

## 2 Methodology

### 2.1 Background

This chapter describes the people and techniques used to derive the clinical recommendations that follow in later chapters.

### 2.2 The developers

#### 2.2.1 The National Collaborating Centre for Chronic Conditions (NCC-CC)

The NCC-CC is housed by the Royal College of Physicians (RCP) but governed by a multi-professional partners board inclusive of patient groups and NHS management. The Collaborating Centre was set up in 2001, to undertake commissions from the National Institute for Clinical Excellence (NICE), to develop clinical guidelines for the National Health Service.

#### 2.2.2 The technical team

The technical team consisted of an information scientist, a systematic reviewer, a lead clinical advisor, and a health economist, supported by project management and administrative personnel. The clinical advisor also acted as the appointed Chair of the Guidelines Development Group (GDG, see below). The technical team met monthly in addition to partaking in the meetings of the GDG.

#### 2.2.3 The Guideline Development Group (GDG)

The GDG met twelve times at monthly intervals to review the evidence identified by the technical team, to comment on its completeness, and to develop and refine clinical recommendations based on that evidence and other considerations.

Editorial responsibility for the guideline rested solely with the GDG, which also developed the audit criteria.

#### 2.2.4 The Consensus Reference Group (CRG)

An extension of the GDG, the larger CRG, met three times throughout the process, once early in the development to ensure the aims and clinical questions were appropriate, once after three meetings of the GDG to confirm an operational definition of COPD and agree recommendations on diagnosis. Finally, at the end of the process to review the validity of the recommendations drafted by the GDG. The group employed formal consensus techniques for these latter meetings.

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Nominations for all group members were invited from key stakeholder organisations, which were selected to ensure an appropriate mix of clinical professions and patient groups. Each nominee was expected to serve as an individual expert in their own right and not as a mandated representative, although they were encouraged to keep their parent organisation informed of the process. Group membership details can be found on the inside of the front cover of this document.

All group members made a formal “Declaration of Interests” at the start of the guideline development and provided updates throughout the process. The NCC-CC and the Group Chair monitored these.

### 2.2.5 Involvement of people with COPD

As part of the development process, the NCC-CC was keen to ensure that the guideline development process was informed by the views of people with COPD and their carers. This was achieved in two ways:

- by securing patient organisation representation on the guideline development group
- by having a patient with COPD on the guideline development group.

The patient and a representative of the British Lung Foundation’s Breathe Easy patient support groups was present at every meeting of the GDG and CRG. They were therefore involved at every stage of the guideline development process and were able to consult with their wider constituencies throughout the process.

## 2.3 Searching for the evidence

There are four stages to evidence identification and retrieval:

- i The technical team set out a series of specific clinical questions (Appendix A) that covered the issues identified in the project scope. The CRG met to discuss, refine and approve these questions as suitable for identifying appropriate evidence within the published literature.
- ii A total of 120 questions were identified. The technical team and project executive agreed that a full literature search and critical appraisal process could not be undertaken for all of these areas due to the time limitations within the guideline development process. The technical team identified questions where it was felt that a full literature search and critical appraisal was essential.
- iii The Information Scientist developed a search strategy for each evidence-based question to identify the available evidence. Identified titles and abstracts were reviewed for relevance to the agreed clinical questions and full papers obtained as appropriate.
- iv The full papers were critically appraised and the pertinent data entered into evidence tables that were then reviewed and analysed by the GDG as the basis upon which to formulate recommendations. The evidence tables are available at [http://thorax.bmjournals.com/content/vol59/supp\\_1](http://thorax.bmjournals.com/content/vol59/supp_1)

Limited details of the searches with regard to databases and constraints applied can be found in Appendix A. In general no formal contact was made with authors of identified studies, but occasionally it was necessary to contact authors for clarification of specific points. Additional contemporary articles were identified by the GDG on an ad hoc basis. Stakeholder evidence identified via a process established by NICE<sup>15</sup> was incorporated where appropriate. Both were assessed for inclusion by the same criteria as evidence provided by the electronic searches.

Searches were re-run at the end of the guideline development process, thus including evidence published up to the end of May 2003. Studies recommended by stakeholders or GDG members that were published after this date were not considered for inclusion. This time-point should be the starting point for searching for new evidence for future updates to this guideline.

## 2.4 Synthesising the evidence

Abstracts of articles identified from the searches were screened for relevance. Hard copies were ordered of papers that appeared to provide useful evidence relevant to each clinical question. Each paper was assessed for its methodological quality against pre-defined criteria using a validated quality appraisal tool<sup>16</sup>. Papers that met the inclusion criteria were then assigned a level according to the evidence hierarchy as detailed in section 3. Owing to practical limitations, the selection, critical appraisal, and data extraction were undertaken by one reviewer only. Evidence was considered carefully by the GDG group for accuracy and completeness.

Each clinical question dictated the appropriate study design that was prioritised in the search strategy. In addition certain topics within any one clinical question at times required different evidence types to be considered. Randomised control trials (RCTs) were the most appropriate study design for a number of clinical questions as they lend themselves particularly well to research into medicines. They were not, however, the most appropriate study design for all clinical questions. For example, the evaluation of diagnostic tests is more suited to alternative research designs. Furthermore, RCTs are more difficult to perform in areas such as rehabilitation and lifestyle, where interventions may be tailored to the needs of the individual. As such, pharmaceutical interventions tend to be placed higher in the evidence hierarchy than other equally important interventions. This should not be interpreted as a preference for a particular type of intervention or as a reflection of the quality of the evidence, particularly for those clinical areas where non-RCT evidence is valid and most appropriate.

