

Interim methods guide for developing good practice guidance

NICE process and methods

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www.nice.org.uk/process/pmg15

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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.

The National Institute for Health and Care Excellence (NICE) is a non-departmental public body responsible for providing national guidance and advice to improve health and social care. NICE guidance is developed using the expertise of the NHS, social care, local authorities, and others in the public, private, academic and voluntary sectors, including patients and carers, service users and the public. Further details about NICE and its work programmes are available from [What we do](#).

1.1 NICE guidance

NICE develops [guidance](#) across a number of different areas and on a range of topics.

- All types of NICE guidance are developed using the best available evidence, and by involving stakeholders in a transparent and collaborative manner. Stakeholders include: national organisations representing patients and carers
- national health and social care professional organisations
- the NHS
- other public and private sector organisations that have an interest in the guidance being developed.

This interim methods guide is based on the general principles and methods included in other methods guides for developing NICE guidance. It can be used in conjunction with the [Good practice guidance: integrated process statement](#). This interim methods guide will be considered during the wider NICE methods manual review.

1.1.1 Equality and social value judgements

NICE is committed to promoting equality, eliminating unlawful discrimination and actively considering the implications of its guidance for human rights. It aims to comply fully with the public sector equality duty as outlined in the Equality Act (2010) to:

- eliminate unlawful discrimination on the grounds of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation (the 'protected characteristics') in the way it carries out its functions and in its employment policies and practices **and**
- advance equality of opportunity between people who share a protected characteristic and people who do not share it **and**
- foster good relations between people who share a protected characteristic and people who do not share it.

NICE's revised equality scheme 2010–2013 sets out how it is meeting these obligations on equality and discrimination and what it still needs to do. Further guidance on how equality issues are considered during the development of NICE guidance is provided in Positively equal: a guide to addressing equality issues in developing NICE clinical guidelines.

All NICE guidance, and the processes NICE uses to develop its guidance, follow the principles set out in Social value judgements: principles for the development of NICE guidance (second edition).

1.2 Who this methods guide is for?

This methods guide explains how NICE develops and updates good practice guidance (GPG). It provides advice on the technical aspects of developing the GPG and the methods used. It is aimed primarily at:

- the NICE project team within the Centre for Clinical Practice (CCP)
- other NICE teams who may be involved in producing the GPG
- members of the Guidance Development Groups (GDGs) that support the development of individual guidance
- stakeholders.

It is also likely to be useful and of interest to a broader audience, including all guidance developers.

The structure of this interim methods guide follows the development of NICE GPG from inception to publication. The GPG development process is summarised in [section 1.4.1](#), and the process for including stakeholders and the public is provided in [section 5](#).

1.3 NICE good practice guidance

NICE GPG provides recommendations for good practice for those individuals and organisations involved in governing, commissioning, prescribing and decision-making about medicines. The outputs have a wide range of audiences across both health and social care environments.

The content of the GPG is developed according to the best available evidence, taking into consideration legislation, current processes and systems relating to the guidance topic. The outputs aim to be thorough, effective, relevant and balanced, while remaining appropriate to the target audience with an emphasis on the implications for national practice.

The outputs can be used to develop quality standards when reviewing systems and processes relating to the use of medicines in different care settings and within provider and commissioning organisations.

NICE GPG:

- assesses the processes involving the use of medicines in care settings and organisations
- sets out the processes of care that are suitable for service users who are accessing medicines
- aims to improve the safety and quality of care
- takes account of the views of people who might be affected by the guidance (including health and social care and other professionals, patients and their carers, health service managers, NHS trusts, the public, government bodies and the health and social care industry)

- is based on the best available evidence and expert consensus
- is developed using recognised methods (see [section 8](#)) that are robust and transparent.

The production of good practice guidance is commissioned by the Department of Health. As a non-departmental public body, we are accountable to our sponsor department, the Department of Health, but operationally we are independent of government. The good practice guidance and its recommendations are made by independent committees.

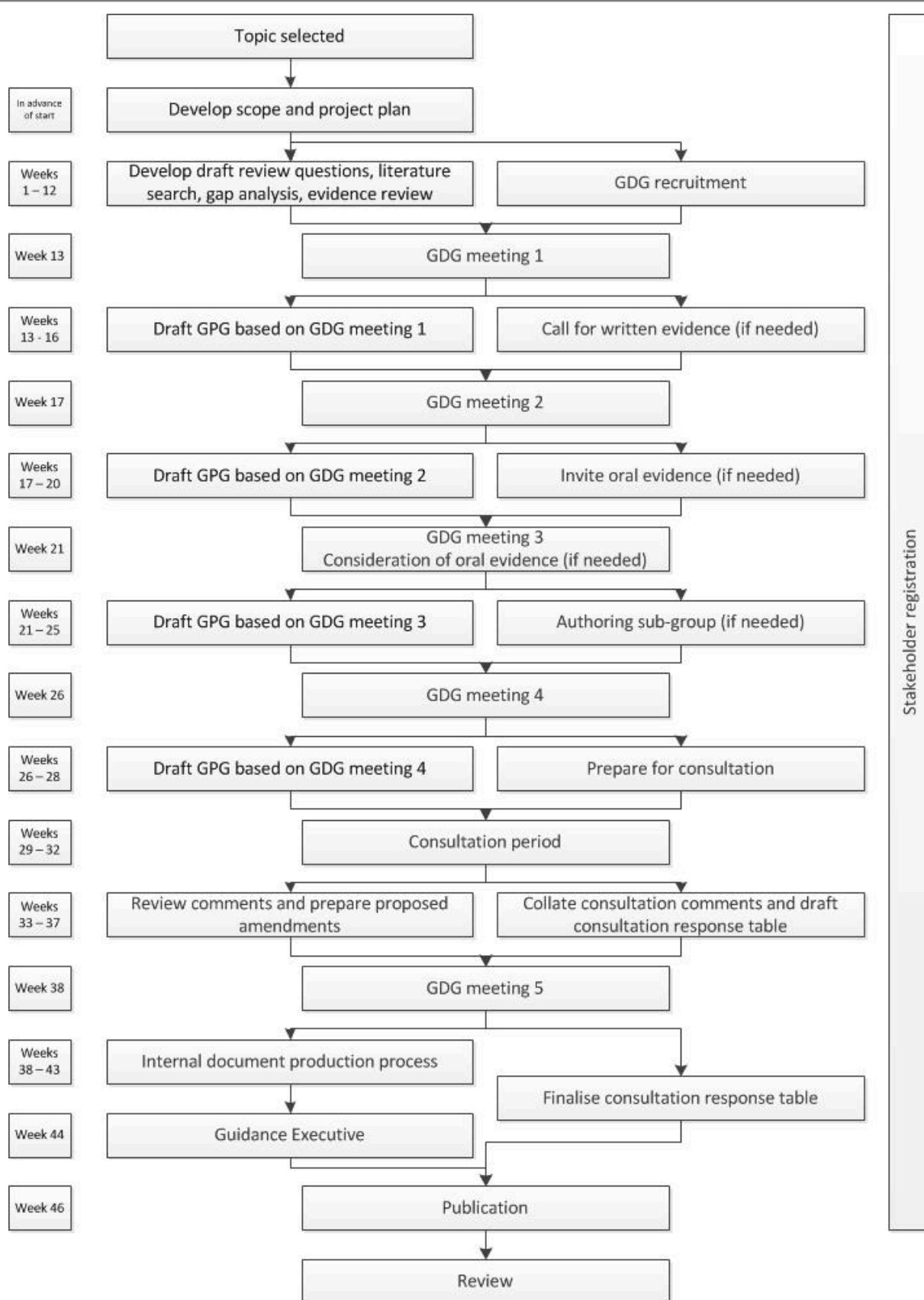
1.4 Development process overview

The development time for NICE GPG (from start of scoping to publication) is between 9 and 12 months. The exact length and timing of each stage of the process will vary depending on the topic and scheduling conflicts. The number of GDG meetings may vary according to the needs of the GPG being developed and will be determined by the NICE project team.

1.4.1 Summary of the good practice guidance development process

Potential topics for NICE GPG will be identified from a review of existing GPG, referral from NHS England and the Department of Health, and formal consultation with stakeholders (see [section 2](#)). The key stages in developing the GPG are summarised in [figure 1.1](#).

Figure 1.1 NICE good practice guidance development process



The authoring of GPG is an iterative process that is ongoing throughout the development and consultation phases.

1.4.2 Who is involved?

The various individuals and groups involved in developing GPG, and their key tasks during guidance development, are listed in [table 1.1](#).

For each topic selected (see [section 2](#)), the NICE Programme Director and the NICE project lead identifies a project team responsible for working with the GDG (see [section 6](#)) to deliver the output.

Table 1.1 Groups involved in good practice guidance development

	Key tasks
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<p>NICE project team (comprising a project lead, senior advisers and project management support)</p>	<p>Prepares the project timeline and project plan (see section 3)</p> <p>Identifies and liaises with stakeholders, manages stakeholder registration (see section 5)</p> <p>Prepares the draft scope and revises the scope after review, workshop and/or consultation as needed (see section 4.3)</p> <p>Runs the scoping workshop (see section 4.5.1)</p> <p>Project lead signs off scope (see section 4)</p> <p>Appoints and works with the GDG to develop the guidance and recommendations (see sections 11 and 12)</p> <p>Provides full technical and managerial support for the GDG (see section 6)</p> <p>Develops the draft review questions for the GDG (see section 7)</p> <p>Arranges evidence searches, then assesses and synthesises the evidence (see sections 8 and 9)</p> <p>Authors and prepares the drafts of the GPG in liaison with the GDG (see sections 6, 11 and 12)</p> <p>Liaises with key national organisations and external expert advisers, as appropriate, to review specific sections, or the full content of the GPG</p> <p>Circulates the draft GPG to the GDG for comments at appropriate stages of the process according to the project schedule</p> <p>Prepares draft GPG for consultation</p> <p>Project lead signs off draft GPG for consultation</p> <p>Coordinates consultation on the draft GPG and collates consultation comments (see section 13)</p> <p>Compiles the formal responses to consultation comments on the draft GPG in liaison with the GDG (see section 13)</p> <p>Revises the GPG in response to comments received</p>
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	<p>during the consultation and in accordance with NICE's review processes (see section 13)</p> <p>Liaises with other NICE teams including those developing quality standards, clinical guidelines and technology appraisals, where relevant</p>
NICE Centre for Clinical Practice (CCP) Director and the Programme Director	<p>The CCP Director and Programme Director sign off:</p> <ul style="list-style-type: none"> • the scope • final draft GPG for consultation • final GPG (following consultation) for review by the NICE Guidance Executive
NICE Guidance Executive	NICE Guidance Executive approves ('signs off') the final GPG and confirms correct processes have been followed in development
Guidance Development Group (see section 6)	<p>Agrees the review questions with the NICE project team</p> <p>Discusses the evidence and draws conclusions</p> <p>Authors and advises on the draft of the GPG in liaison with the NICE project team</p> <p>Develops the GPG recommendations</p> <p>Responds to comments received during consultation and agrees on necessary changes to the GPG</p> <p>Liaises with other NICE teams as appropriate</p> <p>Supports and promotes uptake of the GPG</p>
Stakeholders (see section 5)	<p>Contribute evidence when needed</p> <p>Comment on the draft GPG</p> <p>Support and promote uptake of the GPG</p>
Evidence resources (NICE guidance information services ^a)	<p>Compiles the literature search based on the search terms provided by the NICE project team</p> <p>Provides the NICE project team with a list of all searches and relevant literature identified (see appendix A)</p>

NICE Implementation team	Develops implementation tools and undertakes a range of other activities to support implementation and uptake of the GPG, in collaboration with the NICE project team (see section 15)
NICE Public Involvement Programme	<p>Advises on patient and carer issues</p> <p>Identifies and approaches potential patient and carer stakeholder organisations for each GPG</p> <p>Provides at least 2 patient and carer representatives for the scoping workshop (if needed)</p> <p>Encourages and facilitates applications from patients and carers who are interested in becoming GDG members</p> <p>Advises, supports and provides training for patient and carer members of GDGs</p>
Topic experts	<p>Input into scoping process (see section 4)</p> <p>Review specific sections, or the full content of the GPG</p>
NICE Publishing team	<p>Edits the draft GPG before consultation and before final publication</p> <p>Publishes the final guidance</p>
NICE External Communications	Liaises with the NICE project team before consultation on the draft GPG and final publication
Other NICE teams (including those developing quality standards, clinical guidelines and technology appraisals)	Liaises with the NICE project team and GDG, where relevant
<p>Abbreviations: GDG, Guidance Development Group; GPG, good practice guidance.</p> <p>^a Where NICE guidance information services are referred to, an externally commissioned information service may be used to provide support in this area in some cases.</p>	

1.4.3 Publication and implementation of the good practice guidance

Alongside publication of the NICE GPG, other key documents are published on the [NICE website](#), which include:

- the GDG terms of reference, which include:
 - members of the GDG
 - the final scope
- a list of registered stakeholders
- details of the NICE project team
- a schedule for developing the GPG
- a table of stakeholder comments on the consultation draft of the GPG and responses
- the consultation draft of the GPG
- tools to support implementation of the GPG.

The NICE project team also works with the implementation team to produce tools (such as slide sets, podcasts, templates) as appropriate, and undertake a range of activities to support implementation. See [section 15](#) for further information on implementation support. Each GPG and the associated implementation tools are published on the [NICE website](#).

1.4.4 Practical information

During GPG development, queries can be emailed to a dedicated email address for that specific guidance. The NICE project team will respond to any queries within 20 days of receipt. After publication, queries should be forwarded to nice@nice.org.uk.

1.5 Updating the methods guide

This methods guide is an 'interim methods guide'. As NICE develops the NICE methods manual, the process for developing GPG will be incorporated into this. The interim methods guide will be updated accordingly and will undergo a formal 12-week consultation as part of the process for the NICE methods manual development.

Comments on the content of this interim methods guide can be emailed to nice@nice.org.uk.

1.5.1 Interim updates

It may be necessary to make small changes or more significant amendments to the GPG development process before the NICE methods manual is finalised. Small changes meet the following criteria:

- No fundamental stage in the process is either added or removed.
- No fundamental method, technique or step is either added or removed.
- The efficiency, clarity or fairness of the process or methodology is improved.

More significant changes require approval by the Programme Director and Centre for Clinical Practice Director.

2 Topic consultation, selection and prioritisation

The topic consultation, selection and prioritisation occurs every 2 years and is supported by the NICE project team following:

- Stage 1: Production of proposed list of topics for development
- Stage 2: Consultation and identification of potential topics
- Stage 3: Topic selection and prioritisation
- Stage 4: Formal selection of topics.

2.1 Stage 1: Production of proposed list of topics

The NICE project team produces a proposed list of topics for developing good practice guidance (GPG), which includes:

- topics referred from the Department of Health or NHS England
- additional topics for consideration
- topics not considered for development in the current work programme but suggested in previous consultations.

The NICE project team will use a standard template for the topic selection and prioritisation process.

2.2 Stage 2: Consultation and identification of potential topics

Stakeholders (including government departments, NHS organisations and professional bodies; criteria for stakeholders remain the same as for all stages of GPG development) are invited to submit comments on the proposed list of topics and suggestions for additional topics, including a rationale for each, during a 4-week consultation phase.

The NICE project team reviews each submitted comment and topic suggestion at the end of the consultation phase. The team considers whether each suggested topic is:

- included as a topic on the long list
- added to a long list as a new topic title
- excluded from the long list because of exclusion criteria:
 - topics that have been included in existing NICE publications
 - guidance falls within the domain of other agencies or national bodies
 - specific drug-related topic
- not selected.

Each topic identified is reviewed and collated in a summary table (a standard template for the topic selection – consultation comments will be used). Topics are prioritised according to the number of suggestions made for a particular topic. For example, topic A has been suggested 7 times, topic B has been suggested once and topic C has been suggested 3 times. Topic A will take priority, followed by topic C, then topic B.

The NICE project team collates all comments received and produces a long list, which is reviewed to provide formal responses to comments. Similar topics are grouped together where relevant based on the above exclusion criteria and topic suggested. The NICE project team will use a standard topic selection – long list template.

2.3 Stage 3: Topic selection and prioritisation

The NICE project team uses the long list and applies the following inclusion criteria to create a shortlist^[1]:

- 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 NHS England.

- Topics referred for urgent consideration by NHS England or the Department of Health.

Each topic is reviewed by the NICE project team and assigned criteria as above. The drivers, rationale and organisations and their comments that endorse topic selection are included in the shortlist. Proposed timescales for guidance development are also included. The NICE project team will use a standard topic selection – shortlist' template.

Some topics identified for inclusion in the shortlist may have the same criteria as other topics that have not been shortlisted; prioritisation for the shortlist also considers the urgency and utility to the service, which may prioritise specific areas for shortlisting over others. The shortlist is limited to 6 topics only, covering a 3-year work programme.

2.4 Stage 4: Formal selection of topics

The shortlist and supporting rationale are reviewed by the Centre for Clinical Practice Director. This final shortlist is then reviewed and agreed by the NICE [senior management team](#) as formal topic selection and provides the work programme for developing GPG.

The NICE GPG development webpages are updated to reflect the topics that have been agreed.

After formal selection of topics, the NICE project lead plans a programme of work identifying a NICE project team and resources to deliver outputs over the 3-year period.

For subsequent topic consultations, the process begins with stakeholders being invited to submit suggestions and comments on the existing shortlist and provide suggestions and comments on potential topics for inclusion in the work programme. The process will then start again, following stages 1–4 as outlined above.

^[1] All of the inclusion criteria have equal importance in prioritising the shortlist, with the exception of topics referred for urgent consideration by the Department of Health or NHS England; urgent topics that are referred are considered as priority.

3 Project planning

3.1 Project timeline

A high-level timeline is produced once the good practice guidance (GPG) topic is formally selected. A detailed project timeline is then developed once work on the project starts.

3.2 Project plan

Preparing the project plan is 1 of the first steps in developing the GPG. The plan describes the rationale for the project, key outputs and requirements for delivery of the project outputs.

The project plan contains the following sections and information:

- Background to the project
- Key objectives, outlining the purpose
- The scope
- How the project will be delivered
- The NICE project team
- Process being followed
- Guidance Development Group (GDG) requirements
- The mix of skills and experience needed on the GDG
- Estimated costs for delivery
- Work schedule
- Specific development process and project timeline
- Risks associated with project delivery

- Project approval.

The NICE project team will use a standard project plan template for each GPG.

3.3 Communications

3.3.1 Working with other NICE teams

Once the project timeline has been agreed, it is communicated across NICE so that all relevant teams are aware of the project in development. NICE teams can include:

- Implementation team
- Public Involvement Programme
- Publishing team
- External Communications
- Clinical Guidelines and Technology Appraisals
- Quality Standards
- Evidence Resources and Information Services.

