Guideline Development in the Emergency Department

Guideline Development Methods

Notes for staff and students

developing a CDSG

This document is largely based on: ***National Institute for Clinical Excellence (February 2004) Guideline Development Methods: Information for National Collaborating Centres and Guideline Developers. London: National Institute for Clinical Excellence. Available from: www.nice.org***

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Acknowledgements

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Overview of the guideline development process

The information in this document has been prepared primarily for those involved in the development of guidelines for the Emergency Department and follows the methodology promulgated by NICE as closely as is possible.

A summary of key stages of guideline development	
Key stage	**Tasks**
Scope the guideline	• Consider guideline remit • Undertake preliminary literature search • Identify key aspects of care to be included • Review scope after consultation
Prepare the work plan	• Describe key aspects of methods to be used • Define key timelines
Form the GDG	Supplement the GDG with: • expert health professionals outside the Emergency Department • those familiar with issues affecting patients and carers • technical experts if needed
Formulate the clinical questions	• Identify clinical issues from the scope • Identify economic issues • Structure questions
Identify the evidence	• Develop search strategy for each question • Search relevant databases • Ensure sensitivity and specificity • Consider stakeholders' submissions
Review and grade the evidence	• Select relevant studies • Assess quality of studies selected • Summarise evidence and assign level

Create guideline recommendations	• Develop recommendations based on clinical and cost effectiveness • Classify recommendations • Prioritise recommendations for implementation • Develop audit criteria
Write the first consultation draft of the guideline	Consult and respond to comments
Review in light of comments	
Prepare second consultation draft of guideline	Consult and respond to comments
Review in light of comments	
Prepare final guideline	

1 Introduction

The Emergency Department at Manchester Royal Infirmary (ED – the department) has been undertaking primary and secondary research for a number of years designed to improve the clinical effectiveness of care. This research has recently been distilled into practical advice for clinicians. These Clinical Decision Support Guidelines (CDSGs) are available for use on the shop floor as a Clinical Decision Support Manual, and as “pinks” that can be used to guide care for individual patients.

1.1 The Departments’ guidance

The department issues guidance developed through its clinical guidelines development process. The departments’ clinical guidelines will cover aspects of emergency clinical care and the emergency management of conditions.

The development process is underpinned by the key NICE principles of basing recommendations on the best available evidence and involving all stakeholders in a transparent and collaborative manner.

1.1.1 Clinical guidelines

The departments clinical guidelines are recommendations, based on the best available evidence, for the emergency care of patients by professionals. In general, clinical guidelines have been defined as “systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances”, although they are also relevant to health service managers..

Good clinical guidelines change the process of healthcare and improve outcomes. For example, well-constructed and up-to-date clinical decision support guidelines will provide recommendations for the emergency management of patients. They can be used to develop audit standards to assess the clinical practice and can be used in the education and training of departmental clinicians.

1.2 The aim of this document

This document provides advice on the technical aspects that guideline developers need to consider and incorporate into the production of each guideline.

The advice in this document draws on NICE guideline development methods which in turn are based on international guideline development methodology, the expertise of the Institute’s guidelines advisors and the experience of the organisations commissioned to develop NICE guidelines. It is based on internationally acceptable criteria of quality, as articulated by the AGREE

instrument (www.agreecollaboration.org).

The structure of this document follows the development of the guideline from its inception though to publication. The topics for which guidelines will be developed have been selected by the consultants in the department. They are listed below:

MAJOR ILLNESS AND INJURY IN ADULTS

Number	Protocol name	Stakeholders
2003 – 01	Cardiac Chest Pain	Cardiol, Biochem
2003 – 02	Atraumatic Pleuritic Chest Pain	Radiol, Haem, Resp
2003 – 03	Atraumatic Swollen Lower Limb	Radiol, Haem
2003 – 04	Lone Acute Severe Headache	Radiol, Neuro
2003 – 05	Acute Upper GI Bleed	Gastro
2003 – 06	Adult Asthma	Resp
2003 – 07	Pneumothorax	Resp
2003 – 08	Acute Allergic Reaction	Immunol
2003 – 09	Cellulitis	GIM, microbiology
2003 – 10	Community-acquired Pneumonia	Resp
2003 – 11	Heart Failure	Cardiol
2003 – 12	Adult Fits	Radiol
2003 – 13	Alcohol Intoxication	GIM, neurology
2003 – 14	Deliberate Self-harm	GIM, Psy
2003 – 15	Low Back Pain	Radiol, Ortho
2003 – 16	Adult Head Injury	Radiol, Neuro
2003 – 17	Abscess	Surg
2003 – 18	Loin Pain	Radiol, Urol
2003 – 19	Fractured Hip	Ortho
2003 – 20	Abdominal Pain	Radiol, Surg
2003 – 21	Abdominal pain in women	Surg, Gynae
2003 – 22	Sickle cell crisis	Haem
2003 - 23	Elderly Faller	COE
2003 - 24	Stroke	COE
2003 – 25	Atrial Fibrillation	Cardiol
2003 - 26	PV Bleed	Gynae
2003 – 27	Pancreatitis	Surg
2003 – 28	COPD	Resp
2003 - 29	Testicular Pain	Radiol, Urol
2003 – 30	Acute paracetamol Overdose	GIM, Psy
2003 – 31	Staggered paracetamol overdose	
2003 – 32	Tricyclic Overdose	GIM
2003 – 33	Heroin Overdose	GIM
2003 – 34	Diabetic Emergencies	GIM, Diabetol
2003 - 35	Haematuria	Urol
2003 – 36	Wide-complex`tachycardia	Cardiol
2003 – 37	Narrow-complex tachycardia	Cardiol
2003 – 38	Urinary retention	Urol
2003 - 39	*Possible meningitis*	ICU
2003 – 40	*Possible septicaemia*	ICU

PAEDIATRIC ILLNESS AND INJURY

Number	Protocol name	Stakeholders
2004 - 51	Croup	Paed
2004 – 52	Childhood Asthma	Paed
2004 - 53	Childhood Poisoning	Paed
2004 - 55	Childhood Head Injury	Paed
2004 - 56	Joint Dislocation in children	Paed, Ortho
2004 - 57	Childhood Fracture	Paed, Ortho
2004 - 58	Limping Child	Paed, Ortho
2004 - 59	Diarrhoea and Vomiting	Paed
2004 - 60	Febrile Convulsions	Paed
2004 - 61	Urinary Tract Infection in Children	Paed
2004 - 62	Afebrile Fits in Childhood	Paed
2004 - 63	Elbow injury in children	Ortho
2004 - 64	The febrile child	Paed
2004 - 65	Constipation in childhood	Paed
2004 - 66		
2004 – 67		
2004 - 68		
2004 - 69		
2004 -70		
2004 - 71		
2004 - 73		
2004 - 74		
2004 – 75		

MINOR ILLNESS AND INJURY

Number	Protocol name	Stakeholders
2004 – 76	Needlestick injury	GUM
2004 – 77	Ankle and foot Pain	Ortho
2004 – 78	Knee Pain	Ortho
2004 – 79	Burns	Plastics
2004 – 80	Shoulder Pain	Ortho
2004 - 81	Wounds	
2004 - 82	Bites and Stings	
2004 - 83	Wrist injury	Ortho
2004 - 84	Foreign body in the ear and nose	
2004 - 85	Foreign body	
2004 - 86	Foreign body in the eye	Ophth
2004 - 87	Neck Pain	
2004 - 88	Red eye	Ophth
2004 - 89	Painful eye	Ophth
2004 –90	Acute visual disturbance	Ophth
2004 - 91	Toothache	MF
2004 - 92	Elbow pain	Ortho
2004 - 93	Earache	ENT
2004 - 94	Sore throat	ENT
2004 - 95	Joint injury in haemophilia	Haem
2004 - 96	Sexually acquired infection	GUM
2004 - 97	Finger infection	Ortho, Plastics
2004 – 98	Hand infection	Ortho, Plastics
2004 - 99	Hand injury	Ortho, Plastics

THERAPEUTIC AND MANAGEMENT PROTOCOLS

Number	Protocol name	Stakeholders
2004 - 100	Cardiac reperfusion	
2004 - 101	Nitrate infusion	
2004 – 102	Ketamine sedation	
2004 - 103	Sedation for ventilation	
2004 - 104	Glucose control	
2004 - 105	Naloxone infusion	
2004 - 106	Tetanus immunisation	
2004 - 107	Procedural sedation	
2004 - 108	N Acetyl-cysteine infusion	
2004 - 109	Intravenous regional anaesthesia	
2004 - 110	Social Assessment for discharge	Community
2004 - 111	Alcohol withdrawal	
2004 - 112	Sedation in acute psychiatric disturbance	

2 Scoping the guideline

Guideline topics are selected by the Consultants in the department after consultation with other clinical staff and the Trust. The guideline topic is then translated into the scope document for the guideline (usually known simply as the 'scope'). Preparing the scope is the first stage in developing a guideline, and it determines the shape of future work. This chapter describes what the scope is, and how it is drafted and then finalised following consultation and discussion.

2.1 Purpose of the scope

The purpose of the scope is to:

- provide an overview of what the guideline will include and exclude
- identify the key aspects of care that must be included
- set the boundaries of the development work and provide a clear framework to enable work to stay within the priorities agreed by the sponsoring professional organisations.
- inform the development of the clinical questions and search strategy

The scope provides a framework within which to conduct the development work. Its content briefly describes the background epidemiology relevant to the disease or condition and defines the aspects of care that the guideline will cover in terms of:

- population to be included or excluded – for example, age groups or people with certain types of disease
- emergency setting – for example resus, MIU, PCEC etc
- interventions and treatments to be included and excluded – for example, diagnostic tests, surgical, medical and psychological treatments and rehabilitation, lifestyle advice.

2.2 Drafting the scope

The steps in producing a first draft of the scope for consultation include considering the remit, searching the literature and consulting with experts.

2.2.1 Considering the remit

The remit set by the consultants in the department forms the basis of the scope, and all areas specified by the remit are normally addressed in the scope. On occasion the developer may query the remit with the consultants. This may involve redefining the topic in order to specify the boundaries and the magnitude of the work.

