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Executive summary

Child health clinical guidelines are increasingly being developed in order to help improve the health outcomes for children and young people and to help reduce variation in clinical practice. However, clinical 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 (RCPCH) 2016 publication on standards for guideline development within the United Kingdom and has been produced by the Research and Evidence Team in the Research and Quality Improvement Division at the College.

This document:

1. describes the process that the RCPCH follows to develop clinical guidelines and has been accredited by the National Institute for Health and Care Excellence (NICE) since 2009
2. is aimed at those individuals and/or organisations intending to develop a clinical guideline with the expectation of RCPCH endorsement.

The purpose of this document is:

- to set out the key characteristics of a high-quality clinical guideline and summarise the methodologies for developing child health clinical guidelines in order to meet the RCPCH’s criteria/standards for endorsement
- to provide advice about guideline dissemination and implementation
- to provide a list of useful sources of information available on the internet about high quality guideline development
- to present an outline of the RCPCH’s revised process for endorsing products that set clinical standards for paediatric practice. It is hoped that the College’s clinical guideline appraisal and endorsement programme encourages paediatricians and other child health professionals to practice evidence-based medicine and to implement clinical guidelines by incorporating the recommendations into their practice.

This updated version presents changes made in line with the revised NICE process manual published in 2018 and includes:

- the introduction of the requirement to have a minimum of two lay representatives as part of the guideline development group
- changes to the conflict of interest policy which relates to the guideline development group members
- an introduction on Delphi Consensus methodology
- the addition of a section on research recommendations.
1. Introduction

Clinical guidelines are defined as: ‘Statements that include recommendations intended to optimise patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options’[2]. Clinical guidelines are crucial in a health service geared towards delivering appropriate, efficient and cost-effective healthcare[3]. They are an important part of clinical governance and provide a systematic and transparent method by which organisations can deliver evidence-based practice.

The methodologies detailed in this document relate specifically to the development of high quality paediatric clinical guidelines. However, the development principles could be applied to other documents that set standards for child health services or clinical practice.

Clinical guidelines can assist clinicians, patients and health service managers. For the clinician, clinical guidelines can assist with decision making to help achieve better health outcomes for children and young people and keep them up to date with new developments. Clinical guidelines can also ensure children and young people, parents and carers are informed about what clinicians should be doing, the harms and benefits of various treatment options and the services they can expect, which can in turn, enhance the children and young people/parent/carer-doctor relationship. Clinical guidelines also help to improve efficiency and optimise value for money, thus benefiting both managers and commissioners of services[4].

However, clinical guidelines can only bring these benefits if they have been rigorously developed and if clinicians are aware of their existence and agree to incorporate the recommendations into clinical practice. This requires effective communication, identifying barriers to change and specific interventions which can help to implement the clinical guideline. Key stakeholders, including parent and carer groups and children and young people, should be involved and consulted with at all stages in the process of clinical guideline development. Dissemination and implementation must be carefully planned and transparent in order to be successful in changing practice[5].

In practice, various types of guidance exist including consensus and practice statements, some of which may detail local logistics for optimisation of efficiency, but directly affect patient care. Such documents have a valuable role to play in guiding the clinician, however, to gain RCPCH endorsement they should be developed using the principles outlined in this document.

1.1 Information about the College

The RCPCH facilitates the training and examination of paediatricians in the UK and is committed to improving the health of children everywhere by supporting members and policymakers to build on evidence-based practice.

The RCPCH aims to improve the quality of clinical practice, by ensuring that clinical guidelines that set standards for paediatric practice are evidence-based and offer evidence-based recommendations made by Guideline Development Groups (GDG) formed of clinical experts, lay members and a technical team.
The RCPCH Research and Quality Improvement Division holds the prestigious National Institute for Health and Care Excellence (NICE) accreditation for the development process used to produce clinical guidelines. The accreditation was originally granted by National Health Service (NHS) Evidence (to later become NICE accreditation) in 2009 and was last renewed in May 2015. The accreditation remains valid until May 2020. The accreditation applies to guidance produced using the methods and processes described in this document. For further information on NICE accreditation, see http://www.nice.org.uk/About/What-we-do/Accreditation.

1.2 Information about this document

This document describes what constitutes a high-quality clinical guideline and summarises the processes and methods used by the RCPCH to develop and update clinical guidelines, including information on grading evidence, consensus methods, dissemination and implementation.

Clinical guideline developers are also referred to documents produced by NICE\(^6\) and the Scottish Intercollegiate Guideline Network (SIGN)\(^7\) which provide greater detail on the methodology of guideline development (see Appendix 4: Useful resources for further information).

This document will be reviewed in three years (2023).

1.3 Key Principles for developing guidelines

The RCPCH develops guidelines according to ‘Developing NICE guidelines: the manual’\(^6\). The following principles underline NICE accredited guideline development and describe the ‘gold standards’ for methodology by:

- ensuring that guidance is based on the best available evidence of what works, and what it costs
- ensuring guidance is developed by independent and unbiased committees of experts
- ensuring all GDGs include at least two lay members (children and young people with personal experience of using health or care services, parents or carers, or a community affected by the guideline)
- conducting consultations which allow organisations and individuals to comment on the recommendations
- checking published guidelines every five years and updating the guideline in light of new evidence or intelligence if necessary
- ensuring the processes, methods and policies necessary for guideline development remain up-to-date.

7
2. Attributes of high-quality clinical guidelines

A clinical guideline’s attributes and how it is constructed can influence the likelihood of its uptake\(^8\)-\(^10\). Clinical guidelines are more likely to be used if they are evidence-based, rigorously produced, simple, flexible and perceived to be helpful\(^5\), thereby allowing them to be adapted to local requirements and patient needs. The validity of any clinical guideline is related to four important factors:

- the composition of the GDG and its processes
- the identification and appraisal of evidence
- the method of guideline construction\(^11\)
- external peer review\(^12\)

The objective of the development process must be to arrive at national guidelines with the attributes listed in Table 1 below.

**Table 1. Attributes of high-quality guidelines (adapted from Effective Healthcare Bulletin: No 8)\(^{12}\).**

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

Although many obstacles exist in the development of multidisciplinary, patient-focused clinical guidelines[13,14], NICE now expect a rigorous methodology to be followed compared to what was previously an informal process[15]. This section describes a method for developing high quality clinical guidelines and standards for clinical practice that meet the RCPCH’s standards for endorsement (see Section 5). The areas of methodology described are considered essential, if the clinical guidelines are to be adopted by professionals and their organisations.

The principles described in this section can also be applied to the development of other products that set standards for clinical practice such as consensus statements and the development of service health standards.

The Appraisal of Guidelines for Research and Evaluation (AGREE) II Instrument (http://www.agreetrust.org/) (Appendix 2) is a tool that assesses the methodological rigour and transparency in which a clinical guideline is developed. It includes 23 items which target various aspects of practice guideline quality. The AGREE II tool is used by the RCPCH and other groups developing paediatric clinical guidelines to help ensure methodological rigour, and each domain criteria should be carefully considered from the outset[16]. It also helps ensure all required methodical information is reported in the guideline. By following the principles, clinical guidelines are more likely to meet the criteria for RCPCH endorsement.

To help achieve high standards of guideline development and aid methodology reporting, boxes have been added throughout the document to highlight which criteria and domain of the AGREE II tool, each section is related to.

Recent improvements in methodology have led to increasing numbers of clinical guideline development groups using GRADE (the Grading of Recommendations, Assessment, Development and Evaluation) in clinical guideline development. GRADE offers a number of potential benefits including a more systematic and transparent scheme for developing questions, summarising evidence and translating evidence into recommendations. However, this approach is more technical and time consuming compared to previously used guideline methodologies and as a result could theoretically form a barrier to guideline development particularly for some of the smaller organisations/bodies that the RCPCH works with. As such, the RCPCH Research and Evidence Team will encourage the use of this overarching approach but will continue to consider clinical guideline development using the more ‘traditional’ non-GRADE approach. Those groups interested in GRADE methodology are referred to: http://www.gradeworkinggroup.org, from where detailed information on this approach and additional references can be obtained[17-22].

3.1 Selecting a topic

Developing clinical guidelines and standards is a resource-intensive and time-consuming process. Although 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. The RCPCH uses the following criteria (adapted from the NICE criteria) for determining priorities for development (presented in no particular order):
• relevance to paediatric/child health practice
• potential to improve healthcare quality/reduce health inequality for children, young people, parents or carers
• prevalence of condition/population affected
• evidence of unwarranted variation in practice
• burden on NHS/resource impact of the condition on health system
• College priority area and/or complements an existing piece of College work
• the need for guidance, if there is no existing guidance on this topic area or aspect of care produced by a developer accredited by NICE
• academic and clinical expertise available to help with the review of evidence and/or consensus methods
• topic suggestion received from a national organisation (e.g. Department of Health) or speciality group.

3.2 The process and stages for development

The time necessary to develop a clinical guideline from scoping to its final publication can take between 12 and 30 months depending on the breadth of the scope and the number of clinical questions to be covered. This time frame also takes into consideration time for consultation and any revision necessary after receiving responses from registered stakeholders.

The expected stages during the development of a clinical guideline are (see Figure 1):

• topic selection
• scoping
• clinical guideline development
• consultation on draft clinical guideline
• clinical guideline revision
• endorsement by other organisations
• publication and dissemination
• process for updating the guideline.

It is important to prepare a process document once the scope has been agreed. This will specify the methods to be used with the key dates for delivery of the clinical guideline. The document may cover the following areas:

• group membership including a list of stakeholder groups that will be represented with an associated engagement plan
• clinical questions
• process to identify the evidence (details of databases and sources that will be searched, inclusion and exclusion criteria)
• process to select and review the evidence (abstract screening, critical appraisal, data extraction, synthesis, and evidence summaries)
• process for formulating recommendations (GRADE or other methodology including consensus methods)
• process for managing conflicts of interests
• external review process
• endorsements by other organisations to be sought
• dissemination and implementation plans
• process for updating the document
• timeline for producing the document
• costs and resources
• scope as an appendix.

