

Developing a Green-top Guideline Guidance for developers

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1. Introduction

The Royal College of Obstetricians and Gynaecologists (RCOG) produces Green-top Guidelines (GTGs) principally to support their membership to deliver high quality care for women and people using obstetrics and gynaecology services and their families. Although GTGs are developed with the UK NHS in mind, the guidelines are used globally.

GTGs comprise evidence-based recommendations that assist clinicians and individuals in making decisions about appropriate tests or treatment for specific conditions or circumstances. The recommendations are not intended to dictate an exclusive course of care or treatment. They must be evaluated with reference to each individual's needs, as well as resources and limitations unique to the institution, and variations in local populations. It is hoped that this process of local ownership will help to incorporate these guidelines into routine practice.

In addition to GTGs, the College produces Scientific Impact Papers (SIPs), Consent Advice (CA) and Good Practice Papers (GPPs), as well as Patient Information. More information on these can be found on the RCOG website.¹

This document aims to be a comprehensive outline of the process for developing a GTG but cannot cover every issue that may be encountered. Any circumstance not covered in this guide should be highlighted to the RCOG Clinical Quality team via clinicaleffectiveness@rcog.org.uk.

<u>Figure 1</u> is an overview of the guideline development process, which is estimated to take 36 months from beginning to end; however, the RCOG Guidance team is working on reducing this timeframe.

1.1 Governance

The RCOG Guidelines Committee (GC) is responsible for overseeing the development of GTGs.

The committee is supported by RCOG staff, with quality assurance provided by the Clinical Quality Assurance Group (CQAG).

The RCOG Guidelines Committee is accountable to the Clinical Quality Board (CQB) of the RCOG.

The membership of the GC includes:

- clinicians, both generalists and specialists in obstetrics and gynaecology
- two patient/lay representatives (appointed via the RCOG Women's Network)
- National Institute of Health and Care Excellence (NICE) representative to ensure GTGs are aligned with NICE guidance
- Vice President, Clinical Quality
- RCOG staff, including Director of Clinical Quality and members of the Guidance team.

All members of the RCOG GC are expected to fulfil the Terms of Reference for the Committee, which include managing the development, update and publication of GTGs as determined by the GC and CQAG.

Furthermore, specific role descriptions describing the responsibilities of the clinical members and lay representatives of the GC are available and should be referred to during a member's term.

When they arise, vacancies on the Committee are advertised on the RCOG website and in a Membership email to Members and Fellows, allowing the entire membership to apply in a fair and open process.

As part of the applications process, applicants will be asked to assess a guideline draft and submit comments. Their response is assessed by the GC co-Chairs and RCOG staff who select candidates, who are then approved by the RCOG Council. Committee terms are three years and commence in June of each year.

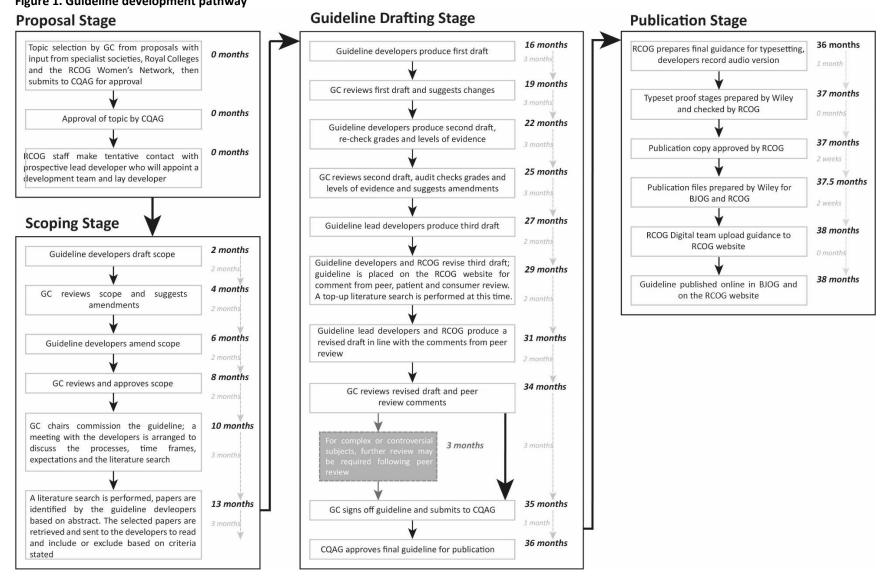
The GC has two co-Chairs who oversee the work of the Committee. The role of co-Chair has a term of three years which is in addition to any time already served as a GC member. Those interested in the role of GC co-Chair must first apply for the role of shadow Chair, which allows incoming co-Chairs to shadow the existing co-Chairs and familiarise themselves with the role.