2.2.2 Preliminary search of literature (stage-one search)

A broad preliminary search of the literature is important to obtain an overview of the issues likely to be covered by the guideline – the clinical need and the clinical management of the condition – and to help define key areas. The focus of this stage-one search is to identify systematic reviews and guidelines relevant to the topic. The main sources to use during this preliminary search are listed in Box 2.1, but other sources may be used depending on the guideline topic. More information on searching is given in Chapter 6.

Box 2.1 Main sources to use for the stage-one search to identify systematic reviews and guidelines.

For clinical guidance

Medline, CINAHL and Embase
Cochrane Library
US Guidelines Clearinghouse
ACEP
National Library of Health (NLH)
NICE and health technology assessment (HTA) websites

2.2.3 Consulting with experts and potential guideline group members

It can be helpful to consult with clinical experts and patients when preparing the draft scope. This consultation ensures that all relevant areas have been considered and enables the consultants to define the expertise and experience required within the guideline group.

2.3 The consultation process

The draft scope should be discussed at a consultants meeting and may then be subject to wider consultation.

2.4 Finalising the scope after consultation

2.4.1 Dealing with comments

The Consultants Group should review the scope in the light of any comments received. It may be that additional aspects of care need to be included in the guideline, which could make the development of the guideline unmanageable within the time permitted. Relevant suggested additions that might make the guideline more useful and so improve patient care should not be ignored. Suggestions clearly outside the original remit should not be included

2.4.2 Signing off the scope

After consultation, the Consultants Group should consider whether comments have been appropriately and adequately addressed by the developers.

3 Preparing the project plan

A project plan is prepared to set out the guideline development process for each guideline. Its purpose is to specify methods and timelines. It is an internal document that constitutes the reference from which the progress of the work can be assessed. It is expected that the methods described in the workplan will reflect those stated in this document unless there are specific reasons for them to differ. This chapter describes the structure of the workplan and the stages required in its development.

3.1 Structure of the workplan

Key components of the workplan are described below; they include membership of the guideline group, identification of evidence, approach to assessing clinical effectiveness, stakeholder involvement, writing of the guideline, review processes, project management and timelines. It is reasonable to include a summary of areas that the clinical questions might address.

3.1.1 Membership of the Guideline Group

The workplan should include the likely need for extended membership of the guideline group (and the range of roles required if this is envisaged).

3.1.2 Identification of evidence

The workplan should describe any existing guidelines or health technology assessment (HTA) reviews that will inform the guideline, how evidence will be identified and synthesised, and how areas without evidence will be handled.

A preliminary search of the literature will be required to inform some of these areas.

3.1.2.1 Evidence identification and synthesis

A description of the databases that will be searched should be included in the workplan, detailing the time period from which evidence will be sourced and the reasoning for this selection. The likely search strategies that will be used should be listed and the workplan should note whether foreign language journals will be included. However, in many clinical areas the evidence base is not influenced by the inclusion of foreign language journals. Therefore, in most cases, foreign papers need not be translated.

Ideally, the volume of papers that will be identified in the search should be estimated. How the final set of papers will be decided upon and how long the evidence-synthesis process will take should also be determined. To do this, the

guideline developer should conduct a preliminary stage-two search (see Chapter 6). It is also necessary to indicate whether searches will be repeated during the development of the guideline recommendations.

The workplan should also describe:

- how the evidence will be synthesised to produce a summary of the evidence
- if meta-analysis is to be used, the areas of the guideline to which it will be applied
- how the evidence will be displayed (narrative summary, evidence tables, meta-analysis and trial tables)
- the levels of evidence and classification scheme for the recommendations (a reference should be included and the selection justified if these differ from those described in Chapter 7)
- how the levels of evidence and class of recommendations will be used within the guideline.

3.1.2.2 Areas lacking evidence

The workplan should describe how any areas lacking an evidence base will be dealt with when the recommendations are being developed (see Chapter 9). This section should also describe the steps that will be taken to address the availability of evidence at subsequent review (for example, by highlighting the need for further research in a particular area in the research recommendations section of the guideline).

3.1.3 Writing the guideline

The details of the person or people who will be responsible for writing the versions of the guideline should be included.

3.1.4 Project management

The document should include a Gantt chart of the project that includes: staff working on the project, including details of the time period and estimated proportion of time that they will work on the project, and a timetable of work.

The timetable of the guideline process should contain a detailed estimate of key dates. This timetable should include sections on estimates of time for literature searches and reviews.

3.1.5 Development time

The key dates for delivery of the guideline should be estimated after careful consideration in the light of the anticipated workload, because the date of the delivery of the first draft will determine the timing of the consultations.

4 Forming and running a Guideline Working Group

Convening an effective guideline working group is one of the most important stages in producing a guideline. The group agrees the clinical questions, considers the evidence and develops the recommendations. Extended membership of the group therefore needs to be carefully considered. Additional members might comprising clinicians (both content-area specialists and generalists) from outside the department, patients and/or carers and technical experts. Its exact composition needs to be tailored to the topic covered by the guideline. In addition to the working group members, there may be individuals with relevant expertise who will be invited or visited for discussions.

This chapter covers the core elements of forming and running a guideline working group.

4.1 Forming the GWG

A maximum workable size for the GWG is 4 to 6 people. There should be a balance struck between the opportunity for individuals to contribute effectively, the need for a broad range of experience and knowledge and affordability.

There are four key constituents of the GWG:

- the group leader (usually a consultant)
- professional members (medical, paramedical and nursing as appropriate)
- patient/carer members (if appropriate and feasible)
- technical members (the searcher / appraiser).

The following sections outline the roles of the members and describe how they should be selected.

4.1.1 Group leader

To work well, a GWG needs an effective leader; this will usually be one of the departmental consultants. The leader guides the group in terms of task (developing the guideline) and process (how the group works). The group leader further aims to facilitate the interpersonal aspects of the group processes. He or she should ensure that all members work in a spirit of collaboration, with a balanced contribution from all individuals, and in so doing enable the GWG to achieve the task of developing the guideline successfully (see Box 4.1).

Box 4.1 Key roles and functions of the GDG leader.

The group leader needs relevant background knowledge, including:

- in-depth knowledge or appreciation of the scope of the guideline and the topics to be covered during the meeting
- good knowledge of the skills mix within the group

To facilitate the **group process**, the group leader:

- sets up the rules for GWG functioning
- assists with the planning of the GWG meetings
- ensures that the group has relevant information and required resources
- establishes a climate of trust and mutual respect between members
- provides opportunities for all members to contribute to the discussions and activities of the group
- may meet individual GWG members outside GWG meetings

In **GWG meetings** the group leader:

- has a directive role in steering the discussions according to the agenda
- keeps the group discussion unified and avoids the disruption of sub-conversations and dominance by some members
- encourages constructive debate, without forcing agreement
- winds up repetitive debate
- summarises the main points and key decisions from the debate

4.1.2 Professional members

Professional members should be representative of the healthcare professionals involved in the care of patients affected by the guideline topic. Fundamentally they are on the group as clinicians, and detailed research expertise is not essential although an understanding of evidence-based medicine is desirable.

The roles and responsibilities of the professional members of the GWG are shown in Box 4.2.

Box 4.2 Key roles of professional GWG members.

GWG members from the healthcare professions are expected to:

- contribute constructively to meetings and have good communication and team-working skills; this should include commitment to the needs of service users
- use background knowledge and experience of the management of, and services for, the topic to provide guidance to the technical members carrying out systematic reviews and economic analyses
- read all relevant documentation and make constructive comments and proposals at GWG meetings and in the interim
- use their own informal networks to inform their contribution
- formulate with other members of the group recommendations based on the evidence reviews
- advise on how to identify best practice in areas where research evidence is absent, weak or equivocal

They are not expected to:

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

4.1.2.1 Selecting professional members

It is expected that most of thethe professional members of the GWG will be drawn from the department. All professional groups with a real interest in the guideline should be represented. If clinicians with sufficient expertise are not available in the department then they should be recruited from other parts of the Trust whenever possible.

4.1.3 Patient/carer members

Lay members with experience and/or knowledge of patient/carer issues on each GWG (the 'patient/carer members') would add considerably to the work of the group. They ensure that patient and carer issues, as well as healthcare professionals' views, inform the guideline development process. In general, the

patient/carer members will have direct experience of the condition, as a patient or a carer/family member, and/or will be officers of a patient or carer organisation or support group. When present the patient/carer members have equal status on the GWG. Their specific roles are shown in Box 4.3. Patient/carer members should **not** be excluded from specific activities carried out by other members of the group (for example, consensus methods).

Box 4.3 Key roles of patient/carer members.

The key contributions of patient/carer members are to:

- ensure that clinical questions embrace patient as well as professional issues
- identify grey literature (for example, patient surveys) highlighting patient issues that may inform the work of the GWG
- consider the extent to which published evidence has measured and taken into account outcome measures that patients consider important
- identify areas where patient preferences and patient choice may need to be acknowledged in the guideline
- ensure that recommendations address patient issues and concerns
- ensure that the guideline as a whole, and recommendations specifically, are sensitively worded (for example, treating patients as people not as objects of tests, investigations or treatments)

4.1.3.1 Selecting patient/carer members

As was the case with professional membership it is expected that the majority of patient / carer members will be recruited from the Central Manchester area.

4.1.4 Technical experts

These roles will usually be taken by students (on attachment) or staff (consultants, specialist registrars or clinical; effectiveness fellows) within the department. One person will usually be the lead systematic reviewer. They will be supported by the Senior Emergency Information Officer.

4.1.4.1 Systematic reviewer

The role of the systematic reviewer within the group is to provide summarised tables of the evidence to inform other GWG members. The role of the systematic reviewer may include: setting evidence-based questions; abstracting; critical/quality appraisal of evidence using a validated system; distillation of evidence into tables; synthesis of evidence into statements; and maintenance of comprehensive audit trails. These will be in the form of a BestBET.