A GPG lead is identified in each of these teams. The NICE project team liaises with these leads throughout the development of the GPG. An overview of the key tasks of the teams is included in [table 1.1](#).

4 Scope

Topics for new good practice guidance (GPG) are identified using the topic consultation, selection and prioritisation process (see [section 2](#)). The topic selection documentation identifies the broad areas to be covered by the GPG, which is then translated into the scope for the GPG. The scope is agreed during the preliminary work stage of the development process and cannot be changed once the project plan has been signed off.

4.1 Purpose of the scope

The purpose of the scope is to:

- provide an overview of what the GPG will include and will not include
- identify the key issues and most important aspects of care that should be included
- define the breadth and depth of the GPG
- set the boundaries of the development work and provide a clear framework to enable the work to stay within the agreed priorities
- inform the development of the detailed literature search (see [section 8](#)) from the key issues
- provide information to healthcare and other professionals, stakeholders and the public about the expected content of the GPG
- ensure that the GPG can be developed within the specified time period.

The scope provides a framework within which to conduct the guidance development work.

4.2 Content of the scope

The title of the GPG is considered carefully by the NICE project team to ensure it adequately reflects the content of the scope. The scope briefly defines:

- the high-level systems and processes that the GPG will and will not cover

- an indication of how much detail will be provided for each system or process – for example, the breadth and depth of the GPG
- the healthcare setting – for example, NHS-commissioned services, care homes or independent hospitals
- the audience for the GPG – for example, health and social care professionals.

The scope may also include, for clarification when necessary:

- populations to be included or excluded – for example, specific age groups
- geographical relevancy.

4.3 Scope development

The scope is prepared by the NICE project team using the following stages of development:

- Stage 1: Identification of key areas for inclusion
- Stage 2: Preparation of first draft
- Stage 3: Expert and/or stakeholder review
- Stage 4: Finalisation of scope
- Stage 5: Sign off and publication.

4.4 Stage 1: Identification of key areas for inclusion

This stage involves considering any relevant remit from the NICE senior management team (including GPG topic selection), the Department of Health and/or NHS England to identify key areas for inclusion. This remit forms the basis of the scope, and all issues specified by the remit are addressed in the scope. The remit may also be intended to support the subsequent development of a NICE quality standard. Identification of these key areas informs the preliminary literature search and helps to identify the systems and processes to be covered by the GPG.

4.4.1 Preliminary literature search

A high-level preliminary literature search is undertaken to inform both the draft scope and the scoping workshop. The search is developed using a broad PICO (population, intervention, comparator and outcomes) framework and is based on the key areas for inclusion. Each search is divided into 4 components:

- population
- intervention
- comparators
- outcome.

Box 4.1 Features of a well-formulated, high-level search using the PICO framework

Population: Which populations of patients are we interested in? How can they be best described? Are there subgroups that need to be considered?

Intervention: Which intervention, system or processes are, or should be, used?

Comparators: What are the main alternatives to compare with the interventions, systems or processes being considered?

Outcome: What is really important for the patients? Which outcomes should be considered?

The overarching themes are identified from the preliminary search and are used to identify the overarching themes, systems and processes which, along with the scoping process, identify the review questions for the GPG and refine the PICO framework for the main literature search.

4.5 Stages 2 and 3: Draft scope preparation and review

The draft scope is prepared by the NICE project team after review of the literature search results. It is then reviewed and revised. This involves:

- a scoping workshop

- liaison with experts.

4.5.1 Scoping workshop

A scoping workshop is held. An email alert is sent inviting people with specific knowledge and experience relevant to the topic to submit an expression of interest in attending the event. Delegates are chosen by the NICE project team to ensure the group provides the correct mix of backgrounds and experience to inform the scope. The scoping workshop is also used to identify key stakeholders and help inform the composition of the Guidance Development Group (GDG).

4.5.2 Liaison with relevant experts

The proposed scope is written by the NICE project team, which is reviewed, clarified and validated by relevant experts and delegates from the scoping workshop.

4.6 Stages 4 and 5: Finalising, sign off and publication

After review, the draft scope is finalised by the NICE project team and signed off by the Centre for Clinical Practice Director and Programme Director. It is published on the NICE website within the 'Terms of Reference' of the GDG.

5 Stakeholders

5.1 Stakeholder organisations

Stakeholders play an integral role in developing good practice guidance (GPG) and are encouraged to get involved at all stages. Organisations representing the NHS, social care, patient and carer representative bodies, as well as government organisations and private sector organisations with an interest in a particular topic, can register as stakeholders for a particular GPG topic. Registered stakeholder organisations can comment on the draft GPG during consultation (see [section 13](#)).

5.1.1 Organisations that can register as stakeholders

The following organisations can register as stakeholders for NICE GPG:

- national patient and carer organisations that directly or indirectly represent the interests of people whose care will be covered by the GPG
- local patient and carer organisations, but only if there is no relevant national organisation (see [section 5.1.2](#))
- national organisations that represent the health and social care professionals who provide the services described in the GPG
- companies that manufacture the medicines or devices used in the area covered by the guidance and whose interests may be significantly affected by the GPG
- providers and commissioners of health and social care services in England, Wales and Northern Ireland
- statutory organisations including the Department of Health, NHS England, the Welsh Government, Healthcare Improvement Scotland and the Care Quality Commission
- research organisations that have carried out nationally recognised research in the area.

NICE GPG is produced for the NHS in England and Wales. Therefore, a 'national' organisation is defined as one that represents England or Wales has a commercial interest

in England or Wales.

5.1.2 Who cannot register as stakeholders

For reasons of capacity, local patient and carer and professional groups cannot register as stakeholders unless there is no national organisation representing the group's specific interests.

Individual people cannot register as stakeholders. However, anyone with an interest in the topic is encouraged to participate by contacting a registered stakeholder and expressing their views to them. Additionally, external expert advisers may be identified by the NICE project team (see [section 5.5](#)).

5.2 Alerting and identifying potential stakeholders

Once new topics for the GPG are agreed after the topic selection process (see [section 2](#)), they are listed on the NICE website along with details of how to register as a stakeholder.

At the start of the development process for new GPG topics, an email is sent to potential stakeholders to alert them to the topic and the stakeholder registration process. The alert is sent to:

- people signed up to receive [NICE's medicines and prescribing email alerts](#)
- a list of organisations identified by the NICE project team that may have an interest in the GPG topic, which may include:
 - patient and carer organisations
 - professional organisations
 - local authority organisations
 - industry representative organisations
- organisations that registered as stakeholders for previous GPG or other relevant NICE guidance/standards.

Delegates of any possible scoping workshop are also encouraged to identify potential stakeholders who are not registered.

The NICE project team cannot guarantee that all organisations that may have an interest in a particular GPG topic will be notified about the topic. Potential stakeholders are encouraged to visit the website regularly to check the list of GPG topics in development and register if appropriate.

5.3 Stakeholder registration

Stakeholder organisations are encouraged to register their interest in a particular piece of GPG as soon as possible after the topic is announced (see [section 2](#)). This enables them to participate in the early stages of guidance development (including development of the scope as appropriate). However, organisations may register as stakeholders at any time in the development process and can be involved in the remaining stages of guidance development.

To register an organisation as a stakeholder, registration details (name of organisation, name of contact and email address) should be entered using the [stakeholder registration](#) page on the website. Organisations can register for any currently selected GPG topic. Organisations receive an automated response once the registration process is completed. Stakeholder applications are reviewed and organisations are contacted if additional information is needed or they are not eligible to be a stakeholder.

The current list of registered stakeholders for each GPG topic is published on the website at the time of consultation and updated when the GPG is published.

5.4 Role of stakeholders

Stakeholders can be involved in different ways throughout the process and this varies depending on the needs of the specific topic. Stakeholders may, where appropriate for the GPG being developed:

- be notified regarding a scoping workshop (see [section 4.5.1](#))
- respond to a call for evidence in guidance development (see [section 8.9](#))
- comment during the consultation period on the draft GPG (see [section 13](#)).

All registered stakeholders are notified when the GPG is available for consultation and when the final GPG is published.

5.5 External expert advisers

Although NICE does not routinely commission peer review from external experts, the NICE project team may occasionally consider arranging additional external expert review of specific sections or the full content of the GPG. These experts may include health and social care professionals, people with a patient and carer perspective, or those commissioning care.

The expert review may take place during GPG development or at the consultation stage. If the review occurs during development, the process and comments remain confidential, but the adviser(s) is named in the final GPG. Comments from external expert advisers during the development of the GPG are discussed by the GDG.

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 GPG consultation comments table on the NICE website under 'expert advisers'. All expert advisers are required to complete a declaration of interests form.

6 Guidance Development Group

A Guidance Development Group (GDG) is established for each good practice guidance (GPG). The GDG is the primary source of expertise that determines the content of the GPG as defined within the scope of the project.

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 knowledge and experience. All members of the GDG have equal status, reflecting the relevance and importance of their different expertise and experience.

The GDG considers the NICE project team's initial review of the existing evidence, confirming (or challenging) the appropriateness for inclusion in the GPG. It 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 project team.

All GDG members are committed to developing the GPG according to the processes set out in this methods guide and to work within [NICE's equality scheme](#). They are expected to attend all GDG meetings (usually 5).

Members of the GDG are not permitted to submit comments as stakeholders during the consultation on the draft guidance (see [section 13](#)). If a GDG member is involved with a registered stakeholder organisation, they should not submit comments during the consultation on behalf of that organisation – someone else in the organisation should submit the comments.

6.1 Forming the Guidance Development Group

The chair, vice chair and members of the GDG are appointed for the duration of a particular piece of guidance development. Discussion about GDG membership takes place at the scoping workshop (see [section 4.5.1](#)).

6.1.1 The composition of the Guidance Development Group

The composition of each GDG is described in the project plan that is prepared by the NICE project team after the scoping workshop. This plan is agreed by the project lead and signed off by the Programme Director. Each GDG usually consists of 15–25 people, excluding the NICE project team.

The GDG has 5 key constituents:

- the chair
- the vice chair
- members from health, social care and other professions (both specialists in the topic and generalists)
- public, patient and/or carer representatives ('lay members')
- NICE project team members.

Membership of the GDG is multidisciplinary and the exact composition of the GDG is tailored to the topic covered by the GPG. It should reflect the range of stakeholders and groups whose professional activities or care will be covered by the GPG, and should include at least 2 lay members. Members of the GDG should have sufficient expertise and credibility to command the respect of people within their field.

The GDG may also be supported by expert advisers (see [section 5.5](#)).

As far as possible, the GDG will have an appropriate balance with regard to the principles of [NICE's equality scheme](#).

Ideally, GDG members are drawn from different parts of England and Wales, but this is influenced by the expertise available and does not exclude anyone from any other home country.

New members are not usually added to the GDG once the first GDG meeting has taken place, because this may disturb the group dynamic. After appointment, if a GDG member is unable to fulfil their duties (for example, because of illness), the project team may consider recruiting to replace that person. If additional expertise is needed, the GDG may co-opt (see [section 6.1.5](#)) an 'expert adviser' on the group or invite them to attend a

specific portion of a meeting.

Vacancies for GDG positions are posted on the [NICE website](#). Other means are also used to alert people to GDG vacancies, including sending email alerts to target groups from the [NICE medicines and prescribing email alert system](#) and using local networks.

6.1.2 Recruiting the Guidance Development Group chair and vice chair

Recruitment for the positions of chair and vice chair for each GDG follows NICE's policy [Appointments to guidance producing bodies advisory to NICE \(November 2006\)](#).

Applicants are required to submit a curriculum vitae (CV; including names and contact details of 2 referees), a completed declaration of interests form, a completed equality monitoring form and a statement explaining how they meet the criteria laid out in the person specification. The chair and vice chair are appointed after interview by the selection panel, which should include the Centre for Clinical Practice Director (or delegate) and a non-executive director of NICE.

6.1.3 Recruiting Guidance Development Group members from health, social care and other professions

Recruitment of members for each GDG follows NICE's policy [Appointments to guidance producing bodies advisory to NICE \(November 2006\)](#).

Health and social care (and other professions where relevant) professional members of the GDG are recruited shortly after scoping. They should represent the perspective(s) of health and social care professionals (and other professionals where relevant) involved in the care of people affected by the guidance topic.

The members are professionals with appropriate knowledge and skills; detailed research expertise is not necessary.

A GDG has, on average, between 11 and 21 health and social care professional members (excluding chair, vice chair and lay members), the list of professions represented is agreed as part of the project plan.

The roles and responsibilities of the health and social care (and other professions)

professional members of the GDG are shown in box 6.1.

Box 6.1 Key roles of health and social care (and other professions) professional members of the Guidance Development Group

GDG members from health and social care professions (and other professionals where relevant) are expected to:

- agree the terms of reference for the GDG and abide by them
- agree the draft GPG structure including review questions, based on the key issues in the scope
- contribute constructively to meetings and have good communication and team-working skills; this should include a commitment to the needs of patients and carers
- use their background knowledge and experience of the GPG topic to provide guidance to the NICE project team
- author and advise on the draft of the GPG in liaison with the NICE project team
- read all relevant documentation and make constructive comments and proposals at (and between) GDG meetings
- with other members of the GDG, develop recommendations based on the evidence reviews, or on consensus when evidence is poor or lacking
- advise on how to identify good practice in areas where research evidence is absent, weak or equivocal
- with other members of the GDG, consider implementation issues arising from recommendations, feed back to the NICE implementation team and assist with developing identified implementation support tools (see [section 15](#))
- with other members of the GDG, agree the minutes of GDG meetings.

Vacancies for health, social care and other professional GDG members are advertised on the NICE website. NICE informs registered stakeholder organisations about the advertisement via email. In addition, other means are used to alert people to GDG vacancies, including sending an email alert to relevant groups signed up to receive [NICE medicines and prescribing email alerts](#) and using local networks.

Applicants are required to submit a CV (including names and contact details of 2 referees), a completed declaration of interests form, an equality monitoring form and a statement explaining how they meet the criteria laid out in the person specification. Members are selected by the NICE project team in agreement with the programme director. They are not usually asked to attend an interview.

6.1.4 Recruiting lay members

Patients, carers and other members of the public can apply to become GDG members by responding to advertisements posted on the [NICE website](#). NICE's [Public Involvement Programme](#) contacts all registered patient and carer stakeholder organisations to alert them to these advertisements. However, a person does not need to be a member of a registered stakeholder organisation to apply. The process includes:

- People who want to reply to the advertisement can download an application pack from the NICE website, which includes a 'job description' and a person specification to help them decide whether they have the experience and skills to make an effective contribution to the GDG. This pack can be sent by post on request.
- Applicants are asked to complete an application form describing how their skills and experience meet the specified requirements. They must also complete a declaration of interests form and an equality monitoring form.
- Applications are sent to the Public Involvement Programme, which can also offer advice and support during the application process, both to patient and carer organisations and to individual applicants.
- The Public Involvement Programme forwards all applications to the NICE project team. The NICE project team selects lay members according to the criteria in the job description and person specification. Applicants are not usually interviewed.

6.1.5 Non-Guidance Development Group members attending Guidance Development Group meetings

People who are not members of the GDG may also attend GDG meetings, as either expert advisers or observers. They may be health or social care or other professionals, patients or carers, other experts, or NICE staff. They are expected to follow the code of conduct of the GDG and to sign the confidentiality agreement form (see [section 6.3](#)).

6.1.5.1 Expert advisers and presenters of oral evidence

If the GDG does not have sufficient knowledge or expertise to make recommendations in a particular area, it may call on presenters of oral evidence (see [section 8.9](#)) and/or 'expert advisers'. Stakeholders and/or relevant organisations or individuals with a significant role or interest in the GPG topic being developed may be invited to present oral evidence.

To support the GDG to make decisions, external expert advisers can be appointed to provide additional evidence from their specific expertise. The advisers can also include people with a patient and carer perspective. Expert advisers attend a GDG meeting because of their knowledge in a particular area. It is therefore important that they sit within the group and enter fully into any discussion. However, they are not full members of the GDG; they do not have voting rights, and they should not be involved in the final decisions or influence the wording of recommendations. They are required to submit a declaration of interests form before attending the GDG meeting (see [section 6.3](#)).

6.1.5.2 Observers

An observer at a GDG meeting may be asked to sit apart from the group, and should enter into discussions only if invited to do so by the GDG chair. Observers at GDG meetings may include members of NICE staff (for example, the lead editor and the implementation lead). Observers who are not members of NICE staff are required to sign a declaration of interests form, and need prior permission of the group to attend.

6.2 Induction to the Guidance Development Group

As part of the first GDG meeting, the NICE project team conducts a brief induction for all GDG members. This includes an overview of the development process and timelines and relevant NICE policies and procedures. The project team ensures that the group has the project team's contact details for ongoing support. Additional support is available for lay members from NICE's Public Involvement Programme.

6.3 Governance

6.3.1 Terms of reference for the Guidance Development Group

The NICE project team produces a draft terms of reference for the GDG that is discussed

and agreed at the first GDG meeting. All members of the GDG must agree to terms of reference and abide by them. The NICE project team will use a standard GDG 'terms of reference' template.

6.3.2 Code of conduct and declaration of interests

On appointment, all GDG members are asked to sign a [declaration of interests form](#) and a [confidentiality form](#) stating that they agree not to disclose any of the draft GPG recommendations before the public consultation begins. This is to ensure that recommendations in the public domain have been agreed by all members of the GDG. NICE has a [code of practice for declaring or dealing with conflicts of interest \(October 2008\)](#).

All people who see documents or who are party to discussions relating to GPG before public consultation are required to sign the declaration of interests and confidentiality agreement forms before becoming involved.

6.3.3 Social value judgements and equality scheme

Before the GDG starts its work, all GDG members are sent an electronic copy of NICE's most recent report on social value judgements: [Social value judgements: principles for the development of NICE guidance](#) (2nd edition; 2008) (paper copies are provided on request). The NICE project team also makes sure that GDG members are aware of [NICE's equality scheme and action plan](#).

6.3.4 Dealing with enquiries on Guidance Development Group work

If GDG members are asked by external parties – including stakeholders or their professional organisation – to provide information about the work of the GDG, they should first discuss the request with the NICE project team. They should also declare this at the next GDG. Any media-related enquires should be directed immediately to NICE's Enquiry-handling team via nice@nice.org.uk and the NICE project team should also be informed.

6.4 Running the Guidance Development Group

Running the GDG is the responsibility of the NICE project team, in consultation with the

chair. Core responsibilities for all meetings include:

- setting meeting dates (which is done well in advance)
- planning agenda items
- sending out papers
- keeping records of all meetings
- ensuring that all GDG members have a copy of the current interim methods guide for developing GPG.

