NICE National Institute for Health and Care Excellence

Good practice guidance – Interim process statement

Process and methods
Published: 1 August 2012

www.nice.org.uk/process/pmg3

Contents

1 Introduction

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

1.1 Introduction to interim process statement

This interim process statement has been produced to guide the development of good practice guidance. It provides an overview of the key process principles and describes all stages of the development of good practice guidance. These procedures are designed to ensure that a robust, quality-assured, resource is developed for the NHS in an open, transparent and timely way, with appropriate input from key groups.

This interim process statement of good practice guidance will be superseded when the final process guide is issued later in 2012, following engagement and discussions with key groups.

1.2 Background to good practice guidance

The National Institute for Health and Clinical Excellence (NICE) is part of the NHS. NICE's evidence-based guidance and other products help resolve uncertainty about which medicines, treatments, procedures, technologies and devices represent the best quality care and offer the best value for money for the NHS. Further information about NICE and its work is available on the NICE website (www.nice.org.uk).

The NICE Medicines and Prescribing Centre provides advice and support for delivering safety, efficiency and effectiveness in the use of medicines. The NICE Medicines and Prescribing Centre is responsible for developing good practice guidance.

Good practice guidance provide advice and guide good practice for those involved in handling, prescribing, commissioning and decision-making about medicines. The outputs have a wide range of audiences across both health and social care environments.

2 Good practice guidance

2.1 Aims

The aim of good practice guidance is to provide advice and guides to good practice for those involved in handling, prescribing, governance, safety, commissioning and decision-making about medicines. The content of the good practice guidance is developed according to the best available evidence. The outputs aim to be practically relevant, with an emphasis on the implications for UK practice.

Good practice guidance allows NICE to respond to developments in the evidence relating to medicines and prescribing, supporting the implementation of NICE guidance by providing best practice information about the systems, processes and governance arrangements required about medicines.

2.2 Key audiences

Good practice guidance is written for a wide range of audiences including:

- patient-facing practitioners
- local medicines optimisation services
- NHS commissioners.

2.3 Key activities

The key activities for the production of good practice guidance are:

- identifying and selecting the most relevant evidence from a range of evidence sources
- summarising the evidence
- critically reviewing the strengths and weaknesses of the evidence
- synthesising evidence in the context of good practice

- using evidence to formulate recommendations and validate them.

3 Who is involved in producing good practice guidance?

3.1 The NICE Medicines and Prescribing Centre

The Medicines and Prescribing Centre is part of NICE's Centre for Clinical Practice (CCP). The NICE Medicines and Prescribing Centre consists of a programme director, associate directors and clinical, technical, project and administrative staff. For good practice guidance, members of the NICE Medicines and Prescribing Centre are responsible for:

- developing and reviewing processes and methods to develop good practice guidance
- identifying potential topics in accordance with topic selection and prioritisation process (see section 4)
- preparing good practice guidance for publication, including identifying, selecting and critically appraising the evidence
- identifying and liaising with stakeholders
- providing quality assurance of the content of good practice guidance
- ensuring agreed timelines and quality assurance standards are followed
- reviewing and updating content of published good practice guidance where required.

For each good practice guidance the NICE Medicines and Prescribing Centre Programme Director and the Associate Director Medicines Advice will identify a project team which will be responsible for working with the Guidance Development Group (see section 3.4) to deliver the output.

3.2 Other NICE teams

The NICE Medicines and Prescribing Centre works closely with other NICE teams. The teams involved will depend on the good practice guidance in production. NICE teams can include:

Evidence Resources, NICE Implementation team, Clinical Guidelines and Technology Appraisals, Editorial team, Patient and Public involvement, External Communications and Information Services team.

Further detail of the role and functions of the NICE teams in relation to these outputs will be included within the methods manual for the good practice guidance.

3.3 Government departments and other public bodies

The NICE Medicines and Prescribing Centre liaises with relevant government departments and public bodies such as the Department of Health, Home Office and the NHS Commissioning Board as part of topic identification and defining the scope of good practice guidance. As key stakeholders, these agencies can also comment on the content of an output during the consultation phase of the production process.