4.1.4.2 Information specialist

The information specialist assists in the identification of relevant literature to answer the clinical questions developed by the GWG (see Chapter 5). The role may include support for: setting evidence-based questions; designing and testing population and study filters; leading the discussion of the questions and their parameters within the GWG; identifying relevant databases to search; maintaining audit trails including search strategies and rationales and search results; and keeping track of papers in the document-delivery process. Part of this role will be filled by the lead systematic reviewer.

4.1.4.3 Health economist

Occasionally an health economist may be required to inform the GWG about potential economic issues and to perform additional economic analyses. The Trust R&D support unit includes a Health Economist and any support required should be sought from this group.

4.2 Identifying interests and conflict of interest

4.2.1 Declaring interests

Even though these guidelines are only being developed within our own department, it is still important that any conflicts of interest are declared.

4.3 Identifying and meeting training needs

4.3.1 Group leader

If the person selected to perform this crucial role is not one of the departmental consultants then they may need support and training. They will need in-depth knowledge of the guideline development process and an understanding of the group processes involved in carrying out the role effectively.

4.3.2 Professional members

To work effectively, GWG members may need technical training and support in areas of guideline development. As a minimum they should understand the

guideline development process and should have attended a BestBETs course.

4.3.3 Patient/carer members

Patient / carer members should be appropriately briefed and supported throughout the process.

4.4 Running the GWG

Running the GWG is the responsibility of the department and, in particular, the group leader

4.4.1 General principles

As the GWG is multidisciplinary, its members will bring with them different beliefs, values and experience. It is important that all these perspectives are listened to and that each member has an equal voice in the process. It is important to check that the terminology members use is understood by all and that the group obtains clarifications when needed. The group leader should ensure there is sufficient discussion to allow a range of possible approaches to be considered, whilst making sure that the group remains focused on the guideline scope and the timescale of the project. The GWG leader needs to allow sufficient time so that all members can express their views without feeling intimidated or threatened and should check that **all** the members in 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.

4.4.2 Specific tasks

There are specific aspects of the process that need to be covered in the first GWG meeting.

The meeting should cover how systematic reviews are performed, how patient/carer members contribute and the role of the GWG. The group should examine the scope and build questions based on it. It may be helpful to establish an explicit framework that clarifies the objectives of the work, the specific tasks needed and the timetable. This enables the group to focus, and to develop a working relationship that is structured and well defined.

4.4.3 Role of external members

There may be occasions when someone external to the group attends a particular meeting, either as an observer or an expert.

4.4.3.1 Observers

An observer attending a GDG should sit apart from the group and not enter into the discussions unless invited to do so by the GDG.

4.4.3.2 Experts

Experts attending a GDG are present because of their knowledge in a particular area. Therefore, it is important that they sit within the group and enter fully into any discussion.

4.5 Further reading

Royal College of General Practitioners (1995) *The Development and Implementation of Clinical Guidelines: Report of the Clinical Guidelines Working Group*. London: Royal College of General Practitioners.

Eccles M, Grimshaw J, editors (2000) *Clinical Guidelines from Conception to Use*. Abingdon: Radcliffe Medical Press.

Hutchinson A, Baker R (1999) *Making Use of Guidelines in Clinical Practice*. Abingdon: Radcliffe Medical Press.

Choudhry NK, Stelfox HT, Desky AS (2002) Relationships between authors of clinical practice guidelines and the pharmaceutical industry. *Journal of the American Medical Association* 287:612–17.

5 Developing clinical questions

Once the final scope of the guideline is agreed, the next stage is to refine it into structured clinical questions. These questions vary depending on the scope, but must be clear, focused and closely define the boundaries of the topic. They are important both as the starting point for the subsequent systematic literature review, and as a guide to facilitate the development of recommendations by the GWG. The clinical questions should be developed as soon as the GWG is convened.

This chapter describes how clinical questions are selected, how they are formulated and how they are agreed. It describes the different types of question that may be required, and gives examples.

5.1 Number of questions

There is no proscriptive approach to the exact number of clinical questions required for each guideline, as this depends on the topic and the breadth of the scope. However, it is important that the number of questions is of a manageable size for the GWG to handle, especially in relation to the agreed timescale. On this basis it is expected that for guidelines taking 3 months to develop some 5-10 questions might be answered while for those taking 12 months, approximately 15-20 questions would be a reasonable number. If a guideline topic requires a larger number of questions it may be necessary to divide it into subtopics.

5.2 Selecting questions from the scope

Clinical questions should address all the areas covered in the scope, and should avoid introducing new aspects not specified in the scope. They will, however, contain more detail than the scope, and should be seen as building on the fundamental framework of the guideline as laid out in the scope.

The questions are usually drafted by the technical experts. They should then be refined and agreed by all GWG members through discussions. The different perspectives of GWG members ensure that the right questions are identified, thus enabling the literature search to be planned efficiently. Often, however, the main questions need refining once the evidence has been searched, and this may generate subquestions (see Chapter 6).

5.3 Formulating and structuring clinical questions

A good clinical question is clear and focused. It should be formatted in terms of a specific patient problem because this helps identify the clinically relevant evidence. Its exact structure will depend on the question being asked, but it is likely to fall into one of three main areas: intervention, prognosis and diagnosis.

5.3.1 Questions about interventions

Each intervention listed in the scope is likely to require at least one clinical question, and possibly more depending on the populations and outcomes of interest.

A helpful structured approach to formatting questions about interventions is the patient intervention comparison and outcome (PICO) framework (see Box 5.1). This divides each question into four components: the **patients** (the population under study); the **interventions** (what is being done); the **comparisons** (other main treatment options); and the **outcomes** (the measures of how effective the interventions have been).

Box 5.1 Features of a well-formulated question on effectiveness intervention – the PICO guide.

Patients/population: which patients or population of patients are we interested in? How can they be best described? Are there subgroups that need to be considered?

Intervention: which intervention, treatment or approach should be used?

Comparison: what is/are the main alternative/s to compare with the intervention?

Outcome: what is really important for the patient? Which outcomes should be considered: intermediate or short-term measures; mortality; morbidity and treatment complications; rates of relapse; late morbidity and readmission; return to work, physical and social functioning and other measures such as quality of life; general health status; costs?

For each question, the GWG should take into account the various confounding factors that may influence the outcomes and effectiveness of treatment. To facilitate this process, it may be helpful to construct a diagram listing outcomes and other key criteria the group has considered important. Once the question has been framed, key words can be identified as potential search terms. Examples of questions on the effectiveness of an intervention are presented in Box 5.2.

The most appropriate study design to answer a question relating to an intervention is likely to be a randomised controlled trial (RCT). Further information on the side effects of a drug may be obtained from a cohort study.

There are, however, circumstances when an RCT is unnecessary (for example, giving insulin for a diabetic coma). In such situations all the following criteria should be fulfilled.

- An adverse outcome is likely if untreated (high/very high control-event

rate).
- Treatment gives a dramatic benefit (high relative-risk reduction).
- The side effects of treatment are acceptable (high/very high number needed to harm).
- There is no alternative treatment.
- There is a convincing physio-pathological basis to treatment.

Box 5.2 Examples of clinical questions on the effectiveness of interventions

Are antibiotics useful in technically compound finger fractures?
Do proton pump inhibitors improve outcome in patients with upper GI bleeding?
Do all patients with a pneumothorax after trauma need a chest drain?
Is tubigrip beneficial after simple ankle sprains?
Should all patients with new neurological deficit receive aspirin?

5.3.2 Questions about diagnosis

Questions relating to diagnosis do not involve an intervention designed to treat a particular condition, therefore the PICO framework is not as helpful a structure. Questions should still be clear and focused, but they have to pick up key issues specifically relevant to diagnostic tests, for example their accuracy, reliability, safety and acceptability to the patient. Examples of questions relating to diagnosis are given in Box 5.3.

Box 5.3 Examples of clinical questions on diagnosis.

How long after chest pain Is troponin T useful in ruling-out myocardial damage?

Is USS of the hip an accurate method for diagnosing septic arthritis?

Does CT scan of the right iliac fossa reliably rule-out appendicitis?

Is slit lamp examination better than simple ophthalmoscopy at diagnosing corneal trauma?

The most appropriate study designs to answer a question relating to diagnosis are likely to be cross-sectional cohort studies or blind prospective comparisons of the investigation with a gold standard (diagnostic cohort studies).

5.3.3 Questions about service-delivery guidance

In general, clinical guidelines do not cover issues of service delivery but

occassionaly such questions will be implicit in the scope.

Examples of questions on service-delivery guidance are given in Box 5.4.

Box 5.4 Examples of clinical questions on service-delivery guidance

Does the 4 hour target improve patient outcome? Is telephone triage effective at reducing demand on face-to-face services? Do nurse practitioners in emergency departments deliver timely care?

Ideally the most appropriate study design to answer these questions is an RCT. However, a wide variety of methodological approaches and study designs have been used.

5.4 Further reading

NHS Centre for Reviews and Dissemination (2001) Undertaking systematic reviews of research on effectiveness: CRD's guidance for those carrying out or commissioning reviews. *CRD Report Number 4*. 2nd edition. NHS Centre for Reviews and Dissemination, University of York. Available from: www.york.ac.uk/inst/crd/report4.htm

New Zealand Guidelines Group (2001) *Handbook for the Preparation of Explicit Evidence-based Clinical Practice Guidelines.* Available from www.nzgg.org.nz/development/documents/nzgg_guideline_handbook.pdf

Richardson WS, Wilson MS, Nishikawa J et al. (1995) The well-built clinical question: a key to evidence-based decisions. *American College of Physicians Journal Club* 123:A12–13.

Carley SD. Writing a systematic evidence review in emergency medicine . http://www.bestbets.org/

6 Identifying the evidence

identification and selection of evidence is an essential step towards answering the clinical questions developed by the GWG. It is important to ensure that this process is as thorough and unbiased as possible. Searching should focus on locating the best evidence from all relevant sources – potentially, this involves extensive work. Ongoing research should also be identified as this may be important when formulating recommendations and planning updates to the guideline. The aim is to generate a comprehensive body of evidence that will:
• allow the clinical questions to be answered
• highlight any significant gaps in the evidence base where formal consensus methods may be required.

