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Executive summary

Clinical guidelines are increasingly being developed in order to help improve the health outcomes for patients and to help reduce unacceptable variations in clinical practice. However, guidelines can only be effective if they are developed to the highest standards and are based upon the best available evidence. Clinical guidelines must also be seen to be of value to clinicians so that they are implemented in everyday clinical practice.

This document is a revision of the Royal College of Paediatrics and Child Health’s 2001 publication on standards for guideline development1 and has been produced by the College’s Quality of Practice Committee. Its purpose is:

• To provide methodological guidance to individuals and groups planning to develop guidelines at both national and local levels.

• To set out the key characteristics of a high quality guideline and describe how evidence-based guidelines are developed. To provide advice about how to facilitate guideline implementation. Implementing guidelines locally requires identifying the key individuals who should be involved, identifying and addressing any barriers to change and evaluation.

• To describe the role of the Quality of Practice Committee in endorsing evidence-based guidelines produced by organisations external to the College. This process involves appraising the research evidence underpinning guideline recommendations and then circulating the findings to College members. It is hoped that the College’s guideline appraisal programme encourages paediatricians and other health professionals to practice evidence-based medicine and to implement guidelines by incorporating the recommendations into their practice.

• To provide a list of useful sources of information available on the internet about guideline development and implementation.
1. Introduction

Clinical guidelines are crucial in a health service geared towards delivering appropriate, efficient and cost-effective healthcare. They are an important part of clinical governance and provide a systematic and transparent method by which organisations can deliver evidence-based practice.

Guidelines can assist clinicians, patients and health services managers. For the clinician, guidelines can assist with decision making to help achieve better health outcomes for patients and keep them abreast of new developments. Guidelines can also ensure patients are informed about what their clinicians should be doing, about the harms and benefits of various treatment options and about the services they can expect, which can enhance the patient-doctor relationship. Guidelines also help to improve efficiency and optimise value for money, thus benefiting both managers and commissioners of services.

However guidelines can only bring these benefits if they have been rigorously developed and if clinicians are aware of their existence and decide to incorporate the recommendations into clinical practice. This requires identifying barriers to change and specific interventions, which can help to implement the guideline. Key stakeholders including patients should be involved and consulted at all stages and the process of guideline development, dissemination and implementation must be carefully planned and transparent in order to be successful in changing practice.

This document describes what constitutes a good quality guideline and provides guidance about guideline development, describes the process of appraisal and endorsement used by the Quality of Practice Committee (QPC) and provides guidance on how clinical guidelines can be successfully disseminated and implemented. Guideline developers are also referred to documents produced by the National Institute for Health and Clinical Excellence (NICE) and the Scottish Intercollegiate Guideline Network (SIGN) which provide greater detail on the methodology of guideline development than can be usefully reproduced here.
2. Attributes of high quality guidelines

A guideline’s attributes\(^7,8\) and how it is constructed\(^9\) can influence the likelihood of its uptake. Guidelines are more likely to be used if they are evidence-based, simple, flexible, rigorously produced and perceived to be helpful,\(^4\) thereby allowing them to be adapted to local requirements and patient needs. The validity of any clinical guideline is related to three important factors:

- The composition of the Guideline Development Group and its processes;
- The identification and appraisal of evidence;
- The method of guideline construction.\(^{10}\)

The objective of the guideline development process should be to arrive at guidelines with the attributes listed in Table 1.

Table 1: (Adapted from Effective Healthcare Bulletin: No 8\(^{11}\))

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Valid</strong></td>
<td>Correctly interpreting the available evidence in order that, when followed, guidelines lead to improvements in health.</td>
</tr>
<tr>
<td><strong>Reproducible</strong></td>
<td>Given the same evidence, another guideline group would produce similar recommendations.</td>
</tr>
<tr>
<td><strong>Reliable</strong></td>
<td>Given the same clinical circumstances, another health professional would apply them similarly.</td>
</tr>
<tr>
<td><strong>Representative of key disciplines &amp; interests</strong></td>
<td>All key disciplines and interests (including patients) have contributed to the development of the guideline.</td>
</tr>
<tr>
<td><strong>Clinically applicable</strong></td>
<td>The target population (those whose health the guideline aims to improve) is defined in accordance with scientific evidence</td>
</tr>
<tr>
<td><strong>Clinically flexible</strong></td>
<td>The guidelines identify where exceptions to the recommendations lie, and indicate how patient preferences are to be incorporated in decision-making.</td>
</tr>
<tr>
<td><strong>Clearly expressed</strong></td>
<td>The guidelines use precise definitions, unambiguous language and a user-friendly format</td>
</tr>
<tr>
<td><strong>Well documented</strong></td>
<td>The guidelines’ methodology records all participants, any assumptions and methods and clearly links recommendations to the available evidence.</td>
</tr>
<tr>
<td><strong>Scheduled for review</strong></td>
<td>The guidelines state when, how and by whom they are to be reviewed.</td>
</tr>
</tbody>
</table>
3. Guideline development

Although many obstacles exist in the development of multidisciplinary, patient-focused guidelines, there is now some rigour to what was previously an informal process. This section describes a method for developing clinical guidelines that meet the criteria for quality outlined in the previous section.

The areas of guideline methodology described are considered essential, if guidelines are to be adopted by professionals and their organisations. The AGREE form and notes included in Appendix A can be used to help ensure that these areas are carefully considered at an early stage during guideline development.

3.1 Selecting a topic

Guideline development is a resource-intensive and time-consuming process and not one to be entered into lightly! Although clearly the most important criterion when choosing a topic is the clinical need for guidance in the area, there are other important factors to take into consideration. Local Trusts may wish to consider linking the choice of topic to the Trust’s risk management priority areas or findings from serious untoward incidents. The College uses the primary and secondary criteria given below for determining priorities for guideline development:

**Primary criteria**

- Prevalence/seriousness of condition
- Relevance to paediatric/child health practice
- Availability of evidence-based and supporting data
- Potential to improve health outcomes for patients
- Area with wide variation in clinical practice and outcomes.

**Secondary criteria**

- Availability of systematic reviews that may aid development of a guideline
- Area where increased paediatric attention/involvement would be helpful
- High cost of a health intervention

3.2 The Guideline Development Group

Guideline development is a multi-professional activity, which is usually led by the Guideline Development Group (GDG). On average, the GDG will comprise between 10 to 15 representatives from relevant healthcare services and groups, depending on the scope of the topic under consideration. Each guideline group should have a mix of the following skills:
- Clinical expertise in the topic
- Other specialist expertise (e.g. health economics)
- Practical understanding of the issues involved in the delivery of care
- Communication and team working skills
- Critical appraisal skills.

