NICE National Institute for Health and Care Excellence

Good practice guidance – Integrated process statement

Process and methods

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Contents

1 Introduction

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

From February 2014, good practice guidance became known as medicines practice guidelines. This is to bring the guideline naming in line with other NICE products. This is purely a name change, the processes and methods used to develop the guidelines remains the same.

1.1 Introduction to process statement

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

1.2 Background to good practice guidance

The National Institute for Health and Care Excellence (NICE) is a non-departmental public body. 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.

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.

2 Good practice guidance

2.1 Aims

The aim of good practice guidance is to provide recommendations for good practice for people who are involved in governing, prescribing and commissioning medicines, and those involved in decision-making about medicines. The content of the good practice guidance is developed according to the best available evidence. The guidance aims to be thorough, effective and appropriate to the target audience, with an emphasis on the implications for national practice.

2.2 Scope of good practice guidance

Good practice guidance allows NICE to develop guidance based on evidence relating to medicines and prescribing. Good practice guidance considers broad topics covering the systems, processes and governance arrangements relating to medicines. The guidance has a wide range of audiences across both health and social care environments.

2.3 Key audiences

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

- patient-facing practitioners
- local medicines optimisation services
- NHS organisations
- local authorities
- NHS-commissioned services provided by non-NHS organisations, such as:
    - independent organisations, for example independent hospitals
    - independent contractors, for example community pharmacies
    - voluntary and charitable agencies, for example hospices.

2.4 Key activities

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

- topic selection
- 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 the topic selection and prioritisation process (see Section_4)
- overall developing of the good practice guidance, 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 if required.

For each topic selected, the NICE Medicines and Prescribing Centre Programme Director and the Associate Director Medicines Advice identifies a project team that is responsible for working with the Guidance Development Group (GDG, 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 depend on the good practice guidance in production. NICE teams can include:

- Evidence Resources
- NICE Implementation team
- Clinical Guidelines and Technology Appraisals
- Quality Standards

- Publishing team
- Public Involvement Programme
- External Communications
- Information Services team.

Further detail of the role and functions of the NICE teams in relation to these outputs will be included within the process manual for 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 Care Quality Commission, Department of Health, Home Office, Local Authorities, NHS England and Public Health England as part of topic selection and defining the scope of good practice guidance. As key stakeholders, these organisations can also register to comment on the guidance during the consultation phase of the production process.

3.4 Guidance Development Group

A Guidance Development Group (GDG) of usually 15 to 25 people is established for each good practice guidance. Recruitment for the positions of chair, vice chair and members for each GDG follows NICE recruitment processes for committees and groups.

The chair, vice chair and members of each GDG may be drawn from the NHS, healthcare professionals, key stakeholders (including the pharmaceutical industry), social care, patients and carers, and academia. Members do not usually represent their organisation(s) and are selected for their expertise and experience.

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.

The GDG considers the NICE project team's initial review of the existing evidence, confirming (or challenging) the appropriateness for inclusion within the guidance. The GDG also identifies potential additional evidence sources, and when needed calls for expert oral and written testimony. The GDG also determines 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. Organisations may register as a stakeholder to review draft guidance at a pre-defined stage of the process. Criteria for stakeholder registration are available on the NICE website for each guidance topic.

A list of potential stakeholders is compiled during the development of the guidance. This starts when a topic is formally selected. Potential stakeholders are notified of details of the process for registration, when appropriate.

NICE communicates the expected dates of consultation periods, indicating methods of access and feedback via the website and email alerts.

3.6 Conflicts of interest

NICE staff and members of the GDG are 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

4.1 Topic identification and prioritisation

The identification and selection of relevant and appropriate good practice guidance topics and associated outputs follows the following process:

Stage 1: Identifying potential topics

Views on potential topics for NICE good practice guidance are sought through consultation. Stakeholders, including government departments, NHS organisations and professional bodies are invited to submit suggestions and comments. A proposed list of topics is produced for a consultation document, known as the 'long list'.

Stage 2: Prioritising topics

The long list is reviewed by the NICE Medicines and Prescribing Centre team and used to create a prioritised shortlist of topics for development in line with the NICE good practice guidance process manual. The shortlist is limited to 6 topics.

Stage 3: Formal selection of topic

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

Stage 4: Topic scheduling

Selected topics are scheduled for production. The NICE Medicines and Prescribing Centre Medicines Advice Associate Director plans a programme of work and identifies key NICE Medicines and Prescribing Centre personnel and resources to deliver outputs.

Stage 5: Topic consultation

For subsequent topic consultations, stakeholders are invited to submit suggestions and comments on the short list and provide views on potential topics for inclusion in the work programme. The proposed topics form a new long list. The process then starts again from stage 2.

4.2 Scoping individual good practice guidance

The scope for individual good practice guidance is determined by the NICE Medicines and Prescribing Centre by identifying key questions and objectives. This may involve a scoping workshop, liaison with key stakeholders and experts, literature searches and any relevant remit from NICE, the Department of Health and NHS England.

5 Development process

5.1 Equality and diversity considerations

All good practice guidance is developed in accordance with the NICE equality scheme.