Notes are taken at each meeting by the NICE project team, which include:

- where the meeting took place
- who attended
- apologies for absence
- any changes to declarations of interest of those in attendance, including actions and decisions made about any conflict of interest
- a list of the subjects discussed
- a summary of the discussion that took place with any actions or decisions
- date, time and venue of next meeting.

Each set of notes is approved by the GDG at the following meeting, and signed off by the GDG chair and the NICE project team.

6.4.1 General principles

Because the GDG is multidisciplinary, its members bring with them different beliefs, values and experience. All these perspectives should be valued and respected. Each GDG member should have an equal opportunity to contribute to the guidance development process. It is the role of the NICE project team to ensure terminology used by GDG members is understood by all and clarified if needed. The chair should ensure that there is sufficient discussion to allow different beliefs, values and experiences to be considered, while keeping the group focused on the GPG scope and the timescale of the project.

6.4.2 Quorum

The quorum of the GDG is 50% of appointed members. No business relating to the formulation of GPG recommendations may be conducted unless the meeting is quorate. If a member is excluded because of a conflict of interest and this causes membership to fall below the quorum, no business may be transacted.

Expert advisers (see [section 5.5](#)) are not appointed members of the GDG and do not count towards the quorum.

6.4.3 Guidance Development Group meetings

There are usually 5 GDG meetings that are scheduled in advance and form part of the project plan. Most are 1-day meetings, but some may take place over 2 days. Some meetings may be rescheduled to meet the needs of the GDG.

[Box 6.2](#) provides an overview of the purpose of each GDG meeting.

Box 6.2 Guidance Development Group meetings

	Purpose
GDG meeting 1	<ul style="list-style-type: none">• Provide an overview of the GPG development process and introduce the role of the GDG• Provide an overview of the project timeline• Introduce the NICE policies relevant to GDG members• Gain agreement of the GDG terms of reference• Present and review the literature search• Discuss the Gap analysis (see section 8.8) including a discussion on methods to address gaps and a discussion of the proposed draft review questions (see section 7)

GDG meeting 2	<ul style="list-style-type: none"> • Discuss the progress made on the development of the guidance wording and on the additional evidence received since GDG meeting 1 • If necessary, the GDG should agree organisations that will be called to give oral evidence at GDG meeting 3
GDG meeting 3	<ul style="list-style-type: none"> • Discuss the progress made on the development of the guidance wording • If needed, include an oral evidence session led by the chair. After an oral evidence session, the GDG discusses the evidence presented and how this feeds into the development of the GPG
GDG meeting 4	<ul style="list-style-type: none"> • Discuss the final wording of the draft GPG for consultation including recommendations • Approve and confirm final draft recommendations prior to consultation
GDG meeting 5	<ul style="list-style-type: none"> • Discuss the comments received during consultation and any amendments needed to the GPG • Agree the final wording of the recommendations

6.5 Making group decisions and reaching consensus

6.5.1 Reaching agreement

GDG members need to make collective decisions throughout the development of the GPG. These include agreeing review questions ([section 7](#)), interpreting the evidence ([section 9](#)) and developing GPG recommendations ([section 12](#)). There are many different approaches to making group decisions, and there is no blueprint about which approach should be used in which circumstances. Also, because GDGs function in different ways to reflect their individual membership, it is difficult to be prescriptive about the approach that should be used.

In most cases, the GDG reaches decisions through a process of informal consensus. The role of the chair is to ensure that each person on the GDG is able to present their views, that assumptions can be debated and that the discussions are open and constructive. The GDG chair needs to allow sufficient time for all members to express their views without feeling intimidated or threatened, and should check that all members of the group agree to endorse any recommendations. If the group cannot come to consensus in a particular area, this is reflected in the wording of the recommendation. Any areas of uncertainty are acknowledged by the GDG.

Some GDGs may choose to use more formal voting procedures for certain decisions, but it is beyond the scope of this guide to offer guidance on when these should be used, or which of the many variants might be used.

7 Review questions

At the start good practice guidance (GPG) development, the key areas for inclusion identified in the scope are translated into review questions. The review questions must be clear, focused and closely define the boundaries of the topic. They are important both as the starting point for the systematic literature review and as a guide for the development of recommendations by the Guidance Development Group (GDG). The development of the review questions starts after scoping and the search results should be available for the GDG1 to review.

7.1 Number of review questions

The exact number of review questions for the GPG depends on the topic and the breadth of the scope (see [section 4](#)). However, the number of review questions must be manageable to enable the GDG and the NICE project team to complete guidance development within the agreed timescale. For most GPG topics, 8–12 review questions is a reasonable number. However, review questions vary considerably in the number of relevant studies and the complexity of the question and analyses, and the numbers of questions given here are only a guide. For example, a single review question might involve a complex analysis of a large volume of evidence. At the other extreme, a question might address the effects of a single, simple process and have little relevant evidence.

7.2 Developing review questions from the scope

Review questions are developed by the NICE project team after approval of the scope of the GPG. The review questions should address all areas covered in the scope, and should not introduce new aspects not specified in the scope. They contain more detail than, and should be seen as building on, the key areas identified in the scope.

7.3 Formulating and structuring review questions

A good review question is clear and focused. The exact structure of the review question depends on what is being asked, but it is likely to fall into 1 of 5 main areas:

- Legislation and regulation

- Systems and processes
- Governance
- Patient safety
- Training and competencies.

The review questions are based on thematic analyses of the issues raised by the scoping process and are developed using a broad PICO (population, intervention, comparator and outcomes) framework (see [section 4.4.1](#)).

Each review question takes into account the various confounding factors that may influence the outcomes and effectiveness of a system or process and specifies the healthcare setting for the question if necessary. To facilitate this process, outcomes and other key criteria considered to be important are listed.

7.4 Using the review questions to inform the search strategy

Once the review question has been developed, this is signed off by the NICE project lead. After sign off, the NICE project team uses the review questions to identify search terms that inform the literature search strategy. Search terms are provided to NICE's guidance information services^[2] on a literature search request template (see [appendix A](#)). The information service providers then develop the search strategy. Search results, including the search strategy are returned to the NICE project team (see [section 8.4](#)). The review questions and search results are reviewed, discussed and agreed by all GDG members at the first GDG meeting. The different perspectives among GDG members help to ensure that the right review questions are identified. On occasion, the questions may need refining once the evidence has been searched; such changes are documented.

^[2] Where NICE guidance information services are referred to, an externally commissioned information service may be used to provide support in this area in some cases.

8 Identifying the evidence: literature searching and evidence submission

The systematic identification of evidence is an essential step in developing the good practice guidance (GPG). Systematic literature searches are undertaken by NICE's guidance information services^[3] to identify the evidence. Sources used to search for evidence depend on the review questions identified from the scoping workshop (see [section 4](#)). Search terms are provided to the information service for the literature search (see [appendix A](#)).

8.1 Methods of obtaining evidence

This section contains the main methods used to gather evidence for developing the GPG. The NICE project team will use a standard template to request literature search from NICE guidance information services^[3].

8.1.1 Devising a search strategy

The evidence underpinning the GPG is derived from review questions arising from the scope and scoping workshop with stakeholders. The NICE project team develops the review questions into search terms for request using a PICO (population, intervention, comparator and outcome) framework (see [section 4.4.1](#)).

The search strategy is constructed by NICE guidance information services^[3] for terms relating to the population; this can be combined with terms relating to the interventions and comparators (if any) to be evaluated. Not all components of a search term or review question are always mentioned in the abstracts or subject headings of database records – outcomes are often not mentioned. Therefore, these components may not be included when developing a strategy. For GPGs being updated, previous strategies can be used to inform the search strategy design.

8.1.2 Identifying search terms

Search strategies usually consist of a combination of subject headings and 'free-text' terms from the titles and abstracts of relevant studies. Search terms used are derived from

the review questions identified during the scoping process. Subject headings are used to identify the main theme of an article. When identifying subject headings, variations in thesaurus and indexing terms for each database are included; for example, MeSH in MEDLINE and the Cochrane Library, and Emtree in Embase. Free-text terms may include synonyms, acronyms and abbreviations, differences in terminology across national boundaries, different spellings, old and new terminology, brand and generic drug names, and lay and medical terminology. Misspellings or typographical errors may also affect a search, particularly with records being indexed, for which there may be only a title and no abstract or subject headings.

8.1.3 Sensitivity and precision

The key attributes of a search strategy are:

- sensitivity: the number of relevant records retrieved by a search strategy as a proportion of the total number of relevant records ([Jenkins 2004](#))
- precision: the number of relevant records retrieved by a search strategy as a proportion of the total number of records retrieved ([Jenkins 2004](#)).

Both attributes are influenced by the time period covered and by the search terms used. Although it is important that searches for systematic reviews attempt to identify all the relevant literature, there needs to be a trade-off between conducting an exhaustive search requiring additional resources compared with undertaking a more modest search that may miss some studies. Identifying key studies for a review question can assist in checking search sensitivity; such studies can also act as a guide to search terms.

8.1.4 Grouping review questions

Review questions that overlap and can be grouped together are identified for searching purposes (for example, questions about factors contributing to medication errors in care homes).

Questions that have the 'population' and 'intervention' in common but a different comparator can be grouped together by identifying and combining search terms for the population and intervention only.

8.1.5 Limiting searches

Using certain parameters to limit searches can improve precision without affecting sensitivity:

- Date parameters depend on the GPG topic and when most of the research was published. The date range for the search is agreed by the NICE project team, in consultation with experts in the area if appropriate. If relevant good-quality published systematic reviews exist, additional searching may be limited to updating the reviews, covering the time period since the searches for the published systematic reviews were conducted. Existing reviews may not address all of the relevant outcomes, in which case new searches may be needed. Authors of published reviews may be contacted for updates, particularly for reviews found in the Cochrane Database of Systematic Reviews.
- Depending on the review question, it may be appropriate to limit searches to particular study designs. The best way to do this is to use an appropriate search filter rather than limiting searches by the publication type field (see [appendix A](#)).
- If a decision has been taken to limit a review to studies reported in English, the appropriate database limit function can be used to improve precision.

8.2 Databases and sources to search

Databases and other sources that are searched to identify evidence depend on the review question.

8.2.1 Core and subject-specific databases

The core databases listed in [table 8.1](#) are searched for every review question. Additional subject-specific databases and other resources may also need to be searched, depending on the subject area of the review question and the type of evidence sought. Links are provided in [table 8.1](#) and [table 8.2](#) for sources that can be easily accessed.

Table 8.1 Databases that can be searched

Question type	Databases
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Review questions about interventions, systems and processes, patient experience and service delivery	Core databases: <ul style="list-style-type: none">• Cochrane library• NICE Evidence• MEDLINE/MEDLINE In-Process• Embase• Health Business Elite• Clinical evidence
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	<p>Subject-specific database/ websites (this list is not exhaustive):</p> <ul style="list-style-type: none"> • <u>AMED (Allied and Complementary Medicine Database)</u> • <u>Audit Commission</u> • British Nursing Index • <u>The Campbell Collaboration Library of Systematic Reviews</u> • Cumulative Index to Nursing and Allied Health Literature (CINAHL) • <u>Education Resources Information Center (ERIC)</u> • Health Management Information Consortium • <u>Medicine journal</u> • <u>PsycINFO</u> • <u>Canadian Agency for Drugs and Technologies for Health</u> • <u>Health Technology Assessment Programme</u>
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An awareness of the strengths and weaknesses of each database is important when undertaking a systematic literature search.

The various databases use different:

- index journals

- subject headings
- time periods
- amounts of bibliographic information.

For example, Embase is considered stronger than MEDLINE in covering pharmacology, toxicology, drug research and psychiatric literature, but contains selected dental and nursing literature. MEDLINE contains a collection of scope notes for its subject heading (MeSH) terms, which can assist in developing the search strategy. Records retrieved from the different databases for a particular review question may overlap; the extent of this overlap for MEDLINE and Embase is reported as being between 10% and 87% depending on the topic ([Lefebvre et al. 2008](#)). Cross-database searching, although time-consuming, is needed to comprehensively identify evidence for GPG development.

8.2.2 Other sources of information

The sources listed in [table 8.2](#), including databases and websites, can provide useful information about ongoing research, patient experience, audits and statistics to help guide the Guidance Development Group's (GDG's) decision-making. Because the GPG is aimed at providing advice and guide good practice for people involved in handling, prescribing, commissioning and decision-making about medicines, for most of the topics it is necessary to use regulatory authorities and professional bodies as a source of information. This list is not exhaustive; the 'Searching for studies' chapter in the [Cochrane handbook](#) provides an overview and further examples of sources to search ([Lefebvre et al. 2011](#)). Other sources used depend on the GPG topic.

Table 8.2 Other sources of information

Source	Website
NICE-accredited organisations (<i>this list is not exhaustive</i>)	All Wales Medicines Strategy Group (AWMSG) Healthcare Improvement Scotland Medicines and Healthcare products Regulatory Agency NICE Social Care Institute for Excellence (SCIE) Scottish Intercollegiate Guidelines Network (SIGN)

Legislation	http://www.legislation.gov.uk
Department of Health	https://www.gov.uk/government/organisations/department-of-health
International Standard Randomised Controlled Trial Number Register	www.controlled-trials.com/isrctn
National organisations	NHS England Public Health England National Audit Office Care Quality Commission
Regulatory Authorities (<i>this list is not exhaustive</i>)	General Dental Council General Medical Council General Optical Council General Pharmaceutical Council Health Professions Council Health and Safety Executive Council for Healthcare Regulatory Excellence Nursing and Midwifery Council
Professional bodies (<i>this list is not exhaustive</i>)	Royal College of Nursing British Medical Association Royal Pharmaceutical Society British Dental Association
Web of Knowledge	www.isiwebofknowledge.com
Conference Papers Index	www.csa.com/factsheets/cpi-set-c.php
The King's Fund	www.kingsfund.org.uk
NHS Education for Scotland	http://www.nes.scot.nhs.uk
Health Education England	http://hee.nhs.uk
Hospital Episode Statistics	www.hesonline.nhs.uk
Patient Episode Database for Wales	www.wales.nhs.uk/sitesplus/922/page/50308

National or regional audits	Search by topic or geographical area for appropriate audit data.
Information about patient experiences	www.healthtalkonline.org www.youthhealthtalk.org
Surveys of patients' experiences	Search for relevant patient organisation websites; condition-specific or topic-specific as appropriate.
Others	eGuidelines InfoPOEMS Drugs and Therapeutic Bulletin (DTB) Bandolier Regional Drug & Therapeutics Centre Office of Health Economics

8.3 Quality assurance of search strategies

The quality and accuracy of search strategies during the development of the GPG is checked. Although it is not usually possible to check all strategies for every search, the following approaches may be used to ensure that the key studies are retrieved:

- Ask GDG members to identify, for example, key studies, legislation and policies (if relevant to the GPG topic) that are already published, but not included in the search results.
- Check search strategies used in existing published systematic reviews.
- Check the bibliographies of included studies to ensure all relevant papers have been retrieved by the search strategy used.
- If relevant papers have not been retrieved by the search strategy, investigate and amend the strategy if appropriate.

8.4 Reference management software

Electronic records of the references retrieved by searches are stored using the reference management software 'Reference Manager'. Records are exported from bibliographic

databases such as MEDLINE and imported automatically into the software using import filters by NICE guidance information services^[3] who then forward the prepared reference management files to the NICE project team. Details of any additional references identified in guidance development or any oral submissions needed by the GDG are added to the files manually.

In addition to storing records of references, the NICE project team use the reference management software for the following:

- coding the references with additional information, such as:
 - the source of the reference
 - the review question it was identified to answer
 - the study design
 - selection decisions
- providing links to the full text of articles, where possible
- logging the ordering and/or receipt of articles
- keeping track of the printed copies of papers.

The coding scheme is determined and agreed by the NICE project team before working with a reference management database to ensure consistency of use (see [appendix B](#)).

8.5 Sifting

8.5.1 First sift

A first sift reviews each article by title and abstract against search criteria, removing any irrelevant results. This may be done by either the NICE project team or NICE guidance information services^[3] (see [appendix A](#)).

8.5.2 Second sift

Two members of the NICE project team independently sift each article by title and abstract in the reference management database. An opinion is recorded on whether each

article meets the criteria for inclusion or exclusion taken from the PICO framework (see [section 4.4.1](#)), drawn up to answer the review questions for the GPG.

Once complete, a reconciliation meeting assesses and resolves any difference of opinion on articles over which there is disagreement. If there is no resolution, a third opinion that is binding is sought from a third NICE project team member. A final list of articles for inclusion is signed off by the NICE project lead after agreement by the GDG at GDG meeting 1. Any articles excluded at this stage have a rationale for exclusion recorded in the reference management database.

8.6 Acquiring full text of references

The NICE project team accesses the full text of references from several sources and asks the NICE guidance information services^[3] for those references that cannot be sourced using these methods.

The full text of references can be obtained from several sources:

8.6.1 Free online journal articles

Many journals provide free access to some or all of their content. Several journals apply this to all material more than 1 or 2 years old; others provide access to particular types of articles only (for example, the British Medical Journal provides free access to all research articles). Individual articles can be purchased from the websites of most journals that do not allow free access, but this can be expensive.

Some websites provide links to medical journal web pages with freely available articles. Two that are used are [Free Medical Journals](#) and [Genamics JournalSeek](#).

NICE Evidence Services and its Welsh equivalent, [NHS Wales eLibrary for health](#), provide free access to some journals for all NHS staff and staff in organisations such as NICE using an Athens log-in. This log-in can be obtained by applying to the NICE guidance information services^[3].

8.6.2 Free online reports

Many institutions make their reports and guidelines freely available online, so the relevant

websites can be checked.

8.6.3 Libraries

Many libraries that stock a wide range of journals, books and reports have an inter-library loan or document delivery service. All supply articles within copyright law and some loan documents. There is usually a charge for this service, and for loans the cost of postage is usually extra. Some libraries provide articles at a reduced cost if an annual subscription is taken out. Three major libraries offering this level of service are the British Library, the British Medical Association (BMA) Library and the Royal Society of Medicine Library. A British Library account also allows users to pay for articles from other libraries that accept payment in this way.

When these references are needed, the NICE project team uses NICE guidance information services^[3] to source the reference.

8.7 Documenting search strategies

An audit trail is kept of the searches for all types of evidence carried out during the GPG development process to ensure the process for identifying the evidence is transparent and reproducible.

8.7.1 Internal documentation

The following information is recorded for each search carried out during the GPG development process:

- details of the question for which the search was conducted
- the names of the databases and database host systems used
- the database coverage dates; for example, Ovid MEDLINE 1950 to February week 3 2012
- the date on which the search was conducted
- the search strategy (this should be stored in an easily accessible form, such as Microsoft Word)

- any limits applied to the search or to study designs searched for
- the number of records retrieved from each database
- a text file and/or database (Reference Manager) of results.

Enough detail is provided to allow searches to be repeated if needed.