The group will be involved in a range of activities such as:

- Identifying the purpose of the guideline,
- Agreeing the scope,
- Developing clinical questions,
- Advising on finding best practice in areas where the evidence is limited,
- Considering the evidence and formulating the recommendations for the specific guideline topic under development and
- Developing a plan for disseminating and implementing the guideline.

However, guideline production can be logistically complicated and some organisations also choose to recruit a guideline project manager, or research fellow, to manage the project depending on its scale. The assistance or advice of a guideline methodologist should also be sought at the outset and it is likely that, during the process, the services of reviewers who are trained and experienced in critical appraisal may also be needed. As a minimum, there should be some kind of project management process, with an indication of timescale and interim goals at the outset.

The guideline development process is also an opportunity for junior grades to undertake and learn about systematic reviews, given sufficient support and adequate training. Specific tasks that they may undertake include searching medical databases for evidence, critically appraising research articles and developing evidence statements.

### 3.2.1 Patient/Carer involvement

It is also very important that patients and their carers should be involved in the process of guideline development to ensure that the guideline reflects their needs and concerns. Although ideally patients/carers should be included in the guideline development group, this may not always be possible or appropriate. Lay individuals might feel intimidated attending meetings with a group of health professionals or they may not be able to spare the time to attend GDG meetings. Involving more than one parent/patient representative or encouraging patient representatives to contribute by e-mail or telephone rather than having to attend meetings are alternatives. However open and honest relationships between health professionals and patient groups are best encouraged by face-to-face discussions such as can take place in a well-chaired GDG.
Patients can be involved in the guideline development process in various ways which include:

- Identifying patient and carer issues to help identify the questions that guide the literature search
- Helping to formulate the guideline recommendations
- Helping to produce the patient version of the guideline
- Commenting on the draft scope or final draft of a guideline

For example, the RCPCH clinical guideline for the management of ‘Chronic Fatigue Syndrome/Myalgic Encephalopathy (CFS/ME) in children and young people involved the young persons support group AYME (Association of Young people with ME) and a parent of a child with this condition in the GDG. The parent was also involved in commenting on the literature search and developing a patient information leaflet.

3.2.2 Children and young people
It is more of a challenge to involve children and young people in the guideline development process as most will not want or be able to attend committee meetings. However if the guideline will impact on their care, ways to involve them should be explored. Many patient groups for paediatric conditions will have a young persons committee or forum, which can be used to seek young peoples’ views on the scope of the guideline and on guideline drafts. Children and young people should also be involved in the design and content of any patient leaflets targeted at this age group.

3.3 The scope of the guideline
One of the first and most important tasks for the GDG is to define the scope of the guideline. This will involve a dialogue between clinicians, patients/carers and other stakeholders in the guideline (e.g. Royal Colleges, professional bodies and charities). The scoping document sets the limits of the guideline, defining what should and should not be included as well as providing a framework within which to work. It will describe a background outlining why the guideline is needed and define the target population, health setting and areas of care being considered. It is important to develop a scope that is not too broad, to ensure that the development of the guideline is achievable within the constraints of time and money. The draft scope needs to be agreed by all stakeholders before the work on the guideline begins.

It may also be helpful to prepare a work plan for local use once the scope has been agreed. This will specify the methods to be used with the key dates for delivery of the guideline.

3.4 Developing clinical questions
Once the scope has been defined, the next stage is to formulate the structured clinical questions which will help to identify the evidence needed from the subsequent systematic review. The
clinical questions should be focused and limited to addressing the topic areas covered in the scope and specify the key issues and target population concerned. For example, questions about interventions can be framed in terms of population concerned, intervention under investigation, comparison used and outcome measures (PICO) such as:

*In young children with otitis media (population), does antibiotic treatment (intervention) compared with no antibiotics (comparison) reduce the duration of infection (outcome)?*

The expertise of a methodologist should be used to help formulate questions. More guidance to help with constructing clinical questions can be found in the NICE guideline development methods manual.5

### 3.5 Identifying the evidence

In the past, groups of experts have developed guidelines without formal literature reviews, based on the group’s knowledge of the literature and their own experience of clinical practice. Although there may be very practical reasons for developing guidelines in this way, such as availability of time and other resources, such guidelines cannot be described as ‘evidence based’ and will be inevitably be flawed by the limitations of the knowledge of the “experts”. The RCPCH does not endorse guidelines produced in this way.

The development of an evidence-based guideline requires a systematic literature review using explicit search strategies and pre-defined inclusion/exclusion criteria to identify evidence. Appropriate databases which should be searched to identify the evidence might include Embase, Medline, PsychInfo, the Cochrane Collaboration for systematic reviews, CENTRAL for current trials, technology appraisals and existing guidelines. Wider sources may need to be considered if there is insufficient evidence to answer all questions. Hand searching may be undertaken at the development group’s discretion and should relate to the availability of existing evidence and to the clinical questions being asked. At this stage decisions will need to be made about which source languages will be included and the costs of translating papers taken into consideration.

The development of an appropriate search strategy designed to identify the best available evidence for each topic area should be undertaken in collaboration with an information specialist with expertise in techniques relating to evidence-based medicine. The search protocol should also state the outcomes under consideration (e.g. side effects, quality of life etc.) and identify studies appropriate to the question being asked, for example:

<table>
<thead>
<tr>
<th>Topic area</th>
<th>Appropriate study type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutics</td>
<td>Randomised controlled trials, meta-analyses and systematic reviews of randomised controlled trials where available</td>
</tr>
</tbody>
</table>
Diagnosis  Independent comparison with a reference standard

Prognosis  Cohort studies

The search strategies including search terms, details of the databases searched, and time period covered should be reproduced in the technical report along with a description of the methodology employed in developing the guideline. There should be sufficient information in this report to allow the search to be repeated.

Some medical libraries employ information specialists with expertise in literature searching who may be able to help identify the evidence.

3.6 Evaluating and synthesizing the evidence

Once the papers have been identified, inclusion and exclusion criteria should be applied to select relevant studies. In some cases this can be done using the title of the paper and the abstract but it may be necessary to obtain a full text copy before deciding if the paper is relevant or not. Each relevant paper should then be critically appraised using specific criteria to assess the quality of the evidence with respect to its methodology and the significance of the results. Appraisal tools and data extraction forms can be used to ensure the literature is appraised systematically and consistently using the same standards. Evidence tables may be used to help collate and summarise the data to identify similarities and differences between studies. Examples of useful data extraction forms and criteria for assessing methodological rigour of studies can be found in SIGN’s publication, “A guideline developers’ handbook”6. A level of evidence should be assigned to each study to indicate the type of evidence upon which the recommendations will be based.