The evidence used by the GWG will come from two main sources:

• searches of electronic databases

• via groups that are invited to submit relevant information.

6.1 Database searching

Developing a search strategy is an iterative process. The strategy will go through several stages of refinement following discussions of the search results with the GWG. The literature search undertaken for the scope (the stage-one search) may have to be revisited to ensure that specific aspects of the clinical questions have been adequately covered. It is not possible to define a search strategy that will be appropriate for all scenarios. The stages in Box 6.1 should be seen as guides that may need to be modified for some clinical questions.

Box 6.1 Stages of database searching (this is a guide only).

Stage-one search

Identification of systematic reviews and guidelines (see Chapter 2).

Stage-two search

Identification of best evidence. Agreed clinical questions should be mapped against the available primary evidence.

Search standard databases only – Embase, Medline, the Cochrane Library and Cumulative Index to Nursing and Allied Health Literature (CINAHL).

Stage-three search

Supplementation of the primary research evidence identified in stage two, if required. In some cases, sufficient high-quality evidence will have been identified to answer the clinical questions. In other cases, a full literature search will be required to map against the questions. The following sources should be searched.

• Standard databases – Embase, Medline, Cochrane Library, CINAHL

• Subject-specific databases – for example, Allied and Complementary Medicine (AMED), or PsychINFO – when relevant to the questions.

• Wider sources if these are considered important by the GWG. This evidence may include conference proceedings or other grey literature, though hand searching is not expected. Examples of wider sources include:

– NHS EED (NHS Economic Evaluation Database http://agatha.york.ac.uk/welcome.htm)

– HEED (Health Economic Evaluation Database www.ohe-heed.com/)

– HTA database (http://agatha.york.ac.uk/welcome.htm)

– ERIC (Education Resources Information Center www.eric.ed.gov/)

– Conference Papers Index (www.datastarweb.com/)

– NRR (National Research Register www.doh.gov.uk/research/nrr.htm)

– PEDro (Physiotherapy Evidence Database www.pedro.fhs.usyd.edu.au/)

– SIGLE (System for Information on Grey Literature in Europe; for further information, visit the SIGLE home page www.kb.nl/eagle)

– the Kings Fund Library (www.kingsfund.org.uk)

– ABPI clinical trials database (Association of the British Pharmaceutical Industry www.cmrinteract.com/clintrial)

– hospital episode statistics (HES www.doh.gov.uk/hes/)

– patient episode data Wales (PEDW)

– national or regional registers (for example, cancer registers)

– national or regional audits

– surveys of patients' experiences

6.1.1 Sensitivity and specificity

The key attributes of a search strategy are sensitivity (ability to identify relevant information) and specificity (ability to exclude irrelevant documents). Sensitivity and specificity will be influenced by the time period covered (see below) and by the search terms used. There needs to be a trade-off between conducting an exhaustive search with the additional resources required and undertaking a more modest search that may miss some small studies that would not alter the overall findings. Exhaustive searching on every topic may not be practical or even necessary.

6.1.2 Time period for searching

Date parameters should be set to take into account sensitivity and specificity; the timings should reflect the number of hits and the topic. The period that the search should cover depends on the guideline topic and when the bulk of the research was published. The time limits for the search should be agreed by the GWG, in consultation with experts in the area.

Where adequate published systematic reviews exist, additional searching may be limited to updating, covering the time period since the review was conducted. Existing reviews may not address all the relevant outcomes, however, and in this case new searching may be required. Contacting review authors for updates should be considered, particularly for reviews found in the Cochrane Library and BestBETs.

6.1.3 Documenting the search

The process for identifying the evidence should be repeatable and transparent. The search strategy, including search terms, should be documented. This is important because it provides an audit trail describing modes of searching and reasons for changes and amendments. A full description of an appropriate documentation process is provided in the Centre for Reviews and Dissemination's *Report Number 4* (see 'Further reading'). Electronic records of the references retrieved should be stored in a bibliographic database such as Reference Manager, ProCite or Endnote, as should details of ongoing research. This type of database allows the use of 'cite-as-you-write' and can be linked into word processors to facilitate the production of reference lists for the preparation of the guideline.

6.1.4 Timetabling

Searches should be prioritised by topic according to the material required for GWG meetings. Additional time may be needed for areas with a lot of pharmacological topics, where there are likely to be large numbers of published papers. This should be taken into consideration early on in the process and

should be included in the planning. Specific searches will need to be carried out for each of the topics that will be discussed at the planned GDG meetings.

6.2 Submissions of evidence

Lists of potential evidence may be submitted outside the searching process. References received should be entered into a bibliographic database as described above and the details cross-checked with evidence identified through database searching. Items that may be included as evidence are: systematic reviews; RCTs; other guidelines on the same topic; representative epidemiological studies (observational); quantitative and qualitative studies or surveys that examine patients', healthcare professionals' or carers' experiences of treatment or management; and published or unpublished economic models. Commercial 'in confidence' data will not be accepted. Full company trial reports relating to clinical trials where these provide additional evidence over and above data already published or accepted for publication in peer-reviewed journals may also be considered as evidence by the GWG, provided they are made publicly available.

The types of evidence listed in Box 6.3 should not be considered. If these types of evidence are reviewed, they should **not** be considered by the GWG.

Box 6.3 Material <u>not</u> eligible for consideration by the GWG.

- Studies with weak designs when better-designed studies are available
- Commercial 'in confidence' material
- Promotional literature
- Papers, commentaries and editorials that interpret the results of a published paper
- Representations and experiences of individuals (unless assessed as part of a well-designed study or a survey)

6.3 Additional requirements for service-delivery guidance

In addition to evidence identified through routine literature searches, the GWG will require information describing the current configuration of clinical services, the level of activity and any significant regional variations. This will help members to:

- identify the gaps between current clinical practice, service provision and patient experience and what it concludes should be in place

- shape the guidance and identify recommendations that are likely to have the greatest impact on the service, as well as clinical outcomes.

A detailed baseline assessment of service activity is therefore required and should be conducted before the GWG starts work. This should be available for consideration early in the development process, and ideally it should also be available to inform the scope. The following data sources might be drawn upon to provide an overall picture of service configuration and activity.

- Departmental attendance and discharge code statistics
- Hospital episode statistics (HES)
- National or regional registers (for example, MINAP or UK TARN)
- National or regional (EMSAG) audits
- Surveys of patients' experiences
- Morbidity statistics from general practice: fourth national survey 1991–1992, Office of Population Census and Survey (OPCS).

6.4 Further reading

NHS Centre for Reviews and Dissemination (2001) Undertaking systematic reviews of research on effectiveness: CRD's guidance for those carrying out or commissioning reviews. *CRD Report Number 4*. 2nd edition. NHS Centre for Reviews and Dissemination, University of York. Available from: www.york.ac.uk/inst/crd/report4.htm

New Zealand Guidelines Group (2001) *Handbook for the Preparation of Explicit Evidence-based Clinical Practice Guidelines.* Available from www.nzgg.org.nz/development/documents/nzgg_guideline_handbook.pdf

7 Reviewing and grading the evidence

Studies identified following the literature search need to be reviewed to identify the most appropriate data to help answer the clinical questions and to ensure that the recommendations are based on the best available evidence. This process should be explicit and transparent and should be carried out through a systematic review process. This involves four major steps: selecting relevant studies; assessing their quality; synthesising the results and grading the evidence.

7.1 Selecting studies of relevance

Before acquiring papers for assessment, the senior emergency information officer or the reviewer who carried out the search needs to sift the evidence identified in the search in order to discard irrelevant material. As a preliminary stage, the titles of the retrieved citations should be scanned and those that fall outside the topic of the guideline should be eliminated. A quick check of the remaining abstracts should identify those that are clearly not relevant to the clinical questions and that should be excluded at this stage.

The remaining abstracts should then be scrutinised against the clinical criteria agreed by the GWG. Abstracts that do not meet the inclusion criteria should be eliminated. If there is any doubt about inclusion, this should be resolved by discussion with the GWG. Once the sifting is complete, hard copies of the selected studies can be acquired for assessment. Studies that fail to meet the inclusion criteria should be excluded. Those that meet the criteria can be assessed. Because there is always an element of bias in selecting the evidence, periodic double sifting of a random selection of abstracts should be performed.

The study-selection process should be clearly documented and should detail the inclusion criteria agreed by the GWG that were applied in the selection process.

7.2 Assessing the quality of studies

The quality of studies should be evaluated from an assessment of the methods and methodology used. This is a key stage in the guideline development process because the result will affect the level of evidence ascribed to the study. In turn, this will have an impact on the class of recommendations it underpins (see section 7.4).

7.2.1 Published studies

The published studies selected from the search should be assessed for their methodological rigour against a number of criteria. Because these criteria will differ according to the study type, a range of checklists have been designed to provide a consistent approach to the assessment and its reporting. The department has developed and uses the appraisal checklists that are available

on the BestBETs website (under resources).All these checklists are presented in Appendices B to H. The overall assessment of each study is graded using a code '++', '+' or '–', based on the extent to which the potential biases have been minimised. This is used as a basis for classifying the recommendations (see Chapter 11). Critical appraisals should be uploaded to the BestBETs website by following the online instructions given. Those that refer to papers used to answer the clinical questions as BestBETs should be appropriately cross-referenced.

To minimise any potential bias in the assessment, independent assessment by two reviewers on a random selection of papers is desirable. Any differences arising from this should be discussed fully at the GWG meeting.

7.2.2 Unpublished data and studies in progress

Unpublished data may be obtained in the course of the review, particularly from stakeholders. The GWGs are not routinely expected to search the grey literature. Any unpublished data should be subjected to an assessment of quality in the same way as published studies. Authors should be contacted and requested to provide the necessary information so that the reviewers can complete the relevant quality checklist, or to provide details on individual patient data.