8.7.2 Documentation for the good practice guidance

A full description of the searching process is included in the methods section of the GPG, which should include:

- details of the scoping search (see [section 4.4.1](#))
- details of the development of the search strategies
- dates on which the searches were carried out
- any limits placed on the type of evidence searched for and details of methodological search filters, if used
- names of the databases, database host systems and any other sources searched
- date or language limits applied to searches
- a consort diagram.

8.8 Gap analysis

From the evidence identified in the main literature search, the NICE project team determines if there is sufficient published evidence to address the review questions identified from the scoping workshop. The gap analysis documents the sources, type (nature of the published information) and, where appropriate, the quality of the retrieved published literature. Information describing current practice, the level of activity and any significant regional variation is summarised alongside the published evidence. The gap analysis is provided to the GDG for discussion at GDG meeting 1. This helps the GDG to:

- identify the gaps between current practice, service provision and patient experience
- shape the GPG and formulate recommendations likely to have the greatest impact on

practice, including clinical outcomes.

8.9 Additional evidence

8.9.1 Call for written evidence

For some review questions, the GDG and NICE project team may agree that information exists that has not been found using standard searches. Therefore, the GDG and the NICE project team may 'call for evidence'. This call goes to all stakeholders and/or relevant organisations or individuals with a significant role or interest in the GPG topic being developed. It specifies the question(s) being addressed and detail the type of evidence being sought, for example, in terms of PICO framework (see [section 4.4.1](#)) and study design for questions of effectiveness. The need for a call for evidence is agreed at GDG meeting 1. The opportunity to provide written evidence is usually open for 2 weeks. All written evidence submissions are considered at GDG meeting 2.

8.9.1.1 Confidential Information

In addition to published studies, organisations or individuals may submit relevant unpublished information in response to a call for evidence. When the NICE project team and the GDG send out a call for evidence, respondents are asked to complete a checklist that lists and identifies the location of all confidential information contained in their submission. The NICE project team keeps the checklists for their records to ensure that the draft and final versions of the GPG do not contain confidential information.

[Box 8.1](#) summarises what may and may not be considered confidential by NICE.

Box 8.1 Information on what may and may not be considered confidential

Data that may be included as confidential include those that may influence share price values ('commercial in confidence') or are intellectual property ('academic in confidence'; that is, awaiting publication).

Confidential information should be kept to an absolute minimum; for example, just the relevant part of a sentence, a particular result from a table or a section of code.

NICE does not allow a whole study to be designated confidential. As a minimum, a structured abstract of the study or economic model needs to be made available for public disclosure during consultation on the GPG.

Results derived from calculations using confidential data are not considered confidential unless releasing those results would enable back-calculation to the original confidential data.

In addition to completing the checklist, respondents indicate the part of their submission that contains the confidential information, for example, by using a highlighter pen on a hard copy, or the highlighter function in an electronic version. These markings are then maintained on those sections so that the GDG knows which parts are confidential. When the draft and final version of the GPG is prepared for publication, the NICE project team ensures that these sections are replaced by a note stating that confidential information has been removed, so that readers know exactly where confidential data have been used.

Following the principles in [box 8.1](#), the amount of confidential information is kept to a minimum. As a minimum, a summary is publicly available by the time of the consultation on the GPG. NICE needs to be able to justify the recommendations in the GPG on the basis of the evidence considered by the GDG. The NICE project team therefore works with the data owners to agree a balance between confidentiality and transparency.

8.9.1.2 Information not eligible for submission

Organisations or individuals are asked not to submit the types of evidence listed in [box 8.2](#), as these will not be considered.

Box 8.2 Material not eligible for consideration by the GDG

Studies with weak designs if better designed studies are available

Promotional literature

Papers, commentaries and editorials that interpret the results of a published paper

8.9.2 Call for oral evidence

After review of the written evidence submissions, the GDG select up to 10 submissions to be called to give oral evidence at GDG meeting 3. The NICE project team records a written summary of the oral evidence presented.

8.9.3 Experts

If the GDG and the NICE project team identify gaps in the evidence that can be addressed by experts in that topic, the identified experts can be contacted directly to provide evidence. This can either be as written evidence or can be presented directly at a GDG meeting (either in person or virtually). An example could be to aid interpretation of legislation or regulations.

8.9.4 Using formal consensus methods outside the Guidance Development Group

Exceptionally, if the literature search has found no evidence that addresses the review question, the GDG may identify best practice by using formal consensus methods (for example, the Delphi technique or the nominal-group technique). Any formal consensus method used is documented in the GPG.

8.10 Further reading

Jenkins M (2004) Evaluation of methodological search filters – a review. Health Information and Libraries Journal 21: 148–63

Lefebvre C, Eisinga A, McDonald S et al. (2008) Enhancing access to reports of randomized trials published world-wide – the contribution of EMBASE records to the Cochrane Central Register of Controlled Trials (CENTRAL) in The Cochrane Library. Emerging Themes in Epidemiology 5: 13

Lefebvre C, Manheimer E, Glanville J (2011) Searching for studies. In: Higgins JPT, Green S, editors. Cochrane handbook for systematic reviews of interventions, version 5.1.0 (updated March 2011). The Cochrane Collaboration.

^[3] Where NICE guidance information services are referred to, an externally commissioned

information service may be used to provide support in this area in some cases.

9 Reviewing the evidence

Good practice guidance (GPG) provides recommendations for good practice for people who are involved in governing, prescribing and commissioning medicines, and those involved in decision-making about medicines according to the best available evidence.

The nature of the GPG topics means that the best available evidence on which to produce the guidance may include evidence other than randomised controlled trials.

Studies identified during literature searches need to be reviewed to identify the most appropriate data to help address the review questions, and to ensure the GPG recommendations are based on the best available evidence.

The same rigour is applied to assessing fully and partially published studies, as well as unpublished data supplied by stakeholders, for example from a call for evidence (see [section 8.9.1](#) and [section 8.9.2](#)) or evidence provided by experts (see [section 8.9.3](#)).

The NICE project team appraises the evidence using a technique appropriate for the type of evidence, which includes applying inclusion and exclusion criteria. This allows the GDG to consider the strength of the evidence available when making recommendations (see [section 9.1.5](#)).

9.1 Methods of review

The method of review is based on the type of evidence retrieved. Given the nature of the topics, the best available evidence on which to produce the GPG may include evidence other than randomised controlled trials.

The review process for the evidence needs to be clearly documented, giving details of the inclusion and exclusion criteria that were applied.

9.1.1 Clinical studies

Before acquiring papers for assessment, the NICE project team sifts the evidence identified in the search to discard irrelevant material. First, the titles of the retrieved citations are scanned. Those falling outside the GPG topic are excluded. A review of the

remaining paper identifies those that are clearly not relevant to the review questions and are therefore excluded.

Once sifting is complete, full versions of the selected studies are requested for assessment (see [section 8.6](#)). Full versions of the studies failing to meet the inclusion criteria are excluded; those meeting the criteria are assessed. Because there is a potential for error and bias in selecting the evidence, double sifting (sifting by 2 people) of a random selection of abstracts is performed periodically ([Edwards et al. 2002](#)). Any doubts about inclusion are resolved by discussion with the Guidance Development Group (GDG) before the results of the study are considered. The quality of individual research studies is assessed using an appropriate NICE methodological checklist and process for the type of study under consideration. See links provided below:

- [systematic reviews and meta-analyses](#)
- [randomised controlled trials](#)
- [case-control studies](#)
- [cohort studies](#)
- [economic evaluations](#)
- [qualitative studies](#).

The checklists have been linked to the appendices of the [guidelines manual](#). The term 'guideline' can be replaced with 'guidance' for purpose of this methods guide.

9.1.2 Legislation and policy

Relevant legislation or NHS policies may be identified in the literature search and used as evidence to develop the GPG. This does not need assessment, given the nature of the source.

Assessing the robustness of NHS policies for inclusion as evidence is discussed at GDG meeting 1. The NICE project team use a standard template for this assessment.

9.1.3 Published guidance

Relevant published guidance from other organisations may be identified in the search for

evidence.

Any guidance produced by a NICE-accredited guidance producer is not subject to further quality appraisal having already undergone formal process appraisal by NICE.

Guidance not produced by a NICE-accredited guidance producer is assessed for quality using the [AGREE II](#) (appraisal of guidelines research and evaluation II) instrument ([Brouwers et al. 2010](#)) to ensure there is sufficient documentation to be considered. There is no cut-off point for accepting or rejecting guidance and each GDG needs to set its own parameters. These are documented in the methods section of the GPG, along with a summary of the assessment. The results are presented as an appendix to the guidance.

Reviews of evidence from other guidance that considers questions formulated by the GDG and the NICE project team may be considered as evidence if:

- they are assessed using the appropriate methodology checklist from this methods guide and are judged to be of high quality
- they are accompanied by an evidence statement and evidence table(s)
- the evidence is updated according to the methodology for exceptional updates of NICE GPG (see [section 16](#)).

The GDG creates its own evidence summaries or statements. Evidence tables from other guidance are referenced with a direct link to the source website or a full reference of the published document. The GDG formulates its own recommendations, taking into consideration the whole body of evidence.

9.1.4 Oral testimony and written evidence

During development of the GPG, if there is limited primary research available as evidence on which to produce recommendations on, oral or written evidence may be needed. The written submission of evidence identifies the evidence most relevant to current NHS practice and the GPG topic, therefore informing GDG decision-making. Inclusion criteria for the evidence specifies relevant population and interventions for the review question, to support filtering and selection of oral and written submissions to be included for GDG review.

9.1.5 Other evidence

Given the nature of the GPG and the topic being covered, other sources of relevant evidence such as editorials, reports, audits, qualitative studies (which may include patient experience), surveys and standard operational procedures to guide recommendations may be included. Such evidence is assessed for the reasonableness and rigour of the process used to develop the source of evidence in question and their relevance to the topic under consideration.

9.2 Documenting evidence found outside of the literature search

All evidence reviewed is documented using a standard template for inclusion in an evidence table (see [appendix C](#)). Evidence tables help to identify the similarities and differences between studies, including the key characteristics of the study population and interventions or outcome measures. This provides a basis for comparison. Qualitative studies can be recorded using a similar table as for clinical studies (see [appendix C](#)).

Meta-analysis may be needed to pool treatment estimates from different studies. Recognised approaches to meta-analysis are used, as described in the manual from [NHS Centre for Reviews and Dissemination \(2009\)](#) and in the [Cochrane handbook](#).

The NICE project team may produce evidence profiles if a body of evidence answers a review question. The profiles contain a 'quality assessment' section summarising the quality of the evidence and a 'summary of findings' section presenting the outcome data for each important outcome.

Information received in response to a call for evidence is entered into a reference management database, and the details cross-checked against evidence identified through database searching. It is assessed in the same way as published studies identified through the searches (see [section 8](#)).

9.3 Further reading

Brouwers M, Kho ME, Browman GP et al. for the AGREE Next Steps Consortium (2010) [AGREE II: advancing guideline development, reporting and evaluation in healthcare](#). Canadian Medical Association Journal 182: E839–42

Centre for Reviews and Dissemination (2009) Systematic reviews: CRD's guidance for undertaking reviews in health care. University of York: Centre for Reviews and Dissemination

Edwards P, Clarke M, DiGuseppi C et al. (2002) Identification of randomized trials in systematic reviews: accuracy and reliability of screening records. *Statistics in Medicine* 21: 1635–40

Higgins JPT, Green S, editors (2011) Cochrane handbook for systematic reviews of interventions. Version 5.1.0 (updated March 2011) [online]

10 Linking good practice guidance to other NICE publications

As more NICE guidance is published, the cross-linking with other NICE programmes and NICE Pathways becomes even more important. The following list provides an overview on the types of NICE guidance available:

- Good practice guidance (GPG) provides advice and guides good practice for people involved in handling, prescribing, commissioning and decision-making about medicines.
- Clinical guidelines focus on managing a particular disease or condition.
- Technology appraisal guidance focuses on the clinical and cost effectiveness of 1 or more technologies, such as new drugs, surgical procedures and medical devices.
- Interventional procedures guidance covers the safety and efficacy of interventional procedures used for diagnosis or treatment.
- Public health guidance deals with promoting good health and preventing ill health.
- Medical technologies guidance covers the efficacy and cost effectiveness of new or innovative medical technologies.
- Diagnostics guidance covers the efficacy and cost effectiveness of new diagnostic technologies.
- Social care guidance and quality standards are intended for use in conjunction with the frameworks and regulations already in place, providing practical support to help drive up the quality of adult and children's care.

10.1 Identifying appropriate publications

Clinical Guidelines and internal clinical guidelines are produced by the Centre for Clinical Practice, the same directorate that the GPG is produced under. The Centre for Health Technology Evaluation at NICE develops technology appraisal, interventional procedures, medical technologies and diagnostics guidance. Public health guidance is produced by the Centre for Public Health Excellence. Details of the development processes and methods

for other programmes can be found on the [NICE website](#).

The scoping stage of the GPG identifies topics from other programmes that are relevant to the GPG being developed.

This section deals with the approaches that are taken when:

- guidance from another programme has already been published and needs to be incorporated into the GPG
- a relevant piece of guidance from another programme is being developed concurrently.

10.2 Rationale and documentation for inclusion and exclusion

When newly commissioned GPG covers a topic or area for which there is 1 or more previously published related guidance, there are 2 possible approaches:

- the published guidance is incorporated verbatim into the GPG
- the GPG cross refers to the published guidance.

When recommendations from published guidance are incorporated into a GPG, they should usually be reproduced unchanged. Under exceptional circumstances where suggested changes to recommendation wording are proposed (for example, if the recommendation covers both primary and secondary care, but the guidance recommendation is concerned with secondary care only), the proposed change to the wording must be discussed with the relevant NICE programme team and agreed by NICE Guidance Executive. This should be done on a case-by-case basis.

The NICE project team checks for both published and 'in development' NICE guidance during the scoping process and literature review.

11 Writing the good practice guidance

11.1 Guidance structure

Good practice guidance (GPG) contains all the recommendations, together with details of the methods used and the evidence underpinning the recommendations. It specifies the date of publication and the version of the methods guide used for developing the GPG. The NICE project team will use a standard GPG template.

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

- title and contents page
- date and version control information
- introduction, which includes:
 - purpose
 - audience
 - scope
- policy context
- legislation and regulatory requirements
- good practice recommendations
- evidence and recommendations
- how the GPG has been developed (methodology)
- appendices:
 - glossary and abbreviations, if applicable to the GPG
 - key resources

- scoping workshop attendees
- Guidance Development Group and project team members
- literature search strategy
- additional evidence.

11.2 Writing style

Detailed instructions for writing GPG recommendations are given in Developing and wording guidance recommendations (see [section 12](#)).

When writing the GPG, the NICE project team follows NICE processes for writing guidance. The GPG is written in a style that can be understood by anyone who has a good knowledge of the guidance topic. Plain English is used, and unnecessary jargon avoided. The NICE Publishing team will advise on this.

11.2.1 Flowcharts

The GPG may contain a flowchart summarising a process. The flowchart should be uncluttered and follow a logical sequence. Arrows should mostly flow from top to bottom. Each decision should flow from the question that precedes it.

11.3 The role of the NICE Publishing team

One person from the NICE publishing team is designated as the lead editor for a particular GPG, although other members of the team also work on the GPG. The lead editor works with the project team and members of the GDG before, during and after consultation, and has a formal responsibility for NICE's publication. The lead editor and other members of the editorial team work on the GPG to ensure that:

- they conform to NICE's requirements in terms of style and format
- the recommendations are unambiguous
- the information is clear and appropriate for the intended audience.

The lead editor advises the NICE project team and the GDG on recommendation wording

during GPG development, and carries out detailed editing of the recommendations before consultation of the draft GPG.

After consultation, if required, the lead editor usually attends the GDG meeting at which stakeholder comments and changes to the GPG are discussed. They can advise on the wording of the recommendations at this meeting, and with the NICE project team, may edit the recommendations in detail after the meeting, if needed.

11.4 Version control

When drafting the GPG, version control is used to provide an audit trail for the revision and update of the finalised version. This allows for records to be made of the various drafts produced during the development process (see [figure 1.1](#)).

Version control allows development of the document to be easily understood and changes made by different individuals at different times can be identified.

12 Developing and wording guidance recommendations

Many users of good practice guidance (GPG) may not have time to read the guidance in full, and may want to focus only on the recommendations. It is therefore vital that recommendations are clear, can be understood by people who have not read the GPG in full, and are based on the best available evidence. This section addresses key areas in developing GPG recommendations:

- interpreting the evidence to make recommendations
- wording the recommendations
- formulating research recommendations.

These processes are at the heart of the work of the Guidance Development Group (GDG). However, they are not straightforward and it may not be easy for the GDG to reach agreement. Consensus techniques may need to be used within the GDG (see [section 6.5](#)).

12.1 Interpreting the evidence to make recommendations

The GDG must decide what the evidence means in the context of the review questions posed, and decide what recommendations can usefully be made to health and social care professionals. The aim of the GPG is to show clearly how the GDG moved from the evidence to the recommendation.

The 'strength' of a recommendation is agreed by the GDG. This takes into account the source and quality of the evidence. Some recommendations are 'strong' in that the GDG believes if others (including health and social care professionals and patients) considered the evidence in the same way they would agree with the recommendations.

The GRADE system (see [appendix D](#)) allocates labels or symbols to represent the strength of a recommendation. NICE has chosen not to do this, but instead to reflect the concept of strength in the wording of the recommendation (see [section 12.2.4](#)). The GDG's view of the strength of a recommendation should be clear from its discussions.

The following points are included in the discussions.

12.1.1 Relative value placed on the outcomes considered

For each review question, the GDG decides which outcomes are considered important for decision-making and what relative importance is given to them. This might be done informally or formally.

This discussion should be clearly separated from the discussion of the evidence, because there is a potential to introduce bias if outcomes are selected on the basis of the results.

It may be important to note outcomes that were not considered to be important for decision-making, and why.

12.1.2 Trade-off between benefits and resource use

There should be an explanation of how the GDG considered the cost and resource implications of following the recommendations. This will usually be informal.

12.1.3 Other trade-offs

Dependent on the GPG topic, the GDG also considers the trade-off between other factors, for example, time, service redesign and policy development. This discussion would be considered when wording the recommendation.

12.1.4 Quality of the evidence

There should be discussion of how the presence, likely magnitude and direction of potential biases and uncertainty in the evidence have influenced the recommendation, and why. This should reflect the judgement on the quality of the evidence as described in the GRADE profile. In principle, lower-quality evidence makes it more difficult to justify a strong recommendation in general, although there are likely to be exceptions to this.

The discussion may include whether the degree of uncertainty warrants delay in making a recommendation to await further research, considering any potential harm of failing to make a clear recommendation.