Shadow chairs have a term of one year, after which they are expected to take over as co-Chairs. Applicants for the role of shadow Chair do not have to be current members of the Committee.

Shadow Chair applications are reviewed by the existing GC co-Chairs, the Director of Clinical Quality, the Vice President and members of the Guidance team. Shortlisted candidates are ratified at the RCOG Council.

2. Green-top Guideline development

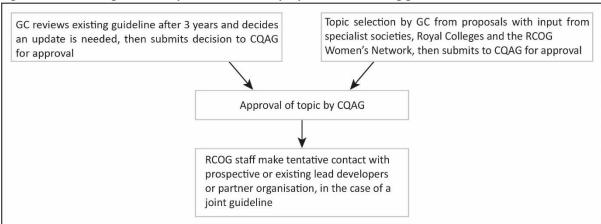
Figure 1. Guideline development pathway



2.1 Green-top Guideline topic selection

Guideline topics are either selected from proposals for new guidelines or are updates to existing guidelines (Figure 2).

Figure 2. Process of guideline topic selection from proposals and existing guidelines



Topics for new guidelines can be proposed by anyone. The proposal form is available on the RCOG website and once completed, should be submitted to <u>clinicaleffectiveness@rcog.org.uk</u>.

2.1.1 Proposing a new guideline

Proposals for new guidelines are initially considered by the Guidelines Committee, with GC decisions being reviewed by CQAG.

Both groups consider the clinical need for the guideline and potential for duplication with guidance produced by organisations such as NICE or RCOG Specialist Societies.

Once a new guideline topic has been approved by the GC and CQAG, the guideline lead developers will be agreed and a scope requested. Topics are expected to focus on the speciality specific part of the care pathway/clinical area and have a narrower remit than NICE clinical guidelines; it may become necessary for some guideline topics to be divided (or in some circumstances combined) at the scoping phase to ensure advice is coherent.

The GC and CQAG may consider some topics are better suited for NICE guidelines, in which case they should be submitted to NICE via the topic selection process.

2.1.2 Update of existing guideline

Once published, GTGs are valid for three years.

At the three-year point, the GC considers need and priority for an update, specifically the extent to which recommendations may need to be updated due to new research being published.

The GC may consult with the developers of the previously published edition to reach a decision on the need for an update.

Guidelines can be archived (<u>see section 7</u>), revised or have their revision date extended by one to two years if GC believes they remain valid. Guidelines may have their revision date extended multiple times as long as they remain valid.

If the revision date is extended, the webpage on the RCOG website will be updated to indicate how long the revision date has been extended.

The content development process for updating GTGs is the same as for developing a new guideline.

2.1.3 Joint guidelines

For new guidelines, the proposal may suggest the guideline is produced jointly by the RCOG and another organisation.

To support such partnerships, the Guidance team have developed several collaborative models outlined in <u>Figure 3</u>, which also describe the ways of working underlying each one.

If a joint guideline is produced:

- The development will be led by the RCOG, according to the methodology outlined in this guide.
- The guideline will be published in BJOG, though will be co-badged and the contributing organisation acknowledged.
- The responsibility to determine if an update is needed lies with the RCOG.

2.1.4 Endorsement

The RCOG may be approached to endorse a guideline published by another organisation, for example one of the RCOG Specialist Societies. More information on this is available on the RCOG website.²

The RCOG may also seek endorsement from other organisations or Specialist Societies for their guidelines. These products will be developed in the RCOG format and style, with the endorsing organisation or Specialist Society consulted as required.

Figure 3. GTG collaboration options

Stakeholder

RCOG format used

Specialist Society

can propose new

Consulted during

Share work plan

peer-review

topics

Endorsed by RCOG

- · Not an RCOG format
- Developed solely by Specialist Society
- RCOG consulted at 3 stages
- Endorsement process/ criteria, incl. CQAG sign-off and Council approval
- RCOG badged (time limited)

Endorsed by Specialist Society

- RCOG format used
- · Developed solely by RCOG
- Specialist Society consulted as required
- Specialist Society badged

Joint Guideline

- · RCOG format used
- Led by RCOG
- Developers appointed by both organisations
- Specialist Society acknowledged and badged
- Specialist Society contacted when guideline is reviewed/updated

Collaboration

2.2 Selection of guideline lead developers

2.2.1 New guideline

The guideline lead developer(s) is either self-nominated via the RCOG topic proposal form or proposed by members of the GC. Developers should have appropriate methodological expertise in guideline development and credibility with stakeholders within the topic area.