Where available, evidence from well-conducted systematic reviews was appraised and presented. Trials included within these reviews are listed in the evidence table but were not critically appraised. Studies identified in addition to those included in the systematic review were included in the appraisal process.

The study populations considered varied between clinical questions. At times evidence was not available from studies that were specific to a COPD population; therefore, it was necessary to consider studies in either a heterogeneous respiratory disease population or other chronic conditions.

Study quality, although formally assessed, was not used as a basis for informing the evidence level assigned to evidence statements. Descriptive limitations of studies are included in the evidence statements as appropriate.

### 2.4.1 Expert papers

On occasion the GDG identified a clinical question that could not be appropriately answered through undertaking a systematic review (where the evidence was scarce, or where the question could not usefully be answered with the largely dichotomous output of a review). These questions were addressed via an expert-drafted discussion paper, subject to consideration by the GDG. In these instances Medline and Cochrane databases were searched together with a review of frequently cited papers and key review articles but there was no formal assessment of the studies cited. These review papers were developed and used as a basis for discussion by the GDG as a whole.

Finally, national and international evidence based guidelines were referred to during the development process. These were not formally appraised owing to the inherent difficulties of such a process, in that the consistency of process and of evidence base can be difficult to ascertain across such documents.

## 2.5 Health economic evidence

While evidence on cost effectiveness was extracted from the main searches wherever it existed, this was rare. It was necessary to undertake a separate search for information on the potential costs and benefits of the interventions and management strategies considered in this guideline. These searches were carried out by the health economist. The GDG realised that few formal cost effectiveness analyses would be identified, therefore the search for economic evidence was very broad and designed to identify information about the resources used in providing a service or intervention and/or the benefits that can be attributed to it. No study design criteria were imposed a priori i.e. the searches were not limited to RCTs or formal economic evaluations. Further details of the searches for economic evidence are given in section 15.

Identified titles and abstracts from the economics searches were reviewed by the health economist and full papers obtained as appropriate. The full papers were critically appraised by the health economist and the relevant data was conveyed to the GDG alongside the clinical evidence for each question. Given that the economics searches were broad and that no standard measure of assessing the quality of economic evidence is available, careful consideration was given to each study design and the applicability of the results to the guideline context. An important issue in this respect is that much of the evidence on costs and benefits comes from the health care systems around the world and is therefore of limited applicability to a guideline for England and Wales.

As well as presenting existing evidence on the costs and benefits of a broad range of interventions to the GDG, the issue of opportunistic case finding linked to targeted smoking cessation programmes was identified as an important area for further economic analysis. This choice was made on the grounds that this approach may be associated with:

- potentially large health benefits
- a potentially large effect on NHS resources
- uncertainty surrounding the benefits and resources
- a potentially large service impact.

Health economic analysis can provide a framework for collating information from a variety of sources in order to estimate, and systematically compare, costs and benefits. This is a complex and labour intensive process and it does require a level of clinical evidence that is not always readily available. The results of this analysis are discussed briefly in section 15.

## 2.6 Drafting recommendations

Evidence for each topic was extracted into tables and summarised in evidence statements. The GDG reviewed the evidence tables and statements at each meeting and reached a group opinion. Recommendations were explicitly linked to the evidence supporting them and graded according to the level of the evidence upon which they were based, using the grading system detailed in section 3.

*It should be noted that the level of evidence determines the grade assigned to each recommendation and as such does not necessarily reflect the clinical importance attached to the recommendation.*

## 2.7 Agreeing recommendations

Once the evidence review had been completed and an early draft of the guideline produced, a one-day meeting of the CRG was held to finalise the recommendations. This included a pre-meeting vote on the recommendations and a further vote at the CRG meeting, where the group were asked to consider the draft guideline in 2 stages:

- Are the evidence-based statements acceptable and is the evidence cited sufficient to justify the grading attached?
- Are the recommendations derived from the evidence justified and are they sufficiently practical so that those at the clinical front line can implement them prospectively? There were 3 types of recommendation to be considered:
  - 1 a recommendation from the GDG based on strong evidence - usually non controversial unless there was important evidence that had been missed or misinterpreted
  - 2 a recommendation that was based on good evidence but where it was necessary to extrapolate the findings to make it useful in the NHS - the extrapolation approved by consensus
  - 3 recommendations for which no evidence exists but which address important aspects of COPD care or management - and for which a consensus on best practice could be reached.

This formal consensus method has been established within the NCC-CC, drawing on the knowledge set out in the Health Technology Appraisal<sup>17</sup>, and practical experience. It approximates to a modification of the RAND Nominal Group process (as cited in the Health Technology Appraisal<sup>17</sup>) and will be fully described in future publications.

## 2.8 Writing the guideline

The first formal version of the guideline was drawn up by the technical team in accord with the decisions of the Guideline Development Group. The draft guideline was circulated to stakeholders according to the formal NICE stakeholder consultation and validation phase<sup>18</sup> prior to publication.

The evidence tables can be found at [http://thorax.bmjournals.com/content/vol59/supp\\_1](http://thorax.bmjournals.com/content/vol59/supp_1)



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