Setting Standards for Development of Clinical Guidelines in Paediatrics and Child Health

4th Edition

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RCPCH
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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 unacceptable variations 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 2006 publication on standards for guideline development[1] and has been produced by the Clinical Standards Team in the Research and Policy Division at the College.

This document is:

1. The process manual that the RCPCH follows to develop clinical guidelines and has been accredited by National Institute for Health and Care Excellence (NICE) since 2009.

2. Aimed at those individuals and/or organisations intending to develop a clinical guideline and its purpose is:

    - to set out the key characteristics of a high quality clinical guideline and summarise the methodologies for developing child health clinical guidelines that will be expected to follow 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

3. 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.

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].

The methodologies detailed in this document relate specifically to the development of high quality paediatric clinical guidelines, but could equally apply to any product that sets standards for child health services or clinical practice.

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.

Clinical guidelines can assist clinicians, patients and health services 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 abreast of 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 representatives, should be involved and consulted 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 be single page documents detailing local logistics for optimisation of efficiency, but which nevertheless directly affect patient care. Such documents have a valuable role to play in guiding the clinician and should be developed using the broad principles outlined in this document.

1.1. Information about the College

The Royal College of Paediatrics and Child Health (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 offers evidence-based recommendations made by Clinical Guideline Development Groups (GDG) formed of clinical experts and lay members.

The RCPCH Research and Policy 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 become NICE accreditation) in 2009 and renewed in May 2015. This accreditation will remain valid until 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 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 than can be usefully reproduced here (see Appendix 4: Useful resources for further information).

This document will be reviewed in 3 years.

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.

Table 1. Attributes of high quality guidelines (adapted from Effective Healthcare Bulletin: No 8[13]).

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

3. Developing high quality guidelines

Although many obstacles exist in the development of multidisciplinary, patient-focused clinical guidelines[13,14], there is now an expected 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 College'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 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 College and groups developing paediatric clinical guidelines to help ensure methodological rigour, and each domain criteria should be carefully considered from the outset[116]. By following the principles, clinical guidelines are more likely to meet the criteria for RCPCH endorsement and also more likely to gain accreditation if applying for the NICE Accreditation Mark (http://www.nice.org.uk/aboutnice/accreditation/) (see Section 3.13). To help aid the identification of each of the AGREE II expected criteria, text boxes with the AGREE domain referred to has been added to the corresponding section.

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 College works with. As such, the RCPCH Clinical Standards 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/intro.htm, from where detailed information on this approach and additional references can be obtained[17-22].

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.

3.1. Selecting a topic

Developing clinical guidelines and standards is a resource-intensive and time consuming process and not one to be entered into lightly. Although clearly, the most important criterion when choosing a topic is the clinical need for guidance in the area, there are other important factors to take into consideration. The College 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 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
- need for guidance - no existing guidance on this topic area or aspect of care produced by a developer accredited by NICE
- availability of good quality evidence that may aid development of a clinical guideline
- 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. Who is involved

Different groups are involved in the development of a clinical guideline such as the guideline development group (GDG), appropriate stakeholder organisations, 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 typically 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).
- 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 also can aid dissemination and implementation. During clinical guideline development, registered stakeholders should be periodically informed of progress and consulted on different documents throughout the development (i.e. scope and draft). **In order to meet criteria for RCPCH endorsement, paediatric representation is**

expected in the GDG. The Clinical Standards team can help identify a suitable paediatric expert or register/confirm any already identified paediatric expert already identified by the 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.