If endorsement is required from any professional body and/or other organisation, the organisation concerned (such as the RCPCH) must be approached from the outset to understand the process involved and the amount of time that will be needed for the assessment and endorsement process. The extra time that will be needed to coordinate an endorsement should be built into the timeline.

Figure 1. Different stages of clinical guideline development
3.3 Scoping the guideline

One of the first and most important tasks is to define the scope of the clinical guideline. This will involve a dialogue between clinicians, children and young people, parents and carers, and other stakeholders involved in the clinical guideline \(^{23}\) (e.g. Royal Colleges, professional bodies, Engagement or Advisory Group such as RCPCH &Us Network for Children, Young People, and their Families and any relevant charities). This often requires a scoping meeting. The scoping document sets the limits of the clinical 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 clinical 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 and that focuses on well-defined areas \(^{12,14,23}\) to ensure that the development of the clinical guideline is achievable within the constraints of time and resources and is of high quality. The draft scope needs to be agreed by all stakeholders before the work on the clinical guideline begins.

The scoping document should cover the following as a minimum:

- remit
- background
- aims and overall objectives
- clinical need for the guideline
- target population: groups that will be covered and not covered
- healthcare setting
- areas to be covered (and areas not covered)
- target audience
- planned clinical guideline development dates
- references (including links to any relevant guidelines).

The final scope is expected to be consulted among the identified stakeholder groups. The Research and Evidence Team will administer a consultation among RCPCH members and appropriate specialty groups during this development stage.

The scope (and later the full guideline) should specifically describe the overall objectives, the population (including age range for children) to whom the guideline is meant to apply and the target users. This information should be included in the final draft of the guideline to fulfil development/endorsement methodology requirements (in line with the AGREE II tool - Domain 1, criterion 1 & 3 and Domain 2, criterion 6). (For full AGREE II requirements, see Appendix 2).

3.4 Who is involved?

Different groups are involved in the development of a clinical guideline such as the guideline development group (GDG), appropriate stakeholder organisations representatives, and a technical and administration team.

- The GDG is set up to consider the evidence and to develop the recommendations
while taking into consideration the views of the external stakeholders. GDG members should include paediatricians (specialists and generalists), other child health professionals working in the area covered by the clinical guideline, and lay members (i.e. children and young people, parents or carers, representatives from patient organisations).

- Stakeholders are organisations or associations that have been identified by the GDG as having an interest in the clinical guideline topic, or who represent people whose practice or care may be affected directly. These stakeholder groups play an important role in clinical guideline development and can aid dissemination and facilitate implementation. During clinical guideline development, registered stakeholders should be periodically informed of progress and consulted on different documents throughout the development (i.e. the scope and guideline draft). In order to meet criteria for RCPCH endorsement, paediatric representation must be involved in the GDG. The Research and Evidence Team can help identify a suitable paediatric expert or register/confirm any paediatric expert already identified by the GDG.

- The close involvement of a technical team expert in research methodology including systematic reviewing and critical appraisal is crucial in the development of a clinical guideline. In the absence of a specific team, a number of members within the GDG are expected to have this knowledge and expertise and to have access to the appropriate resources to do literature searches and access scientific journals so that they are able to undertake this activity in their role as a member of the GDG.

- Other support to be taken into account is the access to regular administrative support that the GDG will need to deliver the clinical guideline. In particular, consideration should be given to the coordination of activities such as planning the work, scheduling meetings, and liaising with all individuals/organisations involved with the development of clinical guidelines (including stakeholders) and managing the process of consultation of key documents as well as supporting the launch of the finished product.

3.5 The Guideline Development Group

Developing child health clinical guidelines is a multi-professional activity and should be led by a GDG or working group. The development group must include individuals from all relevant professional groups as well as patient support groups and lay representatives. Depending on the how extensive the guideline topic is, the group will comprise between 8 and 15 representatives who could be identified in different ways (e.g. following recommendation from GDG chair or other experts, identified by relevant specialty groups and stakeholders or appointed through advertisements). The group will be involved in a range of activities such as developing clinical questions to conduct a systematic review of the literature, identifying the evidence after comprehensive searches, advising on finding best practice in areas where the evidence is limited, considering the evidence after critical appraisal and quality reviews and formulating the recommendations as well as developing a plan for disseminating and implementing the clinical guidelines. Each working group must, as a minimum, therefore 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
• systematic review/critical appraisal skills.

The GDG chair can be appointed for their expertise and skill in chairing groups and not necessarily their knowledge of the topic. Specialist knowledge can be provided by other committee members. The chair ensures that the guideline recommendations reflect the evidence and the committee's consideration. The chair should also be appointed before the guideline scoping in order for them to contribute to the early development of the guideline.

In order to meet criteria for RCPCH endorsement, paediatric expert representation is expected in the GDG. The Research and Evidence Team can help identify a suitable paediatric expert or register/confirm any already identified paediatric expert identified by the GDG.

Producing clinical guidelines can be logistically complicated and it is therefore important to recruit an experienced project manager and/or research fellow to co-ordinate the activity and establish timescales, costs and delivery of outputs. The assistance or advice of a clinical guideline methodologist and/or systematic reviewer should also be sought at the outset. The services of reviewers who are trained and experienced in critical appraisal may also be needed. This will help the GDG members to ensure timely delivery of their clinical guideline in a planned and structured way.

The development process is also an opportunity for medical trainees to undertake and learn about systematic reviews, when provided with sufficient support and training. Specific tasks that they may undertake include searching medical databases for evidence, critically appraising research articles and developing evidence statements. GDG members are encouraged to engage trainees in this process from the outset.

The full guideline should clearly document the name, discipline, institution, geographical location and role of each development group member. This information should be included in the final draft of the guideline to fulfil development/endorsement methodology requirements (in line with the AGREE II tool - Domain 2, criterion 4). (For full AGREE II requirements, see Appendix 2).

3.5.1 Children and young people/parent and carer involvement

The group should also seek to include two lay members. It is very important that children and young people and parents/carers are involved in the process of child health clinical guideline development to ensure that the end product reflects their needs and concerns[24]. Patient support groups are a valuable resource and may be able to help identify a representative or an individual with personal experience of receiving care in relation to the topic. Recruitment should begin early in the process[25].
The College might be able to help GDGs on the recruitment of appropriate children and young people and families through RCPCH & Us (see http://www.rcpch.ac.uk/and_us for more information).

Children and young people/parents or carers can be involved in the development process in various ways including:

- identifying children and young people/parents or carers issues to help identify the questions that guide the literature search
- helping to formulate the clinical guideline recommendations
- helping to produce the patient version of the clinical guideline and other related lay resources
- reviewing the draft scope or final draft of the clinical guideline[^24].

For example, the RCPCH clinical guideline, ‘Stroke in childhood’[^26], involved two different support groups during the development of the guideline and different initiatives were used to influence the recommendations for practice. Several focus groups were carried out during guideline development and the findings helped shape some of the recommendations for practice, meanwhile parent groups were involved in developing a parent version of the guideline.

Wider children and young people, parent and carer views and preferences can also be explored using focus groups outside the GDG for example at the start of the development process and/or at the end to test recommendations and their applicability[^25].

A well chaired GDG and appropriate training and support[^25] will help to ensure meaningful participation by children and young people/parents or carers and other group members. In order to meaningfully involve children and young people in the development process, it is important to identify their needs, address any barriers to participation and allow their voice to be heard. Some children and young people will not want to, or be able to, attend committee meetings and other alternatives should be explored. However, if the clinical guideline will impact on their care, other ways to involve them should be considered.

Many patient groups for paediatric conditions will have a young person’s advisory committee or forum (e.g. different charities and RCPCH & Us® Voice Network for Children, Young People, Parents and Carers and their Families, http://www.rcpch.ac.uk/and_us), which can be used to seek young people’s views on the scope of the document and comment on drafts. Children and young people can also be involved in the design and content of any patient information targeted at this age group. It is also important to include meaningful involvement of children and young people in the process document and project plan.

The full guideline/supporting methodology document should document the process used to seek the views and preferences of the target population. This information should be included in the final draft of the guideline to fulfil development/endorsement methodology requirements (in line with the AGREE II tool - Domain 2, criterion 5). (For full AGREE II requirements, see Appendix 2).
3.5.2 Conflicts of interest

Conflicts of interest may influence the recommendations and evaluation of evidence by group members.[27] Conflicts of interest should be recorded at the beginning of the guideline development and at different stages during development. Conflicts of interests can be specific or non-specific; financial and non-financial. Financial conflicts of interests can also be personal and non-personal.

Examples may include:

- **Financial conflicts of interest:** Personal financial interests could be an opportunity for personal financial gain (or to a family member), these may include consultancy work, directorships, commercial payments, shares and hospitality. Typically, applied to any involvement in such work over the last 12 months. Non-personal financial interest could include payments, grants or contracts to a department or organisation. These are also limited to the previous 12 months.

  - Financial conflicts of interest: Personal financial interests could be an opportunity for personal financial gain (or to a family member), these may include consultancy work, directorships, commercial payments, shares and hospitality. Typically, applied to any involvement in such work over the last 12 months. Non-personal financial interest could include payments, grants or contracts to a department or organisation. These are also limited to the previous 12 months.

- **Personal non-financial conflicts of interest:** Personal conflicts of interest may include holding office in a professional organisation, charity or other directly interested groups. Loyalty to different organisations may result in conflicts of interest which may prevent members from making a decision in the best interest of the guideline clinical development. Intellectual conflicts of interest such as authorship of original studies and books that might be potentially included for review. Any potential conflicts of interest of lay representation (i.e. patients or parent/carers) such as potential conflict of interest with patients and professionals on their care which may have an impact on power dynamics on their involvement in the GDG.

