in Psychology and an MSc in Healthcare Leadership and Management.

Jane Cowl is a patient and public involvement programme manager at NICE (National Institute for Health and Clinical Excellence) in the UK. Jane leads the team that provides advice and support on involving patients and the public in NICE clinical practice guidelines, public health guidance and quality standards. Following an earlier career in teaching, Jane has specialised in patient and community advocacy and involvement. She has run health advocacy services, research projects and campaigns, and was the lead for consumer issues in the national team set up by government to help improve maternity services. She has a master's degree in conflict resolution and a BSc (Hons) degree in sociology from the London School of Economics.

Carrie M. Davino-Ramaya is a member of the G-I-N PUBLIC steering committee, and is the toolkit's primary coordinator. She is a physician at Kaiser Permanente working as a practice leader for evidence-based medicine (EBM), guidelines and medical technology assessment. She is a member of the Kaiser Permanente Care Management Institute's National Guideline Directors and Guideline Quality Group. After earning her medical degree, Carrie gained international experience working with the United States Agency for International Development (USAID) and the American International Health Alliance (AIHA) to introduce primary care models which included guideline development and implementation in two Central Asia republics (Turkmenistan and Tajikistan).

Javier Gracia is a physician, specialising in preventive medicine and public health. He is a senior researcher at UETS (Health Technology Assessment Unit) in Madrid, Spain for projects related to health service research, clinical practice guidelines and patient decision aids. He is director of the scientific committee of GuíaSalud, the National Guideline Development Program in Spain. He is a steering committee member of G-I-N PUBLIC and the Interest Sub-group for Patient and Citizen Involvement with Health Technology Assessment international (HTAi). He has published a number of research articles on patient and public involvement in guideline development, HTA and patient decision aids.

Karen Graham has more than 10 years experience of involving patients and the public in health service design and development and she is currently Patient Involvement Officer at the Scottish Intercollegiate Guidelines Network (SIGN). Karen's career in public involvement started within the

voluntary sector where she was responsible for engaging young people in the development of smoking cessation services within the NHS. Karen joined SIGN in 2004 where she developed the patient/public involvement programme significantly. Her work includes the development of patient versions of guidelines; the involvement of patients in guideline implementation and dissemination activity; and sharing best practice at national and international levels. karen.graham2@nhs.net

Nancy Huang is a clinician with over 20 years of experience in public health and guidelines implementation. She has worked in the academic and not-for-profit sectors to implement knowledge translation initiatives in the primary care setting. From 2009 to 2011, she was the Director of the Guidelines Research Program for the National Health and Medical Research Council (NHMRC) of Australia where she oversaw the review and update of NHMRC's 'Standards for Guideline Development'. Currently, she is the national manager of MedicineInsight, a new Australian initiative to establish a general practice post market surveillance database for medicines to inform quality improvement programs.

Loes Knaapen is co-Chair of the Guidelines International Network for Patient and Public Involvement Working Group (G-I-N PUBLIC) and a PhD candidate at the Sociology Department of McGill University in Canada. Her doctoral research is a qualitative study of the production of clinical practice guidelines, for which she examined the Guidelines International Network and other guideline institutions. The resulting dissertation focuses on the justification and regulation of guidelines at local, national and international levels. In 2013 she will take up a postdoctoral position at the Institute de Recherche en Santé Publique de l'Université de Montréal, examining public involvement in drug regulation.

Marije Koelewijn-van Loon is a health scientist working as a post-doctoral researcher at the School for Public Health and Primary Care (CAPHRI) at Maastricht University in the Netherlands. Marije has a master's degree in health promotion and education and received her PhD in 2010, investigating a nurse-led intervention to involve patients in cardiovascular risk management in general practice. She was coordinator of the 6th international conference on Shared Decision Making (held June 2011 in Maastricht), and currently holds a Dutch Cancer Foundation fellowship for research on patient involvement in clinical decision-making.

Barbara Meredith is project manager for the Patient and Public Involvement Programme at the National Institute for Health and Clinical Excellence (NICE) since 2003. Barbara has previously worked in health and social care policy at Age Concern England, Age Concern London and the National Consumer Council. She chaired the Patients Forum and the Department of Health working group on copying letters to patients. She is the author of 'The Community Care Handbook' and joint author with Jane Lewis of 'Daughters Who Care', and has a particular interest in the role of guidelines in helping to ensure patients and carers have a full and informed say in their health and social care. Barbara.meredith@nice.org.uk, +44 (0)20 7045 2053

Carol Sakala is director of programs at Childbirth Connection, a national USA, not-for-profit organisation that works to improve the quality and value of maternity care through consumer engagement and health system transformation. Childbirth Connection brings perspectives of childbearing women and families to policy and quality deliberations, including through their national *Listening to Mothers* surveys, and supports the involvement of others in such work. Carol works across the continuum of clinical effectiveness activities, including systematic reviews, performance measures, clinical practice guidelines and patient decision aids. She is a member of the G-I-N PUBLIC Working Group Steering Committee.