3.7 Formulating recommendations

Deriving recommendations from research evidence is a complicated and potentially subjective process. As the recommendations make up the majority of the guideline, it is important that considerable care and attention is paid to their development.

3.7.1 Evidence-based recommendations

Once the evidence has been critically appraised and summarised, evidence statements should be made which can be translated into recommendations. Each recommendation needs to be carefully worded to reflect the evidence and then graded appropriately. A variety of grading schemes exist but there is no agreement as to which is best.14 Whichever is used, it should be applied consistently and transparently. The SIGN grading scheme is widely used and is reproduced below (Table 2 and 3). This scale is of particular relevance to research studies relating to treatment interventions but is less appropriate for diagnostic or prognostic studies.

There are often conflicts between the evidence and the clinical importance of the findings.16
The grading of evidence based upon this hierarchy of methodological quality does not address the clinical importance of the evidence – it merely assesses the strength or quality of the evidence to support a recommendation. “Strong evidence does not always produce a strong recommendation.”14 Separating the strength of the recommendation from the level of evidence also helps in situations where extrapolation is required to take the evidence of a methodologically strong study and apply it to the target population. The strength of the recommendation should be qualified even if the strength of evidence is high.

To give an example of how it is used, consider a recommendation based on the results of one high quality randomised controlled trial with very low risk of bias. The study would be categorised as providing level \textbf{1++} evidence (table 2). If the study was conducted on a representative sample of the population for whom the guideline is written, it would then be categorised as a \textbf{Grade A} recommendation (table 3). However, if for example it was conducted on a different group of children or on adults, the recommendation would then be categorised as a \textbf{Grade B}.

Guidelines normally contain many different recommendations based upon different levels of evidence. It is important that users are aware of the level of evidence on which each guideline recommendation is based. \textit{The links between the recommendations and the evidence that supports them should be made explicit}, i.e. reference numbers should be included with each recommendation with a corresponding list of full references in an appendix.

The key recommendations should also be prioritised for implementation. Recommendations also need to take into account the resource implications, feasibility of implementation and the impact on those providing the service. For example:

\begin{center}
\textbf{Key recommendations for implementation}
\end{center}

\begin{center}
\textbf{Making a diagnosis}
\end{center}

- Diagnosis of any cancer on clinical grounds alone can be difficult. Primary healthcare professionals should be familiar with the typical presenting features of cancers, and be able to readily identify these features when patients consult with them.

- Primary healthcare professionals must be alert to the possibility of cancer when confronted by unusual symptom patterns or when patients who are thought to not have cancer fail to recover as expected. In such circumstances, the primary healthcare professional should systematically review the patient’s history and examination, and refer urgently if cancer is a possibility.

\textit{Taken from NICE ‘Referral guidelines for suspected cancer’, 2005}18
Table 2: Levels of evidence

<table>
<thead>
<tr>
<th>Level</th>
<th>Type of evidence (based on SIGN, 2000)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1++</td>
<td>Evidence from high quality meta analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias</td>
</tr>
<tr>
<td>1+</td>
<td>Evidence from well conducted meta analyses, systematic reviews of RCTs, or RCTs with a low risk of bias</td>
</tr>
<tr>
<td>1-</td>
<td>Evidence from meta analyses, systematic reviews of RCTs, or RCTs with a high risk of bias</td>
</tr>
<tr>
<td>2++</td>
<td>Evidence from high quality systematic reviews of case-control or cohort studies or high quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a moderate probability that the relationship is causal</td>
</tr>
<tr>
<td>2+</td>
<td>Evidence from 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</td>
</tr>
<tr>
<td>2-</td>
<td>Evidence from case control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal</td>
</tr>
<tr>
<td>3</td>
<td>Evidence from non-analytic studies, e.g. case reports, case series</td>
</tr>
<tr>
<td>4</td>
<td>Evidence from expert opinion</td>
</tr>
</tbody>
</table>

Table 3: Grading of recommendations

<table>
<thead>
<tr>
<th>Grade</th>
<th>Type of Recommendation (based on SIGN 2000)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Requires at least one meta analysis, systematic review or RCT rated as 1++, and directly applicable to the target population, and demonstrating overall consistency of results</td>
</tr>
<tr>
<td>B</td>
<td>Requires 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+</td>
</tr>
<tr>
<td>C</td>
<td>Requires 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++</td>
</tr>
<tr>
<td>D</td>
<td>Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+</td>
</tr>
</tbody>
</table>
3.7.2 Non evidence-based recommendations

In many areas of paediatric practice it is likely that there will be insufficient good quality evidence to answer some of the clinical questions. In these areas a formal method of consensus may be needed to produce recommendations or good practice points (GPP).

There are several formal methods that can be used to gain expert consensus and each has its own merits. In the Delphi method each member of a panel of stakeholders scores their level of agreement with a draft recommendation or good practice point. These responses are combined and fed back to participants. Consensus is defined according to a predetermined level of agreement. This process is done anonymously by email or by post, usually over at least two rounds, in such a way that individuals cannot unduly influence the outcome. Other methods of formal consensus include the nominal group technique and consensus development conference.

Non evidence-based recommendations and good practice points may be of value, provided that there is transparency through full documentation about the processes by which they have been derived, and that they do not run counter to the evidence. Both evidence- and consensus-based recommendations within guidelines may be important for the identification and prioritisation of future research needs.

3.8 Writing the guideline

Guidelines are more likely to be used if recommendations are easy to follow and are written in concrete, unambiguous and specific terms. Guidelines should list the key recommendations and provide audit criteria, and where appropriate include algorithms or clinical pathways to lead readers through the patient care process.

High quality guidelines are usually published in two formats. A short version will often only include the guideline recommendations for ease of use in clinical practice. However there should also be a more comprehensive and explicit version outlining exactly how the guideline was developed and including search strategies, conflicts of interest and all other issues that may affect the findings and, therefore, the recommendations.

Educational packages, such as PowerPoint presentations, including case scenarios and details of the recommendations, can be helpful in disseminating the key messages and encouraging professionals to use the guideline. The asthma guideline produced jointly by SIGN and the British Thoracic Society provides a good example.
The short version
As a minimum this should include:

- A ‘quick reference guide’, containing graded recommendations
- Algorithms for treatment/management of a condition
- Outline of key priorities
- Details of where to find the full guideline
- Date of issue and review date

It may also include information relating to implementation, research recommendations, useful contacts, information for the public, and information on the composition of the GDG, the guideline review panel and criteria for audit.

