

### **3 The Guideline Development Group**

Convening an effective Guideline Development Group (GDG) is one of the most important stages in producing a NICE clinical guideline. The GDG agrees the review questions, considers the evidence and develops the recommendations. Membership of the GDG therefore needs to be multidisciplinary, comprising:

- healthcare professionals (both specialists in the topic and generalists)
- patients and/or carers
- the technical team (systematic reviewer, information specialist, health economist).

The exact composition of the GDG should be tailored to the topic covered by the clinical guideline. It should reflect the range of stakeholders and groups whose professional activities or care will be covered by the guideline, and should include at least two members who have experience or knowledge of patient and carer issues.

During guideline development, people who are not members of the GDG but who have relevant expertise may be asked to attend meetings to take part in specific discussions (see section 3.1.7). Manufacturers of pharmaceutical products or medical devices are not represented on the GDG because of potential conflicts of interest; they have input into the guideline development process through the Guideline Review Panels and as stakeholders.

Members of the GDG are not permitted to submit comments as stakeholders during the consultation on the draft guideline (see chapter 11). 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.

This chapter describes the core elements of forming and running a GDG, including the appointment and role of the Chair and members.

#### **3.1 Forming the GDG**

The Chair and members of the GDG are appointed for the duration of a particular guideline's development. The Chair is appointed before the guideline scoping stage and is a member of the scoping group. If there is a Clinical Adviser for the guideline, he or she is also appointed before scoping. Other GDG members are appointed after the stakeholder scoping workshop (see section 2.4).

##### **3.1.1 The composition of the GDG**

The composition of each GDG is described in a workplan that is prepared by the relevant National Collaborating Centre (NCC) as part of its contractual agreement with NICE (the template is available from the NICE webboard for NCCs). The composition of the GDG is agreed by the guideline lead (Associate Director) at the Centre for Clinical Practice (CCP) at NICE. A

workable size for a GDG is 13–15 people, including the technical team from the NCC. This balances the opportunity for individuals to contribute effectively with the need for a broad range of experience and knowledge.

The GDG has five key constituents:

- the Chair
- members from the healthcare professions ('healthcare professional members'; they may include a Clinical Adviser for the group), and from the social care professions where relevant
- patient and carer members
- technical members
- a project manager.

Box 3.1 presents an example of GDG membership.

For some guideline topics, it may be important for the GDG to include an epidemiologist with knowledge of the subject. The GDG may also be supported by expert advisers (see section 3.1.7.1).

**Box 3.1 GDG membership for the clinical guideline 'Heavy menstrual bleeding' (NCC for Women's and Children's Health [NCC-WCH], published January 2007)**

- Two gynaecologists
- One obstetrician
- Two GPs
- One gynaecology specialist nurse practitioner
- One radiologist
- One epidemiologist
- One clinical director
- Two members representing women's interests ('patient and carer members')
- NCC-WCH technical team (information specialist, systematic reviewer, health economist, Director)

As far as possible, the GDG will have an appropriate balance with regard to the principles of NICE's equality scheme<sup>1</sup>.

Ideally, GDG members should be drawn from different parts of England, Wales and Northern Ireland (because guidelines apply to the NHS in England and Wales, and in Northern Ireland under special arrangements), but this will be influenced by the expertise available. For example, healthcare professional members (see section 3.1.4) may come from Scotland if they cannot be recruited from England, Wales or Northern Ireland.

All GDG members should be committed to developing the clinical guideline according to the processes set out in this manual, and to working within

<sup>1</sup> See [www.nice.org.uk/aboutnice/howwework/NICEEqualityScheme.jsp](http://www.nice.org.uk/aboutnice/howwework/NICEEqualityScheme.jsp)

NICE's equality scheme (see section 3.2.3). They are expected to attend all GDG meetings (usually between 12 and 15). New members should not usually be added to the GDG once the first GDG meeting has taken place, because this may disturb the group dynamic. In exceptional circumstances, if additional expertise is needed or if a GDG member needs to be replaced, the NCC should discuss and agree this with NICE.