Corinna Schaefer is co-Chair of the Guidelines International Network for Patient and Public Involvement Working Group (G-I-N PUBLIC) and head of the department for patient information and patient involvement at the German Agency for Quality in Medicine (ÄZQ). She coordinates patient involvement within the German National Disease Management Guidelines Program and develops patient versions of evidence-based clinical practice guidelines. She is member of two national working groups aimed at quality improvement for patient information in Germany.

Victoria Thomas is associate director of the Patient and Public Involvement Programme at NICE where she has worked since 2001. Following a degree in Art History, Victoria has worked exclusively in the public and voluntary sector, specialising, since 1995, in health care quality improvement activities and in patient and public involvement. Victoria's MSc, in Science and Society, concentrated on issues of science communication, science and the public, and an evaluation of lay people's engagement with evidence-based health care initiatives. Victoria has an interest in shared decision-making, in particular the role of national clinical guidelines as the basis of informed decision-making by both patient and clinician. victoria.thomas@nice.org.uk, +44 (0)20 7045 2052

Sara Twaddle is a health services researcher and health economist by background. She has been director of SIGN since 2003 and from 2008–2010 she was the Chair of the Guidelines International Network.

Helen Tyrrell is a public partner with the Scottish Intercollegiate Guidelines Network (SIGN). Holding a master's degree in Public Health (MPH), Helen has worked in academic research, for the NHS and for many years in the non-governmental organisation (NGO) sector. Here, she led the national umbrella body for health-focused NGOs in Scotland, which has a brief, among others, to promote effective patient and public involvement in health services. Recently Helen completed an enquiry for SIGN into patient and public awareness of SIGN guidelines and of their value in health care improvement.

Trudy van der Weijden is full professor of Implementation of Clinical Practice Guidelines at the School for Public Health and Primary Care (CAPHRI) at Maastricht University, department of General Practice (www.caphri.nl/page_person.aspx?id=37&persid=24). She received her medical degree in 1989, certified as epidemiologist and defended her thesis 'Implementation of the Cholesterol Clinical Practice Guideline in General Practice' in 1997, for which she received the CaRe Award 1997, the dissertation award of the Netherlands School of Primary Care. In 2011 she chaired the International Conference on Shared Decision Making in Maastricht.

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 you 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 guideline developers have a need for practical advice on developing effective patient and public involvement programs,[1] clarified needs and expectations regarding such advice,[2] 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 members[4-7] 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 journals[11-13] 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 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). And as experience, literature and methodology continue to evolve (especially of the evaluation of PPI[27]), existing chapters can be updated, and new topics can be added.

Acknowledgements

August 2012

G-I-N PUBLIC Steering Committee

Loes Knaapen
Corinna Schaefer
Antoine Boivin
Sarah Chalmers
Carrie M. Davino-Ramaya
Javier Gracia
Rich Rosenfeld
Anne Hilde Røsvik
Carol Sakala
Helen Tyrrell
Madeleine Wang
Trudy van der Weijden

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.

References

[1] Boivin A, Currie K, Fervers B, Gracia J, James M, Marshall C, Sakala C, Sanger S, Strid J, Thomas V, van der Weijden T, Grol R, Burgers J. (2010) Patient and public involvement in clinical guidelines: international experiences and future perspectives. *Qual Saf Health Care*. Apr 27.

[2] Boivin A, Légaré F, van der Weijden T, Pakenham C, Burgers J. (2009) What tools in the toolbox? Supporting effective patient and public involvement in guidelines. *Acta Med Port* 1-4;22(5):64-5.

[3] Boivin A, van der Weijden T, Dickersin K, Sakala C, Thomas V, Nix M, Pinsonneault L, Chalmers S, Cowl S, Browman G, Burgers J. (2010) Interested but challenged by patient and public involvement? Practical ways to develop high quality patient-oriented guidelines. Guidelines International Network Preconference Workshop; Chicago, Aug 28.

[4] Légaré F, Boivin A, van der Weijden T, Pakenham C, Tapp S, Burgers J. (2009) A knowledge synthesis of patient and public involvement in clinical practice guidelines: study protocol. *Implement Sci* ;4(3).

[5] Légaré, F, Boivin, A., van der Weijden, T., Pakenham, C., Burgers, J., Légaré, J., St-Jacques, S. Gagnon, S. (2011) Patient and Public Involvement in Clinical Practice Guidelines: Knowledge Synthesis of Existing Programs. *Med Decis Making* 31(6):E45-74.