A role description for lead developer(s) has been developed to ensure their role and responsibility within the development team is clear. The appointment of the lead developer(s) must be approved by the GC.

Additional developers may be proposed by the guideline lead and will also require approval by the GC. If the person proposing the topic is not best placed or declines to be the lead developer, or the GC does not identify a suitable lead developer, the role is advertised on the RCOG website. Additional developers can also be recruited by advertising on the RCOG website if needed. A role description for co-developers has been developed to ensure their role and responsibility within the development team is clear.

The lead developer is the main point of contact for the RCOG Guidance team and will oversee the development of the content and production of the guideline within the expected time frame, liaising with their co-developers as required.

All developers should complete a declaration of interest form both at the beginning and end of the development process; please see <u>section 2.5</u> for details.

2.2.2 Update of existing guideline

In the case of an update, the previous guideline lead developer is approached to undertake the update.

If they decline, are unable to update the existing guideline, or if other individuals are thought to be better placed to lead the guideline by the GC or partnering organisation (in the case of joint guidance), then new or additional guideline lead developers will be sought.

As with new guidelines, the role of lead developer can be advertised on the RCOG website; additional developers can also be recruited this way.

In instances where a guideline is not developing at a reasonable pace, both for new guidelines and updates, the GC may permit new developers to be sought.

For new and revised guidelines, agreement will be sought on the proposed order of developers in the published document, which should reflect each individual's contribution to the guideline process.

Developers should make sure that all those listed as developers meet the criteria for authorship set out by the International Committee for Medical Journal Editors (ICMJE).³

2.2.3 Partial updates of existing guideline

In cases where new evidence requires only specific sections of a guideline to be updated, a partial update of the guideline can be undertaken.

Appointing developers for partial updates follows the same process as full updates.

It is expected the timeline to complete a partial update will be reduced (compared to development of a new guideline or full update); however, this will be determined by the extent of the update as well as other considerations such as resourcing the literature review.

When published, the landing page on the RCOG website, as well as the document published in BJOG will indicate to the reader which sections have been updated.

2.3 Support for guideline lead developers

Guideline developers are supported by RCOG Guidance team, the GC and other RCOG colleagues. This includes RCOG library staff who undertake the primary literature search and retrieve relevant papers.

Individual guidelines are assigned to two specific members of the GC who will act as Committee Lead Reviewers. The GC-nominated Lead Reviewers will lead on discussions regarding the clinical questions, the supporting evidence and the recommendations.

The guideline Lead Developers are encouraged to consult with the GC Lead Reviewers, GC co-Chairs and the Guidance team to resolve any queries or issues that come up during the development process.

2.4 Funding for guideline development

All those involved in the development of GTGs, including the GC, GC co-Chairs, guideline developers and peer reviewers are unpaid volunteers and receive no direct funding for their work in producing the guideline.

The exception to this are the RCOG staff involved who are salaried employees of the College.

GC members receive reimbursement for expenses for attending GC meetings.

2.5 Conflicts of interest

All those involved in the development of GTGs must complete an RCOG declaration of interest and good standing form. Table 1 details how declarations of interest are recorded.

Table 1. Recording of declarations of interest

GTG developers	- Complete RCOG form when GTG is		
	commissioned		
	- Complete ICMJE form at end of process		
GC committee*	- Complete form at beginning of term		
	- Renew annually when new members join		
Peer reviewers and other external reviewers	- Complete digital version of RCOG form**		

^{*}Includes GC co-Chair. **Currently part of peer review form on dotdigital platform. ICMJE: International Committee of Medical Journal Editors.

The RCOG declaration of interest and good standing form captures declarations of interest relating to:

- any office held in professional bodies, Specialist Societies, medical Royal Colleges, charities, voluntary and private sector organisations
- consultancies, directorships or advisory positions
- public appointments, research positions, contracts and secondments
- any other professional, personal or non-personal interest, either financial or non-financial.

Details of the declarations interest recorded in the ICMJE form, as well as the form itself, are available on the ICMJE website.⁵

It is the responsibility of the developers to return the completed declaration of interest and good standing forms to the RCOG Guidance team. Those involved in the development of the guideline should have no conflicts of interest. Any conflicts of interest declared are reviewed by the GC; if a second opinion is required this is obtained from the CQAG. All conflicts of interest, including those of the GC co-Chairs, are reviewed and managed at the GC meetings to ensure an unbiased and transparent development process.

The developers' conflicts of interest are listed at the end of the published guideline; other conflicts of interest (GC, GC co-Chairs, peer reviewers and other reviewers) will be published alongside the guideline as supporting information.

