NICE National Institute for Health and Care Excellence

The guidelines manual: appendix M – Guide to the short clinical guideline process

Audit and service improvement

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Contents

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 (2012) 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
- Factsheets for patients and carers about contributing to a NICE clinical guideline, which explain how individual patients and carers, as well as patient organisations, can get involved.

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 stakeholders and to facilitate their comments on this work programme.

1.2 This 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. Cross-references are included to the relevant sections of 'The guidelines manual'.

1.3 Each short clinical guideline is developed by an independent Guideline Development Group (GDG). In most cases the GDG is supported by a technical team within the Internal Clinical Guidelines Programme at NICE. This technical team is constituted in the same way and undertakes the same functions as the established National Collaborating Centre (NCC) technical teams, but it 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 (CCP), a CCP lead for the guideline 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:

- Phase 1 – referral of the topic to NICE by the Department of Health or the NHS Commissioning Board.
- Phase 2 – scoping the short clinical guideline.
- Phase 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.
- Phase 4 – consultation and publication. This consists of consultation with stakeholders on the draft guideline, revision of the guideline in light of comments received during consultation, preparation of the final draft, sign off by NICE's Guidance Executive and publication.

2.1.2 Each phase of the short clinical guideline process (referral, drafting of and consultation on the scope, development of the guideline, and consultation and publication) follows the principles set out in Social value judgements: principles for the development of NICE guidance (2nd edition) and NICE's revised equality scheme 2010–2013. 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 M1 sets out the timeline in more detail.

Figure M1 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 stakeholder scoping workshop	0	0
	Scope drafted and key clinical issues identified based on scoping searches	5	5
	Stakeholder scoping workshop	3	8
	Scope revised after workshop	1	9
	Advertisement and appointment of GDG members	4	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, validation and publication	Public consultation on guideline	4	36–46
	Guideline revised	6	42–52
	Guidance Executive sign off	1	43–53
	Publication	2	45–55
	Total		**11–13 months**

2.2 Phase 1 – referral of topic

2.2.1 Topics are referred to NICE by the Department of Health or the NHS Commissioning Board. 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.

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 Internal Clinical Guidelines Programme technical team at NICE. It is based on the remit from the Department of Health or the NHS Commissioning Board, input from relevant experts, patients, service users and carers[1], 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 technical 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. Review questions, which specify in some detail the particular interventions to be compared and the health outcomes of interest (see chapter 4 of The guidelines manual), may be included in the scope.

2.3.1.2 **Comparison with the standard clinical guideline process.** The process for drafting the scope 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 or the NHS Commissioning Board. 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 by inviting all registered stakeholder organisations to offer

suggestions of possible workshop attendees; 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 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 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 Internal Clinical Guidelines Programme technical team, the GDG Chair and the Clinical Adviser (if one is appointed; see section 2.4.1.1 below). A revised scope is prepared, which is signed off by the CCP lead for the guideline 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 8–12 members, supported by the Internal Clinical Guidelines Programme technical team at NICE. 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 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). The development phase 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 from a pool of suitable members. This pool is recruited through a formal advertisement and recruitment process to act as standing members for each guideline. They are appointed on 3-year rolling contracts.

2.4.1.3 Healthcare professional members and patient and carer members of the GDG are recruited using the standard process (see section 3.1 of The guidelines manual).

2.4.1.4 The GDG makes its decisions using the best available evidence presented to it at GDG meetings by technical 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.

2.4.1.5 **Comparison with the standard clinical guideline process.** The process of forming and running the GDG outlined here is consistent with that for the standard clinical guideline programme (see chapter 3 of The guidelines manual). However, the development phase takes 4–6 months, compared with up to 18 months in the standard process. The process outlined in here 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 approximately 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 per day at a 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). However, there is no requirement to re-run searches for short clinical guidelines (as in section 5.9 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 The short clinical guideline process follows the standard process for

creating guideline recommendations (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.

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.

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 and formulating research recommendations (see chapter 9 of The guidelines manual).

2.4.7 Writing the guideline

2.4.7.1 There are four versions of short clinical guidelines (see chapter 10 of The guidelines manual for further details):

- The full guideline – all the recommendations, details of how they were developed and summaries of the evidence they are based on.
- The NICE guideline – the recommendations from the full guideline, without the information on methods and evidence.
- The NICE pathway – all of the recommendations summarised in an interactive online pathway, with links to related guidance.
- 'Information for the public' – a summary for patients, carers and the public.

2.4.7.2 The full guideline is written by the Internal Clinical Guidelines Programme technical team, following the principles in chapters 9 and 10 of 'The guidelines manual'. The NICE guideline, NICE pathway and 'Information for the public' are written by NICE editors.

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.

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 Following consultation with stakeholders, the guideline is revised by the Internal Clinical Guidelines Programme technical team working in collaboration with the GDG.

2.5.3 The guideline is signed off by NICE's Guidance Executive and published.

2.5.4 **Comparison with the standard clinical guideline process.** The consultation period for short clinical guidelines is 4 weeks, compared with 6 weeks for standard clinical guidelines. The Internal Clinical Guidelines Programme technical team works with the GDG in the same way that the NCCs work with their GDGs (see chapter 11 of The guidelines manual).

[1] When the term 'patients and carers' is used in this manual, it is intended to include all lay people involved in developing NICE clinical guidelines. This includes people with specific conditions and their family members (including parents for children and young people under 16) and carers. It also includes employees of organisations representing the interests of patients and carers. The term 'patients' is used as a general term to indicate a wide range of people who may be referred to differently elsewhere, such as service users of mental health services and healthy pregnant women.

3 Linking short clinical guidelines to other NICE guidance

3.1 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 The process and methods used for reviewing the need to update a published short clinical guideline are the same as those used for standard guidelines (see chapter 14 of The guidelines manual).