A conflict of interest is non-specific if it does not refer directly to the guideline. Specific conflicts are those that will need a decision from the GDG chair and hosting organisation.

A list of any conflicts of interest and how they had been managed must be included in the full report of the guideline or in a separate appendix (if their publication is not appropriate, they should be made available on request). Any conflict of interest discussions and any consequent decisions to exclude a member from all or part of the development process must also be reported in the clinical guideline document.

**GDG Chair**

The GDG chair must:

- be free of any conflicts of interest
- ask all members to declare any conflicts of interest at the beginning of the process of development of the guideline, ensuring a policy exists and is enforced to manage any conflicts of interest that might exist.

**GDG members**

All GDG members, including the technical team and lay members must:

- disclose all conflicts of interest including specific and non-specific; financial and
non-financial; personal and non-personal

- include both current conflicts and any potential planned conflict of interest
- declare any conflicts of interest preferably at every GDG meeting or at least at different milestones of the clinical guideline development process (i.e. at the initial registration of membership to the working group, during the scope, during the development of the recommendations and before publication).

The competing interests (conflicts of interest) of all guideline development group members should be recorded and addressed. This information should be included in the final draft of the guideline to fulfil development/endorsement methodology requirements (in line with the AGREE II tool - Domain 6, criterion 23). (For full AGREE II requirements, see Appendix 2).

3.6 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 reviews. Types of clinical questions that may be asked include but are not limited to epidemiology or aetiology of a disease, cost effectiveness, accuracy of diagnostic tests, effectiveness of an intervention, prognosis, clinical prediction models for diagnosis or prognosis, experiences and views of patients, families and service providers. The exact number of clinical questions will depend on the extent of the scope and resources, it is recommended to limit them to up to 15.

The clinical questions must be focused and restricted to addressing the topic areas covered in the scope and specify the key issues and target population concerned. They must be specifically described. For example, questions about interventions can be framed in terms of the population concerned, intervention under investigation, comparison used and outcome measures (PICO framework) such as:

- In children aged under 16 years with acute otitis media (population), does antibiotic treatment (intervention) compared with no antibiotics (comparison) reduce the duration of symptoms (outcome)?

Inclusion and exclusion criteria must also be developed at this stage and be specifically described. This must be relevant to the topic. For example, inclusion of studies published during a specific time period (e.g. if the topic is a relatively new concept) or specific study designs, and it may be appropriate to exclude studies of mixed adult and child data where child related data cannot be extracted separately.

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 expertise of a methodologist should be used to help formulate questions and develop a systematic review protocol. More guidance to help with constructing clinical questions can be found in ‘Developing NICE guidelines: the manual’[6].
3.7 Identifying the evidence

In the past, groups of experts have developed clinical 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 clinical guidelines in this way, such as lack of available time and other research resources, clinical guidelines such as those cannot be described as 'evidence based' and will inevitably be flawed by the limitations of the knowledge of the 'experts'. The RCPCH does not endorse clinical guidelines produced in this way.

The development of an evidence-based clinical guideline requires a systematic literature review using explicit search strategies and pre-defined inclusion/exclusion criteria to identify the evidence. Appropriate databases which should be searched to identify the evidence might include Embase, MEDLINE, PsycINFO, CINAHL, The Cochrane Collaboration for Systematic Reviews, Centre for Reviews and Dissemination and CENTRAL for current trials, technology appraisals, economic evaluations and existing clinical guidelines. Usually more than one database will need to be searched as a single database may only provide partial coverage of the medical literature for any specific topic. Selection of sources depends on the clinical question. A good start would be to use Healthcare Databases Advanced Search provided by NICE and Health Education of England (https://hdas.nice.org.uk). For further information on different databases, please visit https://www.nice.org.uk/process/pmg20/resources/developing-nice-guidelines-the-manual-appendices-2549710189/chapter/appendix-q-sources-for-evidence-reviews.

Wider sources of evidence should be considered. These become especially important if there is insufficient evidence on the initial searching to answer all questions. These avenues include hand searching, searching conference abstracts and unpublished scientific literature (commonly known as 'grey literature') e.g. institutional reports, doctoral theses. This should relate to the clinical questions being asked, the availability of existing evidence, and concerns about publication bias.

The development of an appropriate search strategy designed to identify the best available evidence for each topic area must be undertaken in collaboration with an information specialist with expertise in techniques relating to evidence-based medicine. Some medical libraries employ information specialists with expertise in literature searching who may be able to help identify the evidence.

Important elements for a search strategy include: accurate translation of the questions...
into search concepts, correct choice of logical operators, relevant subject headings, correctly adapting the search strategy for each database used and absence of spelling errors[30].

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, see Table 2 below for a detailed example.

**Table 2. List of appropriate study types to review depending on the proposed topic area**

<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>
<tr>
<td>Diagnosis</td>
<td>Independent comparison with a reference standard</td>
</tr>
<tr>
<td>Prognosis</td>
<td>Cohort studies</td>
</tr>
</tbody>
</table>

The search strategies, including search terms, details of the databases/sources searched, and time period covered, must be reproduced in the technical report along with a description of the methodology employed in developing the clinical guideline. There should be sufficient information in the methodology report to allow the search to be repeated. When applying limits, include only English papers and human studies. Relevant filters such as age, setting, geography, study designs and date can be applied as deemed appropriate.

A widely used and clear method for detailing the search results and flow of information is detailed by PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses)[31].

The resulting references are best stored in a spreadsheet or using bibliographic and reference management software such as EndNote, Reference Manager or RefWorks.

The literature searches may need to be re-run to identify further evidence that has been published since the initial search was conducted. This can be particularly important if the evidence base is evolving quickly or where the clinical guideline development time is particularly long. The decision to re-run the conducted searches should be made following a discussion amongst the GDG members and the technical team.

**The full guideline/supporting methodology document should include details of the strategy used to search for the evidence including search terms used, sources used, and dates covered as well as details of any hand-searching. This information should be included in the final draft of the guideline to fulfil development/endorsement methodology requirements (in line with the AGREE II tool - Domain 3, criterion 7). (For full AGREE II requirements, see Appendix 2).**
3.8 Evaluating, synthesising and presenting the evidence

Appropriate appraisal tools and data extraction forms must be used to ensure the literature is appraised systematically and consistently using the same standards.

Once the search has been completed, the list of retrieved citations should be screened to identify potential studies by applying the inclusion and exclusion criteria. This must be undertaken independently by two reviewers. Where reviewers disagree about whether a study should be included this can be resolved by discussion, or by using a third reviewer. Where double screening is undertaken on only a sample of retrieved citations (e.g. 10%), inter-rater reliability should be assessed and reported in the clinical guideline methodological report. A full text copy of all potentially relevant studies should then be obtained and the selection criteria re-applied and the individual studies reassessed independently by two reviewers.

Each relevant publication should be critically appraised using pre-specified criteria to assess the quality of the evidence with respect to its methodology and the significance of the results.

The assessment of the quality of the evidence should be carried out by one reviewer and checked by another. There are two ways to assess the quality of research studies: as a whole study or by outcome.

One approach for assessing levels of evidence as a whole study is the one developed by the Oxford Centre for Evidence-Based Medicine (OCEBM) which was reviewed in 2011. Evidence is categorised as levels 1, 2, 3, 4 or 5 depending on the type of study that is drawn from (e.g. systematic reviews, randomised control trials, cohort studies, cross sectional studies, case control studies or case series). The evidence levels can be graded up or down depending on the quality of the study. For a full explanation on how to apply the OCEBM levels of evidence, refer to http://www.cebm.net/wp-content/uploads/2014/06/CEBM-Levels-of-Evidence-2.1.pdf.

Previously, the RCPCH suggested the use of SIGN methodology to assess levels of evidence. Since 2013 however, SIGN no longer recommend the traditional ‘ABCD’ grading system and advocates for GRADE instead (see https://www.sign.ac.uk/assets/sign50_2019.pdf for more information).

To assess the levels of evidence by outcome, the GRADE approach is recommended. If using this approach, quality is assessed and summarised by outcomes across all relevant studies while looking at internal validity, inconsistency, indirectness, imprecision and publication bias. For more information on GRADE methodology refer to http://www.grade-workinggroup.org/.

If GRADE is not being used and an alternative approach to appraise quality is applied, the choice and rationale must be documented in the methodology report. Any judgement on how extracted data is to be synthesised must be detailed in the process document and the synthesis carried out accordingly.
Evidence should usually be presented for each review question. There may be exceptions, for example when separate questions are closely related and need to be interpreted together.

The clinical guideline must include summaries of evidence, evidence tables, evidence statements and narrative summaries:

- **Summary of evidence and evidence tables** are used to help collate and summarise the data to identify similarities and differences between studies. The type of data in the table can include the bibliography, location, study design, funding details, population, intervention/comparator, outcome, key findings and statistics, allocation/randomisation/drop-out data, quality rating and comments about quality\(^6\). In addition, and where appropriate, for example where GRADE is used, summary of findings tables may be included (e.g. GRADEpro available from [https://methods.cochrane.org/gradeing/gradepro-gdt](https://methods.cochrane.org/gradeing/gradepro-gdt) can help with this). These tables look at outcomes and the quality of evidence relating to them across studies.

- **A narrative summary of a study and its findings** builds on information in an evidence table and places a study and its findings in context. This must include descriptions of the study, its findings, and quality, and conclude with a short discussion and one or more evidence statements which reflect key findings, quantity, quality and consistency of the evidence and applicability to the review question. The evidence statements are an overall summary of all relevant included studies with key elements of evidence, even in the absence or lack of evidence. They represent the balance, strength and limitation of evidence. Evidence statements should be presented in a clear manner in order to support recommendations. A PICO framework can be used to produce clear evidence statements.