[6] van der Weijden T, Légaré F, Boivin A, et al. (2010) How to integrate individual patient values and preferences in clinical practice guidelines? A research protocol. *Implement Sci*.;5:10.

[7] Díaz del Campo, P., Gracia, J., Blasco, J.A. & Andradas, E. (2011) A strategy for patient involvement in clinical practice guidelines: methodological approaches. *BMJ Qual Saf* 20(9):779-84.

[8] AGREE Collaboration. (2003) Development and validation of an international appraisal instrument for assessing the quality of clinical practice guidelines: the AGREE project. *Qual Saf Health Care*. 12(1):18-23.

[9] Institute of Medicine (2011) Clinical Practice Guidelines We Can Trust. Washington, DC: National Academies Press. Accessed at http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx.

[10] Schunemann, H. J., Fretheim, A. & Oxman, A. D. (2006) 'Improving the use of research evidence in guideline development: 10. Integrating values and consumer involvement'.*Health Res Policy Syst,* 4**,** 22.

[11] Krahn, M. & Naglie, G. (2008) The next step in guideline development: incorporating patient preferences. *JAMA,* 300**,** 436-8.

[12] Murphy, J. F. (2008) Paternalism or partnership: clinical practice guidelines and patient preferences. *Ir Med J,* 101**,** 232.

[13] Boivin, A and Légaré, F. (2007) Public involvement in guideline production. Letter. *CMAJ* 176(9)1308-9.

[14] Bastian H. (1996) Raising the standard: practice guidelines and consumer participation. *Int J Qual Health Care* 8:485e90.

[15] Chong C, Chen I, Naglie C, Krahn M. Do clinical practice guidelines incorporate evidence on patient preferences? *Med Dec Making* 2007;27:E63-4.

[16] Boivin, A., Green, J., van der Meulen, J., Légaré, F. and Nolte, E. (2009) Why Consider Patients' Preferences? A Discourse Analysis of Clinical Practice Guideline Developers. *Med Care* 47:908–15.

[17] Greer, A. L., Goodwin, J. S., Freeman, J. L., & Wu, Z. H. (2002). Bringing the patient back in. Guidelines, practice variations, and the social context of medical practice. *Int J Technol Assess Health Care, 18*(4), 747-761.

[18] McCormack JP, Loewen P. (2007) Adding 'value' to clinical practice guidelines. *Can Fam Physician*; 53:1326e7.

[19] Van Wersch A, Eccles M. (2001) Involvement of consumers in the development of evidence based clinical guidelines: practical experiences from the North of England evidence based guideline development programme. *Qual Health Care* 10(1):10-6.

[20] Kelson, M. (2001) Patient involvement in clinical guideline development - where are we now? *Journal of Clinical Governance* 9: 169-74.

[21] Wait, S., & Nolte, E. (2006). Public involvement policies in health: exploring their conceptual basis. *Health Economics, Policy and Law*, 1(02), 149-162.

[22] Jordan, Z., & Court, A. (2010). Reconstructing consumer participation in evidence-based health care: a polemic. *International Journal of Consumer Studies*, 34(5), 558-561.

[23] Florin, D. & J. Dixon (2004) Public involvement in health care, *BMJ* 328:159–161.

[24] Tritter, J.Q. (2009) Revolution or evolution: the challenges of conceptualizing patient and public involvement in a consumerist world. *Health Expect.*12:275-87.

[25] Tambuyzer E, Pieters G, Van Audenhove C. (2011) Patient involvement in mental health care: one size does not fit all. *Health Expect*. doi: 10.1111/j.1369-7625.2011.00743.x.

[26] Field MJ, Lohr KN (eds.) (1992) Guidelines for Clinical Practice: From Development to Use. Washington, DC: National Academy Press.

[27] van de Bovenkamp HM, Trappenburg MJ. Reconsidering patient participation in guideline development. *Health Care Anal* 2009;17:198e216.

G-I-N PUBLIC toolkit introduction

Author: Antoine Boivin*

*Corresponding author: Antoine.Boivin@usherbrooke.ca

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

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

- Introducing the main involvement strategies discussed in the toolkit

- Helping you identify the strategy that best fits your needs.

Three involvement strategies: consultation, participation, and communication

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

- **Consultation** strategies involve the collection of information *from* patients and the public. This can include methods such as surveys, focus groups, individual interviews, online consultation, the use of primary research on patients' needs and expectations, or the use of a systematic review of studies on patients' and the public's perspective.