People are GDG members in their own right, and do not represent any particular organisation or group.

If service guidance is being developed (see section 1.3.2), or if a clinical guideline contains a service guidance component, additional members should be appointed to the GDG to reflect this. This might include input from:

- commissioning bodies (primary care trusts in England and local health boards in Wales, including specialist commissioning bodies)
- relevant clinical networks
- a chief executive or director of public health with an interest in the topic.

Additional GDG members recruited for service guidance are subject to the same recruitment process as other GDG members (see below).

The following sections outline the roles of the GDG members and describe how the members should be appointed. Vacancies for GDG positions are posted on the NICE website<sup>2</sup>. Templates for job descriptions and person specifications are available from NICE's webboard for NCCs, and from the guidelines team at NICE.

### **3.1.2 The GDG Chair**

To work well, a GDG needs an effective Chair. The GDG Chair is a member of the scoping group (see section 2.2) and should therefore be recruited before work starts on the scope.

The Chair guides the GDG in terms of task (developing the guideline) and process (how the group works). The Chair also helps the GDG to work collaboratively, ensuring a balanced contribution from all members (see box 3.2).

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<sup>2</sup> [www.nice.org.uk/getinvolved/joinnwc/join\\_a\\_nice\\_committee\\_or\\_working\\_group.jsp](http://www.nice.org.uk/getinvolved/joinnwc/join_a_nice_committee_or_working_group.jsp)

### **Box 3.2 Key roles and functions of the GDG Chair**

The Chair needs background knowledge about the guideline, including:

- in-depth knowledge of the scope of the guideline (as a member of the scoping group) and the topics to be covered during GDG meetings
- good knowledge of the skills mix within the GDG.

To facilitate the working of the group, the Chair:

- sets up the rules for how the GDG operates, based on the principles set out in section 3.4.1
- assists with the planning of the GDG meetings
- establishes a climate of trust and mutual respect among members
- provides opportunities for all members to contribute to the discussions and activities of the group
- may meet individual GDG members outside GDG meetings.

In GDG meetings, the Chair:

- ensures that GDG members declare any conflicts of interests and handles any conflicts as they arise, in line with NICE's policy<sup>3</sup>
- steers the discussions according to the agenda
- keeps the group discussion unified and avoids disruption by sub-conversations or dominance by any members
- encourages constructive debate, without forcing agreement
- prevents repetitive debate
- summarises the main points and key decisions from the debate
- signs off meeting minutes once approved by the GDG.

The Chair must ensure that NICE's equality scheme and social value judgements document are adhered to (see sections 1.1.1 and 3.2.3).

The Chair approves the draft full guideline and advises the NCC on responses to stakeholder comments.

#### **3.1.2.1 Appointing the Chair**

In accordance with NICE's policy 'Appointments to guidance producing bodies advisory to NICE' (November 2006)<sup>4</sup>, the position of GDG Chair is advertised on the NICE website. It may also be advertised on the website of the NCC and/or the Royal College or professional body that hosts the NCC, and in other appropriate places identified by the NCC. NICE informs the stakeholder organisations about the advertisement.

Applicants are required to submit a CV (including names and contact details of two referees), a completed declaration of interests form (available from NICE's webboard for NCCs), a completed equality monitoring form and a

<sup>3</sup>[www.nice.org.uk/getinvolved/joinnwc/patientsandlaypeople/invitationtoapplyforlaymembershiptofnicescommissioningprogrammesteeringgroup/declaration\\_of\\_interests.jsp](http://www.nice.org.uk/getinvolved/joinnwc/patientsandlaypeople/invitationtoapplyforlaymembershiptofnicescommissioningprogrammesteeringgroup/declaration_of_interests.jsp)

<sup>4</sup> Available from: [www.nice.org.uk/384476](http://www.nice.org.uk/384476)

statement explaining how they meet the criteria laid out in the person specification. The Chair is appointed after interview by the selection panel, which should include the NCC Director, the Director of the CCP (or delegate) and a non-executive director of NICE.