It is important that the GDG has members with experience or training in developing these tables/summaries and statements.

> **The final guideline should clearly describe the strengths and limitations of the body of evidence. This information should be included in the final draft of the guideline to fulfil development/endorsement methodology requirements (in line with the AGREE II tool - Domain 3, criterion 9). (For full AGREE II requirements, see Appendix 2).**

### 3.9 Incorporating economic evaluation

Economic evaluation compares the costs and consequences of alternative courses of action. Currently, there is no single widely used method of successfully incorporating economic evaluations into a clinical guideline. Given the cost of healthcare interventions, the assessment of the cost-effectiveness of medical interventions can help ensure maximum gain from the use of limited resources.

When considering such an evaluation, the GDG will need to consider factors including any health economic expertise available to them and the likely limitations of the economic evidence. Whilst there are benefits in considering such formal evaluations, the
applicability of findings to different health care settings is likely to be more limited than clinical outcomes. As a result, many clinical guideline developers do not include such formal analyses[33]. The RCPCH makes reasonable efforts where possible to include economic evaluation when resources are available.

The need for such an approach should be considered during the scoping of a clinical guideline and consideration given to involving a health economist at an early stage. In addition, economic considerations such as barriers to carrying out recommendations should be taken into account when making recommendations even if a formal analysis has not been carried out.

More information on economic evaluation can be found in ‘Developing NICE guidelines: the manual’[6].

### 3.10 Formulating recommendations

Deriving recommendations can be a complicated and potentially subjective process. It is therefore important that considerable care and attention is paid to their development. The number of recommendations in a given guideline will depend on the number of clinical recommendations in the scope.

#### 3.10.1 Evidence based recommendations

Once the evidence has been critically appraised and summarised, the GDG should translate the evidence statements into recommendations. This requires looking at the balance of benefits and harms of a particular intervention, the impact of recommendations on health inequalities and the general population, as well as considering economic, resource factors, social values and ethical issues. The full clinical guideline must clearly show how the working group has moved from the evidence to the recommendation. NICE support the use of a table that clearly reports the value placed on outcomes, benefits versus harms, resource use, overall quality as well as other factors considered by the group.

Clinical guidelines normally contain many different recommendations based upon different levels of evidence. The links between the recommendations and the evidence that supports them must be made explicit, i.e. using evidence tables, narrative summaries and evidence statements; reference numbers should be included with each recommendation with a corresponding list of full references in an appendix.

When facing inadequate evidence relating to a particular clinical question, the options available are:

1. use 'consider' in the wording of the recommendation if it is based on limited evidence
2. do not make any recommendation but it could be included in the research recommendations
3. consider indirect evidence derived from other population or settings.

The strength of any recommendation must also be made clear. A variety of grading schemes exist to represent the strength of a recommendation but there is no agreement as to which is best[23]. Whichever scheme is used, it must be applied consistently and transparently.
The concept of the strength of the recommendation is important to understand because although it takes into account the quality of evidence, it is conceptually different\textsuperscript{[6]}\textsuperscript{[28]}. There are often conflicts between the evidence and the clinical importance of the findings\textsuperscript{[28]} therefore, ‘strong evidence does not always produce a strong recommendation’\textsuperscript{[23]}.

‘Strong recommendations’ can be thought of as a recommendation that the group believes most service users would choose if they considered the evidence in the same way as the GDG. This is generally the case where the benefits clearly outweigh the harm and the intervention is cost-effective. However, where the balance between benefit and harm is much closer and thus not everyone would opt for the intervention then the recommendation would be identified as less strong. In such cases, the level of recommendation is lowered even when the corresponding quality of the evidence is very strong.

The GRADE approach is to look at recommendations as existing on a continuum, with recommendations for/against an action or intervention being either ‘strong’ or ‘weak’/ ‘conditional’. Recommendations could be described using symbols to support the wording of a recommendation. For example, a strong recommendation could be described as ++ whilst a conditional recommendation would be +?. There is scope for using numbers/ letters or even a pictorial scheme.

The NICE approach is similar; however, preference is given to ensuring that the wording of a recommendation reflects the strength of the recommendation.

**Wording recommendations**

The wording should reflect the strength of the recommendation\textsuperscript{[6]}. These should be concise, unambiguous, and easy to translate into practice\textsuperscript{[24]}. Each recommendation (or sub-heading within it) should also contain one action and detail the implementer, the population affected, setting, action and timeframe. Use person centred language such as ‘offer’, ‘discuss’ and ‘people with [condition]’ rather than ‘prescribe’, ‘give’, ‘individuals’, ‘cases’, ‘subject’ or ‘service users’ because the recommendations made are going to be directly affecting patients, their family and carers and in support of shared decision making.

The strength of a single recommendation should be highlighted through the use of the wording in the recommendation (i.e. the approach adopted by NICE). Due to the varying levels of evidence, some recommendations can be made with more certainty than others and therefore the strength of evidence behind the recommendations should be reflected in their wording.

- For recommendations that reflect strong evidence, wording including the verb ‘should’ or ‘should not’, ‘offer’ or ‘do not offer’ should be used. Use directive language (e.g. offer, do not offer, advise, ask about) for recommendation on activities or interventions.

- For recommendations that reflect weak evidence or follows expert formal consensus and where there is a closer balance between benefit and harm, wording such as ‘consider’ is more pertinent.

- Where there is a legal duty to apply a recommendation or where the consequences
of not following a recommendation are serious, words such as 'must' or 'must not' should be included in the recommendation along with a clear reference to the supporting evidence.

Guidelines should include clear recommendations in reference to specific clinical, healthcare or social circumstances. Guideline developers should ensure that the clinical recommendations proposed are clear as to the circumstances in which they apply, such as which groups, settings, or pathway stages they relate to. These circumstances should be clearly specified in the guideline.

Recommendations also need to take into account the resource implications, feasibility of implementation and the impact on those providing the service.

It is generally recommended not to state drug dosages routinely when drafting recommendations. If off-label use of licensed medicines or devices are considered to be included in recommendations, it is strongly recommended to always check with electronic Medicines Compendium (https://www.medicines.org.uk/emc), British National Formulary for Children (https://bnfc.nice.org.uk) and Medicines and Healthcare Products Regulatory Agency (MHRA) guideline (https://www.gov.uk/government/publications/medical-devices-off-label-use/off-label-use-of-a-medical-device). If any off-label medicines or devices are recommended for use, there should be a standard disclaimer attached to the recommendation.

**Prioritising recommendations**

The key recommendations should also be prioritised for implementation to help clinical guideline users decide which recommendations they should implement first. These are the recommendations likely to have the biggest impact on children and young people's health care and outcomes as a whole[6]. From this, the working groups can develop clinical audit criteria to support implementation.

3.10.2 **Non evidence-based recommendations and consensus documents**

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). Alternative approaches to a consensus approach are declining to make any recommendations or recommending an intervention in the context of research only[6].

There are several formal methods of formal consensus that can be used to gain expert consensus, and each has its own merits[35]. They include the Delphi method, nominal group technique and consensus development conference[36].

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 disagree with the evidence. Both evidence and consensus-based recommendations within clinical guidelines may be important for the identification and prioritisation of future research needs.
3.10.3 Delphi method

If Delphi methodology is used to produce non evidence-based recommendation and consensus, the planning and implementation of this method must be clearly documented in the guideline\(^{[37]}\).

The first step in the Delphi method involves identifying a panel or participants, including stakeholders and experts who are outside of the GDG. Depending on the topic, scope and objective of the guideline, different experts in the field of concern are selected, such as healthcare professionals and lay members (patients and carers). The panel size is recommended to be around 15 but the number can vary for different reasons such as resources, type of topic, scope and the aim of the guideline. The larger the group of experts, the greater the variety of expertise, but this will be at the risk of more dissension/uncertainty and lower returns of the questionnaire.

All panel members are anonymised to prevent any individuals from unduly influencing the outcome. In contrast to the nominal group technique, the Delphi method does not necessitate participants meeting or direct interaction in order to arrive at an agreement on a particular issue.

A set of recommendations are drafted and shared with a panel of experts to achieve a consensus. These statements are added to a questionnaire (best in electronic form) with the possibility to indicate the level of agreement to each statement. A 9-point Likert scale (1 being strongly disagree, 9 strongly agree) is usually employed to indicate the level of agreement/disagreement with any given statement. The opportunity to add comments and to indicate if the statement is outside their area of expertise is also given. A predefined cut off must be determined at the start of the Delphi process and it is often defined as 75% of ratings falling in the 1-3 or 7-9 categories.

The Delphi method commonly consists of a minimum of two rounds of questionnaires which are sent out by email. In the first round, respondents are required to score each statement and an option for free-text comments is given for each item. The results obtained from the first round are analysed, comments from each round are discussed by the working group and amendments to the recommendation statements are made. This is followed by a second-round personalised questionnaire which displays the individual’s initial rating, median score from the group of participants and comments from the first round for each item. The experts are then asked to rate each statement again with this added information. They may also document their views in light of the group feedback during the second round.

Some modifications can be made in the second-round questionnaire. For instance, the GDG may choose to include only the items which did not arrive at a consensus agreement in the second-round questionnaire. Instead of insisting the respondents rate the statements, alternatives can be provided for respondents to choose from.

**Developing consensus documents**

Consensus documents may still be of value in the absence of high-quality evidence. The RCPCH Research and Evidence Team and its Quality Improvement Committee recommend that these should be developed with the same rigour as evidence based clinical guidelines and follow the steps described in Section 3.
A rigorous literature searching process should be undertaken to establish that there is no or little quality evidence to address the question(s). A specific methodology should be used to ensure that each working group member including children and young people/parents and carers has an equal opportunity to inform the recommendations. This may include formal (such as Nominal-group or Delphi techniques) or informal consensus methods. A formal method prevents the more vociferous or articulate group members or those with specific issues from unduly influencing the outcome of discussions. Whichever method is used, the process must be detailed in the methodology section of the full report.