- **Participation** involves the *exchange* of information between guideline developers and the public. This can be done through participation of patient and public representatives on guideline development groups and other methods.[5]

- **Communication** strategies involve the communication of information *to* patients and the public to support their individual health care decisions and choices. This can include the production of plain language versions of 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 *from* patients and the public)	• Collect information from a large group of people • Possible to collect data from a variety of perspectives and from groups that are harder to involve in participation methods	• Open (online) consultation on guideline scope and topic • Comments on draft guideline • Focus groups, individual interviews, or surveys of patients' experience of care • Literature review of existing qualitative and quantitative research on patients' needs and expectations	Chapter 1
Participation (information is exchanged *between* the public and other guideline developers)	• Foster *mutual learning* and agreement between the public and other experts • Facilitate compromise and consensus on collective decisions about guideline recommendations, content, and process	• Patient or public participation in guideline development group to foster deliberation with other guideline developers	Chapters 2, 3
Communication (information is communicated *to* patients and the public)	• Inform patients and the public about professional standards • Support individual health care decisions and choices among different health options	• Publish patient version of guideline and patient education material • Production of patient decision aids	Chapters 4, 5, 6

References

[1] Boivin A, Green J, van der Meulen J, Légaré F, Nolte E. Why consider patients' preferences? A discourse analysis of clinical practice guideline developers. *Medical Care*. 2009;47:908-15.

[2] Boivin A, Currie K, Fervers B, Gracia J, James M, Marshall C, et al. Patient and public involvement in clinical guidelines: international experiences and future perspectives. *Qual Saf Health Care.* 2010;19:e22.

[3] Legare F, Boivin A, van der Weijden T, Pakenham C, Burgers J, Legare J, et al. Patient and Public Involvement in Clinical Practice Guidelines: A Knowledge Synthesis of Existing Programs. *Med Decis Making.* 2011;31:E45-74.

[4] Rowe G, Frewer LJ. A Typology of Public Engagement Mechanisms.*Science, Technology & Human Values.* 2005;30:251.

[5] Slokum N. Participatory methods toolkit: A practitioner's manual: King Baudouin Foundation. 2003. p.

[6] Abelson J, Forest PG, Eyles J, Smith P, Martin E, Gauvin FP. Deliberations about deliberative methods: issues in the design and evaluation of public participation processes. *Soc Sci Med.* 2003;57:239-51.

[7] van der Weijden T, Boivin A, Burgers J, Schunemann HJ, Elwyn G. Clinical practice guidelines and patient decision aids. An inevitable relationship. *J Clin Epidemiol*. 2012;In Press.

[8] O'Connor AM, Bennett CL, Stacey D, Barry M, Col NF, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev. 2009:CD001431.

[9] Diaz Del Campo P, Gracia J, Blasco JA, Andradas E. A strategy for patient involvement in clinical practice guidelines: methodological approaches. *BMJ quality & safety*.[Research Support, Non-U.S. Gov't]. 2011;20:779-84.

[10] Crawford MJ, Rutter D, Manley C, Weaver T, Bhui K, Fulop N, et al. Systematic review of involving patients in the planning and development of health care. *BMJ*. 2002;325:1263-.

[11] Boivin A, Lehoux P, Lacombe R, Lacasse A, Burgers J, Grol R. Target for Improvement: A cluster randomized trial of public involvement in quality Indicator prioritization (intervention development and study protocol). *Implement Sci.* 2011;6:45.

Chapter 1: How to conduct public and targeted consultation

Authors: Jane Cowl,* Helen Tyrrell, Carol Sakala, Javier Gracia and Nancy Huang
*Corresponding author: Jane.Cowl@nice.org.uk

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 al[1] 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 NICE[2] 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 Medicine[5] 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, NICE[2] 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

---

[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'.

- Obtain declarations of interest from any individual expert reviewers, including identification of sources of funding or support in kind for patient organisations

- Ensure that the final decisions in responding to feedback are in accordance with the guideline development group's ongoing decision-making processes

- List comments in a table with guideline developers' responses

- Make comments and responses publicly available, or at least a summary available on request

- Document the consultation process that was followed and make it publicly available

- Consider evaluating whether and how the consultation process adds value to the guideline

- Consider evaluating the particular contribution of patient/public respondents.

Consulting individual patients and members of the public using research techniques

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

- Important gaps in the evidence base

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

- Gaps in membership of the guideline development group in terms of patients' perspectives, for example, for guidelines covering children or people with learning (developmental) disabilities

- Information on the perspectives of 'seldom heard' patients who are not part of an organised group or who don't have an organisation to advocate for them, or potentially excluded groups such as people from certain minority cultures or ethnic groups.