3.4 Guidance development group

A guidance development group (GDG) of usually 15 to 20 people will be established for each good practice guidance. Recruitment for the positions of chair and members for each GDG will follow NICE recruitment processes for committees and groups. The relevant NICE policy can be found here.

The chair and members of each GDG are drawn from the NHS, healthcare professionals, key stakeholders, patients and carers, and academia. Members do not represent their organisations but are selected for their expertise, experience of working with multidisciplinary and lay colleagues and understanding of evidence-based healthcare and the systems and processes associated with healthcare decision-making.

All members of the GDG have equal status, which reflects the relevance and importance of their different expertise and experience. The GDG is the primary source of expertise to determine the content of the good practice guidance as defined within the scope of the project.

The GDG will consider the NICE Medicines and Prescribing Centre project team's initial review of the existing evidence, confirming (or challenging) the appropriateness for inclusion with the document. The GDG will also identify potential additional evidence

sources, and where required call for expert oral and written testimony. The GDG will also determine the validity and application of such evidence with the NICE Medicines and Prescribing Centre project team.

3.5 Stakeholders

Identifying and engaging with stakeholders is an important stage of the development process for good practice guidance. Both individuals and organisations may register an interest in becoming a member of a guidance development group, as well as stating an interest in reviewing draft documents at a pre-defined stage of the process.

A list of stakeholders will be compiled in the early stages of the project. Stakeholders will be notified of details of the process for registration. A dedicated email inbox will be provided for those choosing to register. The inbox will be managed regularly and registrations logged.

The NICE Medicines and Prescribing Centre will communicate the expected dates of consultation periods, indicating methods of access and feedback. Communications will be through newsletters, bulletins and email alerts. Where appropriate, representative bodies/ organisations as potential external stakeholders will be contacted directly.

The NICE Medicines and Prescribing Centre project team will log the receipt of all stakeholder comments and record a brief summary and actions taken. Feedback that may delay the publication of the document will be escalated to the NICE Medicines and Prescribing Centre Programme Director.

The process for stakeholder registration will be reviewed and documented in the final process statement.

3.6 Conflicts of interest

NICE staff and members of the GDG will be required to comply with the NICE code of conduct on conflicts of interest. For more information about how NICE deals with conflicts of interest, please see 'A code of practice for declaring and dealing with conflicts of interest'.

4 Topic identification, selection and prioritisation for good practice guidance

4.1 Topic selection and prioritisation

The identification and selection of relevant and appropriate good practice guidance topics and associated outputs will follow the following process.

Stage 1 – Identification of potential topics

The NICE Medicines and Prescribing Centre will annually produce a list of potential topics which will include National Prescribing Centre legacy good practice guides identified through a structured review process (see section 4.2). Stakeholders, including government departments, NHS organisations and professional bodies will be invited to submit suggestions for topics for consideration. The invitation will remain open to stakeholders for 8 weeks. The following exclusion criteria will be applied to this list to create a long list of potential topics:

- specific drug-related topics
- topics that have been included within existing NICE publications
- guidance would fall within the domain of other agencies or national bodies.

Stage 2 – Prioritise topics

The following inclusion criteria will then be applied to the long list to produce a short list of potential topics:

- safety concerns relating to systems and processes associated with medicines and prescribing
- gap between evidence and practice
- identifiable inappropriate variation in practice across the country
- relevant priorities set out by the NHS Commissioning Board

- topics referred for urgent consideration by NHS Commissioning Board or Department of Health.

Prioritisation of topics on the short list will be determined and recorded by the NICE Medicines and Prescribing Centre team.