### **3.1.3 The Clinical Adviser**

The Clinical Adviser is a member of the GDG with additional responsibilities. He or she works closely with the NCC technical team to provide expert topic-specific support. The Clinical Adviser is a member of the scoping group (see section 2.2), and is therefore appointed before work starts on the scope. The detailed responsibilities of the Clinical Adviser will differ depending on the guideline and the expert input required. These may include, for example, working with the systematic reviewer on the detail of the evidence reviews where expert topic-specific knowledge is needed, or checking the full guideline to ensure that clinical and technical terminology is correct.

#### **3.1.3.1 *Appointing the Clinical Adviser***

The position of Clinical Adviser is advertised on the NICE website. It may also be advertised on the website of the NCC and/or the Royal College or professional body that hosts the NCC, and in other appropriate places identified by the NCC. NICE informs the stakeholder organisations about the advertisement.

Applicants are required to submit a CV (including names and contact details of two referees), a completed declaration of interests form (available from NICE's webboard for NCCs), a completed equality monitoring form and a statement explaining how they meet the criteria laid out in the person specification. The Clinical Adviser is appointed after interview by the selection panel, which should include the NCC Director, the Director of the CCP (or delegate) and a non-executive director of NICE.

### **3.1.4 Healthcare professional members**

Healthcare professional members of the GDG should be recruited shortly after the stakeholder scoping workshop (see section 2.4.1). They should represent the perspective(s) of the healthcare professionals (and social care professionals where relevant) involved in the care of patients affected by the guideline topic. They are on the GDG as healthcare professionals with appropriate knowledge and skills; detailed research expertise is not necessary, although an understanding of evidence-based medicine is essential. They are not expected to represent the views of their professional organisations.

A GDG has, on average, between six and eight healthcare professional members; the list of professions represented is agreed as part of the workplan between the NCC and NICE (the workplan template is available on the NICE webboard for NCCs).

The roles and responsibilities of the healthcare professional members of the GDG are shown in box 3.3.

### **Box 3.3 Key roles of healthcare professional members of the GDG**

GDG members from the healthcare professions are expected to:

- help develop the review questions from the key clinical 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 guideline topic to provide guidance to the technical team in carrying out systematic reviews and economic analyses
- 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 best practice in areas where research evidence is absent, weak or equivocal
- with other members of the GDG, consider implementation issues arising from recommendations and feed back to the implementation team at NICE to inform the development of the implementation support tools (see section 13.2)
- with other members of the GDG, approve the review protocols (see section 4.4.2)
- with other members of the GDG, agree the minutes of GDG meetings.

They are not routinely expected to:

- review the evidence
- search the literature
- write the guideline.

#### **3.1.4.1 Appointing healthcare professional members**

Vacancies for healthcare professional members of the GDG are advertised on the NICE website. They may also appear on the website of the NCC and/or the Royal College or professional body that hosts the NCC, and in other appropriate places identified by the NCC. NICE informs registered stakeholder organisations about the advertisement.

Applicants are required to submit a CV (including names and contact details of two referees), a completed declaration of interests form (available from NICE's webboard for NCCs), a completed equality monitoring form and a statement explaining how they meet the criteria laid out in the person specification. Members are selected by the Director of the NCC and the GDG Chair, and may be asked to attend an interview. Appointments will be subject to confirmation by the Director of the CCP at NICE.

#### **3.1.5 Patient and carer members**

At least two members of each GDG should have experience and/or knowledge of issues that are important to patients and carers (the 'patient and carer members'). This is to ensure that patient and carer issues, as well as the views of healthcare professionals, inform the guideline development process. In general, patient and carer members will have direct experience of the

condition as a patient, as a carer or family member, or as an officer or member of a patient or carer organisation or support group. They should be willing to reflect the experiences of a wide network of patients, rather than basing their views only on their own experience. They do not represent the views of any particular organisation. Healthcare professionals are well represented on GDGs, so patient and carer members usually do not have a healthcare professional background. Patient and carer members have equal status with other members of the GDG. Their specific roles are shown in box 3.4.

