NICE National Institute for Health and Care Excellence

# Interim process and methods guide for the clinical guideline updates using standing committees pilot programme 2013

NICE process and methods
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www.nice.org.uk/process/pmg17

# Contents

# 1 Purpose

This is not the current manual. From January 2015, guidelines were developed using Developing NICE guidelines: the manual.

This guide outlines the main elements of the interim process and methods for the NICE clinical guideline updates using standing committees pilot programme, including details of the Clinical Guidelines Updates committee, which were agreed by the NICE Board in September 2013. It complements the standard methods and processes for developing and updating clinical guidelines described in the NICE guidelines manual 2012 and the interim clinical guideline surveillance process and methods guide 2013. This process for clinical guideline updates using standing committees will be used to inform the NICE guidance development project and will then be subject to formal consultation.

# 2 Background

Clinical guidelines developed by NICE are published with the expectation that they will be regularly reviewed and updated as necessary. Any decision to update a guideline must balance the need to reflect changes in the evidence against the need for stability, because frequent changes to guideline recommendations would make implementation difficult. However, even though a guideline may not need a substantive update, there are often small discrete areas that could be updated to make sure that NICE guidance reflects the latest evidence.

Evaluation of the outcomes of the previous process for reviewing the need to update a clinical guideline (used until August 2013) highlighted that although only about 1 in 7 guidelines needed a substantive update 3 years after publication, a further proportion had some areas of the guideline that would have benefited from updating. This usually involved small and defined areas of the guideline – perhaps 2 or 3 recommendations, 2 or 3 review questions or a single distinct section of the guideline.

NICE's ability to undertake clinical guideline updates using standing committees has been greatly limited by our standard processes and the way we commission guideline development slots with the National Collaborating Centres. A significant amount of time is needed to prepare for updating a guideline, including recruiting members of the Guideline Development Group (GDG) and scoping the update. This is in addition to the development time and the quality assurance process for the guideline itself. In the 2 or 3 instances where we have undertaken a rapid update, it has been limited to areas where patient safety may have been compromised by the existing guidance.

This pilot programme for clinical guideline updates using standing committees aims to address these capacity and efficiency issues, by creating a standing committee (the Clinical Guidelines Updates Committee) and using processes that significantly reduce the time taken to prepare for the update and to develop recommendations.

The methods and processes described here do not replace those described in chapter 14 of the NICE guidelines manual 2012 for substantive updates of clinical guidelines. They allow small, discrete sections of a guideline to be updated more efficiently.

# 3 Principles of the interim process and methods for clinical guideline updates using standing committees

Given the number of guidelines that make up NICE's library of guideline topics and the resulting number of surveillance reviews, the capacity needed for updating is considerable. To address this, these new processes and methods for clinical guideline updates using standing committees are more streamlined, and the process is more adaptive. Fewer resources are needed, because a rapid update does not include a scoping stage and there is not a Guideline Development Group (GDG) for the topic.

A standing committee model (see section 4) gives NICE the flexibility to schedule clinical guideline updates using standing committees of discrete sections of guidelines, which complements our standard update process for more substantive updates. We can also respond more rapidly to potentially serious or damaging errors or to new evidence identified after publication (such as safety concerns, withdrawal of drugs or interventions, significant changes to legislation, etc.).

Suitable topics for clinical guideline updates using standing committees are usually identified through the new clinical guideline surveillance process (which started a 12-month trial period in August 2013). Topics are then agreed by NICE Guidance Executive. The initial pilot topics (see appendix A and the NICE website) were selected from guidelines that were reviewed using the 2010 reviews process (see chapter 14 of the NICE guidelines manual 2012) and were agreed by NICE Guidance Executive in June 2013.

The Clinical Guidelines Updates Committee develops recommendations for the NHS in accordance with NICE's published methods and processes. As formal NICE guidance, rapid guideline updates are subject to the same level of scrutiny as other NICE products. The underlying principles of transparency of process and methodological rigour continue to hold.

The pilot programme for clinical guideline updates using standing committees is hosted by the Internal Clinical Guidelines team (within the Centre for Clinical Practice at NICE), who provide management, technical and administrative support to the committee. The commissioning, technical and senior management teams of the Centre for Clinical Practice

provide quality assurance oversight of guideline development, in line with the processes described in the NICE guidelines manual 2012.