7.3 Summarising the evidence

7.3.1 Data extraction and evidence tables

Data should be extracted to a standard template, for inclusion in the evidence table of a BestBET. Evidence tables help identify the similarities and differences between studies, including key characteristics of the study population and interventions or outcome measures; this provides a basis for comparison. They also help determine if it is possible to calculate a mean estimate of effect. In some circumstances and if the necessary data are available, it may be appropriate to carry out a meta-analysis. A full description of data synthesis, including meta-analysis and extraction methods, is available from the report produced by the Centre for Review and Dissemination (*Report Number 4*, 2nd edition – see 'Further reading'). Sensitivity analysis could be used to investigate the impact of missing data.

The information to be extracted may vary depending on the clinical question, the level of detail and the analysis needed..

7.3.2 Levels of evidence

7.3.2.1 Intervention studies

Studies that meet the minimum quality criteria should be ascribed a level of evidence to help the guideline developers and the eventual users of the guideline understand the type of evidence on which the recommendations have been

based.

There are many different methods of assigning levels to the evidence and there has been considerable debate about what system is best. A number of initiatives are currently under way to find an international consensus on the subject. NICE has previously published guidelines using different systems and is now examining a number of systems Currently NICE uses the system shown in Table 7.1.

Table 7.1 Levels of evidence for intervention studies. Reproduced with permission from the Scottish Intercollegiate Guidelines Network; for further information, see 'Further reading'.

Level of evidence	Type of evidence
1++	High-quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1 +	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1 -	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias*
2 ++	High-quality systematic reviews of case–control or cohort studies High-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal
2 +	Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
2 -	Case–control or cohort studies with a high risk of confounding bias, or chance and a significant risk that the relationship is not causal*
3	Non-analytic studies (for example, case reports, case series)
4	Expert opinion, formal consensus
*Studies with a level of evidence '–' should not be used as a basis for making a recommendation (see section 7.4)	

It is the responsibility of the GWG to endorse the final levels given to the evidence, although it may delegate this process to the systematic reviewers.

7.3.2.2 Diagnostic studies

The system described above covers studies of treatment effectiveness. However, it is less appropriate for studies reporting diagnostic tests of accuracy. In the

absence of a validated ranking system for this type of test, NICE has developed a hierarchy for evidence of accuracy of diagnostic tests that takes into account the various factors likely to affect the validity of these studies (Table 7.2).

Table 7.2 Levels of evidence for studies of the accuracy of diagnostic tests.
Adapted from *The Oxford Centre for Evidence-based Medicine Levels of Evidence* (2001) and the Centre for Reviews and Dissemination *Report Number 4* (2001).

Levels of evidence	Type of evidence
I a	Systematic review (with homogeneity)* of level-1 studies†
I b	Level-1 studies†
2	Level-2 studies‡ Systematic reviews of level-2 studies
3	Level-3 studies§ Systematic reviews of level-3 studies
4	Evidence obtained from expert committee reports or opinions and/or clinical experience without explicit critical experience, based on physiology, bench research or 'first principles'

* Homogeneity means there are no or minor variations in the directions and degrees of results between individual studies that are included in the systematic review.

† Level-1 studies are studies:
- that use a blind comparison of the test with a validated reference standard (gold standard)
- in a sample of patients that reflects the population to whom the test would apply.

‡ Level-2 studies are studies that have **only one** of the following:

- narrow population (the sample does not reflect the population to whom the test would apply)
- use a poor reference standard (defined as that where the 'test' is included in the 'reference', or where the 'testing' affects the 'reference')
- the comparison between the test and reference standard is not blind
- case–control studies.

§ Level-3 studies are studies that have **at least two or three** of the features listed above**§**.

7.4 Using the quality checklists to grade the evidence

In the quality assessment, each paper receives a quality rating coded as '++', '+' or '–'. Usually, studies rated as '–' should not be used as a basis for making a recommendation. If good-quality studies are available to help answer the clinical question, and their outcomes are consistent, the '–'-rated studies should be rejected. If there is a body of reasonable, but fairly weak, evidence showing a consistent effect and there are '–' studies that show the same effect, the '–'-rated studies should be included in the evidence table to demonstrate the extent of consistent evidence. If the '–' studies suggest a different outcome they should be left in the evidence table for further discussion with the GWG; they should not be used to support the recommendation as their inclusion as supporting evidence

would weaken and downgrade the recommendation.

7.5 Further reading

NHS Centre for Reviews and Dissemination (2001) Undertaking systematic reviews of research on effectiveness: CRD's guidance for those carrying out or commissioning reviews. *CRD Report Number 4*. 2nd edition. NHS Centre for Reviews and Dissemination, University of York. Available from: www.york.ac.uk/inst/crd/report4.htm

Drummond MF, O'Brien B, Stoddart GL et al. (1997) Critical assessment of economic evaluation. In: *Methods for the Economic Evaluation of Health Care Programmes*. 2nd edition. Oxford: Oxford Medical Publications.

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

Eccles M, Mason J (2001) How to develop cost-conscious guidelines. *Health Technology Assessment* 5.

Khan KS, Kunz R, Kleijnen J, Antes G (2003) *Systematic Reviews to Support Evidence-based Medicine. How to Review and Apply Findings of Healthcare Research*. London: Royal Society of Medicine Press.

Scottish Intercollegiate Guidelines Network (2002) *SIGN 50. A Guideline Developer's Handbook*. Edinburgh: Scottish Intercollegiate Guidelines Network.

8 Making group decisions and reaching consensus

Throughout the development of a guideline, GWG members need to make collective decisions. These include generating clinical questions, agreeing the best evidence to answer these questions, and formulating recommendations. There are many different approaches to making group decisions and reaching consensus – there is no blueprint about which approach should be used in which circumstances as research is still lacking in this area. Also, because GWGs will function in different ways to reflect their individual membership, it is difficult to be prescriptive about the approach that should be used. This chapter describes the use of focus groups and formal consensus methods, and examines how they may be used by the GWG at key decision points during guideline development.

8.1 Focus groups

In most cases, a process of informal consensus within the GWG is sufficient to formulate recommendations based on the best available evidence. In areas where information is lacking, however, it may be useful to run specific focus groups to inform this decision-making process. This may occur in areas where it is important to gain wider understanding of particular perspectives, for example from patients or ethnic groups.

Details on how to conduct focus groups have been described elsewhere (see 'Further reading') and the rules for using focus groups are not rigidly defined. In all cases, however, the group facilitator has a key role in conducting the process, which is similar to that of the facilitator's role in the nominal-group technique (see section 8.2.2). Some recommendations for running a focus group to inform guideline development are provided in Box 8.1.

Box 8.1 Recommendations for running a focus group.

- Introduce the group
- Outline the aims of the session (for example, to understand the issues important to patients in the provision of palliative care)
- Outline the procedures for discussion (for example, explain that while honest views are welcome the process is time-limited and the facilitator may have to curtail a discussion if necessary to achieve the objectives of the meeting)
- Define the boundaries of the discussion, outlining the areas of clinical management that will be covered and those that will be excluded
- Ensure that all members talk about topics that provide insight into the area under discussion
- Check that the terminology members use is understood by all and let the group know that clarifications may be requested
- Summarise the key themes at various points of the discussion to help members crystallise their views or to modify them if needed

8.2 Formal consensus methods

In some guidelines there will be core areas of the scope where the scientific evidence needed to answer the clinical questions is of such poor quality, or is inconsistent or non-existent, that the GDG needs to adopt a more formal method of consensus. Using a formal approach will make it possible to trace back how a group came to a decision, and will be explicit and transparent.

Three formal approaches are used regularly in the field of healthcare:

- the Delphi technique
- the nominal-group technique
- the consensus-development conference.

Each has it own advantages and shortcomings. Their use should be tailored to the needs of the guideline group, the type of questions to be answered, and also the time available in the guideline process, as the techniques can be very detailed and time intensive. Often people use hybrids of the methods to make the work more manageable.

Regardless of the consensus method used, there should be a detailed description of the process that was used and the results. Box 8.2 presents the minimum criteria that should be included when reporting the consensus method.

Box 8.2 Core reporting criteria for use of formal consensus methods in developing guidelines.

- What method was used and what were the reasons for choosing it?
- What areas of the guideline were addressed by the consensus methods and what were the exclusion criteria?
- How were the questions or statements for collecting opinion developed?
- How many people participated, what were their denominations and how were they recruited?
- What was the process used for eliciting views (meeting, postal survey) and for voting (for example, electronic, paper)?
- How was agreement defined? (Were the definitions strict or relaxed? Were outliers included or excluded? Were any members' views weighted?)

The composition of a group of individuals selected for formal consensus should reflect the full range of characteristics of those they are trying to represent. A homogeneous group will reach greater consensus, because specialists tend to

favour the interventions/views with which they are familiar. However, such a group may not be wholly representative of the healthcare workers whose practice is being addressed in the guideline, and is unlikely to represent the views of patients. An HTA report suggests that a consensus group of 10–12 people is probably sufficient to allow conclusions to be reached – including more people would be unlikely to result in the group reaching different conclusions (see 'Further reading'). In most cases, therefore, the GwG itself will fulfil the requirements for a consensus group. It should also be noted that a good facilitator is crucial to the quality of the process, and that convergence of views is more likely after continued discussion. However, there may be circumstances when convergence is not possible. The guideline text should highlight where convergence has not been possible and where areas of disagreement remain.

8.2.1 The Delphi method

The Delphi method involves sending participants questionnaires by post and asking them to record their views. The specific issues highlighted by respondents are then circulated in a second questionnaire and participants are asked to respond to these issues. The responses to these issues are collated by the organisers and sent back to participants in a summary form. Participants are usually given the chance to revise their views in light of the group feedback. This process could be repeated several times. The judgements of the participants are statistically aggregated, sometimes after weighting for expertise. The participants never meet or interact directly.

The logic behind the Delphi method is partly statistical; combined participants' views should, in general, lead to more reliable estimates than estimates from an individual. It is also considered to be an effective way of exchanging information between large numbers of people at a relatively low cost. However, this method diminishes the positive aspects of interaction found at face-to-face meetings.