The long version
This should include:

- Background information on the illness/condition, guideline aim and scope
- A list of the guideline development group members, with their specialty areas
- A list of all other stakeholders involved
- Details of the guideline methodology including:
  - How the review of the literature was completed
  - Search strategies employed, databases searched and time period involved
  - Criteria for including/excluding evidence (this may be covered in the scope)
  - Evidence statements
  - How the evidence was graded and the recommendations derived
  - A description of the methodology underpinning any consensus recommendations
- Clarification of how conflicts of interest were investigated and recorded and any declared
- Consideration of risks and benefits and any cost implications of recommendations
- Consultation details
- Algorithms/care pathways for treatment
- A date for review of the evidence and recommendations
- A dissemination strategy
- Audit criteria and strategy
- References
- Any special considerations (e.g. pregnancy, ethnicity, patients with learning difficulties)
- Patient information document

If consumer versions of guidelines are produced they need to be worded for their target audience so as not to be misleading, confusing or disruptive to the doctor-patient relationship.
3.9 Consultation and peer review
Guidelines should be subjected to extensive peer review prior to widespread dissemination and implementation for comment on the content, validity, clarity and applicability of the guideline. Any feedback should be considered by the GDG and necessary changes made to the document before final publication.

External reviewers should include methodological experts, potential users of the guideline and a clinical expert in the topic area of the guideline. Ideally, newly developed clinical guidelines should then be subject to pilot testing, to establish the consequences of their implementation.

3.10 Updating and reviewing
Guidelines need to be up-to-date to be useful to clinicians. The guideline should therefore specify a date for updating the evidence base underpinning the guideline recommendations. It is recommended that guidelines are updated every three years or when there is new evidence that is likely to influence the recommendations. However, the date for review chosen will depend upon how quickly or slowly the topic area is evolving.
4. RCPCH Appraisal and Endorsement process

The Quality of Practice Committee (QPC) of the Royal College of Paediatrics and Child Health oversees the College’s clinical effectiveness programme and as part of this, actively seeks out well produced national or international evidence-based guidelines relevant to UK paediatrics for independent appraisal. Those which meet pre-defined criteria for rigour of development and are approved as part of the appraisal process are endorsed and disseminated to College members.

However as well as evidence-based guidelines, the QPC is often asked to endorse consensus or practice statements on behalf of the College. The QPC’s role in endorsement of guidelines and non-evidence-based statements and the characteristics of the different categories of statement has recently been described.25

This section describes the College’s procedure for identifying, appraising and disseminating evidence-based guidelines. A flow diagram illustrating the key stages of the process can be found in Appendix C.

4.1 Identifying guidelines for appraisal

Clinical practice guidelines submitted to the QPC or identified by the College’s clinical effectiveness team are considered for appraisal using the following criteria:

- The guideline is relevant to UK paediatric and child health practice
- Implementing the guideline is likely to have benefits for children and young people
- The guideline is evidence based with an apparently robust, well documented methodology

When an apparently suitable guideline is identified the guideline methodology is initially assessed against the criteria of the ‘AGREE’ (Appraisal of Guideline for Research and Evaluation in Europe) 26 instrument (Appendix A). This tool provides a ‘prospective assessment of the validity of a guideline, that is, the likelihood that it will achieve its intended outcome’ 26 and is appropriate for both new and existing guidelines. When the AGREE tool has been completed the findings are considered by the QPC who decide whether or not the appraisal process should continue. Whenever possible, the results of the AGREE appraisal are reported back to the guideline developers.

4.2 Independent appraisal of recommendations

The next stage of the appraisal process is the independent review of the Grade A and B recommendations in the guideline. Although these are not always the most clinically relevant recommendations, they are those purported to be supported by good evidence, which can therefore be independently assessed. Appraisal of the evidence underpinning C and D
recommendations is not undertaken as this would in effect be repeating much of the work of the original guideline development group. The supporting evidence is likely to be weak with a greater degree of subjectivity in interpretation, and it would require significant additional resources.

References supporting each Grade A and B recommendation are tabulated and the relevant papers obtained. If the link between the recommendations and supporting evidence is not clear, the guideline development group will be approached for this information, and the lack of transparency highlighted.

The papers are then critically appraised by members of the clinical effectiveness team and the QPC, using established checklists. The evidence for each recommendation is reviewed by a reviewer trained and experienced in critical appraisal.

Reviewers are asked to record their findings on a ‘pro forma’ (Appendix B) where they grade the level of evidence according the grading scheme used by the guideline developers. Any discrepancies between the guideline (whether in relation to the level of evidence, grading or the wording of the recommendation) and the reviewer’s findings are recorded. The findings from each reviewer are collated so that the results can be compared. Areas of disagreement with the original statements are referred to the Chair of the QPC, who undertakes a second critical appraisal. The results of the appraisal process are highlighted and debated by the QPC. The Chair of the committee makes the final decision.

The appraisal of the Grade A and B recommendations can have a number of outcomes:

- The wording and the grading of the recommendations can be endorsed unchanged
- The recommendation wording is unaltered but the grade is changed
- The recommendation wording is changed if it is felt that the level of evidence cited is appropriate but only with a change to the wording of the original recommendation
- The wording and the grading of the recommendation are both changed.
- The recommendation is at such variance with the evidence that only a radical change to the recommendation can be considered: in such circumstances, where possible, the guideline developers will be contacted for clarification.

4.3 The Appraisal Document
As a result of the appraisal process, an appraisal and summary document is produced which reproduces all the recommendations from the original guideline, highlights key messages from the guideline and includes a summary of the scope and AGREE findings and original grading scheme used. Any discrepancies between the findings of the original guideline development group and the reviewers are published alongside those of the reviewers with a clear distinction
made between the findings. Explanations of the reason for altering the grading of a particular recommendation are included.

Where guidelines include recommendations on service configuration, the guideline, together with the QPC’s guideline appraisal and summary, are sent to the Chair of the Health Services Committee for information.

The draft document is approved by members of the QPC before being sent to two College Council readers for checking that the recommendations are not contrary to College policy or have unforeseen implications for practice.

If the decision is taken not to endorse a guideline, the documents will be discussed at the next full RCPCH Council meeting to approve the QPC decision. In this case, a summary of the reasons for not endorsing the guideline will be communicated to College members through the College newsletter.