# 4 The Clinical Guidelines Updates Committee

The main role of the Clinical Guidelines Updates Committee ('the committee') is to advise NICE on updating recommendations in published clinical guidelines. It develops recommendations in accordance with the methods and processes described in this document and the NICE guidelines manual 2012.

The committee normally has 15–18 voting members, comprising the chair, core members and up to 5 topic-specific members.

The core membership of the committee (see appendix B) is drawn from across the NHS. It includes healthcare professionals from a range of disciplines and localities, NHS commissioners and managers, patients and carers, and members from academia. Core committee members are recruited via open advert in accordance with the recruitment policy for NICE committees.

Topic-specific members of the committee are drawn primarily from the Guideline Development Group (GDG) for the existing guideline, recruited via expressions of interest. If none of the original GDG members express an interest in joining the committee, NICE will recruit via open advert and normal processes. Topic-specific members are full voting members for the duration of development for that topic.

Additional expert witnesses may be invited to attend meetings and advise the committee on a topic by topic basis, to assist in considering and interpreting the evidence. They do not have voting rights and do not count towards the quorum of the committee.

The committee meets for one 2-day meeting every quarter, with the first meeting in October 2013. The Terms of Reference and Standing Orders of the committee are available on the NICE website. It is planned that a further committee will start work in 2014.

# 5 Process

Topics suitable for consideration by the Clinical Guidelines Updates Committee are usually identified through the NICE clinical guideline surveillance process. They are then agreed by NICE Guidance Executive.

A topic is normally considered to be suitable for a rapid review if a section of the guideline or a set of review questions form a discrete and distinct area of a clinical pathway. The following scenarios are likely to apply:

- A small number of distinct review questions underpin a limited number of recommendations. The exact number will depend on the types of questions and the likely size of the evidence base to be reviewed.
- Limited economic and costing analyses may be needed, such as the updating of incremental costs and benefits to calculate updated incremental cost-effectiveness ratios (ICERs), but no major new health economic modelling is needed.
- No complex analyses are needed, such as questions involving a network meta-analysis or questions about diagnosis that would significantly affect the treatment pathway covered in the rest of the guideline.

Updates that need complex analyses or that have a major health economic component are unlikely to be suitable for the rapid update process at present.

There is no scoping stage for clinical guideline updates using standing committees (unlike a standard guideline update). This is because the rapid update considers only areas from the existing guideline, and so the review questions and review protocols will already be defined by the existing guideline. However, if the questions and/or protocols are unavailable or there is ambiguity in the existing guideline, the analysts may approach the topic-specific members of the committee for advice before starting the evidence review.

The committee meets quarterly. Each guideline undergoing rapid review is considered at 2 meetings. At meeting 1 the committee is presented with the updated evidence reviews conducted by the Internal Clinical Guidelines technical team and develops recommendations. After public consultation, the committee amends the recommendations as needed at meeting 2, which is usually the next quarterly meeting.

The committee submits the updated guidance to the NICE Centre for Clinical Practice, which carries out quality assurance for the update using existing internal processes and those outlined in the NICE guidelines manual 2012.

# 6 Methods

The methods for reviewing and presenting evidence and developing recommendations for clinical guideline updates using standing committees mostly follow those set out in the NICE guidelines manual 2012. Exceptions to this include the following:

- The guidelines manual section 3.5.1 (Reaching agreement) – the Clinical Guidelines Updates Committee does not have any input or involvement in developing the review questions and review protocols.
- The guidelines manual section 5.9 – the developers do not re-run searches.

# 7 Stakeholder consultation

NICE consults with stakeholders on each rapid update for a 4-week period.

# 8 Key elements of the process

Table 1 summarises the key elements of the interim clinical guideline updates using standing committees process.