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

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

Connection surveys are developed in concert with multi-stakeholder National Advisory Councils, including consumer representatives.[b]

Case Studies

NICE in the UK

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

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

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

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

---

[b] www.childbirthconnection.org/listeningtomothers/.

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

Key messages of this chapter

- Consultation processes should always involve patients and carers and/or organisations representing their interests, as well as health professional stakeholders

- Effective consultation with patients, members of the public and advocates adds value to the process of guideline development and can help support use of the guideline in practice, leading to more effective care

- Best practice requires transparent and inclusive consultation

- Consultation can be conducted at all key stages of the guideline development process, including the scoping, development, draft review, implementation, and updating stages

- A diversity of methods, individuals and organisations are likely to be needed to capture the full range of relevant patient and public issues and perspectives

- Consultation requires additional time and resources, which need to be factored in from the start; in standard consultation processes (such as feedback on draft scoping documents and draft guidelines), patient and public consultation can occur simultaneously with professional consultation.

References

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

[2] National Institute for Health and Clinical Excellence (NICE) (2011) Process manual for accrediting producers of guidance, advice and recommendations for practice: a guide for producers and stakeholders. Available from: https://www.evidence.nhs.uk/accreditation/accreditation-process.

[3] The AGREE Collaboration. Brouwers M, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, et al for the AGREE Next Steps Consortium (2010) AGREE II: Advancing guideline development, reporting and evaluation in healthcare. *Canadian Medical Association Journal*.

[4] National Health Medical Research Council (2011) Procedures and requirements for meeting the NHMRC standard for clinical practice guidelines; v1.1. Available from: http://www.nhmrc.gov.au/guidelines/publications/cp133-and-cp133a.

[5] Institute of Medicine (2011) Clinical practice guidelines we can trust: Standards for developing trustworthy clinical practice guidelines. Available from: http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust/Standards.aspx.

[6] National Institute for Health and Clinical Excellence [NICE] (2009a) The guidelines manual. Available from: http://www.nice.org.uk/aboutnice/howwework/developingniceclinicalguidelines/clinicalguidelinedevelopment methods/GuidelinesManual2009.jsp.

[7] National Institute for Health and Clinical Excellence (NICE) (2009b) Fact sheet 2: How organisations representing patients and carers can get involved. Available from: http://www.nice.org.uk/getinvolved/patientandpublicinvolvement/FactsheetsContributingToNICEClinicalGuidelines.jsp.

[8] Scottish Intercollegiate Guidelines Network (2008) SIGN 100: A handbook for patient and carer representatives. Available from: http://www.sign.ac.uk/patients/publications/100/index.html.

[9] Scottish Intercollegiate Guidelines Network (2011) SIGN 50: A guideline developer's handbook. Revised edition. Available from: http://www.sign.ac.uk/guidelines/fulltext/50/index.html.

[10] Grupo de trabajo sobre GPC (2007) Elaboración de Guías de Práctica Clínica en el Sistema Nacional de Salud. Manual Metodológico. Madrid: Plan Nacional para el SNS del MSC. Instituto Aragonés de Ciencias de la Salud-I+CS. Guías de Práctica Clínica en el SNS*: I+CS Nº 2006/0I. Available from: http://portal.guiasalud.es/web/guest/metodologia-gpc).

[11] Díaz del Campo P, Gracia J, et al (2011) A strategy for patient involvement in clinical practice guidelines: methodological approaches. *BMJ Quality & Safety* 20:779-784.

Chapter 2: How to recruit and support patients and the public in guideline development

Authors: Sarah Chalmers Page,* Jane Cowl and Loes Knaapen

*Corresponding author: Sarah.Chalmers-Page@nice.org.uk

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	• Allows wider range of people to select from • Allows selection of people who 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 • 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	• Fast • Can use patients with existing relationship with medical professionals on group—group formation may be easier, although this can also lead to power imbalances • Can use patients with known background in user-led research • Can use patients with a known ability to work well in committee situations

	Open Recruitment	**Nomination**
Disadvantages	• 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	• 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 Center[4] 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 glossary[8] and series of information resources on evidence-based medicine[9] 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

National Institute for Health and Clinical Excellence [NICE] (2009) The guidelines manual. Available from: http://www.nice.org.uk/aboutnice/howwework/developingniceclinicalguidelines/clinicalguidelinedevelopmentmethods/GuidelinesManual2009.jsp.

National Institute for Health and Clinical Excellence (NICE) (2009) Fact sheets for patients and carers: contributing to a NICE clinical guideline Available from: http://www.nice.org.uk/getinvolved/patientandpublicinvolvement/FactsheetsContributingToNICEClinicalGuidelines.jsp.

Cochrane collaborative consumer online learning.