The final version of the appraisal document is then distributed to the College membership with the College’s quarterly newsletter. All guideline appraisals, together with the full versions of the guidelines, are also available for download via the RCPCH website – www.rcpch.ac.uk. In addition, each year a small number of guideline appraisals are selected for dissemination at the RCPCH spring meeting and guideline developers are invited to present the key messages of their guideline.

4.4 Endorsement of non-evidence-based guidance

The College is sometimes asked to endorse non-evidence-based statements or guidance which relate to clinical practice in a particular area. These are defined as either consensus statements or practice statements.

Consensus statement
A consensus statement would be considered for endorsement and dissemination by the College if the following criteria are met:

- A rigorous literature searching process has identified that no evidence exists to address the clinical area
- The development of consensus involves all appropriate stakeholders
- A transparent and documented consensus methodology has been used

Any document which does not meet these criteria would be defined as a Practice Statement and not endorsed. Such statements would be listed on the College web-site by title only with a disclaimer identifying the lack of an evidence base.
Table 4: College categories of clinical practice statements

<table>
<thead>
<tr>
<th>Nomenclature</th>
<th>Characteristics</th>
<th>College policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence-based guideline</td>
<td>• The composition of the guideline panel and its processes are appropriate for the topic</td>
<td>• May endorse through the recommendation of the Quality of Practice Committee</td>
</tr>
<tr>
<td></td>
<td>• There is a robust and well documented process for the identification and synthesis of the evidence</td>
<td>• A copy of the QPC appraisal is circulated via the College quarterly newsletter</td>
</tr>
<tr>
<td></td>
<td>• The guideline construction includes a transparent link between the questions asked, the supporting evidence, and the derivation of the recommendations</td>
<td>• The guideline appraisal is posted on the clinical effectiveness page of the College website, together with a hotlink to the original guideline</td>
</tr>
<tr>
<td></td>
<td>• May contain consensus statements (see below)</td>
<td>• The topic may be showcased at the annual College meeting in York</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Selected guidelines are summarised and reviewed in the new Education and Practice supplement to Archives of Disease in Childhood</td>
</tr>
<tr>
<td>Consensus statement</td>
<td>• A rigorous process has shown that there is no evidence to answer the question</td>
<td>• As for evidence-based guidelines</td>
</tr>
<tr>
<td></td>
<td>• Consensus takes account of the views of all involved in the area including nurses, doctors, professions allied to medicine, and parent/patient groups</td>
<td></td>
</tr>
<tr>
<td>Consensus statement (continued)</td>
<td>Practice statement</td>
<td></td>
</tr>
<tr>
<td>--------------------------------</td>
<td>--------------------</td>
<td></td>
</tr>
</tbody>
</table>
| • A specific methodology (e.g. Delphi), prevents the more vociferous or articulate or those with specific issues from unduly influencing the outcome | • Absence of characteristics above  
| | • May be listed only by title on the website  
| • The consensus process is transparent | • May be based on the views of a group of eminent individuals and/or lacking clarity about the evidence base used for its production  
| | • Accompanying disclaimer: “Practice statements have not been developed according to RCPCH standards. There may not have been an appropriate stakeholder base and the evidence base may be incomplete. There may be unforeseen cost implications, and there may be other approaches to clinical practice that are equally or more appropriate. Members are asked to note these qualifications when considering them with respect to their own practice.”  


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5. Guideline dissemination and local implementation

If guidelines are to be effective and the time and effort spent on their development not wasted, health professionals need to change behaviour and incorporate guideline recommendations into practice. They need to be aware that a guideline exists (dissemination), decide to adopt it and then regularly use it (implementation). This requires good preparation and strategic planning. Dissemination involves communicating information to health professionals. Many national organisations do this by mailing their guidelines to the Chief Executive or Medical Director in each Trust, or by placing the relevant document and accompanying publications on their website. At a local hospital level, dissemination may involve sending each ward or department a copy of the short guideline as well as posting it on the local Trust intranet. Some Trusts may wish to translate national guidelines into a set of local protocols or policies as a starting point. Although this raises awareness about the existence of a new guideline, it is generally ineffective in changing behaviour by itself. Dissemination should be integrated with an implementation strategy.

This section suggests how College endorsed clinical guidelines can be implemented locally, based on a review of the literature and previous work in the area.

5.1 Identifying stakeholders

The first step towards implementing a guideline involves identifying the key stakeholders who should be involved in the process to ensure a sense of ownership and the success of the project. Stakeholders are those individuals or groups that are most likely to be affected by the implementation of the guideline concerned. As paediatrics is a multi-disciplinary specialty, collaboration is more likely to promote success. Specialist and general paediatricians as well as nurses and professionals from other relevant disciplines will need to be included. Involvement of primary care representatives whenever possible will strengthen the primary/secondary care interface.

The implementation group should also include patients and their representatives. Many Trusts have a Patient Council or service user group, which can help identify individuals who could be involved.

It is important that an individual is selected to project manage or facilitate the implementation process such as a member of the local Trust’s Clinical Effectiveness and Audit Department. This individual should be available throughout the implementation process and ideally during the follow up period to provide support, on-going education and advice to the staff involved.
5.2 Measuring current practice
Clinical audit can provide a framework for guideline implementation (Figure 1). It can be defined as a “quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria.”

Audit criteria are used to determine the extent to which guideline recommendations are currently being adhered to and to identify any deficiencies in local practice. The results of the audit will also highlight the benefits of implementation of the guideline. Many good quality clinical guidelines will already include audit criteria such as guidelines produced by NICE. The RCN guideline on the recognition and assessment of acute pain in children has a particularly well developed audit tool (see http://www.rcn.org.uk).

The clinical audit should be conducted within the framework of a robust clinical audit methodology, which should be predetermined and agreed by the local Trust Audit Committee. Patients and service users should be involved in the process. The local Clinical Effectiveness and Audit department should be contacted for advice and support with the project.

Undertaking clinical audit is now a required element of clinicians continuing professional development (CPD). RCPCH members registered with the CPD scheme participating in clinical audit will therefore be eligible for CPD points.