12.1.5 Extrapolation of evidence

Evidence identified for a specific cohort of patients may include principles that could be extrapolated to other patient populations. For example, medicines management systems in a care home for people with dementia may also be relevant and identify good practice that is relevant in other care home settings. The use of extrapolation must be considered carefully by the GDG, with explicit consideration of the features of the condition or interventions that allow extrapolation. This also applies when extrapolating findings from evidence in different healthcare settings. The GDG should comment on similarities in case mix, staffing, facilities and processes.

12.1.6 Other considerations

The GDG discusses any implications of the recommendations relating to equalities legislation and [NICE's equality scheme](#). This covers inequalities related to age, disability, gender reassignment, marriage and civil partnership, race, religion or belief, sex and sexual orientation and socioeconomic status. The GDG needs to consider whether:

- the evidence review has addressed areas identified in the scope as needing specific attention with regard to equalities issues
- people with disabilities might find it impossible or unreasonably difficult to benefit from a recommendation being implemented
- guidance can be formulated so as to promote equalities.

Before the GPG is signed off, an equality impact assessment form is completed by the NICE project team and the GDG to show how equality issues have been identified and considered during development. The equality impact assessment form is signed by the project lead and GDG chair, and countersigned by the Centre for Clinical Practice Director, before being posted on the NICE website.

The GDG may need to discuss the implementation of a recommendation, particularly where this will involve a change in practice, for example, implementing training programmes.

12.1.7 Challenges in formulating recommendations

There are many reasons why it can be difficult for a GDG to reach a decision about a

recommendation. The evidence base is always imperfect, and so there is always a degree of judgement by the GDG. There may be very little, or no, good-quality evidence that directly addresses the review question the GDG has posed. In this situation, there are several options to consider:

- The GDG may consider basing a recommendation on its view of current practice. Formal consensus techniques may be used to elicit opinions from the GDG, although NICE does not recommend a particular approach. Importantly, it is not usually appropriate to involve stakeholders from outside the GDG in this process, because they will be offering opinions on recommendations without having seen the evidence considered by the GDG; in addition, stakeholders will not have agreed to adhere to the principles underlying NICE's decisions on recommendations.
- The GDG may need to look at evidence that is likely to be more at risk of bias than the evidence it had hoped to find. This approach should be pursued only if there is reason to believe that it will help the GDG to formulate a recommendation.
- The GDG may wish to extrapolate from high-quality evidence in a related area, for example, in a largely similar patient group or setting. The GDG needs to make its approach explicit, stating the basis it has used for extrapolating from the data and the assumptions that have been made. This needs to include consideration of the plausibility of the assumptions. This approach is unlikely to be helpful if the evidence is derived from a question that is too different from the review question, or if the evidence is not of the highest quality.

When formulating recommendations, there are likely to be instances when members of the GDG disagree about the content of the final GPG. There should be a clear record of the proceedings and how areas of disagreement have been handled, for example, in the minutes of the GDG meeting (see [section 6](#)).

12.2 Wording the guidance recommendations

Writing the recommendations is one of the most important steps in developing the GPG. Many people read only the recommendations, so the wording must be concise, unambiguous and easy to translate into practice. Each recommendation, or bullet point within a recommendation, should contain only 1 main action.

The wording of recommendations should be agreed by the GDG, and should:

- focus on the action that needs to be taken
- include what readers need to know
- reflect the strength of the recommendation
- include the involvement of the patient (and/or their carers if needed) and/or stakeholders, as appropriate
- use plain English where possible and avoid vague language.

The rest of this section explains these points in more detail. The lead editor for the guidance from NICE's Publishing team advises on the wording of recommendations.

12.2.1 Who the recommendation is aimed at

When writing recommendations, the GDG aims to identify which individual person or organisation is responsible for implementing it. When this is possible, the recommendation clearly identifies this. When the individual or organisation responsible is not clearly identifiable, this is for commissioners or providers to consider and determine locally.

12.2.2 Focus on the action

Recommendations should begin with what needs to be done. When writing recommendations, keep in mind a reader who is saying, 'what does this mean for me?' Recommendations should be as specific as possible about the exact action being recommended and the group of people for whom it is recommended.

When a recommendation is aimed specifically at an individual person or organisation, this is clearly identifiable. However, the GDG may not be able to identify which individual person or organisation is responsible. In these circumstances, this will be for local consideration and determination

Use direct instructions because they are clearer and easier to follow. Most recommendations should be worded in this way. Assume you are talking to the person who will implement the recommendation.

Examples:

- Include a locally defined mix of members from partner organisations and key

stakeholders, such as patients and the public.

- Hold meetings sufficiently frequently to ensure decision-making is robust and decisions are made in a reasonable and practical timeframe.
- Report to relevant corporate governance bodies for each partner organisation appropriately, and as a minimum annually, and by exception when needed.

Exceptions:

- Recommendations that a specific person 'should' carry out and is directed at a specific person. For example, 'When acting as a doctor, dentist or pharmacist signatory, establish that the clinical and pharmaceutical content is accurate and supported by the best available evidence'.
- Recommendations that a specific organisation 'should' carry out and is directed at the organisation. For example, 'For each PGD, the provider organisation should:
 - identify a senior, responsible person from within the service to authorise named, registered health professionals to practise under the PGD
 - ensure that authorised health professionals have signed the appropriate documentation.'

Start with a verb describing what the reader should do, such as 'offer', 'include', 'advise', 'determine' or 'ask about' (see sections [12.2.3](#) and [12.2.4](#) for advice on the choice of verb).

Examples:

- Include horizon scanning as a standing agenda item on local formulary decision-making group meetings.
- Determine explicitly how local formulary decision-making groups reach final decisions.
- Identify the senior person in each profession who is responsible for ensuring that only fully competent, qualified and trained health professionals use PGDs.

Exceptions:

Sometimes it is clearer to start with other details, particularly if recommending different actions for slightly different circumstances or to make the sentence structure simpler. For example:

- When reviewing the PGD, conduct a literature search to identify new evidence. Ensure this evidence is evaluated to assess its relevance and validity.
- If operating a local formulary covering a small population, consider sharing resources and establishing joint processes with neighbouring local formulary decision-making groups to avoid duplicating work.

12.2.3 Include what readers need to know

Recommendations should contain enough information to be understood without reference to the evidence or other supporting material. Unnecessary details should not be added, because recommendations are more likely to be followed if they are clear and concise.

- Define any specialised terminology that is used in the recommendations. Avoid using abbreviations unless your audience is likely to be more familiar with the abbreviation than with the term in full. If abbreviations are essential, define them at first mention and in a glossary.
- Define the target group or population if it is not obvious from the context. Often it is necessary to define the group or population only in the first of a group of recommendations, if it is clear that the subsequent recommendations in that section relate to the same population, for example, 'patients in care homes'.
- Include cross-references to other recommendations in the GPG if necessary to avoid the need to repeat information.
- Do not include reasons justifying the recommendation unless this will increase the likelihood that it will be followed – for example, if it is required by legislation, involves a change in usual practice or needs particular emphasis.
- Include only 1 main action in each recommendation or bullet point.

12.2.4 Reflect the strength of the recommendation

The description in [section 12.1](#) indicates that some recommendations can be made with more certainty than others. This concept of the 'strength' of a recommendation should be reflected in the consistent wording of recommendations within and across good practice. There are 3 levels of certainty:

- recommendations for practice that must (or must not) be followed

- recommendations for practice that should (or should not) be followed
- recommendations for practice that could be followed.

12.2.4. Recommendations for practice that must or must not be followed

Recommendations for practice that 'must' or that 'must not' be followed are usually included only if there is a legal requirement to apply the recommendation, for example, to comply with medicines regulations. Reference to supporting documents should be included.

Occasionally, the consequences of not following a recommendation are so serious (for example, there is a high risk to patient safety) that using 'must' (or 'must not') is justified.

If using 'must', word the recommendation in the passive voice ('an intervention must be used') because the distinction between 'should' and 'must' is lost when the recommendation is turned into a direct instruction.

Examples:

- PGDs must be authorised only by an appropriate authorising body in line with [legislation](#).
- All legally required information must be included in a PGD. Use a standard blank template to ensure that the format is consistent across the organisation.

12.2.4. Recommendations for practice that should or should not be followed – 'strong' recommendations

For recommendations for practice that 'should' be followed, the GDG is confident that, for majority of people and organisations, the benefits from the recommended practice will outweigh any harm, represent good practice and is cost effective (if cost effectiveness has been assessed). Recommendations using 'should' would normally be supported by 'strong' evidence, for example, randomised controlled trials, systematic reviews or NICE-accredited guidance.

Use direct instructions for recommendations of this type where possible (see [section 12.2.1](#)), rather than using the word 'should'. Use verbs such as 'ensure', 'establish', 'advise' and 'determine'.

Examples:

- Ensure resources are available to undertake all functions needed as determined by the scope and geographical coverage of the local formulary.
- Determine the expiry date for an individual PGD on a case-by-case basis, with patient safety paramount. Ensure that this date does not exceed 3 years from the date the PGD was authorised.

Use similar forms of words (for example, 'Do not use...') for recommendations for practice that should not be used because the GDG is confident that they will not be of sufficient benefit for most individual people.

Example:

- Do not use PGDs for managing long-term conditions, such as hypertension or diabetes, or when uncertainty remains about the differential diagnosis.

12.2.4.3 Recommendations for practice that 'could' be followed

For recommendations that use 'could', the GDG is confident that the practice will be of benefit, represent good practice and will be cost effective (if cost effectiveness has been assessed) for most people and organisations.

However, some people or organisations may choose to practice differently with similar benefits to that of the recommended practice. This may be due limited resources and it is more practical to implement or it has been determined locally.

Use direct instructions for recommendations of this type where possible (see [section 12.2.1](#)), rather than using the word 'could'.

Examples:

- Consider investing in the training of additional non-medical prescribers to enable redesign of services if necessary, as part of a wider development or review of local medicines policy
- Consider collaborating with other organisations and sharing existing educational materials to ensure a comprehensive approach.

Recommendations using 'could' would normally be devised from evidence that would not be considered as 'must' or 'should'. The evidence is not as 'strong' as for recommendations using 'should'.

12.2.5 Emphasise the patient's involvement

To emphasise the patient's role in decision-making and the need for them to consent to treatment, generally use verbs such as 'offer', 'consider' and 'discuss' in recommendations, rather than 'prescribe' or 'give'. The term 'consider' is used for recommendations for good practice that could be used, and implies that more discussion will be needed (see [section 12.2.4.3](#)).

Use 'people' or 'patients' rather than 'individuals', 'cases' or 'subjects'. Where possible, use 'people' rather than 'patients' for people with mental health problems or chronic conditions. For guidance that has a social care remit, the term 'residents' can be used rather than 'patients'. 'Service users' can be used for people with mental health problems if 'patients' is the only alternative.

12.2.5.1 Recommendations about patient-centred care

Where relevant, a section on patient-centred care that covers informed consent and taking into account the patient's individual needs will be included in the GPG.

12.2.6 Recommendations on drugs, including 'off-label' use of licensed medicines

The NICE project team follows NICE's standard procedure when referring to drugs. This includes using standard wording when 'off-label' use of licensed medicines is recommended.

12.2.6.1 Use generic names

Give the recommended international non-proprietary name (rINN), as listed in the [British National Formulary](#) (BNF). Usually, only the generic name is needed. Occasionally (for example, if referring to a specific preparation or device), the proprietary name may be given in parentheses at first mention. Do not give the manufacturer's name.

12.2.6. Do not give dosages

Readers are expected to refer to the summary of product characteristics (SPC) for details of dosages. Include dosage information only if there is evidence that a particular drug is often prescribed at the wrong dosage, or there is clear evidence about the effectiveness of different dose levels. If 'off-label' use of licensed medicines is being recommended and there is no relevant dosage information in the BNF, include details of the dosage regimen. SPCs can be found in the [Electronic Medicines Compendium](#).

12.2.6. Off-label use of licensed medicines

Using a UK licensed medicine outside the terms of its marketing authorisation, is classed as 'off-label' use.

Off-label use of licensed medicines may be mentioned in a recommendation when it is relevant to the GPG topic. For example, 'ensure that off-label use of a licensed medicine is included in a PGD only when clearly justified by best clinical practice. Clearly state that the medicine is being used outside the terms of the marketing authorisation on the PGD. Consider informing the patient or their carer that the use is off-label, in line with [General Medical Council guidance](#)'.

If the recommendation includes off-label use of licensed medicines, the responsibilities of the prescriber and the need to follow relevant professional guidance should be included as given in the example above.

12.2.7 Using tables in recommendations

Do not use tables to summarise several actions in 1 recommendation. Such summaries make it more difficult to link the recommended actions to the summarised evidence from the literature review. A recommendation may include a small table to improve clarity; for example, to present information that should be shared with patients, or if the information is most easily understood when tabulated.

12.3 Formulating research recommendations

The GDG may identify areas in which there are uncertainties or where evidence is lacking. NICE has published a [Research recommendations process and methods guide](#), which details the approach to be used across NICE's guidance-producing programmes to identify

key uncertainties and associated research recommendations.

13 The consultation process and management of stakeholder comments

Consultation with stakeholders lasts 4 weeks for NICE good practice guidance (GPG), and is an integral part of the development process. Comments received from stakeholders are a vital part of the quality-assurance and peer-review processes, and it is important that they are addressed appropriately.

13.1 Principles of the consultation process

The draft GPG is made available on the NICE website for consultation and registered stakeholders are able to submit comments within the specified timeframe. External expert advisers may submit comments during the consultation period (see [section 5.5](#)).

NICE staff may also comment on the consultation draft of the GPG before and/or during the consultation. These staff could include the Public Involvement Programme lead, the implementation lead and the lead editor for the guidance. Comments from NICE staff received during consultation are not posted on the NICE website.

13.1.1 Communications

The consultation period is publicised in a number of ways:

- alerting registered stakeholders via email when the public consultation period opens
- notifying individuals signed up to receive [NICE medicines and prescribing news and alerts](#)
- updating the specific topic guidance development page on the NICE website
- listing the consultation on the 'current NICE consultations' page.

13.1.2 Submitting comments

When the draft GPG is published for consultation, the following are also published:

- instructions and guidance for submitting comments
- a 'comments proforma' (to be used by stakeholders).

Completed proformas are sent to the dedicated email address for the GPG. Comments not submitted on the correct proforma, or which do not use the proforma correctly, are returned to the sender for re-submission. The NICE project team will only accept 1 response from each registered stakeholder organisation. Comments received from non-registered stakeholders are only considered if the organisation subsequently registers as a stakeholder. Comments received after the deadline for submission are not considered and are not responded to.

Because all comments from registered stakeholders are made public on the NICE website, confidential information (such as information about individual patients) must not be included.

The document [Protocol for managing guidance consultation comments](#) contains further details about how NICE deals with stakeholder comments received during consultation.

13.2 Principles of responding to stakeholder comments

Most comments are received from registered stakeholders. These comments, and the responses to them, are published on the NICE website when the GPG is published (see [section 14](#)).

13.2.1 Documentation of comments

All comments received by NICE are entered into a GPG 'consultation comments table' in a Microsoft Word file, which contains the following information:

- Stakeholder organisation – name of the organisation that submitted the comments.
- Section, page and line number – these columns can be used by the project team and Guidance Development Group (GDG) to facilitate the identification of comments by section.
- Comments – comments received from stakeholders, which are entered unchanged.

- Responses – to be completed by the NICE project team and GDG.

13.2.2 Responding to comments

The GDG considers the comments received, and the NICE project team then responds to the comments on their behalf. The following key points are taken into account when responding to comments from stakeholders.

- Each comment must be acknowledged and answered as fully and as factually as possible. It is important to acknowledge that each point has been seen and understood. Some comments may be presented as general commentary, but they should still be acknowledged.
- If changes are made to the GPG as a result of the comment, this must be made clear in the response. If no changes are made, it should be made clear why not.
- For draft GPG, responses to comments and changes to the GPG must be made with the agreement of the GDG before publication. The NICE project team must maintain an audit trail of changes.

Examples of responses to types of comments received during consultation on the GPG are given in table 13.1.

Table 13.1 Examples of responses to stakeholder comments received on Developing and updating local formularies (NICE good practice guidance 1 [2012])

Type of comment	Example(s) of a response
Compliments about the GPG	Thank you for your comments. No response required.
A specific change was recommended and has subsequently been made	Thank you for your comment. The NICE definition of the term 'option for treatment' has now been incorporated into the good practice guidance. See recommendation 2.6.2.

A specific change was recommended and has subsequently been partially made	Thank you for your comment. While the GDG recognised the importance of medicines optimisation, it concluded that this good practice guidance is concerned with systems and processes relating to local formulary development, and it was not appropriate to include a detailed approach to medicines optimisation. To do so would be outside scope. However, the GDG agreed that optimising the use of medicines to improve patient care may be a potential benefit of a local formulary and this has been incorporated into the guidance.
A specific change was recommended and has subsequently NOT been made	<p>Thank you for your comment. While the GDG acknowledge that this may be potentially complex, it would still constitute good practice.</p> <p>Thank you for your comment. The GDG concluded that it was not appropriate to have definitive lists of possible clinicians and organisations. These will be for local determination.</p>
Asks for something that is outside the scope of the GPG	Thank you for your comment. The NICE review process for technology appraisals is outside the scope of this good practice guidance.

The consultation comments table is signed off by the project lead, the Programme Director and the Centre for Clinical Practice (CCP) Director.

The NICE project team may refer some comments, if appropriate, to the Programme Director for consideration before sign off.

13.3 Considering a second consultation

In exceptional circumstances, the Centre for Clinical Practice Director may consider the need for a further 4-week stakeholder consultation, which may be required after the standard 4-week consultation has ended if either of the following criteria has been met:

- Information or data that would significantly alter the GPG was omitted from the first draft.
- Evidence was misinterpreted in the first draft of the GPG and the amended

interpretation significantly alters the guidance.

The final decision on whether to hold a second consultation is made by NICE.

14 Finalising and publishing the guidance

Once the consultation period has ended, the Guidance Development Group (GDG) and NICE project team meet to consider any changes needed to the good practice guidance (GPG) in response to the stakeholder comments received during consultation. Once the changes have been agreed, modifications are made to the GPG.

The content of the GPG and references are checked by the NICE project team before it is sent to NICE editorial team. NICE editorial team carries out the detailed editing of the GPG. Sections [14.1](#) and [14.2](#) describe the roles of the NICE project team and NICE editorial team.