8.2.2 The nominal-group technique

Unlike the Delphi technique, the nominal-group technique is more a method of obtaining a practical result quickly and is effective in obtaining consensus from a range of participants in diverse settings, such as healthcare. It is also recognised as a method for generating a wide range of ideas in situations where the group has to solve problems. Therefore, the method could also be used to generate the clinical questions at the beginning of the guideline development process.

The nominal-group technique uses a variety of postal (or computer) and face-to-face techniques to elicit a consensus view. Individual participants record their ideas independently and privately. The ideas are collected in turn from individuals and are fed back to the group when they are brought together for discussion, followed by a further private vote.

The nominal-group technique uses a facilitator to structure the discussion. The

facilitator should be either an expert on the topic or a credible non-expert. Each idea is discussed in turn, so the discussion covers all the ideas rather than only one or two. Controlling the interaction so that all participants have the opportunity to express their views is believed to reduce the dominance of the discussion by one or two vocal members.

The NICE National Collaborating Centre for Acute Care has used a modified nominal-group technique to identify areas of agreement when the evidence base from the literature was inadequate. Details of this process are given in the full guideline on preoperative testing – *Clinical Guideline on Routine Preoperative Testing: Evidence, Methods and Guidance*, which is available from the NICE website.

8.2.3 A variation of the nominal-group technique

A variation of the nominal-group technique has been used by the NICE National Collaborating Centre for Chronic Conditions to agree key recommendations in a guideline. A summary of the methods used is presented in the full guideline *Chronic Heart Failure: Management of Chronic Heart Failure in Adults in Primary and Secondary Care*, which is available from the NICE website.

8.2.4 Consensus-development conference

The consensus-development conference consists of a selected group of about ten people who are brought together to reach consensus on an issue. They are presented with evidence by various interest groups or experts who are not part of the decision-making group. They then retire and consider the questions in light of the evidence presented and attempt to reach a consensus. Both the open part of the conference and the private group are chaired.

8.3 Further reading

Murphy MK, Black NA, Lamping DL et al. (1998) Consensus development methods, and their use in clinical guideline development. *Health Technology Assessment* 2.

Elwyn G, Greenhalgh T, Macfarlane F (2001) *Groups. A Guide to Small Groups in Healthcare, Management, Education and Research*. Abingdon: Radcliffe Medical Press.

9 Creating guideline recommendations

Many users of guidelines do not have time to read the full document, and may wish to focus only on the recommendations. It is therefore vital that recommendations are clear, can stand alone and are based on the best available evidence of clinical and cost effectiveness. Guideline recommendations are usually classified according to the strength of the supporting evidence to provide the users with an indication of the confidence that guidelines will produce the desired outcome. This chapter addresses four key areas in developing guideline recommendations:

- translating the evidence into recommendations
- wording the recommendations
- classifying the recommendations
- possible approaches to prioritising recommendations for implementation.

9.1 Translating the evidence into recommendations

Once the GWG has examined the evidence and discussed its suitability to answer the clinical questions, it needs to turn the evidence into recommendations. If the evidence is very strong (level 1 evidence), the process should be straightforward and the evidence should translate directly into a recommendation. However, in many cases it may not possible to proceed in this way. Reasons why direct translation may not be possible are described in Table 9.1, together with possible approaches to addressing the difficulty.

Table 9.1 Translating evidence into recommendations: challenges and possible solutions.

Challenge	Possible solution
The literature search has found no evidence that answers the clinical question	The GWG should consider using consensus to identify current best practice. This process should be robust and should follow the methods of formal consensus or resolve the issues through discussions in the group (see Chapter 8)
The quality of the evidence is poor (level 4)	

The available evidence is conflicting and of a similar level	All efforts should be made to identify studies that are most applicable to the population covered by the guideline and the recommendations should be based on those studies
The evidence is not directly applicable to the population covered by the guideline, for example because of a different age group	The GWG may wish to extrapolate the recommendations from the evidence, for example from high-quality evidence in a largely similar but different patient group. The group will need to make its approach very explicit, stating the basis it has used for extrapolating from the data and the assumptions they have made

It is likely that, when formulating the recommendations, there will be instances where members of the GWG disagree about the content of the final product. Formal consensus methods can be used in agreeing the final recommendations (see section 8.2). Whatever the approach used, there should be a very clear record of the proceedings and a clear statement about how areas of disagreement have been handled.

9.2 Wording the guideline recommendations

Wording the final guideline recommendations may be one of the most important aspects of the whole development process. It is these recommendations that will be the focus of attention for most readers when the guideline is published. The final wording should be agreed by the GWG (see Chapter 5), but should take into account the following principles – these are described in more detail in the following sections.

• Recommendations should stand alone.

• Recommendations should be action-oriented.

• All recommendations should be assigned a class (though these are not shown for the key priorities).

• Recommendations referring to drug use should use the generic drug name, avoid stating dosages and indicate where the recommendation refers to off-label use.

• Tables can be used to present recommendations but only where this substantially improves clarity.

• Recommendations should take the patient into consideration and should try to avoid the use of words such as ‘subjects’ rather than ‘people’ or ‘patients’.

Examples of recommendations from guidelines are shown in Box 9.2 at the end of this section.

9.2.1 Stand-alone recommendations

Guideline recommendations should be clear and concise, but should contain sufficient information that they can be understood without reference to other supporting material. Any terminology included in the recommendations therefore needs to be clearly defined and unambiguous.

9.2.2 Action-oriented recommendations

Guideline recommendations should focus on what needs to be done, and should not contain background information. When writing recommendations, the author should have in mind a reader who is saying “what does this mean for me?”

9.2.3 Classifying recommendations

All recommendations should be classified (see section 9.3). The guideline development process assumes that the classification has been agreed by the GDWG, and therefore the GWG should not be specifically mentioned in the recommendations. For example, it is not necessary to say: “in the opinion of the GWG, treatment X should be offered…”. Note that where key priorities for implementation are presented as such, the classification should not be shown.

9.2.4 Referral to drugs

There are three points to consider when referring to a drug: the name, the dose, and whether or not it carries a licence for that particular indication (that is, is the recommendation for off-label use?).

Drug name: Recommended International Non-proprietary Name (rINN) for medicinal substances as in the *British National Formulary* should be used. The generic name should be used throughout, but if appropriate the proprietary name should be given in brackets at first mention. There is no need to name the manufacturer.

Dosages: in general, recommendations should not include drug dosages. Instead, readers should be referred to the summary of product characteristics, which also includes details on possible side effects. If there is evidence that a particular drug is often prescribed at the wrong dosage, or if there is clear evidence about the effectiveness of different dose levels it may occasionally be

appropriate to include information on dose levels. Summaries of product characteristics (SPCs) can be found in the Electronic Medicines Compendium (www.emc.medicines.org.uk/).

Off-label use: guideline recommendations will normally fall within licensed indications; exceptionally, and only where clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use the summary of product characteristics to inform their decisions for individual patients. If a drug is recommended for off-label use, this should be made clear in the wording of the recommendation.

9.2.5 Use of tables

Tables may be used to present recommendations if this is thought to improve clarity. Note, however, that adding tables can cause difficulties in posting the document on the website, so please be sure that a table is necessary to present information most effectively for readers.

Box 9.2 Examples of recommendations from NICE guidelines

Transparent dressings should be changed every 7 days, or sooner if they are no longer intact or moisture collects under the dressing. **[A]**

CT imaging of the cervical spine should be considered if the patient is having other body areas scanned for head injury/multi-region trauma and a definitive diagnosis of cervical spine injury is required urgently. **[B]**

When rapid tranquillisation is urgently needed, a combination of IM haloperidol and IM lorazepam should be considered. **[C]**

Carers and relatives should have as much access to the patient as is practical during transfer and be fully informed on the reasons for transfer and the transfer process. **[D]**

9.3 Classifying the recommendations

Guideline recommendations should be classified according to the strength of the supporting evidence, which is assessed from the design of each study (see section 7.4). The classification system currently used is presented in Table 9.2.

Table 9.2 Classification of recommendations. Adapted by NICE with permission from the Scottish Intercollegiate Guidelines Network; for further information, see ‘Further reading’.

Class	Evidence
A	• At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population, **or** • A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results • Evidence drawn from a NICE technology appraisal
B	• A body of evidence including studies rated as 2++, directly applicable to the target population and demonstrating overall consistency of results, **or** • Extrapolated evidence from studies rated as 1++ or 1+
C	• A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results, **or** • Extrapolated evidence from studies rated as 2++
D	• Evidence level 3 or 4, **or** • Extrapolated evidence from studies rated as 2+, **or** • Formal consensus
D (GPP)	• A good practice point (GPP) is a recommendation for best practice based on the experience of the Guideline Development Group

Recommendations for studies of the accuracy of diagnostic tests are also classified according to the strength of the supporting evidence, assessed from the design of each study (see section 7.3.2.2).

Table 9.3 Classification of recommendations for studies of the accuracy of diagnostic tests. DS, diagnostic studies.

Class	Level of evidence (see Table 7.2)
A (DS)	Studies with level of evidence Ia or Ib
B (DS)	Studies with level of evidence 2
C (DS)	Studies with level of evidence 3

D (DS)	Studies with level of evidence 4

The usefulness of a classification system based solely on the level of evidence has been questioned because it does not take into consideration the importance of the recommendation in changing practice and improving patient care. NICE is currently assessing the best way of presenting guideline recommendations in the future, in particular, the work currently being undertaken by the GRADE Working Group.

9.4 Further reading

Schunemann HJ, Best D, Vist G, Oxman AD, for the GRADE Working Group (2003). Letters, numbers, symbols and words: how to communicate grades of evidence and recommendations. *Canadian Medical Association Journal* 169:677–80.

Scottish Intercollegiate Guidelines Network (2002). *SIGN 50. A Guideline Developer's Handbook*. Edinburgh: Scottish Intercollegiate Guidelines Network.

10 Writing the guideline

Following the process of guideline development, three separate documents will be prepared: the full guideline and the CDSG and the quick reference guide. This chapter describes key principles for writing guidelines, and describes what each version should include.

10.1 Principles for writing guidelines

10.1.1.Language and style

Key points to consider are highlighted here.

