

Appendix N: Guide to the short clinical guideline process

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Foreword

This appendix describes the process by which short clinical guidelines are developed. It should be read in conjunction with the rest of 'The guidelines manual' (2009) and, where relevant, with the other NICE documents on contributing to an individual clinical guideline:

- How NICE clinical guidelines are developed: an overview for stakeholders, the public and the NHS
- A guide for patients and carers: contributing to a NICE clinical guideline

1 Introduction

- 1.1 Short clinical guidelines are clinical guidelines that address only part of a care pathway. They are intended to allow the rapid (11–13-month timescale) development of guidance on aspects of care for which the NHS requires urgent advice. This document sets out the process, including timelines, that the National Institute for Health and Clinical Excellence (NICE) follows when developing a short clinical guideline. It describes an open and transparent process designed to achieve robust guidance for the NHS. The document provides guidance for organisations that are invited to contribute to short clinical guidelines, and has been developed to inform consultees and stakeholders and to facilitate their comments on this work programme.
- 1.2 The document highlights the key differences in the development process for short clinical guidelines compared with that for standard clinical guidelines. The latter is outlined in the chapters of ‘The guidelines manual’ and in ‘How NICE clinical guidelines are developed: an overview for stakeholders, the public and the NHS’ (appendix O). Cross-referral is made to the relevant sections of ‘The guidelines manual’.
- 1.3 Each short clinical guideline is developed by an independent Guideline Development Group (GDG) supported by a technical team based within NICE (the Short Clinical Guidelines Team). This technical team is constituted in the same way and undertakes the same functions as the established National Collaborating Centre (NCC) technical teams. The Short Clinical Guidelines Team does not have voting rights on recommendations made by the GDG. The development and quality assurance of short clinical guidelines is overseen by a Guidelines Commissioning Manager, the Director of the Centre for Clinical Practice and an Executive Lead at NICE.
- 1.4 Occasionally, a short clinical guideline may be externally commissioned by NICE from one of the NCCs; this is decided on a case-by-case basis.

2 The short clinical guideline process

2.1 Overview

- 2.1.1 The short clinical guideline process consists of four phases:
1. Referral of the topic to NICE by the Department of Health.
 2. Scoping the short clinical guideline.
 3. Development of the short clinical guideline. This begins with the first meeting of the GDG and ends when the draft guideline is submitted for stakeholder consultation.

4. Consultation and publication. This consists of consultation with stakeholders on the draft guideline, revising the guideline in the light of comments received during consultation, receiving advice from the Guideline Review Panel and expert reviewers, preparation of the final draft, carrying out the pre-publication check, sign off by NICE's Guidance Executive and publication.

2.1.2 Each phase of the short guidelines process (topic selection, drafting of and consultation on the scope, development of the short clinical guideline, and consultation and publication) follows the principles set out in 'Social value judgements: principles for the development of NICE guidance (2nd edition)',¹ and NICE's 'Equality scheme and action plan 2007–2010'.² These are taken into account when developing the remit and scope and defining the population and management areas to be covered by the guideline; identifying stakeholders and GDG members; developing the review questions; identifying, reviewing and appraising the evidence; developing the recommendations; and producing the guideline publications.

2.1.3 The total time from topic referral to publication is between 11 and 13 months, depending on the length of the development phase. Figure N1 sets out the timeline in more detail.

¹ www.nice.org.uk/aboutnice/howwework/socialvaluejudgements/socialvaluejudgements.jsp

² www.nice.org.uk/aboutnice/howwework/NICEEqualityScheme.jsp

Figure N1 Short clinical guideline process timeline

Phase	Action	Time taken (weeks)	Elapsed time from initiation of process (weeks)
1 Topic referral			
2 Scoping	Registration of stakeholders and invitations to scoping workshop	0	0
	Short Clinical Guidelines Team to draft scope and key clinical issues based on scoping searches	5	5
	Stakeholder scoping workshop	3	8
	Scope revised after workshop	1	9
	Advertisement and appointment of GDG members		13
	Public consultation on scope	4	13
	Scope revised and signed off	2	15
	Final scope available on web	1	16
3 Development	Development of guideline	16–26	32–42
4 Consultation and publication	Public consultation on guideline (including 1 week for editing)	4+1	37–47
	Guideline revised	3	40–50
	Review by Guideline Review Panel	1	41–51
	Pre-publication check	2	42–53
	Guidance Executive sign off	1	44–54
	Total		

2.2 Phase 1 – referral of topic

2.2.1 Topics are referred to NICE by the Department of Health (for more details on the topic selection process, see the NICE website³). The criteria for the referral to NICE should include both suitability for a short clinical guideline and a judgement about the urgency of the requirement for the advice. The Department of Health is responsible for identifying topics for the short clinical guideline process; proposals for topics may be put forward by the topic selection consideration panels.