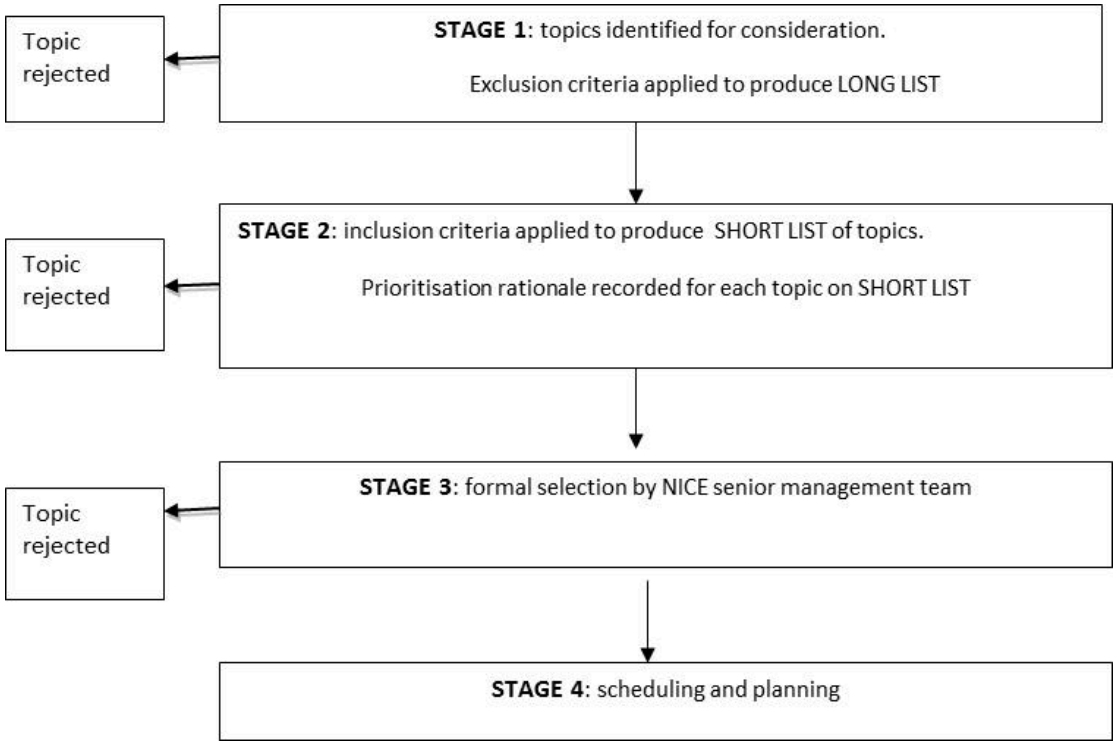
Stage 3 – Formal selection of topic

The short list and supporting rationale will be reviewed by the Director of the Centre for Clinical Practice. Final selection of topics will be agreed by the NICE Senior Management Team.

Stage 4 – Topic scheduling

Selected topics will be scheduled for production. The NICE Medicines and Prescribing Centre Medicines Advice Associate Director will plan a programme of work and identify key NICE Medicines and Prescribing Centre personnel and resources to deliver outputs. The production process is outlined in section 5.

Figure 1. Flow-chart showing main steps in process for topic selection for good practice guidance



4.2 Scope

The scope for each good practice guidance will be determined by the NICE Medicines and Prescribing Centre in liaison with content area experts.

5 Development process for good practice guidance

5.1 Equality and diversity considerations

All good practice guidance is developed in accordance with the NICE equality scheme (available from http://www.nice.org.uk/aboutnice/howwework/niceequalityscheme.jsp).

5.2 Process and timescales

Table 2 shows the key steps in the development of the good practice guidance.

Table 2: Production process outline and timetable

Stage	Week
Preliminary literature search, development of scope	In advance of start of process
Literature search and review	Week 1
GDG recruitment	Weeks 0–6
1st GDG meeting	Week 6
Identification of any additional evidence	Week 6
Request for and receipt of written evidence (if required)	Weeks 6–8
Authoring of 1st draft	Weeks 9–10
2nd GDG meeting (face to face)	Week 11
Authoring of 2nd draft	Weeks 11–15
Consideration of oral testimony (if required)/3rd GDG meeting	Week 15
Authoring of 3nd draft - preparation for consultation	Weeks 16–20
Consultation phase	Weeks 20–24

4th GDG meeting - validation. Review of comments and amendment of final draft	Weeks 24–25
Internal document production process	Weeks 25–28
Guidance Executive	Week 29
Publication	Week 30

Note: the number of GDG meetings may vary according to the needs of each good practice guidance.