**Table 1 Key elements of the process**

| Development phase | Key elements |
|---|---|
| Topic selection | • Topics identified through the interim clinical guideline surveillance process<br>• Updates limited to existing guideline scope and review questions |
| Development | • NICE Information Services search, based on existing review protocols if available<br>• Technical analysts review new evidence<br>• Clinical Guidelines Updates Committee reviews evidence and develops recommendations |
| Consultation | • NICE consults with stakeholders for 4 weeks<br>• Committee reviews stakeholder comments and amends recommendations as needed |
| Validation | • Quality assurance processes as described in section 12.1.2 of the NICE guidelines manual 2012<br>• All recommendations are agreed by NICE Guidance Executive |

| Development phase | Key elements |
| --- | --- |
| Publication | • The new evidence, committee considerations, declarations of interests and final recommendations are published on the NICE website<br>• The NICE pathway, 'Information for the public' and any relevant implementation tools and resources are updated in line with the new recommendations |

# 9 Evaluation of interim process and methods

This interim process and methods will be evaluated formally at the end of the pilot programme, in order to:

- test and evaluate current criteria for what constitutes a rapid update
- gain experience and collect intelligence on how to rapidly update guidance resulting from more complex review questions, such as questions about diagnosis or prognosis, or those requiring more complex analyses (such as network meta-analyses or health economic modelling)
- test and evaluate the structure and operations of the Clinical Guidelines Updates Committee, with the aim of improving its efficiency and flexibility to update clinical guidelines on a variety of topics.

After evaluation, this process and methods guide will be used to inform the guidance development project methods and process manual, which will be consulted on.

# Appendix A: Topics for the pilot programme

The topics that have been identified for the 1-year pilot programme for clinical guideline updates using standing committees are:

- Advanced breast cancer – Management of lymphoedema.
- Irritable bowel syndrome – Antidepressants, relaxation and biofeedback for the management of irritable bowel syndrome.
- Long-acting reversible contraception – Progestogen-only subdermal implants.
- Glaucoma (chronic open angle) and ocular hypertension – Treatment options for people with ocular hypertension and chronic open angle glaucoma, and clarification of the referral threshold for patients to the hospital eye service.
- Colorectal cancer – Organisation and management of services for early rectal cancer and the arrangement of services for the management of bowel obstruction caused by colon cancer.

# Appendix B: Clinical Guidelines Update Committee A

**Damien Longson (Chair)**
Consultant Liaison Psychiatrist, Manchester Mental Health and Social Care Trust

**Susan Bewley (Vice Chair)**
Honorary Professor of Complex Obstetrics, Women's Academic Health Centre, St Thomas' Hospital

**Catherine Briggs**
GP Principle, Bracondale Medical Centre, Stockport

**John Cape**
Head of Psychology and Psychological Therapies, Camden and Islington NHS Psychological Therapies

**Alun Davies**
Professor of Vascular Surgery and Honorary Consultant Surgeon, Charing Cross and St Mary's Hospital and Imperial College NHS Trust

**Alison Eastwood**
Senior Research Fellow, Centre for Reviews and Dissemination, University of York

**Amanda Gibbon**
Patient and carer member

**Jim Gray**
Consultant Medical Microbiologist, The Birmingham Children's Hospital NHS Foundation Trust

**Sarah Fishburn**
Patient and carer member

**Nuala Lucas**
Consultant Anaesthetist, Northwick Park Hospital

**Kath Nuttall**
Director, Lancashire and South Cumbria Cancer Network (to April 2013)

**Tilly Pilay**
Neonatal Consultant, Staffordshire, Shropshire and Black Country Newborn Network

**Nick Screaton**
Radiologist, Papworth Hospital NHS Foundation Trust

**Lindsay Smith**
Principle in General Medical Practice, Somerset PCT

**Sophie Wilne**
Paediatric Oncologist, Nottingham Children's Hospital

# Appendix C: Draft timetable for clinical guideline updates using standing committees

**Timetable for updates**

| Step | Week no. (approx.) |
|---|---|
| Clinical Guidelines Updates Committee meeting 1 | 1 |
| Stakeholder consultation starts | 7 |
| Stakeholder consultation ends | 11 |
| Clinical Guidelines Updates Committee meeting 2 | 15 |
| Validation phase starts | 18 |
| NICE Guidance Executive sign-off | 21 |
| Advance copy of final full guideline released to stakeholders who have signed a confidentiality form | 22 |
| Publication | 23 |

# Update information

**May 2014:** The name of the programme has been changed to better reflect that the guidelines are updated by standing committee.

# About this guide

This guide describes the main elements of the interim process and methods for the NICE clinical guideline updates using standing committees pilot programme. It will be updated as described in section 9.

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