### **Box 3.4 Key roles of patient and carer members of the GDG**

Patient and carer members carry out the same functions as other GDG members, but they are often able to offer specific expertise in:

- ensuring that review questions embrace patient as well as professional issues
- raising awareness of grey literature<sup>5</sup> known to them (for example, patient surveys) that highlights patient issues that may inform the work of the GDG
- considering the extent to which published evidence has measured and taken into account outcome measures that patients consider important
- highlighting areas where patient preferences and patient choice may need to be acknowledged in the guideline
- ensuring that recommendations address patient issues and concerns
- ensuring that the guideline as a whole, and particularly the recommendations, are worded sensitively (for example, treating patients as people, not as objects of tests or treatments).

#### **3.1.5.1 Appointing patient and carer members**

Patients, carers and other members of the public can apply to become GDG members by responding to advertisements posted on the NICE website<sup>6</sup>. NICE's Patient and Public Involvement Programme (PPIP) 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<sup>7</sup>.

- People who respond to the advertisement can download an application pack from the NICE website, which includes a 'mini 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 and submit a personal statement describing how their skills and experience meet the specified requirements. They must also complete a declaration of interests form, and if they wish they can complete an equality monitoring form.

<sup>5</sup> Grey literature is defined as reports that are not formally published or have limited distribution, such as institutional reports, and which may not be identified through the common bibliographic retrieval systems.

<sup>6</sup> [www.nice.org.uk/getinvolved/joinnwc/join\\_a\\_nice\\_committee\\_or\\_working\\_group.jsp](http://www.nice.org.uk/getinvolved/joinnwc/join_a_nice_committee_or_working_group.jsp)

<sup>7</sup> For details of GDGs seeking patient and carer members, see [www.nice.org.uk/getinvolved/patientandpublicinvolvement](http://www.nice.org.uk/getinvolved/patientandpublicinvolvement)

- Applications are sent to the PPIP, which can also offer advice and support during the application process, both to patient and carer organisations and to individual applicants.
- The PPIP forwards all applications to the NCC. Staff at the NCC and the GDG Chair shortlist applicants according to the criteria in the job description and person specification. The NCC interviews shortlisted applicants, either in person or by telephone, before making a final decision.
- The NCC is responsible for notifying successful and unsuccessful applicants.

### **3.1.6 NCC technical team**

A core technical team from the NCC supports the GDG with technical experience and expertise. This team usually includes the NCC Director, an information specialist, a lead systematic reviewer (who can also be the project manager) and a health economist.

NCC staff who act as members of a GDG are voting members. However, to ensure that the NCC does not have too much influence in a vote, no more than three NCC staff members are allowed to vote on any one issue. For each vote, the NCC should decide which of its staff are the most appropriate to vote; these would normally be staff with particular knowledge of the issue under discussion.

#### **3.1.6.1 Information specialist**

The information specialist identifies the relevant literature that is used to answer the review questions developed by the GDG and the technical team (see chapters 4–6). The role of the information specialist involves:

- contributing to the setting of review questions
- designing and testing population and study design search filters (see section 5.2.2.7)
- contributing to discussions among the technical team and in GDG meetings as required, including deciding whether a search is needed and gathering key terms and synonyms
- identifying which databases should be searched
- drafting, refining and executing search strategies
- creating databases of the search results using reference management software (including removing duplicates), in preparation for sifting by a systematic reviewer (see section 6.1)
- maintaining audit trails, including keeping a log of search results, rationales and strategies
- keeping track of which papers are ordered for which review question in the document delivery process.

In addition, the information specialist advises on issues such as copyright and licences, metadata, archiving and record management.