5.3 Evidence gathering and appraisal

5.3.1 Literature search and appraisal

Searching for evidence

A literature search will be undertaken based on the scope.

Sifting and selecting the evidence

The NICE Medicines and Prescribing Centre project team will sift the search results using the title and abstract of each article, applying first exclusion and then inclusion criteria. These criteria include the basic criteria as set out below.

First sift

This process removes evidence based on the following **exclusion criteria**:

- articles of poor relevance against search terms
- non-English language abstracts or non-English language articles with English abstract.

Second sift

This sift of evidence includes relevant primary research that addresses the systems and processes for the safe handling and use of the medicines. Where robust randomised controlled trials or systematic reviews are available, they form the basis of the review.

However, given the nature of the topics, the best available evidence on which to produce the good practice guidance may include evidence other than randomised controlled trials.

The project team will record the reasons for non-inclusion based on the second sift as well as a 'long list' of those articles that are excluded from the first sift.

Appraising and categorising the prioritised evidence

The NICE Medicines and Prescribing Centre project team will critically appraise the evidence, recording decisions in an evidence log. The full text of the prioritised evidence will be appraised using a technique appropriate for the type of evidence.

5.3.2 Gap analysis

Following the appraisal of the published literature the project team will determine if there is sufficient published evidence to address the issues identified within the scope of the generic medicines advice. This will be documented in the form of a gap analysis. A summary of the published evidence and the gap analysis will be provided to the GDG.

5.3.3 Additional evidence

The GDG will review the evidence, its critical appraisal by the NICE Medicines and Prescribing Centre project team, and the project team's gap analysis. The GDG will, if appropriate, determine the most appropriate method for sourcing further evidence identified from the gap analysis. This may be in the form of a call for evidence from service providers and commissioners. The GDG will inform the drafting of and mechanisms for appropriate communications.

Any additional evidence received will be appraised by the NICE Medicines and Prescribing Centre project team in conjunction with the GDG using the same exclusion and inclusion criteria for published evidence. All evidence received will be documented and assessment of the validity of the evidence recorded within the evidence log.

The GDG will review the relevant evidence gathered through this method together with evidence from published sources and determine if further evidence is required to address issues within the scope where there is still an evidence gap or further information relating specific issues is required.

5.4 Framework for good practice guidance

The project team will draft the good practice guidance using a standard framework, which includes as a minimum the following sections:

- Title and contents page
- Date and version control information
- Good practice recommendations
- Introduction
- Policy context
- Methodology
- Evidence
- References
- Appendices:
  - Search strategy
  - Evidence selection process and criteria.

5.5 Reviews of drafts

Draft documents will be circulated to the GDG for comments at appropriate stages of the process according to the project schedule.

A draft will be made available for stakeholders to comment on during a scheduled consultation period (See table 2 and section 5.7).

5.6 Quality assurance

Quality assurance of the good practice guidance will be undertaken by the NICE Medicines and Prescribing Centre project team. The NICE Editorial team will also review and recommend further revisions as necessary.

5.7 Consultation

The draft document will be posted on NICE's website for a 4 week public consultation period (see table 2). When the consultation document is uploaded, all interested parties who have registered as stakeholders will receive an automatic email to alert them of the start of the consultation. Comments will be collated by the NICE Medicines and Prescribing Centre project team for consideration by the GDG. The GDG will agree the final recommendations. Consultation comments and responses will be made available on NICE's website.

5.8 Sign off and publication

The final draft will be signed off by the NICE Medicines and Prescribing Centre Programme Director, and sent to the NICE Guidance Executive for approval for publication.

The good practice guidance is uploaded to the Medicines and Prescribing Centre pages of the NICE website.

6 Review

The process for the review of good practice guidance will be considered as part of the production of the final process guide.

7 About this interim process statement

This interim process statement was used to develop good practice guidance published up to December 2012, but good practice guidance published after this date has used the integrated process statement.

For published 'Good practice guidance', see the list on the NICE website.

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