• The guideline should be written in a style that can be understood by the non-specialist healthcare practitioner – someone who has a good knowledge of the area, but who need not be a trained clinician

• Paragraphs and headings should be used to make it easy to navigate the document.

10.1.1.1 Bulleted lists

It is helpful to keep bulleted lists within numbered paragraphs. When listing items within a paragraph, a bulleted list should be used rather than a numbered one, unless there is a good reason to use numbers. This is because a numbered list can imply a ranking or preference that may not be intended.

10.1.1.2 Tables and figures

Tables need to be readily understood, and have a clear, informative title. Footnotes should be limited to those that are essential for readers to understand the table. A table should not be used if it presents an inappropriate or inaccurate comparison. Comparisons should compare like with like.

Tables should be numbered sequentially and should be cited in the text, but if information is presented in a table it should not be repeated in the text. Tables or figures that are reproduced from another source will require written permission to include them. In the case of published material, this permission usually has to be obtained from the publisher.

10.1.1.3 Abbreviations

The NICE style guide should be followed for abbreviations. If a term is used only a few times in the guideline, it may be appropriate to use the wording in full. However, if it is thought that general readers will be more familiar with the abbreviation, it can be used throughout the guideline and defined at first use. It is important to remember that the final guideline may be downloaded in sections, so

abbreviations should be re-defined at the first use in each section. Abbreviations or acronyms should not appear in the recommendations themselves.

10.1.1.4 Algorithm

The full guideline and Emergency Department CDSG should contain an algorithm (or algorithms). This is a flow chart of the clinical decision pathway described in the guideline, where decision points are represented with boxes, linked with arrows. The algorithm should be uncluttered; boxes should be limited to those defining the clinical problem and those representing a clear decision point. There should be few arrows and these should flow from top to bottom. A logical sequence should be maintained so that all decisions flow from the questions that precede them. It may be necessary to produce more than one algorithm if the recommendations cannot be summarised into one chart.

10.2 Guideline structure

10.2.1 The full guideline

The full guideline contains all the recommendations, plus details of the methods used and the underpinning evidence. Core elements should be:

- summary of recommendations and algorithm
- introduction
    - responsibility and support for guideline development
    - funding
    - GWG membership
    - patient and carer involvement (if any)
    - epidemiological data
    - outcomes
    - clinical issues
- aim and scope of the guideline
- methods
    - literature-search strategy
    - sifting and reviewing the literature
    - synthesising the evidence

    - economic analysis
    - assigning levels to the evidence
    - areas without evidence and consensus methodology
    - forming recommendations
    - consultation
- guideline recommendations
    - evidence statements
    - recommendations
    - audit criteria
    - scheduled review of the guideline
    - recommendations for research
- references
- appendices, which may include:
    - evidence tables (preferably on a CD-ROM), see Chapter 7
    - details of search strategies.

10.3 The CDSG

The Emergency Department CDSG presents the recommendations from the full version in a format focused on implementation by within the clinical area. The CGSG itself will always be presented over 2 sides of A4.

10.4 Quick-reference guide

The quick-reference guide will present recommendations over 4 sides (the first summarising the background of the guideline, the next two the CDSG itself and the last the evidence used in the development.

Appendices

A Methodology checklist: systematic reviews and meta-analyses
B Methodology checklist: randomised controlled trials
C Methodology checklist: cohort studies
D Methodology checklist: case–control studies
E Methodology checklist: diagnostic studies
F Methodology checklist: economic evaluations
G Methodology checklist: qualitative studies
I BestBETs template

REVIEWS AND META-ANALYSES CHECKLIST

How do you rate this paper? 1 2 3 4 5 6 7 8 9 10

1.0 OBJECTIVES AND HYPOTHESES

1.1 Are the objectives of the study clearly stated?	

2.0 DESIGN

2.1 Is the study design suitable for the objectives?	
2.2 **Were the search methods used to locate relevant studies comprehensive?**	
2.3 Was this the right sample to answer the objectives?	
2.4 Is the study large enough to achieve its objectives? Have sample size estimates been performed?	
2.5 Were all subjects accounted for?	
2.6 Were all appropriate outcomes considered?	
2.7 Has ethical approval been obtained if appropriate?	

3.0 MEASUREMENT AND OBSERVATION

3.1 Is it clear what was measured, how it was measured and what the outcomes were?	
3.2 Were explicit methods used to determine which studies to include in the review?	
3.3 Was the selection of primary studies re-producible and free from bias?	
3.4 Was the methodologic quality of the primary studies assessed?	
3.5 Are the measurements valid?	
3.6 Are the measurements reliable?	
3.7 Are the measurements reproducible?	

4.0 PRESENTATION OF RESULTS

4.1 Are the basic data adequately described?	
4.2 Were the differences between studies adequately described?	
4.3 Are the results presented clearly, objectively and in sufficient detail to enable readers to make their own judgement?	
4.4 Are the results internally consistent, i.e. do the numbers add up properly?	

5.0 ANALYSIS

5.1 Were the results of primary studies combined appropriately?	
5.2 Has a sensitivity analysis been performed?	
5.3 Were all the important outcomes considered?	
5.4 Are the data suitable for analysis?	
5.5 Are the methods appropriate to the data?	
5.6 Are any statistics correctly performed and interpreted?	

6.0 DISCUSSION

6.1 Are the results discussed in relation to existing knowledge on the subject and study objectives?	
6.2 Is the discussion biased?	

7.0 INTERPRETATION

7.1 Are the authors' conclusions justified by the data?	
7.2 What level of evidence has this paper presented? (using CEBM levels)	
7.3 Does this paper help me answer my problem?	

How do you rate this paper now? 1 2 3 4 5 6 7 8 9 10

In addition, answer the following questions with regards to local practice.

8.0 IMPLEMENTATION

8.1 Can any necessary change be implemented in practice?	
8.2 What aids to implementation exist?	
8.3 What barriers to implementation exist?	

TRIALS CHECKLIST

How do you rate this paper? 1 2 3 4 5 6 7 8 9 10

1.0 OBJECTIVES AND HYPOTHESES

1.1 Are the objectives of the study clearly stated?	

2.0 DESIGN

2.1 Is the study design suitable for the objectives?	
2.2 Who/what was studied?	
2.3 Was this the right sample to answer the objectives?	
2.4 Is the study large enough to achieve its objectives? Have sample size estimates been performed?	
2.5 Were all subjects accounted for?	
2.6 Were all appropriate outcomes considered?	
2.7 Has ethical approval been obtained if appropriate?	
2.8 Were the patients randomised between treatments?	
2.9 How was randomisation carried out?	
2.10 Are the outcomes clinically relevant?	

3.0 MEASUREMENT AND OBSERVATION

3.1 Is it clear what was measured, how it was measured and what the outcomes were?	
3.2 Are the measurements valid?	
3.3 Are the measurements reliable?	
3.4 Are the measurements reproducible?	
3.5 Were the patients and the investigators blinded?	

4.0 PRESENTATION OF RESULTS

4.1 Are the basic data adequately described?	
4.2 Were groups comparable at baseline?	
4.3 Are the results presented clearly, objectively and in sufficient detail to enable readers to make their own judgement?	
4.4 Are the results internally consistent, i.e. do the numbers add up properly?	
4.5 Were side effects reported?	

5.0 ANALYSIS

5.1 Are the data suitable for analysis?	
5.2 Are the methods appropriate to the data?	
5.3 Are any statistics correctly performed and interpreted?	

6.0 DISCUSSION

6.1 Are the results discussed in relation to existing knowledge on the subject and study objectives?	
6.2 Is the discussion biased?	

7.0 INTERPRETATION

7.1 Are the authors' conclusions justified by the data?	
7.2 What level of evidence has this paper presented? (using CEBM levels)	
7.3 Does this paper help me answer my problem?	

How do you rate this paper now? 1 2 3 4 5 6 7 8 9 10

In addition, answer the following questions with regards to local practice.

8.0 IMPLEMENTATION

8.1 Can any necessary change be implemented in practice?	
8.2 What aids to implementation exist?	
8.3 What barriers to implementation exist?	

COHORT CHECKLIST

How do you rate this paper? 1 2 3 4 5 6 7 8 9 10

1.0 OBJECTIVES AND HYPOTHESES

1.1 Are the objectives of the study clearly stated?	

2.0 DESIGN

2.1 Is the study design suitable for the objectives?	
2.2 Who/what was studied?	
2.3 **Was a control group used if appropriate?**	
2.4 Were outcomes defined at the start of the study?	
2.5 Was this the right sample to answer the objectives?	
2.6 Is the study large enough to achieve its objectives? Have sample size estimates been performed?	
2.7 Were all subjects accounted for?	
2.8 Were all appropriate outcomes considered?	
2.9 Has ethical approval been obtained if appropriate?	

3.0 MEASUREMENT AND OBSERVATION

3.1 Is it clear what was measured, how it was measured and what the outcomes were?	
3.2 Was the assessment of outcomes blinded?	
3.3 Was follow up sufficiently long and complete?	
3.4 Are the measurements valid?	
3.5 Are the measurements reliable?	
3.6 Are the measurements reproducible?	

4.0 PRESENTATION OF RESULTS

4.1 Are the basic data adequately described?	
4.2 Are the results presented clearly, objectively and in sufficient detail to enable readers to make their own judgement?	
4.3 How large are the effects within a specified time?	
4.4 Are the results internally consistent, i.e. do the numbers add up properly?	

5.0 ANALYSIS

5.1 Are the data suitable for analysis?	
5.2 Are the methods appropriate to the data?	
5.3 Are any statistics correctly performed and interpreted?	

6.0 DISCUSSION

6.1 Are the results discussed in relation to existing knowledge on the subject and study objectives?	
6.2 Is the discussion biased?	

7.0 INTERPRETATION

7.1 Are the authors' conclusions justified by the data?	
7.2 What level of evidence has this paper presented? (using CEBM levels)	
7.3 Does this paper help me answer my problem?	

How do you rate this paper now? 1 2 3 4 5 6 7 8 9 10

In addition, answer the following questions with regards to local practice.