### **3.1.6.2 Systematic reviewer**

The role of the systematic reviewer is to provide summarised tables of the evidence to inform other GDG members. This role involves:

- setting review questions
- assessing and selecting published abstracts
- critical and quality appraisal of evidence using a validated system
- distilling evidence into tables
- synthesising evidence into statements
- maintaining comprehensive audit trails.

The systematic reviewer is a core member of the GDG, alongside the rest of the NCC technical team. He or she is crucial to the dissemination, presentation and debate of the evidence within the GDG.

### **3.1.6.3 Health economist**

The role of the health economist is to inform the GDG about potential economic issues and to perform economic analyses. This is described in more detail in chapter 7.

### **3.1.6.4 Project manager**

The project manager oversees and facilitates the whole process, organising GDG meetings and providing administrative support to the GDG Chair and members.

## **3.1.7 Non-GDG members attending GDG meetings**

Occasionally, people who are not members of the GDG may attend a meeting, as either expert advisers or observers. They may be healthcare professionals, patients or carers, other experts, or NICE or NCC staff. They are expected to follow the code of conduct of the GDG and to sign the confidentiality agreement form (see section 3.2.2).

### **3.1.7.1 Expert advisers**

If the GDG does not have sufficient knowledge or expertise to make recommendations in a particular area, it may call on 'expert advisers' – external experts who can provide additional evidence from their experience and specific expertise to help the GDG make decisions. These can 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 should submit a declaration of interests form before attending the GDG meeting.

### **3.1.7.2 Observers**

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

## **3.2 Code of conduct and conflicts of interest**

### **3.2.1 Declaring interests**

The NCC should consider any potential conflict of interest for any person applying to become a GDG member before making a decision on their appointment<sup>8</sup>.

All GDG members and any individuals who have direct input into the guideline (including NCC and NICE staff, expert advisers and expert peer reviewers) should update their declaration of interests form before each GDG meeting. Any changes to a GDG member's declaration of interests should be recorded in the minutes of the GDG meeting (which are published on the NICE website). The Chair, in discussion with the NCC Director, should consider these in accordance with NICE policy.

Declarations of interests will be published in the final full guideline (see section 10.1.1).

### **3.2.2 Code of conduct and confidentiality**

NICE has developed a code of conduct for 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 (see appendix A1). On appointment, all GDG members are asked to sign a confidentiality form stating that they agree not to disclose any of the draft guideline recommendations before the public consultation begins (see appendix A2). This is to ensure that recommendations in the public domain have been agreed by all members of the GDG.

All people who see documents or who are party to discussions relating to a guideline before public consultation will be required to sign the confidentiality agreement form before becoming involved. The NCC should keep copies of signed forms.

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<sup>8</sup> See

[www.nice.org.uk/getinvolved/joinnwc/patientsandlaypeople/invitationtoapplyforlaymembership/fofnicescommissioningprogrammesteeringgroup/declaration\\_of\\_interests.jsp](http://www.nice.org.uk/getinvolved/joinnwc/patientsandlaypeople/invitationtoapplyforlaymembership/fofnicescommissioningprogrammesteeringgroup/declaration_of_interests.jsp)

### **3.2.3 Social value judgements and equality scheme**

Before the GDG starts its work, the NCC should ensure that all GDG members have a copy of NICE's most recent report on social value judgements: 'Social value judgements: principles for the development of NICE guidance' (2nd edition; 2008)<sup>9</sup>. They should also make sure that GDG members are aware of NICE's equality scheme and action plan<sup>10</sup>.

### **3.2.4 Dealing with enquiries on GDG 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 NCC or contact NICE (see appendix A3). They should declare this at the next GDG meeting and inform the NCC Director.

## **3.3 Identifying and meeting training needs**

### **3.3.1 Chair**

The person selected to perform the crucial role of GDG Chair may need support and training so that they can carry out their role effectively. He or she requires in-depth knowledge of the NICE clinical guideline development process and an understanding of group processes. The CCP provides a 1-day training session for GDG Chairs, in collaboration with the NCCs. Everyone who is appointed as a GDG Chair is required to attend one of these training sessions. The training covers the key tasks that the Chair is expected to perform. Box 3.5 outlines the content of the training session.