3.3. 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

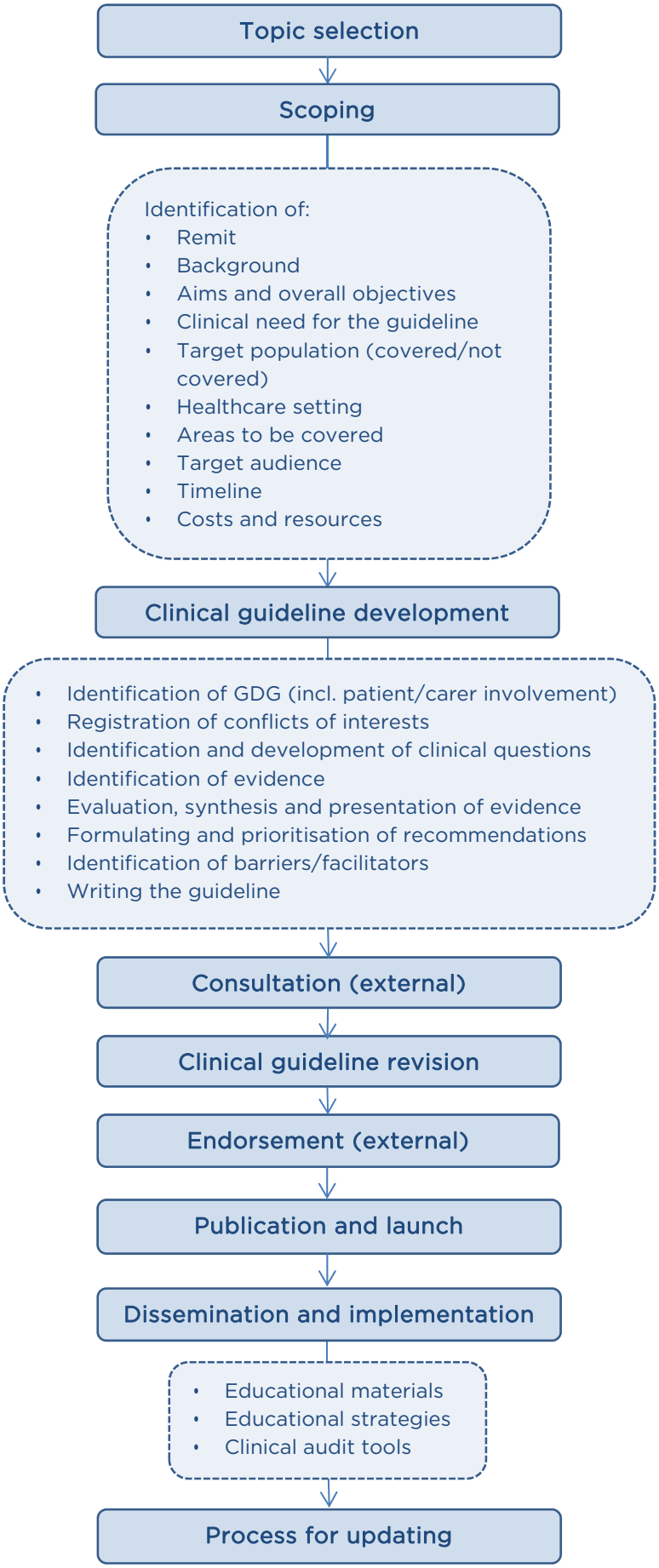


Figure 1. Different stages of clinical guideline development

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 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 professional bodies and other organisations, the body/ies concerned (such as the RCPCH) must be approached from the outset to understand the process and time involved. **This should be built into the timeline.**

3.4. 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*® Voice Network for Children, Young People, Parents, Carers 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 money 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 Clinical Standards team will administer a consultation among RCPCH members and appropriate specialty groups.

AGREE II requirements (Appendix 2): 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 (*Domain 1, criterion 1 & 3; Domain 2, criterion 6).*

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 topic. On average, the group will comprise between 10 and 15 representatives[6,23] who would 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[7]:

- 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 group should also seek to include someone with personal experience of receiving care in the area concerned, where appropriate.

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 activity and establish timescale, costs and 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 trainees to undertake and learn about systematic reviews, given sufficient support and adequate training. Specific tasks that they may undertake include searching medical databases for evidence, critically appraising research articles and developing evidence statements. GDG members are encouraged to engage trainees in this process at the outset.

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

AGREE II requirements (Appendix 2): The full guideline should clearly document the name, discipline, institution, geographical location and role of each development group member (Domain 2, criterion 4).

3.5.1. Children and young people/parent and carer involvement

It is also 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]. Depending on the topic, it may be appropriate to involve more than one child or young person/carer representative; as this would also provide more support for representatives[26].

The College is also able to support GDGs through recruiting appropriate children and young people and families through its & *Us*® network (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 and 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
- reviewing the draft scope or final draft of a clinical guideline[24]

For example, the RCPCH clinical guideline, 'Evidence Based Guideline for the Management of CFS/ME (Chronic Fatigue Syndrome/Myalgic Encephalopathy) in Children and Young People'[27], involved the young person support group AYME (Association of Young people with ME) and a parent of a child with this condition in the GDG. The parent was also involved in commenting on the literature search and developing a patient information leaflet.