Figure 1: The audit cycle as framework for implementing guidelines
5.3 Identifying the facilitators and barriers to change

Once the audit has been completed, an analysis should be performed to identify any potential barriers to change, for example using observation or interviewing staff. This will help to select an appropriate intervention. The barriers may be related to the health professional, the guideline itself or to the environment. Health care professionals may be reluctant to alter their practice where there is no perceived necessity for change or where patient preferences differ to the guideline recommendations. They may also lack the necessary skills and knowledge to carry out care as recommended by the guideline or doubt the validity of evidence upon which the guideline is based. Structures and systems may have to be changed or more resources allocated e.g. access to a specialist with the necessary expertise to make a diagnosis of epilepsy. Once the barriers to implementation have been identified, those that are most likely to prevent uptake should be highlighted.

The analysis should also identify factors that may facilitate change. These may include a multi-professional collaboration, a permanent infrastructure for guideline implementation, ownership and enthusiasm from key professionals, good project management, user involvement, access to expert advice and a supportive environment that is receptive to change.

5.4 Selecting implementation techniques

The findings of the analysis of barriers to change together with the audit findings can be used to select an appropriate intervention that is likely to influence change, guided by the evidence. This will inform the dissemination and implementation strategy. A list of some of the interventions that can be used to change clinician behaviour is given in table 5. These address different elements to improve care and have varying degrees of effectiveness. Computer decision support systems are becoming increasingly available and can be used to remind professionals to perform a particular action.

There is at present no agreement as to which intervention is most likely to be effective and multifaceted interventions may be no more successful in changing behaviour than single interventions. However the implementation strategy should be appropriate to the setting and target group. For example, a strategy could include a range of interventions to change behaviour, such as dissemination of the guideline via the intranet (to raise awareness), audit of a sample of teams across the hospital Trust and feedback at workshops, educational meeting/workshop held in the Trust, use of opinion leaders (e.g. lead nurse) and outreach visits to individual wards/teams to assist with implementation.

If implementation strategies are to be effective in changing practice, any effect on behaviour needs to be sustained through a reinforcement mechanism such as a system of reminders and checklists.
Table 5: Interventions for implementing guidelines

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Educational materials</strong></td>
<td>This can include short versions of guidelines or summaries, educational videos.</td>
</tr>
<tr>
<td><strong>Educational meetings</strong></td>
<td>This includes lectures, conferences and educational sessions. Location, time of day and length of meetings may need to be considered.</td>
</tr>
<tr>
<td><strong>Outreach visits</strong></td>
<td>This includes training professionals as educators e.g. nurses, pharmacists to visit relevant practitioners or practices.</td>
</tr>
<tr>
<td><strong>Local opinion leaders</strong></td>
<td>Highly regarded individuals to influence the practice of peers through educational activities for example.</td>
</tr>
<tr>
<td><strong>Reminders</strong></td>
<td>Act as prompts requiring immediate action. They include stickers, computerised ‘alerts’ or messages and mailed reminders.</td>
</tr>
<tr>
<td><strong>Patient-mediated interventions</strong></td>
<td>Involves collecting new information from patients and giving this to the provider.</td>
</tr>
<tr>
<td><strong>Mass media</strong></td>
<td>Involves reaching a large number of people using posters, leaflets and television.</td>
</tr>
<tr>
<td><strong>Audit and feedback</strong></td>
<td>A quality improvement process evaluating care against explicit criteria.</td>
</tr>
</tbody>
</table>

5.5 Developing and delivering an action plan

The approach to be taken should be incorporated into an action plan agreed by all stakeholders. It should identify the action required to make the changes, identify who will lead each activity, the target dates by which completion of each activity is expected and also identify in which areas of the service change should occur first. It is important to involve managers at an early stage in the implementation process, and especially in the development and delivery of the action plan, as guideline implementation often has resource implications. NICE has published guidance on local implementation (See http://www.nice.org.uk/page.aspx?o=implementationsupport).

5.6 Evaluating changes

The implementation process is a continuous process and requires ongoing evaluation. Once guideline recommendations have been implemented locally, it is important to gather information to determine whether the guideline has been successful in improving health outcomes for patients. Progress should be evaluated in terms of adherence to guideline recommendations, awareness of the guideline and the impact of any behaviour changes on the quality of care. This involves re-auditing practice and comparing results with the first audit.
findings to identify positive changes and highlight any deficiencies. For example, improvements in health care may not have occurred because dissemination has been inadequate (lack of awareness), the guideline has not been adopted (e.g. due to negativity about the proposal for change) or because implementing and sustaining changes has been unsuccessful (e.g. lack of suitable reminders). Results can be compared with other wards or departments within the Trust. National organisations will need to take the lead in evaluating the success of the guideline in improving healthcare by carrying out national audits, for example.
6. Useful resources

*Note:* The RCPCH is not responsible for the content of, and does not necessarily endorse any of the websites. The views expressed in the websites are not necessarily those of the RCPCH.

**British Medical Association (BMA)**
Search 'audit' for information on journals, books and audit related websites.
www.bma.org.uk

**Healthcare Commission**
Commissions national audit.
http://www.healthcarecommission.org.uk

**National Clinical Audit Support Programme (NCASP)**
Commissioned by the Healthcare Commission, it manages the national clinical audits for coronary heart disease (CHD), diabetes and cancer.
http://www.icservices.nhs.uk/ncasp/pages/default.asp

**National Institute for Health and Clinical Excellence (NICE)**
National guidelines, audit and implementation support and guidance for developing guidelines.
www.nice.org.uk

**Turning research into practice (TRIP)**
Allows health professionals to easily find the highest-quality material available on the web including guidelines, medical images, patient information leaflets.
http://www.tripdatabase.com

**Scottish Intercollegiate Guidelines Network (SIGN)**
Develops guidelines for Scotland.
www.sign.ac.uk

**Principles for Best Practice in Clinical Audit**
Endorsed by NICE and CHI, it aims to support NHS staff by detailing the methods, tools, techniques and activities related to each stage of clinical audit.
http://www.nice.org.uk/page.aspx?o=233910

**The New Zealand Guidelines Group (NZGG)**
Information about guideline development, bulletins, guides and various resources.
http://www.nzgg.org.nz
Commission for Patient and Public Involvement in Health
Set up in 2003 to make sure the public is involved in decision making about health and health services in England.
http://www.cppih.org/

National Electronic Library for Health
The Guidelines Finder provides an index to clinical guidelines and currently holds details of over 1400 UK national guidelines with links to downloadable versions of the guidelines. It is updated on a weekly basis.
http://libraries.nelh.nhs.uk/guidelinesFinder/

Centre for Reviews and Dissemination (CRD)
Established in January 1994, and aims to provide research-based information about the effects of interventions used in health and social care.
http://www.york.ac.uk/inst/crd/