#### **Box 3.5 Content of the GDG Chair training session**

- Key principles for developing NICE clinical guidelines
- Formulating review questions
- Reviewing evidence
- Introduction to health economics
- Developing recommendations
- Principles of facilitation
- NICE's equality scheme
- Declaring conflicts of interest
- How the work of the GDG is planned and organised

In addition to the training session, the NCC should identify and meet any additional training needs that a GDG Chair may have. For example, unless the Chair is an experienced facilitator, he or she may need additional training in this area – particularly in relation to the important role of ensuring that the views of patients and carers are given appropriate weight by the GDG. The NCC may consider a 'buddying' approach in which a new GDG Chair learns from someone with previous experience as a Chair.

<sup>9</sup> [www.nice.org.uk/aboutnice/howwework/socialvaluejudgements/socialvaluejudgements.jsp](http://www.nice.org.uk/aboutnice/howwework/socialvaluejudgements/socialvaluejudgements.jsp)

<sup>10</sup> [www.nice.org.uk/aboutnice/howwework/NICEEqualityScheme.jsp](http://www.nice.org.uk/aboutnice/howwework/NICEEqualityScheme.jsp)

### **3.3.2 Healthcare professional members**

To work effectively, GDG healthcare professional members may need training and support in some technical areas of guideline development, such as systematic reviewing and health economics. The Chair and the NCC should be aware of the types of training that individual GDG members may need at the start of or during the guideline development process, so that they can provide the necessary support. Training for GDG healthcare professional members should be provided by the NCC at an early GDG meeting, and should include components similar to those outlined in box 3.5.

### **3.3.3 Patient and carer members**

The PPIP at NICE offers dedicated training to all patient and carer members of the GDG. This training covers topics such as an introduction to health economics, critical appraisal, and developing recommendations from evidence. In addition, the training gives the patient and carer members the opportunity to learn from people who have been on previous GDGs.

The PPIP also gives a short presentation on the role of patient and carer members to the whole GDG at the first meeting.

## **3.4 Running the GDG**

Running the GDG is the responsibility of the NCC, in consultation with the Chair. Core responsibilities for all meetings include:

- setting meeting dates, which should be 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 guidelines manual.

A summary of the minutes of each GDG meeting is made available on the NICE website; this includes:

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

Minutes of GDG meetings are posted on the NICE website during guideline development, before the guideline is published. Each set is approved by the GDG at the next meeting, and signed off by the GDG Chair and the NCC.

### **3.4.1 General principles**

Because the GDG is multidisciplinary, its members will bring with them different beliefs, values and experience. All these perspectives should be valued and respected. Each member should have an equal opportunity to contribute to the guideline development process. It is important to check that the terminology that GDG members use is understood by all and clarified if needed. The Chair should ensure that there is sufficient discussion to allow a range of possible approaches to be considered, while keeping the group focused on the guideline scope and the timescale of the project.

### **3.4.2 Quorum**

The quorum of the GDG will be 50% of appointed members. No business relating to the formulation of guideline 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 3.1.7.1) are not appointed members of the GDG and do not count towards the quorum.

### **3.4.3 Meeting schedule**

There are usually between 10 and 15 GDG meetings, held at approximately monthly intervals. Most are 1-day meetings, but some may take place over 2 days.

### **3.4.4 The first two GDG meetings**

Specific aspects of the clinical guideline development process are covered in the first and second GDG meetings.

The first meeting should focus on providing information for GDG members on the following subjects:

- the process of clinical guideline development
- how systematic reviews are performed
- the role of health economics in decision-making
- how patient and carer members contribute
- the role of the GDG
- the role of individual members of the NCC technical team.

GDG members should also be made aware of and operate within the principles contained in the report 'Social value judgements: principles for the development of NICE guidance' and NICE's equality scheme (see section 3.2.3).