The final guideline should clearly describe the methods used for formulating the recommendations (Domain 3, criterion 10); include an explicit link between the recommendations and the supporting evidence (in line with the AGREE II tool - Domain 3, criterion 12). Recommendations should be specific and unambiguous (in line with the AGREE II tool - Domain 4, criterion 15). The health benefits, side effects, and risks have been considered in formulating the recommendations (in line with the AGREE II tool - Domain 3, criterion 11). This information should be included in the final draft of the guideline to fulfil development/endorsement methodology requirements. (For full AGREE II requirements, see Appendix 2).

3.10.4 Potential barriers and facilitators

Discussions among GDGs should take place to identify any potential barriers to the implementation of recommendations proposed. The barriers may be related to the health professional, the clinical 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 from the clinical guideline recommendations[38]. They may also lack the necessary skills and knowledge to carry out care as recommended by the clinical guideline or doubt the validity of evidence upon which the clinical guideline is based[38]. 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[38].

The analysis should also identify factors that may facilitate change. These may include a multi-professional collaboration, a permanent infrastructure for clinical guideline implementation, ownership and enthusiasm from key professionals and champions, good project management, user involvement, access to expert advice[39] and a supportive environment that is receptive to change.

The clinical guideline should include a consideration from the GDG about any potential organisational and financial barriers to applying the recommendations, in particular about the potential effects that the recommendations might have on resources and on other organisations and health professionals. For example, the impact of implementing a recommendation may be the need for additional resources such as higher numbers of staff, specialised staff, new equipment or different drug treatments. Any new recommendations may have cost implications which should be clearly discussed in the clinical guideline.
If necessary, the GDG may provide additional information on any specific plans. This may include evidence of cost impact assessment, provision of costing tools, health economic modelling and evaluation among others. The clinical guideline should cover detailed information including the identification of the type of costs included, what method was used to calculate them (e.g. health economic evaluations), how the cost information was sought (e.g. by a health economist reporting to GDG) and what specific information was used and how this was used to inform the recommendations.

The guideline should present the facilitators and barriers to its application (in line with the AGREE II tool- Domain 5, criterion 18), information about the potential resource implications of applying the recommendations have been considered (in line with the AGREE II tool - Domain 5, criterion 20). This information should be included in the final draft of the guideline to fulfil development/endorsement methodology requirements. (For full AGREE II requirements, see Appendix 2).

3.10.5 Research recommendations

During development of the guideline, which involves extensive work on literature searches and evaluation of current evidence, the GDG will certainly identify gaps in the current evidence base and areas of uncertainty where robust evidence is lacking/absent. This can be due to few or no studies related to any topic/area within the scope of the guideline and/or lack of rigorous studies or absence of any needed particular study type.

The GDG are encouraged to suggest research recommendations based on the most important clinical questions which are likely to make a sizeable impact on future decision making. These research recommendations should be included during the stakeholder consultation and therefore all those related organisations have the chance to provide comments.

Research recommendations should be limited and placed after clinical recommendations in the guideline, preferably in a separate section so they are easily identifiable. The GDG can select up to five research recommendations depending on the priority.

3.11 Writing the guideline

High quality clinical guidelines are typically published in three formats. A short, quick reference guide with the clinical guideline recommendations for ease of use in clinical practice; a more comprehensive and explicit version outlining exactly how the clinical guideline was developed including search strategies, conflicts of interest and all other issues that may affect the findings and the recommendations. Another publication that might usually be presented in a short format is a lay version which is aimed at parents, carers, children and young people. The recommendations should be concise, unambiguous and easy to translate into practice by the intended audience.

3.11.1 The short version

As a minimum this must 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 clinical guideline
• date of issue and review date
• information about the composition of the GDG

If the clinical guideline is presented in a short version, detailed information about the guideline’s development methodology should be included in a separate documentation. A template for a methodology report can be found in Appendix 1.

### 3.11.2 The full version

This should include:

• background information on the illness/condition, aims and scope
• a list of the GDG members and other stakeholders involved
• details of the clinical guideline methodology including:
  - how the review of the evidence was completed
  - search strategies employed, databases searched, and the time period involved
  - criteria for including/excluding evidence (this may be covered in the scope)
  - 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 with a list of any conflicts declared by each member
  - consideration of potential organisational barriers, potential costs and resource implications in applying the recommendations
  - consideration of any identified research gaps and a proposal of relevant research recommendations
  - consultation details
  - algorithms/care pathways for treatment
  - a date for review of the evidence and recommendations
  - key review criteria for monitoring purposes and/or audit purposes and advice on implementation
  - references
  - any special considerations (e.g. pregnancy, ethnicity, patients with learning difficulties)

A section on patient-health professional communication should be included in the clinical guideline where possible[40].

The lay versions of clinical guidelines need to be worded for their target audience to help children/young people, parents and carers to understand the recommendations and support the doctor patient relationship.

For examples of recently developed clinical guidelines, visit the resources section of the RCPCH webpage [https://www.rcpch.ac.uk/resources/clinical-guidelines-evidence-reviews](https://www.rcpch.ac.uk/resources/clinical-guidelines-evidence-reviews).
3.12 Consultation and external review

Consultation with external reviewers is an essential part of the clinical guideline development process. Clinical guidelines must be subjected to extensive peer review for comment on the content, validity, clarity and applicability of the clinical guideline prior to dissemination\(^{[23]}\). Any feedback received 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 clinical guideline and a clinical expert in the topic area of the clinical guideline\(^{[23]}\). Patient organisations as well as groups such as the RCPCH & Us® Voice Network for children, young people, parents, carers and their families should also be invited to comment on draft guidance.

The guideline should be externally reviewed by experts prior to publication. A description of the methodology used to conduct the external review should be presented (in line with the AGREE II tool - Domain 3, criterion 13). The RCPCH recommends that a list of organisations consulted during development is included on the guidance producer’s website or in the Appendix of the guidance. This information should be included in the final draft of the guideline to fulfil development/endorsement methodology requirements. (For full AGREE II requirements, see Appendix 2).

3.13 Endorsement and accreditation

Once the final version has been developed, it should be sent to any relevant bodies for endorsement. Endorsement by professional bodies can help encourage use and ownership. Endorsing bodies can also help with dissemination. The RCPCH process for appraisal and endorsement is described in Section 5. It is preferred if the RCPCH are notified at the outset by the developer if endorsement is sought. If the RCPCH is contacted during development of a guideline, a minimum set of requirements will be expected before being eligible to enter the appraisal and endorsement process.

The NICE Accreditation Scheme was launched in 2009 by NICE to recognise high standards in producing guidance and to raise standards in the longer term. Clinical guidelines are rigorously analysed and assessed and those meeting the criteria are awarded the NICE Accreditation Mark. This enables users to quickly identify clinical guidelines from accredited organisations. In 2016 NICE stopped accepting applications for their Accreditation Scheme, however, they continue to renew developers who had applied for NICE Accreditation prior to this. Further details about the process can be found here [http://www.nice.org.uk/about/what-we-do/accreditation](http://www.nice.org.uk/about/what-we-do/accreditation).
3.14 Presentation, Launching and Promoting the Guideline

How a clinical guideline is presented is an important factor in whether it is used in practice (see Section 4). Clinical guidelines and standards should be easy to follow. There are a number of options for presentation, both print and digital, and these should be explored early in the proposal phase of the project to ensure there is adequate time given to planning the input requirements, schedule and budget. Quick reference guides and algorithms summarising the pathway to follow for a condition can be helpful and should be included. For example, most NICE guidelines are now presented in full, as a shorter guideline and as a quick reference guide with accompanying algorithms (see www.nice.org.uk).

It is important to consider strategies to promote awareness of the clinical guideline at its development stage to maximise implementation. It is also important to consider what platforms are likely to be more effective to support reaching the target audiences including the use of supporting social media channels and email communications.

Once a clinical guideline is completed all registered stakeholders should be notified and encouraged to promote the clinical guideline. When the team produces a RCPCH guideline, early advice from the RCPCH Content & Brand and Media & External Affairs teams about publishing and promotion is sought. If your clinical guideline is endorsed by the College, it will be promoted via the PCO UK website and on the College social media sites.

3.15 Updating existing guidance: process for review and update

Clinical guidelines need to be up-to-date to be useful to clinicians and must therefore specify a date and process for updating the evidence base underpinning the clinical guideline recommendations.

It is good practice to review clinical guidelines at least every three years, and sooner when there is new critical evidence likely to influence the recommendations. It is recommended to update guidelines every five years. The date for review will depend on the pace at which the topic area is evolving. Specific factors that may influence the timing include changes in evidence on existing benefits and harms of interventions, the availability of interventions, important changes in outcomes and the state of health care resources.

For guidelines developed by RCPCH, an expert review panel (consisting of five to eight experts in the given topic) will be recruited to help make an informed decision on the need to update guidelines and agree on the extent of the update.

An assessment on any new body of literature will be done in which a scoping search for the literature might be undertaken using the original clinical questions and a report prepared summarising the potential impact of any new evidence on the current recommendations for practice. The assessment of the literature will be combined with a consultation with key stakeholders and users of the guideline. The consultation will gather views on the
need to update the guideline and any existing issues with the current recommendations. After assessing all the information collected during the review process, the expert review panel will provide a recommendation to the College on whether there is a need to update the guideline and the extent of it. The review panel might recommend for any guideline to be updated partially or fully. The extent of any update will be indicated by a revised scope. In cases when all or part of the content of the guideline is covered by other existing guidelines or when the clinical recommendations are considered unsafe, the guideline will be withdrawn from public circulation.