2.3 Phase 2 – scoping the short clinical guideline

2.3.1 Drafting the scope

2.3.1.1 A draft scope, which defines the areas the guideline will and will not cover, is prepared by the Short Clinical Guidelines Team. It is based on the remit from the Department of Health, input from relevant experts, patients and carers, and a preliminary search of the literature to identify existing clinical practice guidelines, key systematic reviews and other relevant publications. The literature search facilitates an overview of the issues likely to be covered by the guideline – the clinical need for the guideline and the clinical management of the condition – and helps define key clinical issues. It also informs the Short Clinical Guidelines Team of the volume of literature likely to be available in the topic area, and therefore the amount of work required. The draft scope is tightly focused, covering a small number of key clinical issues.

2.3.1.2 **Comparison with the standard clinical guideline process.** The process for drafting the scope broadly follows that outlined for standard clinical guidelines (see chapter 2 of 'The guidelines manual').

2.3.2 The scope consultation process

2.3.2.1 Stakeholders are invited to register at the time of formal referral of the guideline topic by the Department of Health. Contact with stakeholders is important to ensure that they are included in the development of the guideline and support it.

2.3.2.2 The draft scope is presented at a stakeholder scoping workshop to a relevant group of stakeholders and professional groups. Attendees are identified in two ways: firstly, by inviting all registered stakeholder organisations to offer suggestions of possible workshop attendees; and secondly, by the Short Clinical Guidelines Team identifying key individuals who are active in the topic area in the UK. One person from each registered stakeholder organisation may attend. The scoping search is used to identify UK-based individuals who have led on recent national published guidelines

³ www.nice.org.uk/aboutnice/howwework/howguidancetopicsarechosen

and/or recent key reviews in the topic area. Workshop attendees, including representatives of relevant patient and carer organisations, should have specific knowledge or experience in the topic area. The workshop consists of presentations and tightly facilitated parallel-running working groups. The aim is to obtain detailed feedback on the draft scope and agree core areas of care to be covered in the guideline, to seek input about the composition of the GDG and to raise awareness that NICE is publicly advertising for applications for GDG membership.

2.3.2.3 The draft scope is amended to address and/or include issues raised in the workshop. The scope is then subject to a 4-week consultation with stakeholders. Stakeholder comments are reviewed by the Short Clinical Guidelines Team, the GDG Chair and the Clinical Adviser (if one is appointed; see section 2.4.1.1). A revised scope is prepared, which is reviewed by the Guideline Review Panel (GRP). The GRP considers whether stakeholders' comments have been appropriately and adequately addressed by the developers, and the GRP Chair then prepares a report. Subject to any amendments agreed by NICE as a result of the Chair's report, the revised scope is signed off by the Director of the Centre for Clinical Practice at NICE. Stakeholders are notified once the final version of the scope is available on the NICE website.

2.3.2.4 **Comparison with the standard clinical guideline process.** The process for consulting on the scope follows that outlined for standard clinical guidelines (see chapter 2 of 'The guidelines manual').

2.4 Phase 3 – development of the short clinical guideline

2.4.1 Forming and running the short clinical guideline GDG

2.4.1.1 Each short clinical guideline is developed by a unique GDG consisting of 10–12 members, supported by the Short Clinical Guidelines Team. Each GDG has a Chair, healthcare professional members and a minimum of two patient and carer members. Co-opted expert advisers are recruited, as appropriate. A Clinical Adviser, who has specific content expertise and additional responsibilities, may also be appointed depending on the topic. Recruitment of the GDG Chair and members is carried out in accordance with NICE's policy 'Appointments to guidance producing bodies advisory to NICE' (November 2006)⁴. Development of the guideline takes 4–6 months and the GDG meets approximately every 4–6 weeks.

2.4.1.2 NICE reserves the option of selecting the GDG Chair and some members for a short clinical guideline from a pool of suitable members. This pool will be recruited through a formal

⁴ Available from: www.nice.org.uk/384476

advertisement and recruitment process to act as standing members for each guideline. They will be appointed on 3-year rolling contracts. Healthcare professional members and patient and carer members will be recruited using the standard process. The pool will consist of the following: a) experienced Chairs and b) methodological experts, such as epidemiologists, statisticians and health economists. This option will help foster consistency between the approaches taken with different topics, and will be a more efficient way of setting up GDGs. The system of a unique GDG for every guideline is resource intensive. There is also the risk of ineffective group working, given that the short timeframe requires the GDG to perform as a small group immediately.

2.4.1.3 The GDG makes its decisions using the best available evidence presented to it at GDG meetings by the Short Clinical Guidelines Team. The use of formal consensus methods within the GDG will be considered on a case-by-case basis (see section 3.5 of 'The guidelines manual'). However, formal consensus methods that seek the views of groups outside the GDG are unlikely to be used in the short clinical guideline process because of the short timeframe.

2.4.1.4 **Comparison with the standard clinical guideline process.** The process of forming and running the GDG outlined in section 2.4.1.1 is consistent with that for the standard clinical guideline programme (see chapter 3 of 'The guidelines manual'). However, the guideline development time is 4–6 months compared with up to 18 months in the standard process. The process outlined in section 2.4.1.2 is an adaptation of standard methods.