2.6 Stakeholder involvement

It is anticipated the GC will work closely with a wide range of stakeholder groups including the RCOG membership, relevant Specialist Societies, other Royal Colleges, NICE, the RCOG Women's Network and other stakeholders in the production of RCOG guidelines.

Involvement can take many different forms, which are explored in Figure 3.

2.7 Patient and public engagement

There are representatives of the RCOG Women's Network on the GC, as well as CQAG and CQB.

The guideline will be peer reviewed by patients, the RCOG Women's Network and other relevant stakeholder organisations.

2.8 Patient information

The GC, in consultation with the RCOG Patient Information Committee (PIC), will identify whether patient information is required at the start of the guideline development process. If it is, the PIC will commission and develop the accompanying Patient Information Leaflet (PIL) and any other patient resources.

3. Preparing the work plan

3.1 New guideline

The GTG development pathway outlines the stages of the work plan for a GTG.

As shown (Figure 1), following approval of the topic and guideline leads, the developers produce a scope to be circulated to the GC for review. The scope should include the overall objective of the guideline, as well as specify the clinical and non-clinical questions to be addressed.

The scope is revised in line with GC's comments and then signed off either by the Lead Review or committee (depending on the significance of the changes required).

At this stage the guideline has been commissioned and a work plan can be produced for the remaining stages of the development pathway including submission of first draft.

3.2 Revision of existing guideline

Developers of existing guidelines are not be expected to start a revision unless requested by the GC.

The process of updating a guideline follows the same methodology as newly-commissioned GTGs.

A new scope will be required for a GTG being updated because the update is an opportunity to add to and/or revise the clinical questions. Feedback on the guideline from key stakeholders such as Specialist Societies, patient organisations and the RCOG Women's Network should be considered as part of this process.

Developers should refer to the guidance for developing clinical questions in section 4.2 of this guide.

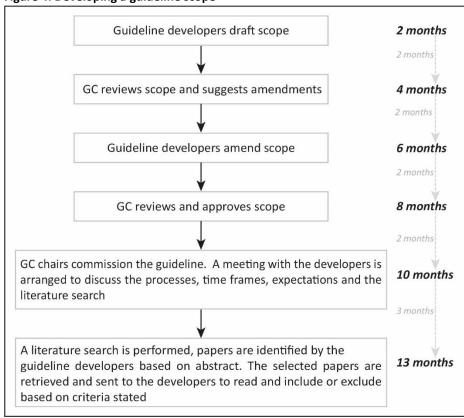
This may well closely reflect the original guideline structure, or it may need to be altered in light of new practice or evidence.

For clinical questions that are re-examined in the update, literature searches will only be performed from the cut-off date of the searches in the previous guideline.

For new clinical questions, searches will cover all literature published on the topic to date.

4. Producing a scope

Figure 4. Developing a guideline scope



4.1 Content of the scope

Following topic selection, developing a scope is the first stage of the guideline development process (Figures 1 and 4). The purpose of the scope is to provide the following.

- Background epidemiology relevant to the condition or disease.
- Clear outline of the aspects of care that the guideline will cover in terms of:
 - o the population to be included or excluded
 - the healthcare setting
 - the interventions and treatments to be included and excluded.
- The clinical questions to be addressed.

Examples scopes can be found within all published GTGs on the RCOG website.

4.2 Formulation of clinical questions

The clinical questions define the areas to be examined within the guideline and provide the framework for the systematic review of the available evidence. It is therefore important all developers within the team are involved in the process of drafting and agreeing the clinical questions.

The exact number of questions within each guideline will depend on the subject area being examined. During the scoping phase it will become apparent whether the number and complexity of the questions proposed are appropriate for a single clinical practice guideline. At this stage the guideline could be split depending on the views of the GC and developer team.

Clinical questions within GTGs will cover a wide range of areas including: identifying women and people at risk of a particular condition or outcome, diagnosis, options for care, and follow-up. Sometimes the questions will include multidisciplinary team composition, service delivery, resources and training. The range and type of questions posed will depend on the scope and the subject area.

The developers should ensure each clinical question is as clear and focussed as possible, for example specifying any subgroups, settings, circumstances or comparators. For example, clinical questions on diagnosis should include outcomes in specific patient groups against a reference standard.