Clinical guideline developers are referred to the process manuals produced by NICE and SIGN which provide greater detail on the methodology for updating clinical guidelines.

The full guideline should include a clear statement about the date and procedure for updating the guideline (in line with AGREE II tool - Domain 3, criterion 14). This information should be included in the final draft of the guideline to fulfil development/endorsement methodology requirements. (For full AGREE II requirements, see Appendix 2).
4. Disseminating and implementing high quality clinical guidelines

If clinical guidelines are to be effective and the time and effort spent on their development not wasted, health professionals need to change behaviour and incorporate clinical guideline recommendations into practice. Health professionals need to be aware that a clinical guideline exists (dissemination), decide to adopt it and then regularly use it (implementation)\(^{[43]}\).

Clinical guidelines which are easy to read and understand and are presented in an accessible format with summaries and algorithms are more likely to be implemented by users\(^{[10]}\). Clear and relevant recommendations which have been developed or endorsed by a credible source are equally identified as factors to facilitate implementation\(^{[10]}\).

In order to change behaviour, dissemination should be integrated with an implementation strategy\(^{[38]}\). This requires good preparation and strategic planning\(^{[39]}\).

Common dissemination and implementation interventions are described below. These address different elements to improve care and have varying degrees of effectiveness\(^{[44]}\). Strategies for dissemination and implementation should also include patient organisations where possible.

4.1 Educational materials

Many national organisations disseminate information by mailing their clinical guidelines to relevant organisations or via websites and other communications such as publications in peer reviewed journals. Distribution of educational materials such as paper as well as electronic versions of the clinical guideline, quick reference guides, or posters are effective methods in disseminating information\(^{[45]}\). Educational packages, such as PowerPoint presentations, webinars or podcasts, including case scenarios and details of the recommendations, can be helpful in disseminating the key messages and encouraging professionals to use the clinical guideline. The asthma clinical guideline produced jointly by SIGN and the British Thoracic Society provides a good example\(^{[46]}\).

4.2 Educational strategies

Educational meetings/interactive sessions and educational outreach can help to increase knowledge of the clinical guideline recommendations amongst teams and can be used to discuss local challenges to implementation and strategies to overcome these.

4.3 Clinical audit and feedback

Clinical audit is a quality improvement process that involves measuring current practice against agreed standards and the implementation of change where necessary\(^{[47]}\). It can provide a framework to support clinical guideline implementation\(^{[10]}\). When developing
clinical guidelines, developers should identify the key recommendations and develop audit criteria and tools to accompany the guidance. With this information, clinical audits can measure if recommendations are being implemented in practice and if specific measures related to any particular recommendation are recorded, the results of the audit will also highlight the benefits of implementation of the clinical guideline. Many good quality clinical guidelines will already include audit criteria. NICE, for example, provides clinical audit tools to accompany their guidance as well as data collection tools for guidance[6].

4.4 Multiple approaches

Multiple interventions are more likely to be effective than single interventions[45,48]. For example, a strategy could include a range of interventions to change behaviour such as dissemination of the clinical guideline via the internet (to raise awareness), audit and feedback, use of opinion leaders (e.g. lead nurse) and outreach visits to individual wards/teams to assist with implementation. The implementation strategy should be appropriate to the setting[38] and target group[54]. The implementation process is a continuous process and requires ongoing evaluation.
5. Ensuring high quality guidelines: The RCPCH Appraisal and Endorsement Programme

The RCPCH Quality Improvement Committee oversees the College’s Clinical Standards, Audit and Quality Improvement Programme and as part of this, appraises and endorses high quality clinical guidelines. The Research and Evidence Team review national and international evidence based clinical guidelines relevant to UK paediatrics for independent appraisal as well as often receiving clinical guidelines for endorsement from other organisations. Those which meet pre-defined criteria for rigour of development and are approved by the Quality Improvement Committee following the appraisal process are endorsed by the College and disseminated to College members.

The RCPCH endorsement criteria for clinical guidelines are based on the AGREE II tool. Although the criteria applied by the RCPCH to appraise clinical guidelines developed by other organisations is similar to that used by NICE, this does not mean that products endorsed by RCPCH are NICE accredited. However, users of any RCPCH endorsed clinical guidelines can be reassured that those clinical guidelines are produced to the highest standards.

This section describes the College’s procedure for appraising and disseminating products that set standards for clinical practice in paediatrics and child health.

5.1 Review process

5.1.1 Before developing a guideline

Organisations seeking RCPCH endorsement for clinical guidelines must register their intention to develop a product with the College from the outset (via the RCPCH Research and Evidence Team at evidence@rcpch.ac.uk). This is to agree to the College becoming a formal stakeholder on the development of the guideline and help identify adequate paediatric involvement via the nomination of an RCPCH representative to be involved during the development of the guideline. If paediatric representation has already been identified by the developer, the College should be informed as soon as possible, and an induction pack will be provided with detailed information about the expected guideline development process. Registration at the outset also facilitates gaining RCPCH endorsement as the key methodological criteria requirements can be communicated before the development starts.

The developer will be asked to complete a proposal form stating the aims of the clinical guideline (visit the College webpage at https://www.rcpch.ac.uk/resources/how-develop-clinical-guideline-rcpch-endorsement for a copy of the form). The proposal will be discussed at the next Quality Improvement Committee meeting and if approved, the Research and Evidence team will liaise with the developers to identify/register adequate paediatric representation and an RCPCH representative, and to inform the developer of the expected clinical guideline development stages and methodological rigour necessary to meet the College’s standards for Endorsement. For more information on the
endorsement processes of a clinical guideline, refer to https://www.rcpch.ac.uk/resources/how-develop-clinical-guideline-rcpch-endorsement.

5.1.2 Appraisal Standards Criteria

The RCPCH has five standard criteria for endorsement of products that set standards for clinical practice; these are described in detail in Table 3 below. Standards criteria 1 and 2 will be automatically met if the intention to develop a clinical guideline has been registered at outset.

Table 3. The College's Standards for endorsement of products that set standards for clinical practice.

<table>
<thead>
<tr>
<th>Standard criteria</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The clinical guideline has been developed with College (Research and Evidence Team) involvement from the outset.</td>
</tr>
<tr>
<td>2</td>
<td>The clinical guideline has been developed with adequate paediatric involvement from the outset.</td>
</tr>
<tr>
<td>3</td>
<td>The clinical guideline has been developed following formal methodology and appropriate development stages (the key criteria of the AGREE II tool have been met).</td>
</tr>
<tr>
<td>4</td>
<td>The wording of the recommendations is a fair reflection of the evidence.</td>
</tr>
<tr>
<td>5</td>
<td>The clinical guideline adequately addresses comments made during consultation.</td>
</tr>
</tbody>
</table>

Standard Criteria 1: RCPCH Research and Evidence involvement

When a national clinical guideline is received, it is first assessed to determine whether there has been College (Research and Evidence Team) involvement from the outset. Involvement from the outset is desirable. Register your intention by sending a completed Application for Development or Endorsement of Clinical Guidelines form (https://www.rcpch.ac.uk/resources/how-develop-clinical-guideline-rcpch-endorsement) to evidence@rcpch.ac.uk.

Standard Criteria 2: Adequate paediatric involvement from the outset

Clinical guidelines are assessed to determine whether there has been adequate paediatric involvement from the outset (see also Section 3.4). The GDG must include a paediatrician who is fully involved in the development process. This is essential to help ensure that the recommendations meet the needs of children, young people, parents and carers. Paediatric involvement also ensures ownership and aids implementation.

Standard Criteria 3: Guideline developed following expected methodology and appropriate developmental stages (the key criteria for the AGREE II tool have been met)

The clinical guideline methodology is assessed against the key criteria of the ‘AGREE II’ (Appraisal of Guidelines for Research and Evaluation instrument: http://www.agreet-rust.org/). This tool assesses methodological rigour and transparency in which a clinical guideline is developed (visit the College webpage at https://www.rcpch.ac.uk/resources/how-develop-clinical-guideline-rcpch-endorsement for the methodology assessment form). Where appropriate, the results of the AGREE II appraisal are reported back to the clinical guideline developers and amendment to the draft is required.
**Standard Criteria 4: Appropriate wording of guideline recommendations**

The next check involves a review of the guideline recommendations to determine whether the wording appears to be a fair reflection of the evidence upon which it is based (as described in the document). If the link between the recommendations and supporting evidence is not clear, the GDG will be approached for this information, and the lack of transparency highlighted.

**Standard Criteria 5: Comments made during consultation adequately addressed**

The final stage of the appraisal process comes after the draft guideline consultation and aims to assess whether the developer has addressed any 'significant' comments (as identified by the RCPCH Quality Improvement Committee) made by RCPCH Members and other stakeholders and during the consultation process. Developers are asked to describe how each 'significant' comment has been addressed or give reasons why a particular comment could not be incorporated if this was the case. The response is reviewed by the RCPCH Research and Evidence Team and a decision made as to whether the criteria have been met. This step helps ensure that products meet the needs of children, young people, parents and carers.

### 5.1.3 Outcome of the appraisal process

The results of the appraisal process are highlighted and debated by the Quality Improvement Committee (QIC) clinical co-leads for Evidence-based Medicine and Appraisals and the Clinical Guidelines Lead. The QIC clinical co-leads for Evidence-based Medicine and Appraisals will provide a recommendation to the QIC Chair on whether endorsement should be granted. For more information about the approval process see Appendix 3. The appraisal process can have two outcomes: College endorsed; or not endorsed with the possibility to resubmit information for re-appraisal (see Table 4).