Your Child's health
This website serves as a portal to many web pages on the internet and provides parents, patients, and paediatricians with a useful resource to access health information on over 500 diagnoses and conditions.
http://www.yourchildshealth.nhs.uk

Paediatric Information and Education Resource (PIER)
Developed to provide a resource for all paediatricians. The site currently contains reviews, guidelines, images, patient information, teaching material such as grey cases, an area that will be developed for multi-centre research and a useful links database.
http://www.pier.org.uk/home.htm

Implementing NICE Guidance: A Practical Handbook for Professionals
NHS National Prescribing Centre, 2001. This handbook is intended to be a practical guide for NHS clinicians and managers on how to adopt and monitor guidance produced by NICE.
http://www.npc.co.uk/publications/nice/nice.pdf

How to Spread Good Ideas: A systematic review of the literature on diffusion, dissemination and sustainability of innovations in health service delivery and organisation
Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R & D (NCCSDO). This report describes a systematic review of the literature on the spread and sustainability of innovations in health service delivery and organisation.
http://www.sdo.lshtm.ac.uk/pdf/changemanagement_greenhalgh_report.pdf
AGREE FORM

Guideline title:
Name:  
Date:  

SCOPE AND PURPOSE

1. The objectives of the guideline is (are) specifically described  

Comments

2. The clinical question(s) covered by the guideline is (are) specifically described  

Comments

3. The patients to whom the guideline is meant to apply are specifically described  

Comments

STAKEHOLDER INVOLVEMENT

4. The GDG includes individuals from all relevant professional groups  

Comments

5. The patients’ views and preferences have been sought  

Comments

RIGOUR OF DEVELOPMENT

6. Systematic methods were used to search for evidence  

Comments

7. The criteria for selecting the evidence are clearly described  

Comments
8. The methods used for formulating the recommendations are clearly described

Comments

9. Health benefits, side effects and risks have been considered

Comments

10. There is an explicit link between the recommendations and the supporting evidence

Comments

11. The guideline has been externally reviewed by experts prior to its publication

Comments

12. A procedure for updating the guideline is provided

Comments

**CLARITY AND PRESENTATION**

13. The recommendations are specific and unambiguous

Comments

14. The different options for management of the condition are clearly presented

Comments

15. Key recommendations are easily identifiable

Comments

16. The target users of the guideline are clearly defined

Comments
17. Potential organisational barriers in applying the recommendations have been discussed

Comments

18. The potential cost implications of applying the recommendations have been discussed

Comments

19. The guideline is supported with tools for application

Comments

20. The guideline presents key review criteria for monitoring and/or audit purposes

Comments

21. The guideline has been piloted among end users

Comments

EDITORIAL INDEPENDENCE

22. The guideline is editorially independent from the funding

Comments

23. Conflicts of interest of guideline development members have been recorded

Comments

24. Further Comments

OVERALL ASSESSMENT

Would you recommend these guidelines for use in practice?

☐ Strongly recommend ☐ Recommend (with provisos or alterations)
☐ Would not recommend ☐ Unsure

Tick one box for each question

<table>
<thead>
<tr>
<th>Strongly agree</th>
<th>Agree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>
AGREE Form User Guide

Instructions for use

Please read the following instructions before you complete the appraisal instrument.

Response Scale
Each item is rated on a 4-point scale ranging from 4 ‘Strongly Agree’ to 1 ‘Strongly Disagree’, with 2 mid points: 3 ‘Agree’ and 2 ‘Disagree’. The scale measures the extent to which a criterion (item) has been fulfilled.

• If you are confident that the criterion has been fully met then you should answer ‘Strongly Agree’.
• If you are confident that the criterion has not been fulfilled at all or if there is no information available then you should answer ‘Strongly Disagree’.
• If you are unsure that a criterion has been fulfilled, for example because the information is unclear or because only some of the recommendations fulfil the criterion, then you should answer ‘Agree’ or ‘Disagree’, depending on the extent to which you think the issue has been addressed.

Comments
You will notice that each item has a box for comments. Please use this box to explain the reasons for your responses. For example, you may ‘Strongly Disagree’ because the information is not available, the item is not applicable, or the methodology described in the information provided is unsatisfactory.

SCOPE AND PURPOSE

1) This deals with the potential health impact of a guideline on society and populations of patients. The overall objectives(s) of the guideline should be described in detail and the expected health benefits from the guideline should be specific to the clinical problem. For example specific statements could be:

• Preventing (long term) complications of patients with diabetes mellitus
• Lowering the risk of subsequent vascular events in patients with previous myocardial infarction
• Rational prescribing of antidepressants in a cost-effective way

2) A detailed description of the clinical questions covered by the guideline should be provided, particularly for the key recommendations (see item 15). Following the examples provided in question 1:
• How many times a year should the Hb1Ac be measured in patients with diabetes mellitus?
• What should be the daily aspirin dosage for patients with proven acute myocardial infarction?
• Are selective serotonin reuptake inhibitors (SSRIs) more cost-effective than tricyclic antidepressants (TCAs) in treatment of patients with depression?

3) There should be a clear description of the target population to be covered by a guideline. The age range, sex, severity, clinical description, co-morbidity may be provided. For example:

• A guideline on the management of diabetes mellitus only includes patients with non-insulin dependent diabetes mellitus and excludes patients with cardiovascular co-morbidity
• A guideline on the management of depression only includes patients with major depression, according to the DSM-IV criteria, and excludes patients with psychotic symptoms and children
• A guideline on screening of breast cancer only includes women, aged between 50 and 70 years, with no history of cancer and with no family history of breast cancer

STAKEHOLDER INVOLVEMENT

4) This item refers to the professionals who were involved at some stage of the development process. This may include members of the steering group, the research team involved in selecting and reviewing/rating the evidence and individuals involved in formulating the final recommendations. This item excludes individuals who have externally reviewed the guideline (see Item 11). Information about the composition, discipline and relevant expertise of the guideline development group should be provided.

5) Information about patients’ experiences and expectations of health care should inform the development of clinical guidelines. There are various methods for ensuring that patients’ perspectives inform guideline development. For example, the development group could involve patients’ experiences could be considered by the group. There should be evidence that this process has taken place.

RIGOUR OF DEVELOPMENT

6) Details of the strategy used to search for evidence should be provided including search terms used, sources consulted and dates of the literature covered. Sources may include electronic databases (e.g. MEDLINE, EMBASE, CNAHL), databases of systematic reviews (e.g. the Cochrane Library, DARE), hand-searching journals, reviewing conference proceedings and other guidelines (e.g. the US National Guideline Clearinghouse, the German Guidelines Clearinghouse).
7) Criteria for including/excluding identified by the search should be provided. These criteria should be explicitly described and reasons for including and excluding evidence should be clearly stated. For example, guideline authors may decide to only include evidence from randomised clinical trials and to exclude articles not written in English.