A useful way of posing questions on interventions is to use the patient intervention comparison and outcome (PICO[T]) framework.⁶

- Patient/population: Which patients or populations are we interested in? Are there any subgroups that need to be considered?
- Intervention: Which policy, treatment or procedure should be used?
- Comparison(s): What is/are the main alternative(s) to compare with the intervention?
- Outcome(s): What are the important outcomes for the patient, including risks, benefits and side effects?
- Timeframe (optional)

4.2.5 Inclusion/exclusion criteria

Once the clinical questions have been developed, developers should use the individual facets of each question – both the type of question and the specific population, intervention, comparison and any outcomes specified – to develop inclusion and exclusion criteria they will apply to the retrieved papers. This helps to develop focused literature searches. For example, when looking at issues relating to early pregnancy complications in relation to tubal pregnancy, studies relating to miscarriage might be excluded. Exclusion criteria can apply to populations, interventions, comparisons or outcomes, as well as study designs and publications years, for example giving a cut-off date excluding studies published prior to 2000.

4.3 Approval of the scope

Following submission of the scope to the GC, all comments from the Committee members will be collated, tabulated and triaged.

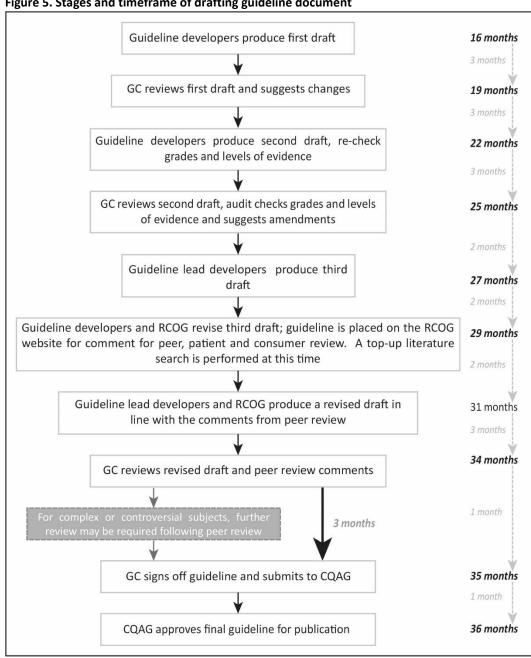
The guideline developer team will be expected to amend the scope in line with these comments and submit a final draft to the RCOG for approval.

Once approved, no changes to the scope should be made without consulting the GC.

The guideline drafts submitted to the GC will be cross-referenced to the final, agreed scope by the RCOG Guidance team.

5. Drafting a Green-top Guideline

Figure 5. Stages and timeframe of drafting guideline document



5.1 Identification of evidence

Identification of evidence for any guideline should have a systematic and structured approach to achieve a comprehensive search, which should aim to be as precise as possible without compromising sensitivity.

To maximise the quality and sensitivity of searches, RCOG staff can perform the searches for the full guideline. Alternatively, if the literature search is carried out by the guideline leads, the search strategy must be sent to RCOG in a proforma provided for this purpose (Appendix 1).

RCOG staff will liaise with the guideline lead developers to develop the search terms and scope accordingly, using the clinical questions and any key published papers for reference.

The dates on which databases are searched are recorded in the literature search proforma which will be published as supporting information with the guideline.

5.1.1 Searching for other guidelines

During the scoping phase of the guideline development, both pre-existing guidelines and systematic reviews should be identified by the guideline developers; additionally, a search of published protocols on the Cochrane Library should also be carried out.

To avoid duplication of effort, the first step is to search for relevant guidelines that might be adapted or updated to provide answers to (some of) the questions formulated. However, only guidelines that use a well-recognised high-quality and transparent methodology should be considered. Guidelines should be reviewed by the guideline developers using the Appraisal of Guidelines for Research and Evaluation in Europe (AGREE II) criteria.⁸

5.1.2 Searching for systematic reviews

Following the search for other guidelines, a search for existing systematic reviews will be performed. This will include a search of the Cochrane Library (including searches of the Cochrane Database of Systematic Reviews and the Database of Abstracts of Reviews of Effects (DARE) and Technology Assessments), as well as detailed searches of the biomedical databases for systematic reviews published in peer-reviewed journals. When searching the Cochrane library, this will include a review of published protocols as well.

5.1.3 Searching for RCTs and observational studies

A wide range of biomedical databases will be searched. These will include MEDLINE and Embase. The main Medical Subject Headings (MeSH) terms and keywords used and the databases searched are stated in the published guideline; the full details of these searches are published online as supporting information. The volume of literature retrieved and details of numbers of rejections and inclusions are also documented by the guideline developers. Once lists of abstracts have been retrieved, the guideline developers will screen these lists before the selected full text articles are reviewed and assessed for suitability.