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 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 and carers and other group members.

3.5.2. Considerations for children and young people involvement

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 important to include meaningful involvement of children and young people in the process document and project plan, identifying resources, support and allowing adequate time in the process.

AGREE II requirements (Appendix 2): The full guideline/supporting methodology document should document the process used to seek the views and preferences of the target population (*Domain 2, criterion 5)*.

3.5.3. Conflicts of interest

Conflicts of interests may influence the recommendations and evaluation of evidence by group members[28]. 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.
- 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 member 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 of a decision from the GDG chair and hosted 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 conflicts of interest discussions and any consequent decisions to exclude a member from all or part of the development process must also be included in the clinical guideline document.

3.5.4. GDG Chair

The GDG chair must:

- be free of any conflicts of interest
- ask all members to declare any conflicts of interest, ensuring a policy exists and is enforced to manage any conflicts of interest that might exist

3.5.5. 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)

AGREE II requirements (Appendix 2): Competing interests of guideline development group members should be recorded and addressed (Domain 6, criterion 23).

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 review. The clinical questions must be focused and limited 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 population concerned, intervention under investigation, comparison used and outcome measures (PICO) such as:

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

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 the NICE guideline development methods manual[6].

AGREE II requirements (Appendix 2): The full guideline/supporting methodology document should specifically describe the health questions covered by the guideline and criteria for selecting the evidence (Domain 1, criterion 2; Domain 3, criterion 8).

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 or standard requires a systematic literature review using explicit search strategies and pre-defined inclusion/exclusion criteria to identify the evidence[29,30]. 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. 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[31].

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 for detailed example.

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

Topic area	Appropriate Study type
Therapeutics	Randomised controlled trials, meta-analyses and systematic reviews of randomised controlled trials where available
Diagnosis	Independent comparison with a reference standard
Prognosis	Cohort studies

The search strategies including search terms, details of the databases searched, and time period covered 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.

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)[32].

The resulting references must be 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 discussion amongst the GDG members and the technical team.

AGREE II requirements (Appendix 2): 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 (Domain 3, criterion 7).

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)[33] 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, cross sectional studies, cohort studies, case controls or case series). The evidence levels can be graded up or down depending on the quality of the study. Levels are graded down depending on quality factors such as imprecision, indirectness; because of inconsistency between studies, or because the absolute effect size is very

small; or graded down depending on effect sizes (i.e. when the study report large and very large size effects)[33]. 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 RCPCH suggested the use of SIGN methodology to assess levels of evidence. Since 2013, SIGN no longer recommend the traditional 'ABCD' grading system and advocates for GRADE instead. For an explanation of their rationale refer to http://www.sign.ac.uk/pdf/SIGN_grading.pdf.

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.gradeworkinggroup.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 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 included can be 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 http://tech.cochrane.org/gradepro 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.

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

AGREE II requirements (Appendix 2): The final guideline should clearly describe the strengths and limitations of the body of evidence (Domain 3, criterion 9).

3.9. Incorporating economic evaluation

There is no single widely used method of successfully incorporating economic evaluations into a clinical guideline. The rationale for trying to do so is that healthcare interventions are not free and so assessing the cost-effectiveness of an intervention 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[34].

The need for such an approach should however 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.

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.

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 as well as considering economic and resource factors. 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 which documents the value placed on outcomes, benefits versus harms, resource use, overall quality as well as other considerations taken into account 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.

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 strength of a single recommendation should be highlighted through the use of the wording in the recommendation (i.e. the approach adopted by NICE) and supplemented through the use of symbols or letters alongside the wording (i.e. the approach taken by GRADE).

The concept of strength of recommendation is important to understand because although it takes into account the quality of evidence, it is conceptually different[6]. There are often conflicts between the evidence and the clinical importance of the findings[29] and so 'strong evidence does not always produce a strong recommendation'[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 less strong (this could be the case where the quality of the evidence itself is very strong which demonstrates why the strength of evidence and recommendation are not identical).

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 should 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 however 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[6]. These should be concise, unambiguous, and easy to translate into practice[35]. Each recommendation (or sub-heading within

it) should also contain one action and detail the implementer, the population affected, setting, action and timeframe.

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.
- 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, 'must' or 'must not' should be used along with a clear reference to the supporting evidence.