Staff from the CCP and the PPIP at NICE will give presentations to explain how the elements of the clinical guideline development process fit together.

The second meeting should focus on developing the review questions. The GDG should examine the scope (including key clinical issues) and build review questions based on it. It may be helpful to establish an explicit

framework that clarifies the objectives of the work, the specific tasks that need to be carried out and the timetable. This will enable the group to focus and to develop a working relationship that is structured and well defined. Chapter 4 describes the process of developing review questions.

### **3.4.5 Working with NICE staff**

At a subsequent GDG meeting, the lead editor, implementation lead, costing lead and communications lead for the guideline from NICE give presentations to explain their roles. At the same time, the NICE leads will ask for nominations for GDG members to work with them on the following aspects:

- the quick reference guide and 'Understanding NICE guidance' – the GDG editorial nominees (see sections 11.3, 12.1 and 12.4)
- the implementation support tools – the GDG implementation nominees and costing nominees (see section 13.2)
- promoting the guideline (see section 12.5).

The roles of the various GDG nominees are described in more detail in the sections of this manual indicated.

Most of the work with the NICE leads is done between submission of the consultation drafts of the guideline and its publication. The lead editor may also attend one or two GDG meetings towards the end of the guideline development process, and can advise on the wording of recommendations as needed.

## **3.5 Making group decisions and reaching consensus**

### **3.5.1 Reaching agreement**

GDG members need to make collective decisions throughout the development of a clinical guideline. These include developing review questions (chapter 4), interpreting the evidence to answer these questions (chapter 6), and developing guideline recommendations (chapter 9). 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 individual 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 should be reflected in the wording of the recommendation.

Some GDGs may choose to use more formal voting procedures for certain decisions, but it is beyond the scope of this manual to offer guidance on when these should be used, or which of the many variants might be used. For example, a variation of the nominal-group technique was used by the NCC for Chronic Conditions to agree key recommendations (now known as ‘key priorities for implementation’) in a guideline. A summary of the methods used is presented in the full guideline ‘Chronic heart failure: national clinical guideline for diagnosis and management in primary and secondary care’<sup>11</sup>.

### **3.5.2 Using formal consensus methods outside the GDG**

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 outside the GDG (for example, the Delphi technique or the nominal-group technique). The use of these methods should be discussed on a case-by-case basis with the CCP at NICE. The final decision on whether these methods are warranted will be made by NICE. If it is decided that such methods may be used, the planning and methods should be clearly set out in a project plan and agreed by the CCP. The methods should also be described in the full guideline.

### **3.6 Further reading**

Choudhry NK, Stelfox HT, Desky AS (2002) Relationships between authors of clinical practice guidelines and the pharmaceutical industry. *Journal of the American Medical Association* 287: 612–7.

Eccles M, Grimshaw J, editors (2000) *Clinical guidelines from conception to use*. Abingdon: Radcliffe Medical Press.

Elwyn G, Greenhalgh T, Macfarlane F (2001) *Groups: a guide to small groups*. In: *Healthcare, Management, Education and Research*. Abingdon: Radcliffe Medical Press.

Hutchinson A, Baker R (1999) *Making use of guidelines in clinical practice*. Abingdon: Radcliffe Medical Press.

National Institute for Health and Clinical Excellence (2008) *Social value judgements: principles for the development of NICE guidance*, 2nd edition. London: National Institute for Health and Clinical Excellence. Available from: [www.nice.org.uk/aboutnice/howwework/socialvaluejudgements/socialvaluejudgements.jsp](http://www.nice.org.uk/aboutnice/howwework/socialvaluejudgements/socialvaluejudgements.jsp)

National Institute for Health and Clinical Excellence (2006) *Appointments to guidance producing bodies advisory to NICE*. Available from: [www.nice.org.uk/384476](http://www.nice.org.uk/384476)

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<sup>11</sup> Available from [www.nice.org.uk/CG5](http://www.nice.org.uk/CG5)