5.1.4 Unpublished literature

Unpublished literature will not be routinely included in the literature search. Grey literature, such as conference proceedings, will only be included when sufficient information is available to appraise its quality.

5.1.5 Document retrieval

The RCOG provides a document retrieval service and will provide full-text copies of requested articles to the guideline developers following the literature search.

The RCOG requests that developers maintain and submit records on the criteria used for selecting documents for review, as well as lists of included and excluded papers.

5.2 Reviewing and grading of evidence

For the development of GTGs, the RCOG uses the SIGN methodology of grading evidence that incorporates aspects of study quality and evidence.⁹

The clinical questions developed in the scope specify the patient groups and outcomes, which should include risks, benefits and side effects as appropriate. When assessing the available evidence, the study type needed to address the question must be considered. For many therapies, RCTs or systematic reviews of RCTs will be sought in the first instance. However, in some instances RCTs may not be available or feasible; where these are not available other study designs should be considered.

Once the evidence has been collated for each clinical question it will need to be appraised and reviewed. For each question, the study type with least chance of bias should be used. If available, RCTs of suitable size and quality should be used, in preference to observational data. But this may vary depending on the outcome being examined.

The methods used to appraise individual study types are not detailed here, but guides are available from the SIGN website.¹⁰ An objective appraisal of study quality is essential, but paired reviewing by guideline leads may be impractical because of resource constraints.

Once evidence has been collated and appraised, it can be graded. A judgement on the quality of the evidence will be necessary using the grading system (Appendix 2).

Any studies with a high chance of bias (either 1– or 2–), including systematic reviews of poor-quality studies, should be downgraded and the reason for this stated within the guideline.

The role of the College is setting standards for women's health and our guidance is evidence-based best practice for patient care. That said, organisational and financial barriers to implementation should be considered by the guideline development group when forming the clinical recommendations, and will be assessed by the GC when reviewing the guideline. The GC is a multidisciplinary group that includes end-users who are aware of potential barriers to implementation, and the recommendations may be altered in line with this specialist advice.

While we do not undertake cost—benefit analyses in our guidance, we do ensure that our recommendations are appropriate for UK practice and, when it is felt that it might be a challenge to implement a particular recommendation, this is highlighted in the guideline.

When formulating recommendations, the guideline developers should consider the evidence around the individual benefit of each recommendation but also keep in mind the risks, benefit and side effects of each clinical scenario.

5.3 Development and grading of practice recommendations

Using the SIGN methodology, the quality of the evidence used and the directness of its application should be incorporated into the formulation and grading of the recommendation.

Examples of recommendations can be found in published GTGs on the RCOG website.

It is expected the recommendations are most commonly agreed using informal consensus and considered judgement of the risks, benefits and side effects of interventions under consideration. If recommendations cannot be reached, decisions can be referred to the GC and GC co-Chairs. Such instances should be documented within the guideline.

For recommendations to influence practice, they need to be specific to populations, settings and/or circumstances and be easy to understand. NICE have produced some useful guidance on the wording of recommendations. Ambiguity in the language used will result in confusion at the implementation phase. Therefore, where possible the recommendations should echo the precision of the original clinical question but recognise where different options are available, which may depend on patient preferences, for example.

5.3.1 Selecting key recommendations

The guideline developers will identify a small set of recommendations to be listed at the beginning of the guideline. These will consist of recommendations the developers have identified to be prioritised for implementation to improve patient outcomes.

5.4 Development of auditable topics

Both NICE¹³ and SIGN¹⁴ have structures for developing audit in view of guideline content. Developers of GTGs are expected to have an understanding of both the need for and the development of tailored audit and review criteria.

Examples of auditable topics can be found in published GTGs on the RCOG website.

5.5 Development of recommendations for future research

During the development of the guidelines, it will become apparent that there are deficiencies within the available research base. Recommendations for future research should be included to inform research agendas.

Examples of research recommendations can be found in published GTGs on the RCOG website.

5.6 Drafting the guideline

As well as developing consistent methodology for GTGs, these documents have a recognisable style, which allows ease of navigation.

GTGs follow a similar structure, which should include sections that cover the following areas:

- Purpose and scope
- Introduction and background epidemiology
- Identification and assessment of evidence
- Clinical questions with a synthesis of the evidence and specific recommendations
- Recommendations for future research
- Auditable topics
- Useful links and support groups
- Key recommendations

Where appropriate, practice algorithms can be included within GTGs. These represent a further distilled version of the recommendations and should aid integration and implementation of the evidence into clinical practice.