14.1 Technical check

Once all the changes have been made after consultation, a member of the NICE project team, other than the author(s), checks the content and all the references used to develop the GPG. This involves checking:

- wording is factual, not alarmist or controversial, or may cause reputational risk
- ensuring any data, facts and figures quoted are correct and are represented in a fair and balanced way
- abbreviations:
 - written out in full at first use in each main section, hyperlinked if appropriate to the relevant text, then abbreviated and not hyperlinked for subsequent use within the section
- hyperlinks:
 - are working and link to the appropriate information
 - no relevant hyperlinks are missing
- legislation:
 - is quoted accurately with the name and date of the piece of legislation
 - where hyperlinks are used, it links to the intended piece of legislation

- references:
 - quoted correctly, are complete, are in consecutive order
 - information/wording that is referenced in the text is actually sourced in the reference material and this is accurately reproduced
 - hyperlinks used where appropriate to link to the relevant reference
 - footnotes used where required
- any cross references to other sections are relevant and discuss what has been referred to
- recommendations:
 - wording style of the recommendations (see [section 12](#))
 - clear and unambiguous on their own, in the context of the section, without needing to refer to the text for clarification
 - are supported by the text in that section – so if a recommendation about expiry dates is made, this must be discussed in that section within the text
 - any cross references to other recommendations are related and relevant, and no relevant cross references have been missed
 - numbering is in order
 - all that relate to legislation is hyperlinked to the relevant legislation, or is referenced if possible.

14.2 Editorial checks

The GPG is edited by the NICE lead editor (see [section 11.3](#)). This involves checking:

- general accuracy
- it conforms to NICE's requirements in terms of style and format
- consistency of wording, format and presentation
- recommendations are unambiguous

- the information is clear and appropriate for the intended audience.

The NICE project team makes any amends necessary after this check.

14.3 Validation procedure with the Guidance Development Group

The GDG validates the GPG at the final GDG meeting. Any requested amendments are made by the NICE project team and the final draft GPG is circulated to the GDG.

14.4 Final content sign off

The final draft of the GPG and the responses to stakeholder comments are reviewed and signed off by the project lead, the Programme Director and Centre for Clinical Practice Director. After changes have been agreed, the GPG is signed off by the NICE Guidance Executive.

14.5 Publication

Once the GPG is signed off by the NICE Guidance Executive, the NICE project team liaises with the Publishing and Web teams to arrange the upload of the GPG to the NICE website, and any related changes to GPG web pages. The GPG is published in both web format and PDF format; the content in each format is the same.

14.6 Launch and promotion

The publication and launch of the GPG is publicised in a number of ways:

- alerting registered stakeholders via email (this happens before the general alert)
- notifying individuals signed up to receive [NICE medicines and prescribing alerts](#)
- releasing a press release
- listing the GPG on the published guidance page.

14.6.1 The press launch

The communications lead at NICE talks to the project team and GDG about what kind of launch is appropriate for each GPG – this may be a press conference or a more targeted approach to the specialist or trade press.

If there is likely to be substantial media interest in the GPG, a press conference will be held 1 or 2 days before publication, usually at NICE's offices. This allows journalists to interview people involved in developing the GPG, and to prepare articles or broadcast pieces in advance. Information provided to the media is confidential until the launch date for the GPG.

Ideally, a press conference panel includes a representative from NICE (preferably the Centre for Clinical Practice Director who is responsible for signing off the GPG), the chair of the GDG, a relevant health or social care professional and a patient and carer representative. NICE provides training for panel members.

The NICE communications lead also ensures that relevant stakeholder organisations, such as professional bodies and patient organisations, are involved in the launch if appropriate.

All GDG members are encouraged to provide details of case studies that can be used to illustrate some of the GPG's key recommendations, because these are a good way of creating media interest.

The aim of the press briefing is to clearly communicate key messages about the GPG to the press and media; it is not a conference for healthcare professionals.

14.6.2 Reaching the target audience

NICE welcomes input from GDG members on how to identify groups of health and social care professionals and specialists who should be sent details of the GPG. GDG members may also be able to identify other ways of raising awareness of the GPG – for example, through newsletters, websites or training programmes of organisations they are affiliated to (particularly for patient and carer organisations), or by suggesting relevant conferences at which the GPG can be promoted.

Members of the GDG work with NICE to promote awareness of the GPG, both at the point of launch and afterwards.

15 Implementation support for good practice guidance

The aim of NICE implementation support is to encourage and promote the uptake of NICE guidance. Priorities identified by the Guidance Development Group (GDG), recommendations identified as having significant resource implications or resulting in a change in practice, and information from stakeholder consultation inform the focus of the implementation support work for good practice guidance (GPG). Support work may include a range of activities to promote uptake and the provision of practical support tools.

Implementation tools are produced by staff in the implementation programme at NICE. The following leads may be involved in developing the tools: the audit lead, the costing and commissioning lead, and the implementation adviser as appropriate to the GPG. Tools are developed with:

- the GDG
- the NICE project team
- the lead from the Public Involvement Programme.

This section outlines the methods and process for developing the implementation tools, and the contributions of the GDG and NICE project support team to this process.

15.1 Needs assessment, support plan and tools

Each GPG is accompanied by an implementation needs assessment, which identifies significant changes to practice, any barriers to implementation and levers to support implementation.

For each GPG, the implementation adviser analyses the information gathered from the GDG, stakeholders and other sources to carry out a needs assessment, and produces an implementation support plan that details the activities that will be undertaken by NICE to address the key implementation issues. During the needs assessment, the implementation adviser consults with members of the GDG and the NICE project team.

15.1.1 Tailored implementation tools based on the needs assessment

The needs assessment may identify additional tools that would be useful for addressing specific learning or education needs of staff and organisations. These targeted tools for GPG are prepared by the implementation adviser with input from the NICE project team. There is some evidence that barriers to uptake of GPG identified in advance can be overcome by designing specific interventions to address them, although it is not always very clear how best to identify the barriers and which particular types of interventions are best for each barrier ([Baker et al. 2010](#)).

When there is an agreed need for specific implementation tools to support recommendations about drugs and prescribing, the implementation adviser works with the [NICE Medicines and Prescribing Centre](#) to produce these materials.

See [Into Practice on the NICE website](#) for examples of the types of tailored tools that are produced. These could include:

- learning and development slide sets
- clinical case scenarios
- podcasts
- training plans
- online educational tools
- examples of how NICE guidance has been put into practice
- shared decision aids.

There might also be signposting to resources developed and promoted with other organisations, such as professional or patient groups. Identifying other organisations that may produce support tools to support implementation of the GPG is also encouraged.

Other tools that could be used are described below; not all guidance will have the same tools and these will be tailored according to the needs assessment. For more information, see the [NICE website](#).

15.1.2 Baseline assessment tool

The baseline assessment tool is prepared by the audit coordinator. It is an Excel spreadsheet that organisations can use to identify whether they are in line with practice recommended in the GPG, and to help them plan activity to implement the recommendations.

15.1.3 Audit tools

Audit tools are prepared by an audit specialist. They help organisations to carry out audits based on some of the GPG's measurable recommendations. They consist of audit standards, data collection tools and action plans. Some will also be produced as Excel electronic audit tools that provide a basic data analysis and audit report.

15.1.4 Costing tools

Costing tools are prepared by a costing analyst. They are intended to help organisations assess the costs and potential savings associated with implementing the guidance. The costing analyst assesses the recommendations to identify those with the greatest resource impact (using [NICE's Assessing cost impact – methods guide](#)). NICE provides costing tools to accompany guidance that includes:

- A costing report, which summarises the estimated national costs and savings associated with implementing the guidance and discusses the assumptions made in reaching this figure.
- A costing template, which allows users to estimate the local impact of implementing the guidance based on their population and to change the assumptions and variables to reflect local circumstances.
- A costing statement, which can be used when the cost impact is considered to be minimal to explain why the cost impact is not considered to be significant.

Further details of costing tools can be found on the [NICE website](#).

15.2 Developing the implementation tools

The needs assessment and development of the implementation tools usually start during consultation and continue through to publication of the GPG.

15.2.1 Initial involvement during guidance development

At the start of the guidance development process, an implementation team is assigned to work with the NICE project team and GDG. The team consists of a costing lead, an audit lead and an implementation adviser, working closely with communications.

During scoping of the GPG, the implementation adviser carries out an initial assessment to ensure that all critical stakeholders have registered and starts to record a log of any implementation issues that arise. This log is kept up to date throughout guidance development to inform the development of the implementation support plan.

At GDG meeting 2 or 3, GDG members are given a general briefing paper from the implementation team explaining its work and future involvement.

At the end of GPG consultation, the costing analyst and the implementation adviser usually attend a GDG meeting to hear the outcome of the consultation and to consider how this affects key implementation issues. They can attend a GDG meeting to discuss their work.

The GDG may also invite other members of the implementation team to meetings at any time if discussion about other implementation issues is needed.

Volunteers from the GDG are needed to work with the implementation teams. Two members are needed to contribute to the development of the costing tools if these tools are needed (the 'GDG costing nominees') and 2 for the development of the implementation support tools (the 'GDG implementation support nominees'). After consultation, the implementation adviser liaises with the GDG implementation support nominees to discuss the implementation support plan and to agree their level of input into tool development.

15.2.2 Commenting on the draft implementation tools

Comments are invited on accuracy, clarity and whether the tools described below provide an accurate interpretation of the key messages of the GPG.

15.2.2.1 Costing tools

The costing analyst uses the recommendations in the consultation draft of the GPG to identify the potential significant changes in resource use that are likely to arise from implementation of the GPG. This is based on baseline practice, how practice might change

and the effect on resources for the areas identified. This is assisted by input from the GDG.

The costing analyst updates the draft costing tools when the final draft of the GPG is submitted. The tools are sent to the NICE project team and the GDG costing nominees 4–5 weeks before publication of the GPG for a 2-week consultation period. Comments are invited on:

- whether the assumptions made are reasonable
- the usability of the costing template at a local level.

The NICE project team and the GDG nominees send their comments back to the costing analyst.

15.2.2.2 Clinical audit tools

The audit coordinator sends drafts of the audit support tools to the NICE project team and the GDG for a 2-week consultation period, approximately 9 weeks before publication of the GPG.

15.2.2.3 Other tailored tools

Other draft implementation tools are usually sent to the NICE project team and the GDG for comment around 4–5 weeks before publication of the GPG for a 1-week or 2-week consultation period, depending on the nature of the tool. Advance notice is given of all timelines. Any delays to the development of the final GPG may reduce these periods.

15.3 Publishing the implementation tools

When implementation tools are published at the same time as the GPG by NICE, they are downloaded more frequently than if they are published later. Therefore the aim is to publish the implementation tools at the same time as the GPG wherever possible.

Achieving this is dependent on the final signed-off version of the GPG being available with sufficient lead time for development of and consultation on the tools. For some support tools, a later timeline after publication of the GPG may be necessary.

Publication of the tools is announced on the NICE website and in the e-newsletter; the latter is available to everyone who wants to be kept up to date with important developments at NICE.

15.4 Post-publication support

NICE may also carry out activities to help users implement good practice guidance after it has been published. These activities are identified in the implementation support plan (see [section 15.1](#)) and may include:

- speaking at, and encouraging and supporting GDG members to speak at, relevant conferences and events
- encouraging and supporting GDG members to contribute to or write journal articles about the GPG
- contributing to or writing journal articles about the GPG
- speaking about the implementation tools at events
- supporting workshops and regional events
- working with the implementation consultants (see [section 15.6](#))
- providing feedback and encouraging submission of shared learning (see [section 15.6](#))
- supporting the development of an online educational tool and other educational initiatives
- supporting work to review uptake of the GPG.

15.5 Working with national organisations

The implementation adviser works in partnership with other NICE teams to engage with national organisations and networks. This work might include embedding recommendations from NICE good practice guidance into other guidance or initiatives, or encouraging the development of patient information.

The implementation advisers welcome suggestions from GDG members on how to work with national organisations to support the implementation of good practice guidance.

15.6 Other NICE implementation services and products

NICE also provides a range of services and products to assist health and social care professionals and organisations in the implementation of its good practice guidance recommendations. The following support is available:

- NICE Medicines and Prescribing Associates work within their own NHS organisation, health board or service and in their wider local health economy to support high quality, cost effective prescribing and medicines optimisation. To help disseminate good practice as widely as possible, the NICE Medicines and Prescribing Associates are responsible for identifying affiliates within their local health economy to form local networks, or support existing networks where they are established. They also develop links with NICE Implementation Consultants and NICE Fellows and Scholars, to support further the sharing and dissemination of good practice.
- A field-based team of 7 implementation consultants work with organisations to help to put NICE guidance into practice. Each consultant visits NHS, local authority and other organisations in their area, ensuring regular interaction with NICE stakeholders.
- Web-based examples of how organisations have implemented NICE guidance are provided on the shared learning database.
- NICE reports and published articles relating to the uptake of NICE guidance are provided on the 'uptake database' – ERNIE (Evaluation and review of NICE implementation evidence).
- Commissioning guides are provided to support commissioners of services. These aid in the local implementation of NICE guidance through commissioning. Because the guides are focused on services commissioned, they may bring together elements from 1 or more pieces of NICE guidance. Each commissioning guide:
 - signposts and provides topic-specific information on key clinical and service-related issues to be considered during the commissioning process
 - offers an indicative benchmark of activity to help commissioners determine the level of service needed locally
 - includes an interactive tool that provides data for local comparison against the benchmark, and resources to estimate and inform the cost of commissioning

intentions.

15.7 Further reading

Baker R, Camosso-Stefinovic J, Gillies C et al. (2010) Tailored interventions to overcome identified barriers to change: effects on professional practice and health care outcomes. Cochrane Database of Systematic Reviews 2010, issue 3

16 Updating or correcting published good practice guidance

Good practice guidance (GPG) is published with the expectation that it will be reviewed and updated as necessary. Any decision to update GPG must balance the need to reflect changes in the evidence against the need for stability, because frequent changes to GPG recommendations would make implementation difficult. This section describes the process and methods for reviewing the need to update NICE GPG and for producing updated GPG.

It is the responsibility of the NICE project team who originally developed the GPG to update it.

When scheduling updates of GPG into its work programme, NICE prioritises topics according to the topic consultation, selection and prioritisation process.

16.1 Process and method for reviewing the need to update published guidance

NICE GPG is updated as needed to ensure recommendations take into account important new information. The NICE project team checks for new evidence 2 and 4 years after publication, to decide whether all or part of the GPG needs updating. If important new evidence is published at other times, the NICE project team may decide to undertake a more rapid update of some recommendations.

The NICE project team will not actively seek new evidence, unless it has been identified in the GPG that important new information is likely to emerge before the 2-year scheduled review that may result in the need for an exceptional update or amendment (see [section 16.4](#)). Ways in which new evidence can emerge are from:

- regular foraging activities for identifying new information
- queries or comments received by NICE after publication
- feedback about guidance implementation
- evidence submitted by other stakeholders.

The review includes the following key stages and methods:

16.1.1 Stage 1

- Collect any new information relevant to the GPG from members of the Guidance Development Group (GDG) that developed the original GPG (including patient, service user and carer members) using a questionnaire. See [table 16.1](#) for criteria.
- Collate other types of information, including the results of a re-run of the original search used for the scope of the published GPG (see [section 4](#)), post-publication comments and feedback about guidance implementation (for example, feedback gathered by the NICE field team of implementation consultants and associates and local and national audit data, where relevant).
- Conduct a broad search for relevant ongoing clinical trials.
- Conduct a high-level search for evidence such as relevant systematic reviews and randomised controlled trials (RCTs) using MEDLINE, MEDLINE In-Process, Embase and Cochrane (CDSR and Central only), with PsycINFO as an optional database for specific mental health topics.
- Assesses the relevance of, and summarises the evidence identified in the high-level search, see [section 8](#)).
- Collate all information and evidence identified so far to assess the need to conduct further focused searches on specific areas in the GPG and/or new areas that may be important for an update of the GPG.
- Confirm with the GDG chair of the original GPG, and other GDG members if necessary, the decisions on further focused searches and discuss developing PICO (population, intervention, comparator and outcome) frameworks for the focused searches.

16.1.2 Stage 2

- Conduct further focused searches based on the relevant PICO frameworks using MEDLINE, MEDLINE In-Process, Embase and Cochrane (CDSR and Central only), plus 2 optional extra databases: PsycINFO (for mental health and psychological interventions questions only) and NHS EED (for health economics and cost-effectiveness questions only).

- Assesses the relevance of, and summarises the evidence identified in the high-level search, see [section 8](#).
- Assess and summarise all information and evidence collected in stages 1 and 2, and develop a draft review decision on the need to update the GPG.
- Confirm with the GDG chair of the original GPG, and other GDG members if necessary, that they agree with the draft review decision before consultation with stakeholders.

16.1.3 Stage 3

- Check the stakeholder list for the original GPG to ensure that stakeholder details are up to date.
- Consult stakeholders on the draft review decision for 2 weeks.
- Consider (and if necessary revise) the draft review decision, taking into account the stakeholders' comments, and decide on the advice for NICE's Guidance Executive (see [table 1.1](#)).
- NICE Guidance Executive makes the final review decision.

16.2 Deciding whether to update good practice guidance

The Programme Director and Centre for Clinical Practice Director consider the draft review decision in the light of evidence and information identified during the review process and stakeholders' comments.

The Centre for Clinical Practice Director advises NICE's Guidance Executive on whether:

- a full update is needed
- an update of particular areas is needed
- no update is needed
- the GPG should be transferred to a 'static list'
- the GPG should be withdrawn.

NICE's Guidance Executive decides which of these options is most appropriate.

The decision is based on predefined criteria, as listed in table 16.1. The decision takes into account the competing priorities of other GPG topics and the capacity to schedule the work within the GPG programme.

If Guidance Executive determines that the GPG requires review, this is included in the next topic consultation process (see [section 2](#)).

Table 16.1 Criteria for deciding whether to update good practice guidance

Update decision	Criteria	Actions
Full update	Major sections of the GPG need updating Many of the recommendations are no longer necessary New good practice areas have been identified	Prepare a new scope after a scoping workshop
Partial update	Some recommendations need updating in the light of new evidence, or because they are unclear or new good practice areas have been identified that need to be covered in the GPG	Prepare a new scope after a scoping workshop
No update	No new evidence has been identified that would overturn any of the recommendations There is no evidence from clinical practice to indicate that any of the recommendations need changing There is no evidence from clinical practice that the original scope needs changing	The GPG is not updated The GPG is reviewed after a further 2 years to determine its update status
Transfer to the 'static list'	The recommendations are unlikely to change in the foreseeable future	No further update planned May be reviewed if new evidence emerges
Withdraw the GPG	The GPG no longer applies	Consult with stakeholders

16.3 Next steps

16.3.1 Conducting an update (full and partial)

If the entire GPG requires a full update, the NICE project team prepares a new scope, after the process described in [section 4](#).

Recruitment of GDG members follows the usual process (see [section 6.1](#)). The NICE project team should inform members of the original GDG that they are recruiting a new GDG, but the composition of the GDG should be tailored to the requirements defined by the new scope. The time required for development of the GPG is agreed between with the Centre for Clinical Practice Director and the NICE project team. The GPG is developed using the same process as for new GPG and is subject to the normal 4-week consultation period (see [section 13](#)). The usual process for finalising and publishing the GPG is also followed (see [section 14](#)).