References

[1] Victoria Thomas. Patient and Carer Involvement in NICE Clinical Guidelines. In Littlejohns, P and Rawlins, M (eds) *Patients, the Public and Priorities in Health Care*. 2009 Radcliffe: Oxford.

[2] Van Wersch A, Eccles M. (2001) Involvement of consumers in the development of evidence based clinical guidelines: practical experiences from the North of England evidence based guideline development programme. *Qual Health Care* 10(1):10-6.

[3] Involve Payment for Involvement: a guide for making payments to members of the public actively involved in NHS, public health and social care research. Downloaded from http://www.invo.org.uk/pdfs/PaymentGuideWEB240510.pdf 4/8/11.

[4] http://us.cochrane.org/free-online-courses.

[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 3: The role of the Chair in patient and public involvement: training and support

Authors: Victoria Thomas,* Barbara Meredith
*Corresponding author: Victoria.Thomas@nice.org.uk

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 Organization (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 2008[4]), 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 processes[6] 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 2010-2013[7]), 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.

References

[1]NICE Patient and Public Involvement Policy (2012) www.nice.org.uk/getinvolved/patientandpublicinvolvement/patientandpublicinvolvementpolicy/patient_and_public_involvement_policy.jsp.

[2]World Health Organization. Clinical guidelines programme of the National Institute for Health and Clinical Excellence (NICE): a review by the World Health Organization, [http://www.euro.who.int/en/home]. 2006. Available from: http://www.euro.who.int/__data/assets/pdf_file/0003/96447/E89740.pdf.

[3]Patient Involvement Unit.A report on a study to evaluate patient/carer membership of the first NICE Guideline Development Groups. [http://www.nice.org.uk]. 2004. Available from: http://www.nice.org.uk/niceMedia/pdf/PIU_Evaluation_report_270704.pdf.

[4]Thomas, V. Involving patients and carers in developing clinical guidelines: an evaluation–summary. [http://ww.nice.org.uk] . 2008. Available from: http://www.nice.org.uk/media/865/EB/2008EvaluationSummaryFindings.pdf.

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

[6]NICE Revised Equality Scheme 2010-2013 www.nice.org.uk/aboutnice/howwework/niceequalityscheme.jsp?domedia=1&mid=9531E7FC-19B9-E0B5-D4A3CC036ABED5AE.

[7]NICE (2009) The Guidelines Manual. National Institute for Health and Clinical Excellence. http://www.nice.org.uk/aboutnice/howwework/developingniceclinicalguidelines/clinicalguidelinedevelopment methods/GuidelinesManual2009.jsp (accessed 4th April 2012).

[8]Cartwright J & Crowe S. Patient & Public Involvement Toolkit. Wiley-Blackwell/BMJ Books. 2011. pp60-77.

[9]TwoCan Associates for the UKCRC and NCRI. Patient and public involvement (PPI) in research groups – Guidance for Chairs. [http://www.twocanassociates.co.uk]. 2010. Available from: http://www.twocanassociates.co.uk/pubs.php.

Acknowledgements

Appendix 3.1

Sample guideline development group Chairs' induction session—NICE

NHS
National Institute for
Health and Clinical Excellence

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 3.2

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

4

NHS
National Institute for
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

NHS
National Institute for
Health and Clinical Excellence

5

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.[1-6] Some of these definitions have been further developed, operationalised and validated as instruments for assessing the quality of patient information or patient decision aids.[1-3] 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:

Ways of development	How?	Who?
Joint editing of patients/consumers and clinicians	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'
Peer review	Patient versions may be produced by clinicians, medical societies or organisations that have developed the CPG The draft is reviewed by patient and/or consumer representatives Patient versions may also be produced by patient or consumer organisations and reviewed by clinicians that have developed the CPG	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.[7-10] It is known, that communicating relative risk reduction leads to the overestimation of treatment or screening effects.[11] 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'.[12]

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.[13,14] 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*   } *Guideline recommendations*

- *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

References

[1] http://www.discern.org.uk/.

[2] http://www.discern-genetics.org/.

[3] http://www.ipdasi.org/.

[4] Klemperer D, Lang B, Koch K et al. Gute Praxis Gesundheitsinformation. Available from: http://www.ebm-netzwerk.de/grundlagen/images/gpgi.pdf.

[5] Bunge B, Mühlhauser I, Steckelberg A. What constitutes of evidence based patient information. An overview of discussed criteria. *Patient Educ Couns* (2009), doi:10.1016/j.pec.2009.10.029.

[6] Ärztliches Zentrum für Qualität in der Medizin (ÄZQ). Manual Patienteninformation – Empfehlungen zur Erstellung evidenzbasierter Patienteninformationen. Berlin: ÄZQ; 2006. Available from: http://www.aezq.de/mdb/edocs/pdf/schriftenreihe/schriftenreihe25.pdf.