Although GTGs should be concise, discussion of evidence pertinent to specific clinical questions is important, specifically how benefits, risks and side effects have been considered as part of the review process and within the formulation of any recommendation. It is also important to outline the circumstance in which different management options exist and how decisions should be made with women and people.

In order to support navigation of the document, summary tables have been developed for key information including a precis of the evidence, grade and recommendations (Figure 6).

Figure 6. Example of a clinical question, recommendation and supporting evidence

Recommendation	Evidence level	Strength	Rationale for the Recommendation
Nomen with PPROM and their partners should be offered additional emotional support during pregnancy and postnatally 2	4 6	GPP	Cohort studies have shown that pos- traumatic stress disorder occurs in a substantial number of women whos pregnancy is complicated by PPROM
5 Prospective cohort studies ha	ve shown tha	t posttraumat	ic stress disorder is more common in
,	ere complicat	ted by PPROM	I compared to uncomplicated controls

1 Clinical question

Structured recommendation

This statement should be directly derived from the clinical question. It should attempt to answer the question and not represent a statement.

Recommendation grade

This must reflect the level of evidence supporting the recommendation, taking into account the issues of quality and directness.

4 Rationale for the recommendation

This statement should outline the reasoning behind the final recommendation and why it was given the direction and strength it was.

Summary of supporting evidence

This should include relevent studies and examine the key population, intervention and outcomes. Discussions of the quality and directness of evidence should be included where relevent. Where possible absolute and relative values should be included.

Evidence level

This will directly reflect the evidence presented. Where outcomes and data are presented from a range of studies, it may be appropriate for evidence from more than one level to be presented.

5.7 Peer review process

Peer review occurs after an initial review of at least two drafts by the GC and aims to be a transparent and robust opportunity for a wide range of stakeholders to review and comment on the draft guideline.

A range of stakeholder organisations and individual peer reviewers are invited to comment. Invited peer reviewers include Specialist Societies, Royal Colleges, clinicians who have published within the subject area, experts who practise in this area and relevant patient/user groups.

The opportunity to comment on guidelines is advertised within regular membership communications.

The draft guideline is also placed on the RCOG website in a prominent position as an open access document. This allows anyone to comment; stakeholder registration is not required.

The peer review process is not anonymous. All those peer reviewing GTGs are asked to declare any interests as part of the peer review proforma; these are published alongside the guideline as supporting information.

Comments received are considered systematically.

All comments are collated by the RCOG and tabulated for consideration by the guideline leads. Each comment requires a response from the developer team. Where comments are rejected, justification will need to be made. Following review of the comments, the guideline is updated and the GC will review the revised draft and the table of comments.

An audit trail of the comments, amendments and various drafts is retained by RCOG staff within the guideline files.

The list of peer reviewers, together with the guideline developers is included in the published guideline.

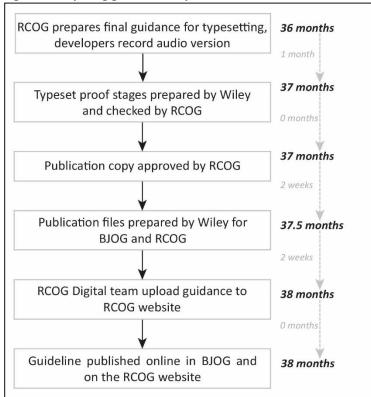
5.8 Approval

Following sign-off of the post peer review draft by the GC, the draft is sent to CQAG for final quality assurance ahead of publication.

Once signed off by CQAG, the Guidance team will prepare the guideline for typesetting and will request that all the guideline developers complete a declaration of interests form, which will be published alongside the guideline.

6. Publishing

Figure 7. Preparing guideline for publication



As of 2016, GTGs are published in electronic format in the British Journal of Obstetrics and Gynaecology (BJOG). This allows the developers names to be indexed on PubMed and citations to be indexed. Guidelines published before 2016 are available in electronic (PDF) format on the RCOG website.

Once approved for publication, the GTG is sent to Wiley for typesetting. The RCOG Guidance team reviews the typeset draft for quality assurance.

Following sign-off of the typeset draft, the guideline is published in BJOG on the Wiley Online Library and the RCOG website (Figure 7).

6.1 Citations

The format for citing guidelines differs, depending on whether a guideline is published in BJOG or on the RCOG website. Examples for each can be found below.

BJOG

Jauniaux ERM, Alfirevic Z, Bhide AG, Burton GJ, Collins SL, Silver R on behalf of the Royal College of Obstetricians and Gynaecologists. Vasa praevia: diagnosis and management. Green-top Guideline No. 27b. BJOG 2018; https://doi.org/10.1111/1471-0528.15307.