2.4.2 Developing review questions

2.4.2.1 A short clinical guideline has a narrow scope and covers only part of a care pathway. It addresses a maximum of three subject areas covering clinical management. This will result in a small number of key clinical issues (listed in the scope). These are broken down into a defined number of review questions – usually one or two per clinical management area. The exact number will be dictated by the size of the short clinical guideline remit and the amount of development time available. As with the standard clinical guideline programme, it is feasible to present a maximum of two systematic reviews at any one GDG meeting. These review questions are formulated and structured according to the process for standard clinical guidelines (see chapter 4 of 'The guidelines manual').

2.4.2.2 **Comparison with the standard clinical guideline process.** The tightly focused scope and short development phase (4–6 months) mean that between three and six review questions are considered, compared with 15–20 review questions in the standard clinical guideline process.

2.4.3 Identifying the evidence

2.4.3.1 The short clinical guideline process follows the standard process for identifying evidence (see chapter 5 of 'The guidelines manual').

2.4.4 Reviewing the evidence

2.4.4.1 The short clinical guideline process follows the standard process for assessing and summarising the evidence (see chapter 6 of 'The guidelines manual').

2.4.5 Incorporating health economics in the guideline and assessing health-economic impact

2.4.5.1 The short clinical guideline process in general follows the standard process for incorporating health economics in the guideline and assessing health-economic impact (see chapter 7 of 'The guidelines manual'). However, given the short overall timeframe, it will be necessary to consider identifying relevant topics for health-economic analysis during the scoping phase.

2.4.6 Creating guideline recommendations

2.4.6.1 Explicit methods of linking the evidence to recommendations are used for short clinical guidelines if the topic is suitable. This involves using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach, which is also being implemented in the standard clinical guidelines programme (see section 9.1 of 'The guidelines manual').

2.4.6.2 The smaller number of review questions results in a smaller number of guideline recommendations. The number of recommendations in each short clinical guideline is likely to be between 5 and 20. In addition, because there are usually fewer than 20 recommendations, short clinical guidelines do not generally have key priorities for implementation.

2.4.6.3 Research recommendations are formulated for short clinical guidelines. Their number is dependent on the size of the short clinical guideline remit and the amount of development time available.

2.4.6.4 **Comparison with the standard clinical guideline process.** The short clinical guideline process broadly follows the standard process for creating guideline recommendations (see chapter 9 of 'The guidelines manual').

2.4.7 Writing the guideline

2.4.7.1 There are usually three versions of short clinical guidelines:

- The full guideline – all the recommendations, details of how they were developed and summaries of the evidence they are based on.

- The quick reference guide – a summary of the recommendations for healthcare professionals.
- 'Understanding NICE guidance' – a summary for patients and carers.

2.4.7.2 The full guideline is written by the Short Clinical Guidelines Team, following the principles in chapters 9 and 10 of 'The guidelines manual'. The quick reference guide and 'Understanding NICE guidance' are written by NICE editorial staff.

2.4.7.3 In cases where an NCC is commissioned by NICE to develop a short clinical guideline, the full guideline is produced by the NCC. NICE also produces a 'NICE guideline' that contains only the recommendations from the full guideline, without the information on methods and evidence.

2.5 Phase 4 – consultation and publication

- 2.5.1 Following the development of the draft short clinical guideline, there is a 4-week consultation period for registered stakeholders to comment on the draft guideline.
- 2.5.2 The formal expert review process that has been established within the Centre for Clinical Practice for standard clinical guidelines is also used for short clinical guidelines (see section 11.2.2 of 'The guidelines manual').
- 2.5.3 Following consultation with stakeholders, the guideline is revised by the Short Clinical Guidelines Team working in collaboration with the GDG.
- 2.5.4 The revised short clinical guideline is reviewed by one of the existing GRPs, is subject to a pre-publication check of 10 working days, and is then signed off by NICE's Guidance Executive and published.
- 2.5.5 **Comparison with the standard clinical guideline process.** The consultation period for short clinical guidelines is 4 weeks, compared with 8 weeks for standard clinical guidelines. For the pre-publication check, the full guideline is posted on the NICE website for a period of 10 working days for short guidelines, compared with 15 working days for standard guidelines. The Short Clinical Guidelines Team works with the GDG in the same way that the NCCs work with their GDGs (see chapter 11 of 'The guidelines manual').

3 Linking short clinical guidelines to other NICE guidance

- 3.1.1 Short clinical guidelines are linked to other NICE guidance in the same way as standard clinical guidelines (see chapter 8 of 'The guidelines manual').

4 Updating short clinical guidelines

- 4.1 Short clinical guidelines are reviewed for consideration of updating by the Short Clinical Guidelines Team using the process for standard clinical guidelines (see chapter 14 of 'The guidelines manual').