5.2 Process and timescales

Table 1 shows the key steps in the development of the good practice guidance.

Table 1 Production process outline and timetable

Stage	Week
Preliminary literature search, development of scope and project plan	In advance of start of process
Literature search, review and gap analysis	Weeks 0–7
GDG recruitment	Weeks 1–9
Produce proposed structure (based on literature search and scope)	Weeks 8–12
1st GDG meeting	Week 13
Identification of any additional evidence	Week 13
Request for and receipt of written evidence (if required)	Weeks 13–17
Authoring of 1st draft	Weeks 13–16
2nd GDG meeting (face to face)	Week 17
Authoring of 2nd draft	Weeks 17–25
Consideration of oral testimony (if required)/3rd GDG meeting	Week 21
Authoring subgroup (if required)	Week 23
4th GDG meeting	Week 26
Authoring of 3rd draft and preparation for consultation	Weeks 26–28
Consultation phase	Weeks 29–32
Authoring of 4th draft	Weeks 33–37

Collate consultation comments and produce consultation response table	Weeks 32–43
5th GDG meeting – validation. Review of comments and amendment of final draft	Weeks 38
Internal document production process	Weeks 39–43
Guidance Executive	Week 44
Publication	Week 46

Note: The exact length and timing of each stage of the process will vary dependent on topic and scheduling conflicts. The number of Guidance Development Group (GDG) meetings may vary according to the needs of the good practice guidance being developed. The overall length of the process will normally be between 36 and 52 weeks.

5.3 Evidence gathering and appraisal

5.3.1 Literature search

Searching for evidence

A literature search is undertaken based on the scope.

Sifting and selecting the evidence

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

The sift of evidence includes relevant primary research that addresses the systems and processes for the safe handling and use of the medicines. If 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.

Appraising and categorising the prioritised evidence

The NICE project team appraises the evidence using a technique appropriate for the type of evidence.

5.3.2 Gap analysis

Following the appraisal of the published literature, the project team determines if there is sufficient published evidence to address the issues identified within the scope of the good practice guidance. This is documented in the form of a gap analysis. A summary of the published evidence and the gap analysis is provided to the GDG.

5.3.3 Additional evidence

The GDG reviews the evidence, its critical appraisal by the NICE project team, and the project team's gap analysis. If appropriate, the GDG determines 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 informs the drafting of, and mechanisms for, appropriate communications.

Any additional evidence received is appraised by the NICE project team in conjunction with the GDG using the same exclusion and inclusion criteria for published evidence. All evidence received is documented and assessed.

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

5.4 Framework for good practice guidance

The NICE project team drafts the good practice guidance using a standard framework, which includes as a minimum the following:

- title and contents page
- date and version control information
- good practice recommendations
- introduction
- policy context
- legislation and regulatory requirements
- methodology

- evidence
- appendices:
    - glossary
    - search strategy
    - evidence selection process and criteria
    - GDG and project team members.

5.5 Reviews of drafts

A draft of the good practice guidance is circulated to the GDG for comments at appropriate stages of the process according to the project schedule.

A draft is also made available for stakeholders to comment on during a scheduled consultation period (see table 1 and section 5.7) after stakeholder registration.

External expert reviewers may be identified by the NICE project team to review part or all of the good practice guidance. This may take place during guidance development or during the consultation phase for the draft guidance. If external advisers comment during consultation, their comments are responded to in the same way as comments from registered stakeholders, and are published in the consultation table on the NICE website under 'expert advisers'.

5.6 Quality assurance

Quality assurance of the good practice guidance is undertaken by the NICE project team. The NICE Publishing team also reviews the good practice guidance and recommends further revisions as necessary.

5.7 Consultation

The draft good practice guidance is posted on NICE's website for a 4-week public consultation period (see table 1). All registered stakeholders receive notification when consultation starts. Only registered stakeholders or experts selected by the NICE project team are able to comment during consultation. The NICE project team logs and collates all stakeholder comments. These are considered by the GDG and responses documented. The GDG agrees the final draft guidance and recommendations. Consultation comments and responses are made available on NICE's website.

Feedback that may delay the publication of the guidance is escalated to the NICE Medicines and Prescribing Centre Programme Director.

5.8 Sign off and publication

The final draft is signed off by the Centre for Clinical Practice Director, Medicines and Prescribing Centre Programme Director and Medicines Advice Associate Director. The draft guidance is then taken to the NICE Guidance Executive for approval for publication.

The final good practice guidance is uploaded to the NICE website.

6 Review

Each good practice guidance will be reviewed to determine whether the guidance is still up to date and relevant or whether new evidence has come to light to warrant an update. The process for the review of good practice guidance will be included in the process manual[1].

[1] MPC are developing a process manual for good practice guidance, prior to NICE accreditation. On publication of the forthcoming NICE methods manual the process manual for good practice guidance will be updated.

7 About this integrated process statement

The process statement for 'Good practice guidance' provides a high-level overview of the process for developing the good practice guidance and will be supported by the forthcoming NICE methods manual.

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

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