8) There should be a description of the methods used to formulate the recommendations and how final decisions were arrived at. Methods include, for example, a voting system, formal consensus techniques (e.g. Delphi, Glaser techniques). Areas of disagreement and methods of resolving them should be specified.

9) The guideline should consider health benefits, side effects and risks of the recommendations. For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes. These may include: survival, quality of life, adverse effects and symptom management or a discussion comparing one treatment option to another. There should be evidence that these issues have been addressed.

10) There should be an explicit link between the recommendations and the evidence on which they are based. Each recommendation should be linked with a list of references on which it is based.

11) A guideline should be reviewed externally before it is published. Reviewers should not have been involved in the development group and should include some experts in the clinical areas and some methodological experts. Patients’ representatives may also be included. A description of the methodology used to conduct the external review should be presented, which may include a list of the reviewers and their affiliation.

12) Guidelines need to reflect current research. There should be a clear statement about the procedure for updating the guideline. For example, a timescale has been given, or a standing panel receives regularly updated literature searches and makes changes as required.

CLARITY AND PRESENTATION

13) A recommendation should provide a concrete and precise description of which management is appropriate in which situation and in what patient group, as permitted by the body of evidence.

- An example of a specific recommendation is: Antibiotics have to be prescribed in children of 2 years or older with acute otitis media if the complaints last longer than 3 days or if the complaints increase after the consultation despite adequate treatment with painkillers; in these cases amoxycillin should be given for 7 days (supplied with a dosage scheme)
• An example of a vague recommendation is: Antibiotics are indicated for cases with an abnormal or complicated course.

However, evidence is not always clear cut and there may be uncertainty about the best management. In this case the uncertainty should be stated in the guideline.

14) A guideline should consider the different possible options for screening, prevention, diagnosis or treatment of the condition it covers. These possible options should be clearly presented in the guideline. For example, a recommendation on the management of depression may contain the following alternatives:

• Treatment with tricyclic antidepressants;
• Treatment with SSRI;
• Psychotherapy;
• Combination of pharmacological and psychological therapy.

Users should be able to find the most relevant recommendations easily. These recommendations answer the main clinical questions that have been covered by the guideline. They can be identified in different ways. For example, they can be summarised in a box, typed in bold, underlined or presented as flow charts or algorithms.

15) Users should be able to find the most relevant recommendations easily. These recommendations answer the main clinical questions that have been covered by the guideline. They can be identified in different ways. For example, they can be summarised in a box, typed in bold, underlined or presented as flowcharts or algorithms.

APPLICABILITY

16) The target users should be clearly defined in the guideline, so they can immediately determine if the guideline is relevant to them. For example, the target users for a guideline on low back pain may include general practitioners, neurologists, orthopaedic surgeons, rheumatologists and physiotherapists.

17) Applying the recommendations may require changes in the current organisation of care within a service or a clinic, which may be a barrier to using them in daily practice. Organisational changes that may be needed in order to apply the recommendations should be discussed. For example:

• A guideline on stroke may recommend that care should be coordinated through stroke
units and stroke services

• A guideline on diabetes in primary care may require that patients are seen and followed up in diabetic clinics

18) The recommendations may require additional resources in order to be applied. For example, there may be a need for more specialised staff, new equipment, and expensive drug treatment. These may have cost implications for health care budgets. There should be a discussion of the potential impact on resources in the guideline.

19) For a guideline to be effective it needs to be disseminated and implemented with additional materials. These may include for example, a summary document, or a quick reference guide, educational tools, patients’ leaflets, computer support, and should be provided with the guideline.

20) Measuring the adherence to a guideline can enhance its use. This requires clearly defined review criteria that are derived from the key recommendations in the guideline. These should be presented. Examples of review criteria are: – the HbA1c should be <8.0% – the level of diastolic blood pressure should be <95 mmHg – if complaints of acute otitis media lasts longer than 3 days amoxycillin should be prescribed.

21) A guideline should have been pre-tested for further validation amongst its intended end users prior to publication. For example, a guideline may have been piloted in one or several primary care practices or hospitals. This process should be documented.

EDITORIAL INDEPENDENCE

22) Some guidelines are developed with external funding (e.g. Government funding, charity organisations, pharmaceutical companies). Support may be in the form of financial contribution for the whole development or for parts of it, e.g. printing of the guidelines. There should be an explicit statement that the views or interests of the funding body have not influenced the final recommendations.

Please note: If it is stated that a guideline was developed without external funding, then you should answer ‘Strongly Agree’

23) There are circumstances when members of the development group may have conflicts of interest. For example, this would apply to a member of the development group whose research on the topic covered by the guideline is also funded by a pharmaceutical company. There should be an explicit statement that all group members have declared whether they have any conflict of interest.
## Proforma for Recommendations

<table>
<thead>
<tr>
<th>GUIDELINE TITLE (Organisation name)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recommendation (Text and reference numbers)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Reviewer Name</strong></td>
<td><strong>Recommendation originally graded as</strong></td>
</tr>
<tr>
<td>Is the evidence reviewed sufficient to support the recommendation? (If no, please give a reason)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>In your opinion, at what level do you think the recommendation should be graded?</th>
<th>Please mark one box</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>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</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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++</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+</td>
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</tbody>
</table>
Appendix C

Guideline Appraisal and Endorsement Programme

Identify clinical practice guideline of appropriate standard.

Assess the quality and methodology of the guideline using the AGREE tool.

Identify the review team - usually 3 reviewers per guideline.

Extract the A and B graded recommendations and record and obtain the papers, which support them.

Allocate a reviewer to each recommendation.

Derive a proforma for each recommendation and compile reviewers’ packs.

Send reviewers’ packs out to the volunteer reviewers with a 4 week deadline.

Collate findings.

If any areas of disagreement with the original recommendations are apparent, notify the QPC Chair, identify a second reviewer, and send all supporting documentation to the second reviewer. Both reviewers’ comments then sent to the QPC Chair.

Prepare appraisal document highlighting any differences in grading or wording for A & B recommendations. The appraisal document also reproduces all the original guideline recommendations.

If any service configuration recommendations, notify the Chair of the Health Services Committee.

Appraisal document approved by QPC and by Council.

Publish College’s appraisal document with date for review and disseminate to College membership.
References