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

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 recommendation or recommending an intervention in the context of research only[6].

There are several formal methods that can be used to gain expert consensus and each has its own merits[36]. In the Delphi method each member of a panel of stakeholders scores their level of agreement with a draft recommendation or good practice point. These responses are combined and fed back to participants. Consensus is defined according to a pre-determined level of agreement. This process is done anonymously by email or by post, usually over at least two rounds, in such a way that individuals cannot unduly influence the outcome. Other methods of formal consensus include the nominal group technique and consensus development conference[37].

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

Developing consensus documents

Consensus documents may still be of value in the absence of high quality evidence. The RCPCH Clinical Standards 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.

AGREE II requirements (Appendix 2): 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 (Domain 3, criterion 12). Recommendations should be specific and unambiguous (Domain 4, criterion 15). The health benefits, side effects, and risks have been considered in formulating the recommendations (Domain 3, criterion 11).

3.10.3. 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 (implementing NICE guidance).

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.

AGREE II requirements (Appendix 2): The guideline should present the facilitators and barriers to its application (Domain 5, criterion 18), information about the potential resource implications of applying the recommendations have been considered (Domain 5, Criterion 20).

3.11. Writing the guideline

High quality clinical guidelines are usually 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 and including search strategies, conflicts of interest and all other issues that may affect the findings and the recommendations. Another usual publication, usually presented in a short format is a lay version which is aimed at parents and carers, children and young people. In any case, the

recommendations should be concise, unambiguous and easy to translate into practice by the intended audience[6].

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 guidelines 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 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 and recorded and any declared
- consideration of potential organisational barriers, potential costs and resource implications in applying the 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 and young people/parents and carers to understand the recommendations and support the doctor patient relationship.

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.

AGREE II requirements (Appendix 2): 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 (Domain 3, criterion 13). 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.

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. **The RCPCH must be notified at the outset by the developer if endorsement is sought.**

The RCPCH also recommends that developers developing their own clinical guidelines consider applying to the NICE Accreditation Scheme for accreditation of their process for developing clinical guidelines to help increase the volume and quality of paediatric content within the NICE library. This 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.

Further details about the process can be found here http://www.nice.org.uk/about/what-we-do/accreditation and http://www.nice.org.uk/about/what-we-do/accreditation/accreditation-process

3.14. Presentation: finalising and publishing the guideline

How a clinical guideline is presented is an important factor in whether it is used in practice (see Chapter 4). Clinical guidelines and standards should be easy to follow. 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, and as a shorter guideline and as a quick reference guide with accompanying algorithms (see www.nice.org.uk).

3.15. Launching and promoting the guideline

It is important to consider strategies to promote awareness of the clinical guideline at its development stage to maximise implementation. The consideration about how the clinical guidelines are going got be presented is also crucial. For example, 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. 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[6]. If you are producing a RCPCH guideline, you should seek early advice from the RCPCH Publications, Marketing and Media & Public Affairs teams about publishing and promotion. If your clinical guideline is endorsed by the College, it will be promoted via the RCPCH website.

3.16. Updating existing guidance: process for update and review

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[23].

It is good practice to update clinical guidelines at least every three years, and sooner when there is new evidence that is likely to influence the recommendations. The date for review will depend

on the pace at which the topic area is evolving[41]. 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[42].
A scoping search for the literature should be undertaken using the original questions and a report prepared summarising the potential impact on the recommendations. This should be combined with a consultation with key stakeholders to inform the decision to update in full or partially[6].

Clinical guideline developers are referred to the process manuals produced by NICE[6] and SIGN[7] which provide greater detail on the methodology for updating clinical guidelines.

AGREE II requirements (Appendix 2): The full guideline should include a clear statement about the date and procedure for updating the guideline (Domain 3, criterion 14). on the guidance producer's website or in the Appendix of the guidance.

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, 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].

The RCPCH and partners, funded by the Healthcare Quality Improvement Partnership (www.hqip.org.uk), have developed a free training resource to support paediatric trainees and other healthcare professionals to undertake high quality clinical audit
http://www.rcpch.ac.uk/training-examinations/education/clinical-audit-e-learning

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[44]. The implementation process is a continuous process and requires ongoing evaluation.