8.0 Implementation

8.1 Can any necessary change be implemented in practice?	
8.2 What aids to implementation exist?	
8.3 What barriers to implementation exist	
8.4 Are the study patients similar to your own?	
8.5 Does the paper give any conclusions that will affect what you will offer or tell your patient?	

CASE-CONTROL (INCLUDING HARM) CHECKLIST

How do you rate this paper? 1 2 3 4 5 6 7 8 9 10

1.0 OBJECTIVES AND HYPOTHESES

1.1 Are the objectives of the study clearly stated?	

2.0 DESIGN

2.1 Is the study design suitable for the objectives?	
2.2 Who/what was studied?	
2.3 Was this the right sample to answer the objectives?	
2.4 Did this include a clearly identified comparison group, identical in all aspects other than the exposure?	
2.5 Did the exposure precede outcome?	
2.6 Is the study large enough to achieve its objectives? Have sample size estimates been performed?	
2.7 Were all subjects accounted for?	
2.8 Were all appropriate outcomes considered?	
2.9 Has ethical approval been obtained if appropriate?	

3.0 MEASUREMENT AND OBSERVATION

3.1 Is it clear what was measured, how it was measured and what the outcomes were?	
3.2 Were the exposures to the agent and outcomes measured in the same way in all of the groups compared?	
3.3 Were the assessments of exposure blinded to outcome?	
3.4 Was follow up sufficiently long and complete?	
3.5 Are the measurements valid?	
3.6 Are the measurements reliable?	
3.7 Are the measurements reproducible?	

4.0 PRESENTATION OF RESULTS

4.1 Are the basic data adequately described?	
4.2 Are the results presented clearly, objectively and in sufficient detail to enable readers to make their own judgement?	
4.3 Can you construct a 2x2 table of exposure and outcome?	
4.4 Was there a dose response effect?	
4.5 Are the results internally consistent, i.e. do the numbers add up properly?	

5.0 ANALYSIS

5.1 Are the data suitable for analysis?	
5.2 Are the methods appropriate to the data?	
5.3 Are any statistics correctly performed and interpreted?	
5.4 **Are relative risks or odds presented with confidence intervals?**	

6.0 DISCUSSION

6.1 Are the results discussed in relation to existing knowledge on the subject and study objectives?	
6.2 Is a causal relationship between exposure and outcome suggested?	
6.3 If so, is this causal relationship justified?	
6.4 Is the discussion biased?	

7.0 INTERPRETATION

7.1 Are the authors' conclusions justified by the data?	
7.2 What level of evidence has this paper presented? (using CEBM levels)	
7.3 Does this paper help me answer my problem?	

How do you rate this paper now? 1 2 3 4 5 6 7 8 9 10

In addition, answer the following questions with regards to local practice.

8.0 IMPLEMENTATION

8.1 Can any necessary change be implemented in practice?	
8.2 What aids to implementation exist?	
8.3 What barriers to implementation exist?	

DIAGNOSIS CHECKLIST

How do you rate this paper? 1 2 3 4 5 6 7 8 9 10

1.0 OBJECTIVES AND HYPOTHESES

1.1 Are the objectives of the study clearly stated?	

2.0 DESIGN

2.1 Is the study design suitable for the objectives?	
2.2 Who/what was studied?	
2.3 Was this the right sample to answer the objectives?	
2.4 Is the study large enough to achieve its objectives? Have sample size estimates been performed?	
2.5 Were all subjects accounted for?	
2.6 Were all appropriate outcomes considered?	
2.7 Has ethical approval been obtained if appropriate?	
2.8 Was an independent blinded gold standard test applied to all subjects?	

3.0 MEASUREMENT AND OBSERVATION

3.1 Is it clear what was measured, how it was measured and what the outcomes were?	
3.2 Are the measurements valid?	
3.3 Are the measurements reliable?	
3.4 Are the measurements reproducible?	

4.0 PRESENTATION OF RESULTS

4.1 Are the basic data adequately described?	
4.2 Are the results presented clearly, objectively and in sufficient detail to enable readers to make their own judgement?	
4.3 Are the results internally consistent, i.e. do the numbers add up properly?	

5.0 ANALYSIS

5.1 Are the data suitable for analysis?	
5.2 Are the methods appropriate to the data?	
5.3 Are any statistics correctly performed and interpreted?	

6.0 DISCUSSION

6.1 Are the results discussed in relation to existing knowledge on the subject and study objectives?	
6.2 Is the discussion biased?	

7.0 INTERPRETATION

7.1 Are the authors' conclusions justified by the data?	
7.2 What level of evidence has this paper presented? (using CEBM levels)	
7.3 Does this paper help me answer my problem?	

How do you rate this paper now? 1 2 3 4 5 6 7 8 9 10

In addition, answer the following questions with regards to local practice.

8.0 IMPLEMENTATION

8.1 Can any necessary change be implemented in practice?	
8.2 What aids to implementation exist?	
8.3 What barriers to implementation exist?	
8.4 Are my patients the same as the patients tested?	
8.5 Will the test improve diagnosis in my patients?	

ECONOMIC CHECKLIST

How do you rate this paper? 1 2 3 4 5 6 7 8 9 10

1.0 OBJECTIVES AND HYPOTHESES

1.1 Are the objectives of the study clearly stated?	

2.0 DESIGN

2.1 Is the study design suitable for the objectives?	
2.2 Who/what was studied?	
2.3 Was this the right sample to answer the objectives?	
2.4 Is the study large enough to achieve its objectives? Have sample size estimates been performed?	
2.5 Were all subjects accounted for?	
2.6 Were all appropriate outcomes considered?	
2.7 Has ethical approval been obtained if appropriate?	
2.8 **Does this economic analysis cite valid evidence on the clinical efficacy of the alternative?**	
2.9 **From who's perspective were costs measured?**	
2.10 Are all costs and effects identified?	

3.0 MEASUREMENT AND OBSERVATION

3.1 Is it clear what was measured, how it was measured and what the outcomes were?	
3.2 Were consequences and costs measured accurately in appropriate units?	
3.3 Were opportunity costs measured?	
3.4 Are the measurements valid?	
3.5 Are the measurements reliable?	
3.6 Are the measurements reproducible?	

4.0 PRESENTATION OF RESULTS

4.1 Are the basic data adequately described?	
4.2 Are the results presented clearly, objectively and in sufficient detail to enable readers to make their own judgement?	
4.3 Are the results internally consistent, i.e. do the numbers add up properly?	

5.0 ANALYSIS

5.1 Are the data suitable for analysis?	
5.2 Are the methods appropriate to the data?	
5.3 Are any statistics correctly performed and interpreted?	

6.0 DISCUSSION

6.1 Are the results discussed in relation to existing knowledge on the subject and study objectives?	
6.2 Is the discussion biased?	
6.3 Has a sensitivity analysis been performed (was appropriate allowance made for uncertainties)?	

7.0 INTERPRETATION

7.1 Are the authors' conclusions justified by the data?	
7.2 What level of evidence has this paper presented? (using CEBM levels)	
7.3 Does this paper help me answer my problem?	

How do you rate this paper now? 1 2 3 4 5 6 7 8 9 10

In addition, answer the following questions with regards to local practice.

8.0 IMPLEMENTATION

8.1 Can any necessary change be implemented in practice?	
8.2 What aids to implementation exist?	
8.3 What barriers to implementation exist?	
8.4 Do the costs apply in my practice?	
8.5 **Are the treatments likely to be effective in my setting?**	

QUALITATIVE CHECKLIST

How do you rate this paper? 1 2 3 4 5 6 7 8 9 10

1.0 Objectives and hypotheses

1.1 Are the objectives of the study clearly stated?	

2.0 Design

2.1 Is the study design suitable for the objectives?	
2.2 Did the researcher aim to understand or illuminate the views or experiences of the subjects?	
2.3 Who/what was studied?	
2.4 Was this the right sample to answer the objectives?	
2.5 Did the researcher recruit subjects with appropriate experiences and in appropriate settings to identify key themes to answer the study question?	
2.6 Is the study large enough to achieve its objectives? Have sample size estimates been performed?	
2.7 Were all subjects accounted for?	
2.8 Were all appropriate outcomes considered?	
2.9 Has ethical approval been obtained if appropriate?	

3.0 Measurement and observation

3.1 Is it clear what was measured, how it was measured and what the outcomes were?	
3.2 Was the data recording independently verifiable (audio or videotape)?	
3.3 Are the measurements valid?	
3.4 Are the measurements reliable?	
3.5 Are the measurements reproducible?	

4.0 Presentation of results

4.1 Are the basic data adequately described?	
4.2 Are the results presented clearly, objectively and in sufficient detail to enable readers to make their own judgement?	
4.3 Are illustrative quotes given to support developing themes?	
4.4 Are the results internally consistent, i.e. do the numbers add up properly?	
4.5 Are negative or discrepant results presented?	
4.6 Is the data available for independent scrutiny?	

5.0 Analysis

5.1 Are the data suitable for analysis?	
5.2 Did the researcher use appropriate methods to enable the study to meet its objectives?	
5.3 Did more than one researcher perform the analysis?	
5.4 Is it clear how the researcher analysed the data?	
5.5 Are any statistics correctly performed and interpreted?	

6.0 Discussion

6.1 Are the results discussed in relation to existing knowledge on the subject and study objectives?	
6.2 Are the results plausible and coherent?	
6.3 **Are alternative explanations explored and discounted?**	
6.4 Is the discussion biased?	
6.5 **What was the researchers perspective?**	
6.6 **Does the researcher critically examine their role, potential bias and influence?**	
6.7 How was the research explained to the participants?	

7.0 Interpretation

7.1 Are the authors' conclusions justified by the data?	
7.2 What level of evidence has this paper presented? (using CEBM levels)	
7.3 Does this paper help me answer my problem?	

How do you rate this paper now? 1 2 3 4 5 6 7 8 9 10

In addition, answer the following questions with regards to local practice.

8.0 Implementation

8.1 Can any necessary change be implemented in practice?	
8.2 What aids to implementation exist?	
8.3 What barriers to implementation exist?	
8.4 Were the subjects in the study similar in important aspects to your patient or problem?	