[7] FDA. Communicating Risks and Benefits: An Evidence-Based User's Guide. http://www.nsuhr.net/?p=380.

[8] Woloshin S, Schwartz LM, Welch GH. Know Your Chances: Understanding Health Statistics. Berkeley, Calif.: Univ. of Calif. Pr.; 2008.

[9] Imogen E, Thornton H, Chalmers I. Testing Treatments. London: Pinter & Martin; 2010.

[10] Making Numbers meaningful: What is 'Number needed to treat' and how can it be used to inform healthcare decisions? *Insight and Action* 2009;50.

[11] Wegwarth O, Gigerenzer G (2011). Statistical Illiteracy in Doctors. Gigerenzer G, Muir Gray JA (Eds): Better Doctors, better Patients, better Decisions. Strüngmann Forum Reports. Cambridge & London 2011.

[12] Gøtzsche PC, Nielsen M.Screening for breast cancer with mammography. Cochrane Database Syst Rev. 2011 Jan 19;(1):CD001877.

[13] Bostock S, Steptoe A (2012). Association between low functional health literacy and mortality in older adults: longitudinal cohort study. *BMJ* 2012;344:e1602.

[14] Berkman ND, Sheridan SL, Donahue KE et al. Low health literacy and health outcomes: an updated systematic review. *Ann Intern Med.* 2011 Jul 19;155(2):97-107.

Chapter 5: How to involve patients and the public in dissemination and implementation of guidelines

Authors: Karen Graham,* Sara Twaddle, Carrie M. Davino-Ramaya and Loes Knaapen
*Corresponding author: Karen.Graham2@nhs.net

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. i*mplementation* 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 in 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 development. 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.

References

National Institute for Clinical Excellence. Involving patients and the public in implementing NICE guidance. London: NICE. Available at http://www.nice.org.uk/usingguidance/benefitsofimplementation/involving_patients_and_the_public_in_implementing_nice_guidance.jsp (accessed 9th August 2011).

Thomas, V. (2010).Patient and voluntary organisation support for implementing NICE guidance. In Littlejohns, P, Rawlings, M.(eds.) Patients, the public and priorities in healthcare. London, Radcliff publishing. (pp. 57-63).

Acknowledgements

Appendix 5.1

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 5.2

Healthcare Improvement Scotland

SIGN
Scottish Intercollegiate Guidelines Network

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:

Address:

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 5.3

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 6: How guidelines can support patient involvement in the clinic

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 talk[8]

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

Initial preferences ──────────────→ Informed preferences

Choice Talk   Option Talk   Decision Talk   → **DECISION**
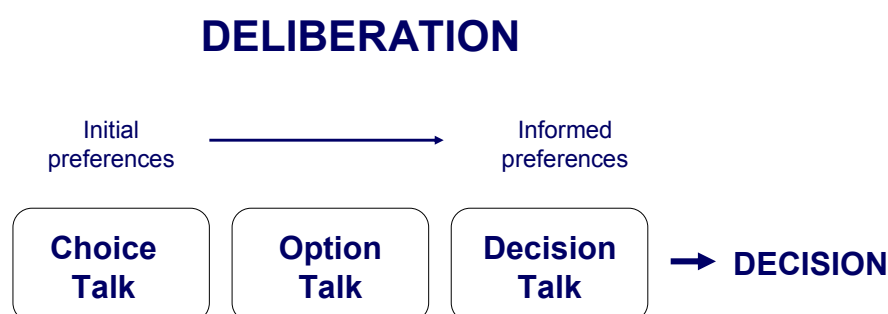
Decision support may be needed in the option talk phase and can be designed in two formats: 1) brief enough to be used by patient and clinician together, and 2) more extensive, designed to be used by patients either before or after clinical encounters. 'Patient decision aids' is a term commonly used 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)
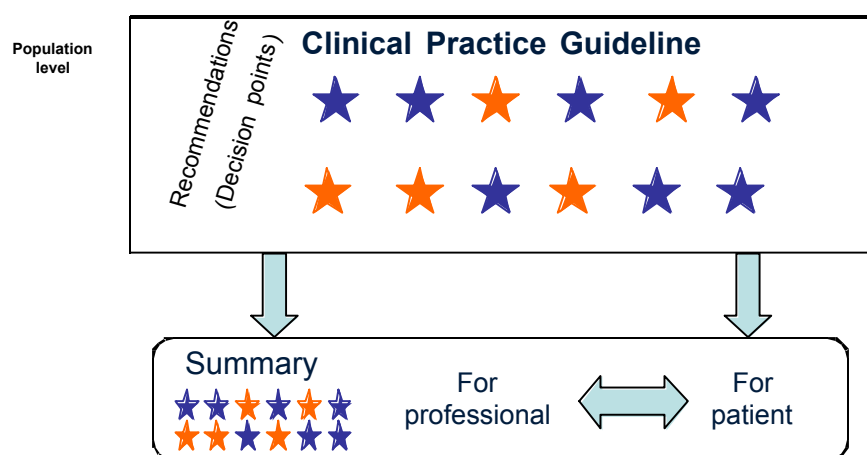