5. Ensuring high quality guidelines: The RCPCH Appraisal and Endorsement process

The RCPCH Quality Improvement Committee (formerly Clinical Standards 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 Clinical Standards team reviews those 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 (which is similar criteria used by NICE to award the NICE Accreditation Mark to the process used to develop clinical guidelines). Although the criteria applied by 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 automatically 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 Governance team at governance@rcpch.ac.uk**).** This is to formally register the College as a stakeholder and help identify adequate paediatric involvement via the nomination of a RCPCH representative to be involved in the development of the clinical 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 clinical guideline development process. Registration at outset also facilitates gaining RCPCH endorsement as the key methodological criteria requirements can be communicated before the development is started.

The developer will be asked to complete a proposal form stating the aims of the clinical guideline (visit the College webpage at http://www.rcpch.ac.uk/develop-guideline for a copy of the form). The proposal will be discussed at the Quality Improvement Committee meeting and if approved,

the Clinical Standards Team will liaise with the developers to identify/register adequate paediatric representation 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 http://www.rcpch.ac.uk/develop-guideline.

5.1.2. Appraisal Standards Criteria

The RCPCH has five standards criteria for endorsement of products that set standards for clinical practice; these are described in detail in Table 3. Standards criteria 1 and 2 must 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.

Standard Criteria	
1	The clinical guideline has been developed with College (Clinical Standards) involvement from the outset
2	The clinical guideline has been developed with adequate paediatric involvement from the outset
3	The clinical guideline has been developed following formal methodology and appropriate development stages (the key criteria of the AGREE II tool have been met)
4	The wording of the recommendations is a fair reflection of the evidence
5	The clinical guideline adequately addresses comments made during consultation

Standard Criteria 1: RCPCH Clinical Standards involvement from the outset

When an apparently suitable national clinical guideline is identified or received, it is first assessed to determine whether there has been College (Clinical Standards) involvement from the outset. As a general principle, lack of Clinical Standards team involvement from the outset will preclude College endorsement. Register your intention by sending completed form to clinical.standards@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 3.2). 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 helps ensure ownership and 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 criteria of the 'AGREE II' (Appraisal of Guideline for Research and Evaluation in Europe instrument: http://www.agreetrust.org/). This tool assesses methodological rigour and transparency in which a clinical guideline is developed (visit the College webpage at http://www.rcpch.ac.uk/develop-guideline for an assessment form). Where appropriate, the results of the AGREE II appraisal are reported back to the clinical guideline developers.

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 is 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 Clinical Standards Team and a decision made as to whether the standard 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 lead for Evidence-base Medicine and Appraisals and the Clinical Standards Appraisals and Endorsement lead. The Committee lead for Evidence-base Medicine and Appraisals and Committee Chair will make the final decision. 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 not to endorse a clinical guideline, a summary of the reasons for not endorsing the clinical guideline will be communicated to the developer and, if appropriate, advised as to how to ensure the College's standards are met.

Table 4. Appraisal outcomes (adapted from McIntosh and Baumer[49]).

Nomenclature	Characteristics	College policy
Endorsed	All Standards met	Endorsed through the recommendation of the RCPCH Quality Improvement Committee and RCPCH Endorsement logo provided
	The composition of the clinical guideline panel and its processes are appropriate for the topic	A summary is posted on the RCPCH clinical guidelines and standards web page together with a link to the original guideline (www.rcpch.ac.uk/guidelines),
	There is a robust and well documented process for the identification and synthesis of the evidence	A summary is circulated via the College e-bulletin
	The clinical guideline construction includes a transparent link between the questions asked, the supporting evidence, and the derivation of the recommendations	The topic may be showcased at the RCPCH Annual conference
	Externally reviewed and College member comments adequately addressed	
Not endorsed	Absence of characteristics above	Feedback to the developer that the document cannot be endorsed. Offer College advice to amend the document to meet the College's standards
	May be based on the views of a group of eminent individuals and/or lacking clarity about the evidence base used for its production	

If the product is endorsed by the RCPCH Quality Improvement Committee, the College Endorsement logo is provided (see Figure 2 for a sample).

Figure 2. Sample of the RCPCH's endorsement logo

5.1.4. Dissemination

If endorsed, the product is widely disseminated to the College membership via the RCPCH website (www.rcpch.ac.uk/guidelines) and RCPCH e-bulletin. In addition a small number of endorsed clinical guidelines are selected for launch and/or dissemination at the RCPCH Annual Conference and developers are invited to present the key messages of the clinical guideline.