If the decision is taken to not endorse a clinical guideline, a summary of the reasons will be communicated to the developer and, if appropriate, further advice on how to ensure the College's standards are met will be given.
Table 4. Appraisal outcomes (adapted from McIntosh and Baumer\(^{49}\))

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Characteristics</th>
<th>College actions</th>
</tr>
</thead>
</table>
| Endorsed      | • The composition of the clinical guideline panel and its processes are appropriate for the topic  
• There is a robust and well-documented process for the identification and synthesis of evidence  
• The clinical guideline construction includes a transparent link between the questions asked, the supporting evidence, and the derivation of the recommendations  
• The guideline has been externally reviewed and College member comments have been adequately addressed | • Endorsed through the recommendation of the RCPCH Quality Improvement Committee and RCPCH Endorsement logo provided  
• A link to the original guideline is posted on the PCO UK guideline directory (https://pcouk.org/guideline-directory.aspx)  
• The topic may be showcased at the RCPCH Annual conference |
| Not endorsed  | • There is an absence of certain criteria listed above  
• The guideline may be based on the views of a group of eminent individuals and/or lacking clarity about the evidence base used for its production | • Feedback will be given to the developer that the document cannot be endorsed  
• The College will offer advice to amend the document to meet the College's standards |

An endorsed clinical guideline will be granted the use of the College Endorsement logo (see Figure 2 below for an example).

![Figure 2. Sample RCPCH endorsement logo](image)

5.1.4 Dissemination

Clinical guidelines endorsed by the RCPCH will be disseminated to the College membership via the College social media channels and as a link on the PCO UK guideline directory (https://pcouk.org/guideline-directory.aspx).

5.2 Endorsement of consensus documents

In addition to evidence-based clinical guidelines, the RCPCH is often asked to endorse practice statements or consensus statements on behalf of the College. Practice statements are no longer supported or promoted by the College without a rigorous methodology base. 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 there is no evidence to address the question
• the development of consensus takes account the views of all appropriate stakeholders including parent/patient groups
• a specific methodology (e.g. Delphi) prevents the more vociferous or articulate of those with specific issues from unduly influencing the outcome
• a transparent and documented consensus methodology has been used.
Appendix 1: Template for a methodology report

1. Title page (including details of developing organisation, month/year of publication)
2. Development Group Members/Stakeholder organisations
3. Key/Summary of recommendations

4. Introduction (including target audience and to whom the guidance applies)
   - overview
   - aims and objectives
   - clinical need

5. Methodology
   - scope
   - development group
   - clinical questions
   - evidence review (include details of the critical appraisal process)
   - formulating recommendations
   - external review
   - update
   - editorial independence

6. Guideline recommendations
   - clinical question
   - evidence summary
   - linking the evidence to the recommendation
   - recommendations

7. Implementation
   - barrier and facilitators
   - resource implications
   - implementation tool and advice
   - guideline audit
   - research recommendations

8. References

Appendix 1: Scope

Appendix 2: Search strategy and selection criteria (as part of the systematic review protocol)

Appendix 3: Evidence tables

Appendix 4: Critical appraisal tools

Appendix 5: Conflict of interests
### Appendix 2: AGREE II Criteria

AGREE reporting checklist 2016

This checklist is intended to guide the reporting of clinical practice guidelines.

<table>
<thead>
<tr>
<th>CHECKLIST ITEM AND DESCRIPTION</th>
<th>REPORTING CRITERIA</th>
<th>Page #</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DOMAIN 1: SCOPE AND PURPOSE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. OBJECTIVES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report the overall objective(s) of the guideline. The expected health benefits from the guideline are to be specific to the clinical problem or health topic.</td>
<td>☐ Health intent(s) (i.e., prevention, screening, diagnosis, treatment, etc.) ☐ Expected benefit(s) or outcome(s) ☐ Target(s) (e.g., patient population, society)</td>
<td></td>
</tr>
<tr>
<td>2. QUESTIONS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report the health question(s) covered by the guideline, particularly for the key recommendations.</td>
<td>☐ Target population ☐ Intervention(s) or exposure(s) ☐ Comparisons (if appropriate) ☐ Outcome(s) ☐ Health care setting or context</td>
<td></td>
</tr>
<tr>
<td>3. POPULATION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Describe the population (i.e., patients, public, etc.) to whom the guideline is meant to apply.</td>
<td>☐ Target population, sex and age ☐ Clinical condition (if relevant) ☐ Severity/stage of disease (if relevant) ☐ Comorbidities (if relevant) ☐ Excluded populations (if relevant)</td>
<td></td>
</tr>
<tr>
<td><strong>DOMAIN 2: STAKEHOLDER INVOLVEMENT</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. GROUP MEMBERSHIP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report all individuals who were involved in 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.</td>
<td>☐ Name of participant ☐ Discipline/content expertise (e.g., neurosurgeon, methodologist) ☐ Institution (e.g., St. Peter’s hospital) ☐ Geographical location (e.g., Seattle, WA) ☐ A description of the member’s role in the guideline development group</td>
<td></td>
</tr>
<tr>
<td>5. TARGET POPULATION PREFERENCES AND VIEWS</td>
<td>☐ Statement of type of strategy used to capture patients’/publics’ views and preferences (e.g., participation in the guideline development group, literature review of values and preferences) ☐ Methods by which preferences and views were sought (e.g., evidence from literature, surveys, focus groups) ☐ Outcomes/information gathered on patient/public information</td>
<td></td>
</tr>
</tbody>
</table>
### 6. TARGET USERS

*Report the target (or intended) users of the guideline.*

- The intended guideline audience (e.g., specialists, family physicians, patients, clinical or institutional leaders/administrators)
- How the guideline may be used by its target audience (e.g., to inform clinical decisions, to inform policy, to inform standards of care)

### DOMAIN 3: RIGOUR OF DEVELOPMENT

#### 7. SEARCH METHODS

*Report details of the strategy used to search for evidence.*

- Named electronic database(s) or evidence source(s) where the search was performed (e.g., MEDLINE, EMBASE, PsychINFO, CINAHL)
- Time periods searched (e.g., January 1, 2004 to March 31, 2008)
- Search terms used (e.g., text words, indexing terms, subheadings)
- Full search strategy included (e.g., possibly located in appendix)

#### 8. EVIDENCE SELECTION CRITERIA

*Report the criteria used to select (i.e., include and exclude) the evidence. Provide rationale, where appropriate.*

- Target population (patient, public, etc.) characteristics
- Study design
- Comparisons (if relevant)
- Outcomes
- Language (if relevant)
- Context (if relevant)

#### 9. STRENGTHS & LIMITATIONS OF THE EVIDENCE

*Describe the strengths and limitations of the evidence. Consider from the perspective of the individual studies and the body of evidence aggregated across all the studies. Tools exist that can facilitate the reporting of this concept.*

- Study design(s) included in body of evidence
- Study methodology limitations (sampling, blinding, allocation concealment, analytical methods)
- Appropriateness/relevance of primary and secondary outcomes considered
- Consistency of results across studies
- Direction of results across studies
- Magnitude of benefit versus magnitude of harm
- Applicability to practice context

#### 10. FORMULATION OF RECOMMENDATIONS

*Describe the methods used to formulate the recommendations and how final decisions were reached. Specify any areas of disagreement and the methods used to resolve them.*

- Recommendation development process (e.g., steps used in modified Delphi technique, voting procedures that were considered)
- Outcomes of the recommendation development process (e.g., extent to which consensus was reached using modified
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>11. CONSIDERATION OF BENEFITS AND HARM</td>
<td>Delphi technique, outcome of voting procedures</td>
</tr>
<tr>
<td></td>
<td>How the process influenced the recommendations (e.g., results of Delphi technique influence final recommendation, alignment with recommendations and the final vote)</td>
</tr>
<tr>
<td></td>
<td>Supporting data and report of benefits</td>
</tr>
<tr>
<td></td>
<td>Supporting data and report of harms/side effects/risks</td>
</tr>
<tr>
<td></td>
<td>Reporting of the balance/trade-off between benefits and harms/side effects/risks</td>
</tr>
<tr>
<td></td>
<td>Recommendations reflect considerations of both benefits and harms/side effects/risks</td>
</tr>
<tr>
<td>12. LINK BETWEEN RECOMMENDATIONS AND EVIDENCE</td>
<td>How the guideline development group linked and used the evidence to inform recommendations</td>
</tr>
<tr>
<td></td>
<td>Link between each recommendation and key evidence (text description and/or reference list)</td>
</tr>
<tr>
<td></td>
<td>Link between recommendations and evidence summaries and/or evidence tables in the results section of the guideline</td>
</tr>
<tr>
<td>13. EXTERNAL REVIEW</td>
<td>Purpose and intent of the external review (e.g., to improve quality, gather feedback on draft recommendations, assess applicability and feasibility, disseminate evidence)</td>
</tr>
<tr>
<td></td>
<td>Methods taken to undertake the external review (e.g., rating scale, open-ended questions)</td>
</tr>
<tr>
<td></td>
<td>Description of the external reviewers (e.g., number, type of reviewers, affiliations)</td>
</tr>
<tr>
<td></td>
<td>Outcomes/information gathered from the external review (e.g., summary of key findings)</td>
</tr>
<tr>
<td></td>
<td>How the information gathered was used to inform the guideline development process and/or formation of the recommendations (e.g., guideline panel considered results of review in forming final recommendations)</td>
</tr>
<tr>
<td>14. UPDATING PROCEDURE</td>
<td>A statement that the guideline will be updated</td>
</tr>
<tr>
<td></td>
<td>Explicit time interval or explicit criteria to guide decisions about when an update will occur</td>
</tr>
<tr>
<td></td>
<td>Methodology for the updating procedure</td>
</tr>
</tbody>
</table>
## DOMAIN 4: CLARITY OF PRESENTATION

### 15. SPECIFIC AND UNAMBIGUOUS RECOMMENDATIONS
Describe which options are appropriate in which situations and in which population groups, as informed by the body of evidence.