If the GPG requires a partial update, there are 2 possible scenarios:

- some recommendations need to be updated **and/or**
- new areas have been identified that require new recommendations.

For both of these scenarios, a new scope is prepared through the usual process (see [section 4](#)). The scope will make clear exactly which sections of the GPG are and are not being updated. The scope will also make clear that all recommendations in the original GPG, including those that have not been otherwise reviewed, will be checked to ensure that they comply with NICE's equality duties.

The NICE project team recruits a new GDG to undertake the work, using the usual recruitment process (see [section 6.1](#)). The time needed to undertake the update is agreed between the Centre for Clinical Practice Director and the NICE project team.

16.3.2 No update

If it is decided that the GPG does not need to be updated, the GPG will be reviewed after a further 2 years. The same process for deciding whether an update is needed will be followed.

16.3.3 The 'static list'

There may be circumstances in which the areas covered in a GPG do not need to be considered for updating. This may be the case, for example, if the evidence base is so poor that it is unlikely that any of the recommendations will change in the foreseeable future. In this case, the GPG will be transferred to a 'static list' and no further update will be required. When GPG has been placed on the static list, this will be made clear on the home page for the GPG on the NICE website. GPGs on the static list may be transferred back to the 'active list' for further review if new evidence or information becomes available that is likely to mean that changes to the recommendations are required.

16.3.4 Withdrawing the good practice guidance

It may be decided that recommendations in GPG no longer apply, but that the GPG is not of sufficiently high priority for updating. In this case, the GPG will be withdrawn. This decision will be consulted on with stakeholders.

16.4 Exceptional updates

Exceptionally, significant new evidence may emerge that necessitates an update of GPG before the 2-year review. This might be a single piece of evidence, an accumulation of evidence or other published NICE guidance (such as other clinical guidelines or technical appraisal guidance). This evidence must be sufficiently robust to make it likely that:

- 1 or more recommendations in the GPG will need updating in a way that will change practice significantly **or**
- patient safety issues need to be addressed
- identification of errors in the GPG after publication.

Examples of such evidence include significant changes in legislation or major changes in systems and processes, such as national organisational changes. Exceptional updates may also be triggered by the identification of errors in the GPG after publication (see [section 16.4](#)).

16.4.1 Determining the need for an exceptional update

The NICE project team advises NICE's Guidance Executive on the following questions:

- Is the update necessary?
- Is there any other evidence (published, unpublished or from ongoing studies) that is relevant to the newly identified evidence?
- Which recommendations need to be reviewed in the light of the new evidence?

Guidance Executive then decides on the need for an update based on the answers to these questions. If an exceptional update is necessary, the Centre for Clinical Practice Director liaises with the NICE project team to carry out the work. Stakeholders are informed at this point by the NICE project team.

The aim of an exceptional update is to be responsive to new evidence, so it is imperative that changes to recommendations are published quickly. The process for developing exceptional updates should be the same as that for conducting an update, except that the original scope is used (see [section 16.4](#)).

16.5 Presenting updates

If a decision is made to fully update the GPG, the process is as for new guidance, except that the previous version of the GPG is available for comparison. The Centre for Clinical Practice Director and NICE project team agree as early as possible how the full updated GPG will be presented for consultation.

When presenting partially updated GPG, the aim is to ensure that there is a single set of publications that bring together relevant information from all previous versions of the GPG and the updated information. In this way, readers of the updated GPG will be able to easily identify which recommendations were made when. Usually, the updated sections will be integrated into a single document with the existing GPG. The rest of this section covers general principles to be used when part of a GPG has been updated.

16.5.1 Consultation draft

The consultation draft is signed off by the project lead, Programme Director and Centre for Clinical Practice Director before consultation. The following are checked before sign off:

- Sections of GPG have been updated as agreed at the scoping stage.
- The GPG includes standard text at the beginning, setting out which sections have

been updated, how these are marked in the consultation draft and which sections are open for comment during consultation.

- The GPG includes updated sections (including the evidence and recommendations) which are clearly marked with paragraph borders, preferably a strip down the right hand side of the relevant pages bearing the word 'updated' and the year of the update. This will allow stakeholders to easily identify what they can comment on. The text that is superseded is placed in an appendix.
- The recommendations have been marked up as described in [box 16.1](#).
- Recommendations from sections not being updated have been checked to determine whether any changes are essential.
- Changes in recommendations from sections that have not been updated are kept to a minimum.
- There is an appendix in the GPG containing a table summarising the proposed changes to the original recommendations (see below for more information).
- All current recommendations (new, updated and unchanged) have been assessed with respect to NICE's equality duties.

Box 16.1 Labelling and rewording recommendations

In both the consultation and final published versions of the GPG, label all recommendations so that it is clear when the evidence was reviewed and whether the recommendation is new. The example below is of a clinical guideline first published in 2008 with an update published in 2012.

Sections where the evidence has been updated

- New recommendations, either an additional good practice area for the GPG or changed because of new evidence – add **[new 2012]** to the end of the recommendation.
- Unchanged recommendations where the evidence has been reviewed for the 2012 update but the recommended action is the same as in the 2008 guideline – add **[2012]**. Reword these recommendations into the direct style (see [section 12.2](#)), but check with the GDG that rewording has not changed the meaning.

Sections where the evidence has not been reviewed

- For the consultation, add a grey background tint to recommendations that are not being updated, to indicate that they are not being consulted on.
- **Unchanged recommendations** from 2008, where the evidence has not been reviewed for the 2012 update – add **[2008]** to the end of the recommendation.
- **Changes to recommendation wording that change the meaning** (for example, because of equalities duties or a change in legislation) – add **[2008, amended 2012]** to the end of the recommendation, mark the change with yellow highlighting for the consultation and add a footnote explaining the reason for the change. This also applies if part of a recommendation (for example, a bullet point) has been deleted because it has been updated by other NICE guidance.
- **Evidence has not been reviewed, but there have been minor changes** in 2012 to the wording of a 2008 recommendation that do not affect the meaning, for specific reasons such as changes in terminology – add **[2008]**. For the consultation, mark small changes in these recommendations with yellow highlighting. Include a general note about these changes in the appendix table.
- **Recommendation is incorporated from other published guidance** – use the label to show when that other guidance was published, for example **[2006]**

Explaining the proposed changes in the consultation version

Standard text at the beginning of the guidance

The NICE project team will use a standard template for the good practice guidance template.

Appendix explaining the changes

Create a table (which will form an appendix to the GPG) summarising the proposed changes to the original recommendations, including:

- The text and recommendation number(s) of the recommendations that have been deleted in the update (either because they are being changed significantly in light of new evidence, or because they have become redundant), and the number(s) and text

of any replacement recommendations. If there is no replacement for a recommendation, explain the reasons for the deletion.

- A general note about any small changes made to recommendations that have not been updated, such as terminology changes. (These changes are marked with yellow highlighting for the consultation.)
- A note about every change to a recommendation that has changed the meaning without an evidence review (labelled 'amended' and marked with yellow highlighting for the consultation). Include the new text of the recommendation.

Keep explanations as short as possible – only brief details are needed.

16.5.2 Final sign off

Before final sign off, the draft GPG, should be checked for the following:

- The recommendations are labelled as described in [box 16.1](#).
- Grey shading and yellow highlighting have been removed from the recommendations.
- Footnotes explaining changes to recommendations labelled **[2008, amended2012]** are retained.
- The appendix table summarising the changes to recommendations has been revised in line with the final recommendations.
- The appendix with the superseded text is retained.
- The standard text box at the beginning of the guidance explaining which sections have been updated has been revised.

16.5.3 Information for the public

Information for the public

When the updated GPG is published, the 'Information for the public', if available, will explain which sections have been updated, particularly if patients are likely to notice changes in their care.

16.6 Maintaining records

The NICE project team maintains records throughout the development of an updated GPG to ensure that the following information is readily available:

- Details of the GDG membership, including declarations of interest.
- Search strategy details, including when the most recent search was conducted.
- Copies of the papers used.
- Data extraction forms.
- Evidence tables.
- Minutes of GDG meetings.
- Any additional information presented to the GDG.

16.7 Correcting errors in published good practice guidance

Measures are in place throughout the development of GPG to ensure that errors in the collection, synthesis, interpretation or presentation of the evidence are avoided as far as possible. However, on rare occasions errors may be found after publication of the GPG. These errors may not always warrant changes to the GPG, in which case they will be logged for consideration when the GPG is reviewed for updating. If an error is found, the following criteria and process will be used by the NICE project team to determine whether changes are necessary.

16.7.1 Criteria and process for a correction

Corrections or changes to published GPG will be made if an error:

- puts patients at risk, or impacts on their care **or**
- damages NICE's reputation **or**
- significantly affects the meaning of the recommendation.

If it is necessary to correct an error in published guidance, an internal policy for dealing with errors will be followed. The individual or organisation who reported the error will be contacted in writing, and the NICE project team will explain the rationale for the decisions and actions taken.

If a correction is to be made, a notification is put on the guidance 'home' page on the NICE website. Depending on the nature and significance of the error and the time since publication of the GPG, stakeholders may also be notified in writing (usually by email). The relevant web-based documentation is corrected, and this is also highlighted on the guidance home page on the NICE website.

16.8 Further reading

Clark E, Donovan EF, Schoettker P (2006) [From outdated to updated, keeping clinical guidelines valid](#). International Journal for Quality in Health Care 18: 165–6

Eccles M, Rousseau N, Freemantle N (2002) [Updating evidence-based clinical guidelines](#). Journal of Health Services Research and Policy 7: 98–103

Shekelle P, Eccles MP, Grimshaw JM et al. (2001) [When should clinical guidelines be updated?](#) British Medical Journal 323: 155–7

Shekelle PG, Ortiz E, Rhodes S et al. (2001) [Validity of the Agency for Healthcare Research and Quality clinical practice guidelines: how quickly do guidelines become outdated?](#) Journal of the American Medical Association 286: 1461–7

Shojania et al. (2007) [Updating systematic reviews](#). Technical Review, Number 16, AHRQ Publication No. 07-0087

Turner T, Misso M, Harris C et al. (2008) [Development of evidence-based clinical practice guidelines \(CPGs\): comparing approaches](#). Implementation Science 3: 45–52

Appendix A External and internal information services

A1: The template that is used when requesting a literature search

Topic:

Information service provider:

Time taken:

Date of search:

Key questions/key words:

Search back to (date):

Databases/sources to search:

A2: Search results and first sift

Results are downloaded into Reference Manager databases to make tasks like editing details, removing duplicates and shifting studies into different categories easier.

Abstracts of all studies are scanned and the studies edited to try to ensure they meet requirements that cannot be included in the search itself (for example, study size, patient orientated outcomes, disease subgroup, etc.).

Final lists of references are created from the Reference Manager databases as dated Word documents and sent to the NICE project team. Paper copies of the reference lists are kept by the Information Services team. A record is kept of the search procedure used (using the above template) and is also sent to the NICE project team.

A3: Other options used for search strategy

Searching step-by-step by study design

For review questions on the effectiveness of interventions, it may be more efficient to

search for systematic reviews, followed by randomised controlled trials (RCTs), followed by cohort or case-control studies. This will prevent unnecessary searching and review work. An absence of good-quality RCTs covering all the key outcomes may mean expanding the search to retrieve observational studies. The use of relevant search filters can help to identify study types and therefore assist in this method of searching.

Search filters

Search filters can be used to make searching more efficient and effective by saving time and bringing consistency and focus to the searching process. Search filters may be developed using a range of research-based and non-research-based methods. The most reliable filters are likely to be those that describe explicit methods, including how the search terms were identified and combined, and how the performance of search strategies was tested using collections of relevant records. The most comprehensive listing of available search filters can be found on the [InterTASC Information Specialists' Subgroup \(ISSG\) website](#), which lists filters by study design, database and interface.

When choosing a search filter, it is important to consider the age of the filter (to take account of changes such as indexing or interface changes), and whether it maximises sensitivity or precision.

Appendix B Coding scheme for Reference Manager

The database files will be formatted to include 4 user-defined fields for each reference type.

User defined field 1 will hold a single code from the following:

Code	Definition
A	The reference has been recommended by the reviewer for inclusion and retrieval of the full-text article
B	The reference has been rejected by the reviewer as it is very unlikely to be of relevance to the good practice guidance (GPG), but it may provide context and the full-text article should be retrieved
R	The reference has been rejected by the reviewer as it is very unlikely to be of relevance to the GPG, and the full-text article should not be retrieved

User-defined field 2 will be reserved for tracking receipt of the full-text article and should contain either the terms 'ordered' when a request has been made for its full text or 'received' when the full text has been received.

User-defined field 3 will be for the reviewers free-text entry of comments on the suitability of the article for inclusion or exclusion from the GPG. For excluded articles, this field will contain a free-text entry explaining the reason for exclusion.

User-defined field 4 will be the final inclusion or exclusion decision field.

Appendix C Examples of evidence tables

Evidence Tables

C1: Example of an evidence table for intervention studies

Title: (review question)

Bibliographic reference	Study type	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures and effect size	Source of funding	Additional comments
[1]	[2]	[3]	[4]	[5]	[6]	[7]	[8]	[9]	[10]

[1] Bibliographic reference: author(s), year, article title, journal, volume, pages.

[2] Study type: for example, randomised controlled trial, cohort or case-control studies.

[3] Number of patients: total number of patients included in the study, including number of patients in each arm, with inclusion and exclusion criteria. Also record the numbers of patients who started and completed the study.

[4] Patient characteristics: characteristics relevant to the area of interest: age, sex, ethnic origin, comorbidity, disease status, community- or hospital-based.

[5] Intervention: treatment, procedure or test studied. If important for the study, specify duration of treatment. For diagnostic studies the intervention is the diagnostic test plus associated treatment studied.

[6] Comparison: placebo or alternative treatment. For diagnostic studies, comparison of the test is with another test and treatment strategy.

[7] Length of follow-up: the length of time that patients take part in the study for, from first staging treatment until either a pre-specified end point (for example, death, specified length of disease-free remission) or the end of the data-gathering phase is reached. If the study is stopped earlier than originally planned for any reason, this should be noted here.

[8] Outcome measures: list all outcome measures defined in the review protocol, including associated harms. For studies with a diagnostic component there will be 2 interventions to consider – the diagnostic test used and the associated treatment. Use a separate line for each outcome.

Effect size: for example, raw data from the study that allow analyses such as absolute risk reduction and relative risk (reduction), number needed to treat, number needed to harm, odds ratios, as required. Give confidence intervals whenever possible.

[9] Source of funding: government funding (for example, NHS), voluntary/charity (for example, Wellcome Trust), pharmaceutical company; and the role of funding organisations.

[10] Additional comments: additional characteristics and/or interpretations of the studies that the reviewer wishes to record. These might include important flaws in the study not identifiable from other data in the table, and additional questions or issues that will need to be considered but do not figure in the results tables in the study.

C2: Example of an evidence table for qualitative studies

Title: (review question)

Reference	Research parameters				Population	Outcomes	Funding	Additional comments	
Bibliographic reference	Research question	Theoretical approach	Data collection	Method and process of analysis	Population and sample collection	Key themes	Source of funding	Limitations	Evidence gap
[1]	[2]	[3]	[4]	[5]	[6]	[7]	[8]	[9]	[10]
.									

[1] Bibliographic reference: author(s), year, article title, journal, volume, pages.

[2] Research question: what was/were the research question(s)?

[3] Theoretical approach: what theoretical approach (for example, grounded theory, interpretive phenomenological analysis) does the study take (if specified)?

[4] Data collection: how were the data collected? Give details of:

method(s)

by whom

setting(s)

when.

[5] Method and process of analysis: what methods were used to analyse the data (for example, constant comparative method)?

[6] Population and sample collection: what population was the sample recruited from? Include the following information:

how they were recruited (for example, specify the type of purposive sampling)

how many participants were recruited

specific exclusion criteria

specific inclusion criteria.

[7] Key themes: list all relevant to this review (with illustrative quotes if available).

[8] Source of funding: government funding (for example, NHS), voluntary/charity (for example, Wellcome Trust), pharmaceutical company; and the role of funding organisations.

[9] Limitations: both those identified by the author(s) and those identified by the reviewer.

[10] Evidence gap and/or recommendations for future research.

Appendix D GRADE profile and economic evidence profile

Profiles

D1: Example of an uncompleted GRADE profile

Quality assessment							No. of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	.	.	Relative (95% CI)	Absolute		
X												
X												
X												
X												
X												
X												
[References, abbreviations and other footnotes].												

See D2 for worked example of a GRADE profile

D2: Worked example of a GRADE profile

Review question: Should duloxetine versus placebo be used for painful diabetic neuropathy?

Quality assessment							No. of patients		Effect		Quality	Importance
No. of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Duloxetine	Placebo	Relative (95% CI)	Absolute		
Patient-reported 30% pain reduction (follow-up 12 weeks)												
2 ¹	Randomised trials	No serious risk of bias	Serious ²	No serious indirectness	No serious imprecision	None	220/327	111/215	RR 1.33 (0.95 to 1.88)	17 more per 100 (from 3 fewer to 45 more)	Moderate	Critical
Patient-reported 50% pain reduction (follow-up 12 weeks)												
4 ²	Randomised trials	No serious risk of bias	Serious ²	No serious indirectness	Serious imprecision ⁵	None	485/896	164/443	RR 1.51 (1.17 to 1.94)	19 more per 100 (from 6 more to 35 more)	Moderate	Critical
No. of withdrawals due to adverse effects (follow-up 12 weeks)												
4 ²	Randomised trials	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	None	113/906	21/448	RR 2.63 (1.68 to 4.12)	8 more per 100 (from 3 more to 15 more)	High	Critical
Dizziness (adverse effects) (follow-up 12 weeks)												
3 ³	Randomised trials	No serious risk of bias	No serious inconsistency	No serious indirectness	Serious imprecision ⁵	None	90/674	26/332	RR 1.81 (1.17 to 2.79)	6 more per 100 (from 1 more to 14 more)	Moderate	Critical
Dry mouth (adverse effects) (follow-up 12 weeks)												
2 ¹	Randomised trials	No serious risk of bias	No serious inconsistency	No serious indirectness	Serious imprecision ⁵	None	37/448	10/224	RR 1.61 (0.82 to 3.20)	3 more per 100 (from 1 fewer to 10 more)	Moderate	Important
GI disturbances (adverse effects) (follow-up 12 weeks)												
2 ⁴	Randomised trials	No serious risk of bias	No serious inconsistency	No serious indirectness	Serious imprecision ⁵	None	28/332	8/217	RR 2.53 (1.13 to 5.67)	6 more per 100 (from 0 more to 17 more)	Moderate	Important
Any adverse effects (non-specified) (follow-up 12 weeks)												
1 ⁴	Randomised trials	No serious risk of bias	No serious inconsistency	No serious indirectness	Very serious imprecision ¹⁰	None	86/106	78/109	RR 1.13 (0.96 to 1.32)	9 more per 100 (from 1 fewer to 23 more)	Low	Critical
¹ Gao et al. (2010); Wernicke et al. (2006). ² Substantial heterogeneity, random-effect model was used. Potential sources of heterogeneity: i) Gao et al. (2010) – ITT data available, used flexible dose between 30 mg and 120 mg, non-pharmaceutical company funded; ii) Wernicke et al. (2006) – only per-protocol data available, combined 2 fixed doses (60 mg and 120 mg), pharmaceutical company funded. ³ Gao et al. (2010); Goldstein et al. (2005); Raskin et al. (2005); Wernicke et al. (2006). ⁴ Substantial heterogeneity, random-effect model was used. Potential sources of heterogeneity: i) Gao et al. (2010) – used flexible dose between 30 mg and 120 mg, non-pharmaceutical company funded; ii) Goldstein et al. (2005), Raskin et al. (2005) and Wernicke et al. (2006) – combined different fixed doses (20 mg, 60 mg and 120 mg), pharmaceutical company funded. ⁵ Confidence interval crossed 1 end of default MID. ⁶ Gao et al. (2010); Goldstein et al. (2005); Wernicke et al. (2006). ⁷ Gao et al. (2010); Goldstein et al. (2005). ⁸ Gao et al. (2010); Wernicke et al. (2006). ⁹ Gao et al. (2010). ¹⁰ Confidence interval crossed both ends of default MID. Abbreviations: CI, confidence interval; GI, gastrointestinal; ITT, intention to treat; MID, minimal important difference; RR, relative risk.												