5.2. Endorsement of consensus documents

As well as evidence-based clinical guidelines, the RCPCH is often asked to endorse practice statements or consensus on behalf of the College. **Practice statements are no longer supported or promoted by the College.** 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 of the views of all appropriate stakeholders including parent/patient groups
- a specific methodology (e.g. Delphi), prevents the more vociferous or articulate or 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
3. Introduction (including target audience and to whom the guidance applies)
    - aims and objectives
4. Methodology
    - development group
    - clinical questions
    - evidence review (include details of the critical appraisal process)
    - formulating recommendations
    - external review
    - update
    - editorial independence
5. Implementation
    - resource implications
    - implementation advice

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 4: Conflict of interests

Appendix 2: AGREE II Criteria

For further information, see: http://www.agreetrust.org/

DOMAIN 1. SCOPE AND PURPOSE

1. The overall objective(s) of the guideline is (are) specifically described.
2. The health question(s) covered by the guideline is (are) specifically described.
3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

DOMAIN 2. STAKEHOLDER INVOLVEMENT

4. The GDG includes individuals from all relevant professional groups.
5. The views and preferences of the target population (patients, public, etc.) have been sought.
6. The target users of the guideline are clearly defined.

DOMAIN 3. RIGOUR OF DEVELOPMENT

7. Systematic methods were used to search for evidence.
8. The criteria for selecting the evidence are clearly described.
9. The strengths and limitations of the body of evidence are clearly described.
10. The methods for formulating the recommendations are clearly described.
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.
12. There is an explicit link between the recommendations and the supporting evidence.
13. The guideline has been externally reviewed by experts prior to its publication.
14. A procedure for updating the guideline is provided.

DOMAIN 4. CLARITY OF PRESENTATION

15. The recommendations are specific and unambiguous.
16. The different options for management of the condition or health issue are clearly presented.
17. Key recommendations are easily identifiable.