- A statement of the recommended action
- Intent or purpose of the recommended action (e.g., to improve quality of life, to decrease side effects)
- Relevant population (e.g., patients, public)
- Caveats or qualifying statements, if relevant (e.g., patients or conditions for whom the recommendations would not apply)
- If there is uncertainty about the best care option(s), the uncertainty should be stated in the guideline

### 16. MANAGEMENT OPTIONS
Describe the different options for managing the condition or health issue.

- Description of management options
- Population or clinical situation most appropriate to each option

### 17. IDENTIFIABLE KEY RECOMMENDATIONS
Present the key recommendations so that they are easy to identify.

- Recommendations in a summarized box, typed in bold, underlined, or presented as flow charts or algorithms
- Specific recommendations grouped together in one section

## DOMAIN 5: APPLICABILITY

### 18. FACILITATORS AND BARRIERS TO APPLICATION
Describe the facilitators and barriers to the guideline’s application.

- Types of facilitators and barriers that were considered
- Methods by which information regarding the facilitators and barriers to implementing recommendations were sought (e.g., feedback from key stakeholders, pilot testing of guidelines before widespread implementation)
- Information/description of the types of facilitators and barriers that emerged from the inquiry (e.g., practitioners have the skills to deliver the recommended care, sufficient equipment is not available to ensure all eligible members of the population receive mammography)
- How the information influenced the guideline development process and/or formation of the recommendations

### 19. IMPLEMENTATION ADVICE/TOOLS
Provide advice and/or tools on how the recommendations can be applied in practice.

- Additional materials to support the implementation of the guideline in practice. For example:
  - Guideline summary documents
  - Links to check lists, algorithms
  - Links to how-to manuals
  - Solutions linked to barrier analysis (see Item 18)
  - Tools to capitalize on guideline facilitators (see Item 18)
  - Outcome of pilot test and lessons learned
<table>
<thead>
<tr>
<th>20. RESOURCE IMPLICATIONS</th>
<th>Describe any potential resource implications of applying the recommendations.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>□ Types of cost information that were considered (e.g., economic evaluations, drug acquisition costs)</td>
</tr>
<tr>
<td></td>
<td>□ Methods by which the cost information was sought (e.g., a health economist was part of the guideline development panel, use of health technology assessments for specific drugs, etc.)</td>
</tr>
<tr>
<td></td>
<td>□ Information/description of the cost information that emerged from the inquiry (e.g., specific drug acquisition costs per treatment course)</td>
</tr>
<tr>
<td></td>
<td>□ How the information gathered was used to inform the guideline development process and/or formation of the recommendations</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>21. MONITORING/ AUDITING CRITERIA</th>
<th>Provide monitoring and/or auditing criteria to measure the application of guideline recommendations.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>□ Criteria to assess guideline implementation or adherence to recommendations</td>
</tr>
<tr>
<td></td>
<td>□ Criteria for assessing impact of implementing the recommendations</td>
</tr>
<tr>
<td></td>
<td>□ Advice on the frequency and interval of measurement</td>
</tr>
<tr>
<td></td>
<td>□ Operational definitions of how the criteria should be measured</td>
</tr>
</tbody>
</table>

**DOMAIN 6: EDITORIAL INDEPENDENCE**

<table>
<thead>
<tr>
<th>22. FUNDING BODY</th>
<th>Report the funding body’s influence on the content of the guideline.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>□ The name of the funding body or source of funding (or explicit statement of no funding)</td>
</tr>
<tr>
<td></td>
<td>□ A statement that the funding body did not influence the content of the guideline</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>23. COMPETING INTERESTS</th>
<th>Provide an explicit statement that all group members have declared whether they have any competing interests.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>□ Types of competing interests considered</td>
</tr>
<tr>
<td></td>
<td>□ Methods by which potential competing interests were sought</td>
</tr>
<tr>
<td></td>
<td>□ A description of the competing interests</td>
</tr>
<tr>
<td></td>
<td>□ How the competing interests influenced the guideline process and development of recommendations</td>
</tr>
</tbody>
</table>


For further information, see: [http://www.agreetrust.org/](http://www.agreetrust.org/).
Appendix 3: RCPCH approval process for clinical guidelines

Guideline proposal
- RCPCH Approval of proposal submitted to Quality Improvement Committee
- RCPCH Stakeholder formal registration (incl. identification of RCPCH rep for GDG)
- RCPCH Consultation on scope (incl. members & specialty groups)

Guideline development
- RCPCH Appraisal at key developmental stages (incl. Quality Assurance for RCPCH or joint clinical guidelines)

Stakeholder consultation
- RCPCH Consultation on complete draft guideline (incl. members & specialty groups)
- RCPCH Appraisal of revised draft guideline (incl. addressed consultation comments)

Approval of final draft
- RCPCH Sign off by Quality Improvement Committee Chair

Publication and launch

Dissemination and implementation
## Appendix 4: 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.

<table>
<thead>
<tr>
<th>Resource</th>
<th>Link</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Critical Appraisal Skills Programme</strong></td>
<td><a href="http://www.casp-uk.net/">http://www.casp-uk.net/</a></td>
</tr>
<tr>
<td>Critical Appraisal Checklists on a range of study designs</td>
<td></td>
</tr>
<tr>
<td>This publication aims to develop and validate an international instrument for assessing the quality of the process and reporting of clinical practice guideline development</td>
<td></td>
</tr>
<tr>
<td><strong>Levels of Evidence from Oxford Centre for Evidence based medicine (OCEBM)</strong></td>
<td><a href="http://www.cebm.net/explanation-2011-ocebm-levels-evidence/">http://www.cebm.net/explanation-2011-ocebm-levels-evidence/</a></td>
</tr>
<tr>
<td>Levels of evidence and grading of recommendations to assess quality of studies a whole</td>
<td></td>
</tr>
<tr>
<td><strong>GRADE (Grading of Recommendations Assessment, Development and Evaluation)</strong></td>
<td><a href="http://www.gradeworkinggroup.org">http://www.gradeworkinggroup.org</a></td>
</tr>
<tr>
<td>A grading scheme for grading quality of evidence and strength of recommendations</td>
<td></td>
</tr>
<tr>
<td><strong>Healthcare Quality Improvement Partnership</strong></td>
<td><a href="http://www.hqip.org.uk">www.hqip.org.uk</a></td>
</tr>
<tr>
<td>Established in April 2008 to promote quality in healthcare, including guidance, support and templates</td>
<td></td>
</tr>
<tr>
<td><strong>How to Spread Good Ideas: A systematic review of the literature on diffusion, dissemination and sustainability of innovations in health service delivery and organisation</strong></td>
<td><a href="http://www.netscc.ac.uk/hsdr/files/project/SDO_FR_08-1201-038_V01.pdf">http://www.netscc.ac.uk/hsdr/files/project/SDO_FR_08-1201-038_V01.pdf</a></td>
</tr>
<tr>
<td>Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R&amp;D (NCCSDO)</td>
<td></td>
</tr>
<tr>
<td><strong>Developing NICE guidelines: the manual</strong></td>
<td><a href="https://www.nice.org.uk/process/pmg20/chapter/introduction-and-overview">https://www.nice.org.uk/process/pmg20/chapter/introduction-and-overview</a></td>
</tr>
<tr>
<td>This manual explains the processes and methods used to develop and update NICE guidelines</td>
<td></td>
</tr>
<tr>
<td><strong>National Institute for Health and Care Excellence (NICE)</strong></td>
<td><a href="http://www.nice.org.uk">www.nice.org.uk</a></td>
</tr>
<tr>
<td>National guidelines, audit and implementation support and guidance for developing guidelines</td>
<td></td>
</tr>
<tr>
<td>Guidance on how to involve lay representatives in research, the principles can be applied to guideline groups</td>
<td></td>
</tr>
<tr>
<td><strong>Scottish Intercollegiate Guidelines Network (SIGN)</strong></td>
<td><a href="http://www.sign.ac.uk">www.sign.ac.uk</a></td>
</tr>
<tr>
<td>Develops guidelines for Scotland</td>
<td></td>
</tr>
<tr>
<td><strong>Applying the GRADE methodology to SIGN guidelines: core principles</strong></td>
<td><a href="https://www.sign.ac.uk/assets/sign_grading_system_1999_2012.pdf">https://www.sign.ac.uk/assets/sign_grading_system_1999_2012.pdf</a></td>
</tr>
</tbody>
</table>
| **Turning research into practice (TRIP)**  
Allows health professionals to easily find the highest-quality material available on the web including guidelines, medical images, and patient information leaflets | http://www.tripdatabase.com |
| **JBI's critical appraisal tools**  
The tools assist in assessing the trustworthiness, relevance and results of published papers | http://joannabriggs-webdev.org/research/critical-appraisal-tools.html |
| **BestBETs**  
Search strategy methods and appraisal tool checklists are available on BestBETs website for use online or downloading as an aid to literature search and the critical appraisal process | http://www.bestbets.org/links/BET-CA-worksheets.php  
https://bestbets.org/links/search-strategies.php |
| **Medicines learning portal**  
Provides online tutorial on critical appraisal | https://www.medicineslearningportal.org/p/critical-evaluation_3.html |
| **BMJ**  
On this website you will find links to articles in the BMJ that explain how to read and interpret different kinds of research papers | http://www.bmj.com/about-bmj/resources-readers/publications/how-read-paper |
| **The EQUATOR (Enhancing the QUAlity and Transparency Of health Research) Network**  
An international initiative that seeks to improve the reliability and value of published health research literature by promoting transparent and accurate reporting and wider use of robust reporting guidelines | http://www.equator-network.org |
| **The Cochrane Handbook for Systematic Reviews of Interventions**  
The official guide that describes in detail the process of preparing and maintaining Cochrane systematic reviews on the effects of healthcare interventions | http://handbook.cochrane.org/ |
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