Patient decision aids are usually organised around one decision point. The format may range from printed fact sheets to be discussed during a consultation to tools that patients need to study before the consultation, such as paper booklets, computerised CD-ROMs, videos, or interactive websites.

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.
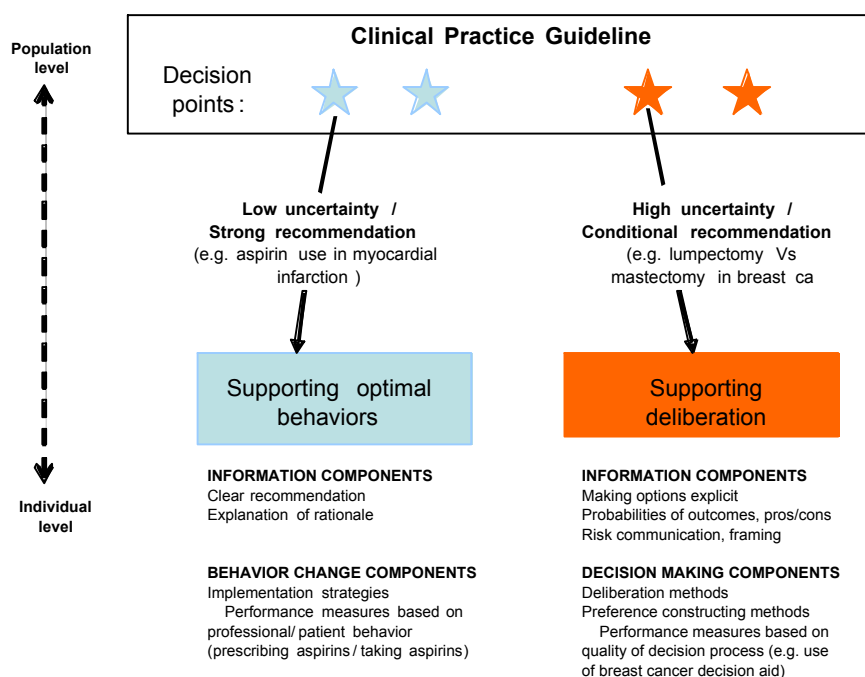
How can clinical practice guidelines support shared decision-making?

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, co-morbidity), 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.

Izquierdo F, Gracia J et al. Health Technology Assessment for a Patient Decision Aids in Breast Cancer. *International Journal of Technology Assessment in Health Care* 2011.

References

[1] Barry MJ, Edgman-Levitan S. Shared Decision Making — The Pinnacle of Patient-Centered Care. *N Engl J Med* 2012;366:780-1.

[2] Brouwers M SD, O'Connor A. Knowledge creation: synthesis, tools and products. *CMAJ* 2010;182 (2):E68-72.

[3] Editorial. Guiding the guidelines. *Lancet* 2011;377:1125.

[4] Elwyn G, Frosch D, A. V, Edwards A, Montori V. Investing in deliberation: a definition and classification of decision support interventions for people facing difficult decisions. *Med Dec Mak* 2010;30:701-11.

[5] Guyatt GH, Oxman AD, Kunz R, Falck-Ytter Y, Vist GE, Liberati A, et al. Going from evidence to recommendations. *BMJ* 2008;336:1049-51.

[6] van der Weijden T, Legare F, Boivin A, Burgers JS, van Veenendaal H, Stiggelbout AM, et al. How to integrate individual patient values and preferences in clinical practice guidelines? A research protocol. *Implement Sci* 2010;5:10.

[7] Van der Weijden T, Boivin A, Burgers J, Schünemann HJ, Elwyn G. Clinical practice guidelines and patient decision aids. An inevitable relationship. *J Clin Epid* 2012 Jan 31. [Epub ahead of print].

[8] Elwyn G, Frosch D, Thomson R, Joseph-Williams N, Lloyd A, Kinnersley P, Cording E, Tomson D, Dodd C, Rollnick S, Edwards A, Barry M. Shared decision making. A model for clinical practice. *J Gen Int Med* 2012; May 23 online [Epub ahead of print].