RCOG website

Royal College of Obstetricians and Gynaecologists. Female Genital Mutilation and its Management. Green-top Guideline No. 53. London: RCOG; 2015.

7. Archiving

As part of the review process of existing GTGs, the GC can decide to archive a guideline. Reasons for archiving a GTG include:

- another body has developed a guideline that covers the topic of the GTG
- the RCOG has endorsed a guideline developed by another body that covers the topic of the GTG
- the GTG is no longer clinically relevant
- an update of the GTG is published making it necessary to archive the previous version.

The relevant page of the RCOG website will be updated to indicate the date the guideline has been archived and removed from the website.

Users will be redirected to any guidance by other bodies that has replaced the archived GTG.

References

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- 14. Scottish Intercollegiate Guidelines Network.
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 [https://www.sign.ac.uk/using-our-guidelines/implementation-support/]
 Accessed 25 March 2025

Appendix 1. Literature search proforma

[Insert name of Guideline] - search strategy

Literature search carried out by: Previous search carried out in [insert date], so papers added to databases before [insert date] (where identifiable) or published before [insert year] were excluded. End date: National Guideline Clearinghouse (https://www.guideline.gov/) Date: Search terms: MeSH terms: XX included NICE Evidence Search (http://www.evidence.nhs.uk/) Date: Search terms: XX included RCOG website (http://www.rcog.org.uk/) Date: Search terms: XX included Trip (http://www.tripdatabase.com/) Date: Search terms: "cholestasis" [limited to guidance] XX included Guidelines International Network (http://g-i-n.net/) Search terms:

XX included

RCOG library database ([insert name]'s Access database) (R:\01 Managing the College\Information
Services\Library\Reference files)
Date:
Search terms:
XX included
Medline
Date: Database: Ovid MEDLINE(R) <[insert date range]>
Search Strategy: [name saved under]
[insert search strategy]
Medline (unindexed)
Date:
Database: Ovid MEDLINE(R) Epub Ahead of Print <[insert date]>, Ovid MEDLINE(R) In-Process & Other Non-
Indexed Citations <[insert date]>
Search Strategy: [name saved under]
[insert search strategy]
Embase Date:
Database: Embase <[insert date range]>
Search Strategy: [name saved under]
[insert search strategy]
The Cochrane Library Date:
Database: EBM Reviews - Cochrane Central Register of Controlled Trials <[insert date]>, EBM Reviews - Cochrane Database of Systematic Reviews <[insert date range]>, EBM Reviews - Database of Abstracts of Reviews of Effects <[insert date range]>, EBM Reviews - Health Technology Assessment <[insert date range]> Search Strategy: [name saved under]
[insert search strategy]

Appendix 2: Explanation of guidelines and evidence levels

Explanation of guidelines and evidence levels

Clinical guidelines are 'systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions'. Each guideline is systematically developed using a standardised methodology. Exact details of this process can be found in the RCOG handbook Developing a Green-top Guideline: Guidance for developers. These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution and variations in local populations. It is hoped that this process of local ownership will help to in- corporate these guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research may be indicated. The evidence used in this guideline was graded using the scheme below and the recommendations formulated in a similar fashion with a standardised grading scheme.

Classification of evidence levels

- 1++ High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias
- 1+ Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias
- 1– Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias
- 2++ High-quality systematic reviews of case—control or cohort studies or high-quality case—control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal
- 2+ Well-conducted case—control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
- 2— Case—control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal
- 3 Non-analytical studies, e.g. case reports, case series
- 4 Expert opinion

Grades of Recommendation

- At least one meta-analysis, systematic reviews or RCT rated as 1++, and directly applicable to the target population; or a systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results
- A body of evidence including studies rated as 2++ directly applicable to the target population, and demonstrating overall consistency of results; or
 - Extrapolated evidence from studies rated as 1++ or 1+
- A body of evidence including studies rated as 2+ directly applicable to the target population, and demonstrating overall consistency of results; or
- Extrapolated evidence from studies rated as 2++
- Evidence level 3 or 4; or
 Extrapolated evidence from studies rated as 2+

Good Practice Points



Recommended best practice based on the clinical experience of the guideline development group.*

*on the occasion when the guideline development group find there is an important practical point that they wish to emphasise but for which there is not, nor is there likely to be any research evidence. This will typically be where some aspect of treatment is regarded as such sound clinical practice that nobody is likely to question it. These are marked in the guideline, and are indicated by \checkmark . It must be emphasised that these are NOT an alternative to evidence-based recommendations, and should only be used where there is no alternative means of highlighting the issue.