D3: Examples of an uncompleted economic evidence profile

Study	Limitations	Applicability	Other comments	Incremental			Uncertainty
				Costs	Effects	ICER	
.							
.							
.							
.							

.							
[References, abbreviations and other footnotes].							

See D4 for worked example of an economic evidence profile

D4: Worked example of an economic evidence profile

Adapted from Crohn's disease: management in adults, children and young people (NICE clinical guideline 152).

Systematic review of economic evaluations of budesonide for maintenance of remission in Crohn's disease

Study	Limitations	Applicability	Other comments	Incremental			Uncertainty
				Costs	Effects	ICER	
Noble 1998 Budesonide controlled ileal release versus no maintenance therapy	Potentially serious limitations ^{1,2}	Partially applicable ³	Study employed a Markov decision-analytic model with a 1-year time horizon	£115	0.017 QALYs ⁵	£6,981 per QALY gained	Incremental cost-effectiveness ratio decreases significantly if the cost of surgery is increased.
NCGC ^a model Oral budesonide versus no maintenance therapy ⁴	Potentially serious limitations ²	Directly applicable	Study employed a Markov decision-analytic model with a 2-year time horizon	£477 ^f £150 ⁷ £528 ⁸ £336 ⁹	0.012 QALYs ⁶ 0.012 QALYs ⁷ 0.006 QALYs ⁸ 0.005 QALYs ⁹	£40,392 per QALY gained ⁶ £15,070 per QALY gained ⁷ £87,610 per QALY gained ⁸ £65,013 per QALY gained ⁹	No treatment most cost-effective option when baseline risk of relapse decreased. In the PSA ^b , probability of budesonide being the most cost-effective treatment at willingness-to-pay threshold of £20,000 per QALY gained ranged from 0 to 8%

^a NCGC – National Clinical Guideline Centre
^b PSA - Probabilistic sensitivity analysis
¹Modelling was undertaken over a short time horizon and no probabilistic sensitivity analysis was conducted.
² Specific costs and disutilities of drug-related adverse events could not be explicitly modelled. Adverse events were captured by modelling treatment-specific withdrawal rates. This may have overestimated the cost effectiveness of maintenance treatment.
³ The cost-effectiveness model was designed to reflect the management of Crohn's disease in the Swedish healthcare setting. Although a cost per QALY (quality adjusted life years) estimate was reported, it was not based on health-related quality of life values elicited from patients.
⁴ The NCGC model compared a number of different maintenance treatments.
⁵ Figures may differ because of rounding off.
⁶ Conservative 4-line model. Conservative treatment effects were used and people relapsing while on azathioprine maintenance treatment had a different induction sequence.
⁷ Conservative 3-line model. Conservative treatment effects were used and people were assumed to have the same induction sequence regardless of maintenance treatment.
⁸ Non-conservative 4-line model. Non-conservative treatment effects were used and people relapsing while on azathioprine maintenance treatment had a different induction sequence.
⁹ Non-conservative 3-line model. Conservative treatment effects were used and people were assumed to have the same induction sequence regardless of maintenance treatment

Glossary of terms

Please see the [NICE glossary](#) for explanations of terms not described in the table below. Additional terms may be found in [The guidelines manual: appendix L2 glossary](#). A glossary may be added to a specific good practice guidance if needed, to provide clarity and understanding of the guidance.

Abstract	Summary of a study, which may be published alone or as an introduction to a full scientific paper.
AGREE (appraisal of guidelines research and evaluation)	An international collaboration of researchers and policy makers whose aim is to improve the quality and effectiveness of clinical practice guidelines. The AGREE II instrument , developed by the group, is designed to assess the quality of clinical guidelines.
Algorithm in guidance	A flow chart of the decision pathway described in the guidance, where decision points are represented by boxes, linked with arrows.
Applicability	The degree to which the results of an observation, study or review are likely to hold true in a particular practice setting.
Arm (of a clinical study)	Subsection of participants within a study who receive 1 particular intervention (for example, the placebo arm).
Association	Statistical relationship between 2 or more events, characteristics or other variables. The relationship may or may not be causal.
Audit support	The provision of ready-to-use criteria, including exceptions, definitions and data source suggestions, in order to make the process of developing clinical audit projects easier. NICE provides audit support for good practice guidance where appropriate.
Audit trail	Records of action to assess practice against standards. Also a record of actions (for example, changes to draft guidance) so that the reasons are apparent to a third party.
Baseline	The initial set of measurements at the beginning of a study (after the period before the study starts when no treatment is given [the 'run-in' period], where applicable), with which subsequent results are compared.

Bias	Systematic (as opposed to random) deviation of the results of a study from the 'true' results, which is caused by the way the study is designed or conducted.
Centre for Clinical Practice (CCP)	The department at NICE that manages the development of good practice guidance.
Clinical effectiveness	The extent to which an intervention produces an overall health benefit in routine clinical practice.
Cochrane Review	A systematic review of the evidence from randomised controlled trials relating to a particular health problem or healthcare intervention, produced by the Cochrane Collaboration. Available electronically as part of the Cochrane Library.
Code of conduct (of the GDG)	A code of conduct developed by NICE for Guidance Development Group (GDG) members and other people who attend GDG meetings. This code sets out the responsibilities of NICE and the GDG, and the principles of transparency and confidentiality.
Comparability	Similarity of groups in terms of characteristics likely to affect study results (such as health status or age).
Comparator	The standard intervention against which an intervention is compared in a study. The comparator can be no intervention (for example, best supportive care).
Conceptual framework	A theoretical structure of assumptions, principles and rules that holds together the ideas comprising a broad concept.
Conceptual model	A descriptive model of a system based on qualitative assumptions about its elements, their interrelationships, and system boundaries.
Conflict of interest	An interest that might conflict, or be perceived to conflict, with duties and responsibilities to an organisation.

Confounding	In a study, confounding occurs when the effect of an intervention on an outcome is distorted as a result of an association between the population or intervention or outcome and another factor (the 'confounding variable' or 'confounder') that can influence the outcome independently of the intervention under investigation. For example, a study of heart disease may look at a group of people that exercises regularly and a group that does not exercise. If the ages of the people in the 2 groups are different, then any difference in heart disease rates between the 2 groups could be because of age rather than exercise. Therefore age is a confounding factor.
Consensus methods	Techniques that aim to reach an agreement on a particular issue. Formal consensus methods include Delphi and nominal group techniques, and consensus development conferences. In the development of clinical guidelines, consensus methods may be used when there is a lack of strong research evidence on a particular topic.
Consort diagram	Diagram showing the flow of steps or stages within a process
Control	An explicitly defined comparator against which the effects of an intervention are compared in a clinical study.
Decision-analytic model (and/or technique)	A model of how decisions are or should be made. This could be 1 of several models or techniques used to help people to make better decisions (for example, when considering the trade-off between costs, benefits and harms of diagnostic tests or interventions).
Delphi technique	A technique used for reaching agreement on a particular issue, without the participants meeting or interacting directly. It involves sending participants a series of questionnaires asking them to record their views. After the first questionnaire, participants are asked to give further views in the light of the group feedback. The judgements of the participants may be statistically aggregated.
Dosage	The prescribed amount of a drug to be taken, including the size and timing of the doses.
Equity	Fair distribution of resources or benefits.

Evidence	Information on which a decision or guidance is based. Evidence is obtained from a range of sources, including randomised controlled trials, observational studies and expert opinion (of healthcare and other professionals and/or patients).
Evidence profile	A table summarising, for each important clinical outcome, the quality of the evidence and the outcome data (part of the GRADE approach).
Exceptional update	Review of existing guidance carried out sooner than originally planned because new data have become available.
Exclusion criteria (literature review)	Explicit standards used to decide which studies should be excluded from consideration as potential sources of evidence.
Expert consensus	See 'Consensus methods'.
Extrapolation	In data analysis, predicting the value of a parameter outside the range of observed values.
Follow-up	Observation over a period of time of a person, group or initially defined population whose characteristics have been assessed in order to observe changes in health status or health-related variables.
Generalisability	The extent to which the results of a study based on measurement in a particular patient population and/or a specific context hold true for another population and/or in a different context.
Generic name	The general non-proprietary name of a drug or device.
Good practice guidance	Guidance and recommendations for good practice for those involved in governing, commissioning, prescribing and decision-making about medicines.
GRADE (Grading of recommendations assessment, development and evaluation)	A systematic and explicit approach to grading the quality of evidence and the strength of recommendations.
Grading (of evidence)	A code given to a study or other evidence, indicating its quality.

Consultation comments table	A table of all the comments received by NICE during guidance consultation. The Guidance Development Group considers the comments received, and the NICE project team then responds to the comments in the table.
Guidance Development Group (GDG)	A group of health and social care and other professionals, patients and carers, and technical staff who develop the recommendations for good practice guidance. The NICE project team responsible for developing the good practice guidance recruits a GDG to work on the guidance. The NICE project team reviews the evidence and support the GDG. The GDG writes draft guidance, and then revises it after a consultation with stakeholders.
Health, social care (and other) professional member	A member of the Guidance Development Group with appropriate knowledge and skills to represent the perspective(s) of the health and social care professionals (and other professionals where relevant) involved in the care of patients affected by the guidance topic.
Health economist	One of the teams within NICE, with skills in economic analysis, the role of which is to advise on economic aspects of the clinical issues or questions, review economic literature, prioritise topics for further analysis and carry out additional cost-effectiveness analyses. (Not all good practice guidance will require a health economist.)
Health inequalities	The gap in health status and in access to health services between different social classes and ethnic groups, and between populations in different geographical areas. For more information, see the Department of Health website .
Health-related quality of life	A combination of a person's physical, mental and social wellbeing; not merely the absence of disease.
Hypothesis	An unproven theory that can be tested by research.
Implementation	The process of putting guidance into practice.
Inclusion criteria (literature review)	Explicit criteria used to decide which studies should be considered as potential sources of evidence.

In confidence material	Information (for example, the findings of a research project) defined as 'confidential' because its public disclosure could have an impact on the commercial interests of a particular company ('commercial in confidence') or the academic interests of a research or professional organisation ('academic in confidence').
Indication (specific)	The defined use of a technology as licensed by the Medicines and Healthcare products Regulatory Agency (MHRA).
Indirect treatment comparison	An analysis that compares interventions that have not been compared directly within a head-to-head, randomised trial.
Information specialists (NICE guidance information services)	Specialists, based either at NICE or an external contractor, with expertise in information retrieval who provide information to support the decision-making groups.
Key areas for inclusion	The key aspects of care that the good practice guidance will cover in order to ensure it focuses on areas in which the NHS most needs advice. Key areas for inclusion relate to systems and processes for medicines use.
Lay member	A member of the Guidance Development Group with knowledge of the issues that are important to patients, carers and the public.
Licence	See 'Marketing authorisation'.
Marketing authorisation	An authorisation that covers all the main activities associated with the marketing of a medicinal product. Medicines that meet the standards of safety, quality and efficacy set by the Medicines and Healthcare products Regulatory Agency (MHRA) are granted a marketing authorisation (previously a product licence), which is normally necessary before they can be prescribed or sold.
Markov modelling	A decision-analytic technique that characterises the prognosis of a cohort of patients by assigning them to a fixed number of health states and then models transitions among health states.

Medicines and Healthcare products Regulatory Agency (MHRA)	The Executive Agency of the Department of Health responsible for protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and are used safely.
MeSH (medical subject headings)	The US National Library of Medicine's controlled vocabulary thesaurus used for indexing articles from biomedical journals for databases such as MEDLINE.
Meta-analysis	The use of statistical techniques in a systematic review to integrate the results of included studies. (Definition from The Cochrane Collaboration website .)
Meta-ethnography	A process of identifying relevant findings or other statements from the literature and sorting them into a pattern of evidence on the subject being studied.
Mixed treatment comparison	An analysis that compares 2 or more interventions using a combination of direct evidence (from trials that directly compare the interventions of interest) and indirect evidence (from trials that do not compare the interventions of interest directly).
Narrative summary	Summary of findings given as a written description.
Nominal-group technique	A technique used to reach agreement on a particular issue. It uses a variety of postal and direct contact techniques, with individual judgements being aggregated statistically to derive the group judgement.
Observational study	Retrospective or prospective study in which the investigator observes the natural course of events with or without control groups (for example, cohort studies and case-control studies).
Off-label prescribing	A situation where a drug is used to treat a condition or disease for which the drug regulatory authority has not granted a marketing authorisation for that particular use. Off-label prescribing of a licensed medicine is particularly common in pregnant women and in children and young people, as these groups have often been excluded from clinical trials during drug development.

Personal social services	Care services for vulnerable people, including those with special needs because of old age or physical disability and children in need of care and protection. Examples are residential care homes for the elderly, home help and home care services, and social workers who provide help and support for a wide range of people. (Department of Health definition.)
PICO (population, intervention, comparison and outcome) framework	A structured approach for developing review questions that divides each question into 4 components: the population (the population under study); the interventions (what is being done); the comparators (other main treatment options); and the outcomes (measures of how effective the interventions have been).
Preliminary literature search/ Scoping search	A search of the literature undertaken at the scoping stage to identify literature including guidance, legislation, national policies, key systematic reviews and economic evaluations relevant to the guidance topic.
Project plan	A document prepared by the NICE project team that describes the rationale for the project, key outputs and requirements for delivery of the project outputs. It is an internal document that provides the reference from which the progress of the work can be assessed.
Proprietary name	The brand name given by the manufacturer to a drug or device it produces.
Quality of life	See 'Health-related quality of life'.
Quorum	The smallest number of group members that must be present to constitute a valid meeting. The quorum of a Guidance Development Group is 50% of appointed members. No business relating to the formulation of guidance recommendations may be conducted unless the quorum is reached.
Relative risk reduction	The proportional reduction in risk between experimental and control participants in a trial.
Remit	The brief that may be given by the Department of Health or NHS England at the start of good practice guidance development. This may define core areas of care that the guidance needs to address.

Research recommendation	Recommendations for future research covering questions relating to an uncertainty or evidence gap that has been identified during the guidance development process.
Resource implication	The likely impact in terms of finance, workforce or other NHS resources.
Review of the literature	An article that summarises the evidence contained in a number of different individual studies and draws conclusions about their findings. It may or may not be systematically researched and developed.
Review question	A structured question about the process, system and/or care that is formulated from a key issue in the scope to guide the systematic review. See also PICO framework.
Scope consultation table	A table of all the comments received by NICE during consultation on the guidance scope and responses. It is published on the NICE website with the final scope. (Good practice guidance will not always undertake scope consultation.)
Scoping workshop	A workshop led by the NICE project team with input from topic experts, NICE, and patient, carer and public representatives. The role of the group is to identify the key areas for inclusion in a piece of guidance and review the draft scope.
Search filter	A collection of search terms designed to retrieve selections of records (for example, records of research using a specific study design or on a specific topic).

Selection bias	<p>1. Systematic differences between comparison groups in prognosis or responsiveness to treatment. Random allocation with adequate concealment of allocation protects against selection bias. Other means of selecting who receives the intervention are more prone to bias because decisions may be related to prognosis or responsiveness to treatment.</p> <p>2. A systematic error in reviews due to how studies are selected for inclusion. Reporting bias is an example of this.</p> <p>3. A systematic difference in characteristics between those who are selected for study and those who are not. This affects external validity but not internal validity.</p> <p>(Definitions from The Cochrane Collaboration website.)</p>
Sensitivity analysis	<p>A means of representing uncertainty in the results of economic evaluations. Uncertainty may arise from missing data, imprecise estimates or methodological controversy. Sensitivity analysis also allows for exploring the applicability of results to other settings. The analysis is repeated using different assumptions to examine the effect on the results.</p> <p>Deterministic sensitivity analysis: tests the impact of potential bias resulting from the selection of data sources for key model parameters.</p> <p>One-way sensitivity analysis (univariate analysis): each parameter is varied individually in order to isolate the consequences of each parameter on the results of the study.</p> <p>Probabilistic sensitivity analysis: probability distributions are assigned to the uncertain parameters and are incorporated into evaluation models based on decision analytical techniques (for example, Monte Carlo simulation).</p>
Stakeholder scoping workshop	<p>Workshop attended by registered stakeholders before consultation on the scope, to discuss the key clinical issues identified by the scoping group.</p>
Study quality	<p>The extent to which a study has conformed to recognised good practice in the design and execution of its research methods.</p>

Synthesis of evidence	A generic term to describe methods used for summarising (comparing and contrasting) evidence in order to address a defined review question. This can include systematic review (with or without meta-analysis), and qualitative and narrative summaries.
Systematic review	Research that summarises the evidence on a clearly formulated review question according to a predefined protocol using systematic and explicit methods to identify, select and appraise relevant studies, and to extract, collate and report their findings. It may or may not use statistical meta-analysis.
Time horizon	The time span that reflects the period over which the main differences between interventions in health effects and use of healthcare resources are expected to be experienced, taking into account the limitations of supportive evidence.
Treatment allocation	The process by which study participants are allocated to a treatment group.
Treatment options	The choices of intervention available.

About this methods guide

About this methods guide

This methods guide describes the methods used in the development of NICE good practice guidance. It will be updated as described in [section 1.5](#).

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