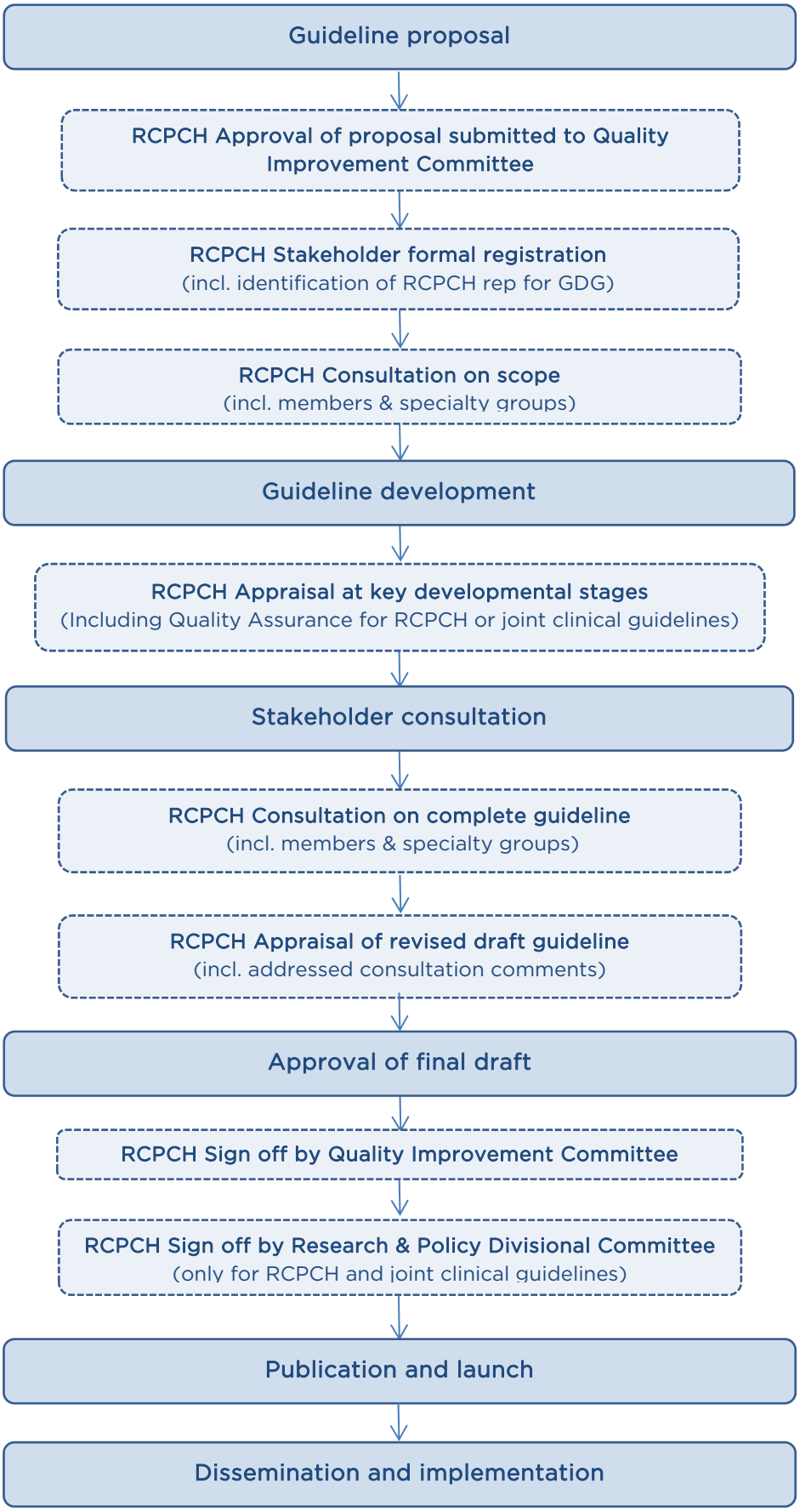
DOMAIN 5. APPLICABILITY

18. The guideline describes facilitators and barriers to its application.
19. The guideline provides advice and/or tools on how the recommendations can be put into practice.
20. The potential resource implications of applying the recommendations have been considered.
21. The guideline presents monitoring and/or auditing criteria.

DOMAIN 6. EDITORIAL INDEPENDENCE

22. The views of the funding body have not influenced the content of the guideline.
23. Competing interests of guide.

Appendix 3: RCPCH approval process for clinical guidelines



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.

Critical Appraisal Skills Programme Critical Appraisal Checklists on a range of study designs	http://www.casp-uk.net/
Development and validation of an international appraisal instrument for assessing the quality of clinical practice guidelines: the AGREE project International interest in clinical practice guidelines has never been greater but many published guidelines do not meet the basic quality requirements. This publication aims to develop and validate an international instrument for assessing the quality of the process and reporting of clinical practice guideline development.	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1743672/
E-learning Training Resource for trainees Free resource developed by RCPCH to support all healthcare professionals working in Clinical Audit	http://www.rcpch.ac.uk/training-examinations/education/clinical-audit-e-learning
Levels of Evidence from Oxford Centre for Evidence based medicine (OCEBM) Levels of evidence and grading of recommendations to assess quality of studies a whole.	http://www.cebm.net/explanation-2011-ocebm-levels-evidence/
GRADE (Grading of Recommendations Assessment, Development and Evaluation) A grading scheme for grading quality of evidence and strength of recommendations	http://www.gradeworkinggroup.org
Healthcare Quality Improvement Partnership Established in April 2008 to promote quality in healthcare. Includes guidance, support, and templates.	www.hqip.org.uk
How to Spread Good Ideas: A systematic review of the literature on diffusion, dissemination and sustainability of innovations in health service delivery and organisation[50] Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R&D (NCCSDO). Describes a systematic review on the spread and sustainability of innovations in health service delivery and organisation.	http://www.netscc.ac.uk/hsdr/files/project/SDO_FR_08-1201-038_V01.pdf

National Institute for Health and Care Excellence (NICE) National guidelines, audit and implementation support and guidance for developing guidelines.	www.nice.org.uk
Patient and public involvement (PPI) in research groups: Guidance for Chairs Guidance on how to involve lay representatives in research. The principles can be applied to guideline groups.	http://www.ncri.org.uk/grantsmanship/includes/content/writing/PPI_Guidance_for_Chairs.pdf
Scottish Intercollegiate Guidelines Network (SIGN) Develops guidelines for Scotland.	www.sign.ac.uk
Applying the GRADE methodology to SIGN guidelines: core principles	http://www.sign.ac.uk/pdf/gradeprincipals.pdf
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

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