



Royal College of
Obstetricians &
Gynaecologists

Developing a Green-top Guideline

Guidance for developers

March 2020

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1. Introduction

The Royal College of Obstetricians and Gynaecologists (RCOG) produces clinical Green-top Guidelines (GTGs) principally to support their membership to deliver high quality care for women, other obstetrics and gynaecology service users and their families. They are aimed at improving the effectiveness and efficiency of clinical care by identifying good practice and desired outcomes. 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 three other main kinds of guidance: Scientific Impact Papers (SIPs), Consent Advice (CA) and Good Practice Papers (GPPs). 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 and/or the Guidelines Committee (GC).

[Figure 1](#) is an overview of the guideline development process, which should take approximately 36 months from beginning to end; however, the RCOG team are working on reducing this timeframe.

1.1 Governance

The RCOG GC is responsible for overseeing the development of the GTGs; it is supported by RCOG staff and is accountable to the Clinical Quality Assurance Group (CQAG) of the RCOG. The CQAG oversees the production of, and provides quality assurance for, all guidance produced by the College.

The GC is comprised of:

- Clinicians, both generalists and specialists in obstetrics and gynaecology who are considered users of Green-top Guidelines;
- Two patient/lay representatives, with personal experience of obstetrics or gynaecology services to ensure patients' perspectives are reflected (appointed via the RCOG Women's Network);
- National Institute of Health and Care Excellence (NICE) representative to ensure GTGs are synchronised with NICE guidance;
- National Guidelines Alliance representative to provide methodological expertise;
- NHS Scotland and NHS England Representatives;
- Vice President, Clinical Quality;
- RCOG staff, including Senior Director of Clinical Quality, Head of Quality Improvement, Guidance Editorial Managers and Editorial Assistant.

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 (see [Appendix 1](#)).

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 ([Appendix 2](#)).

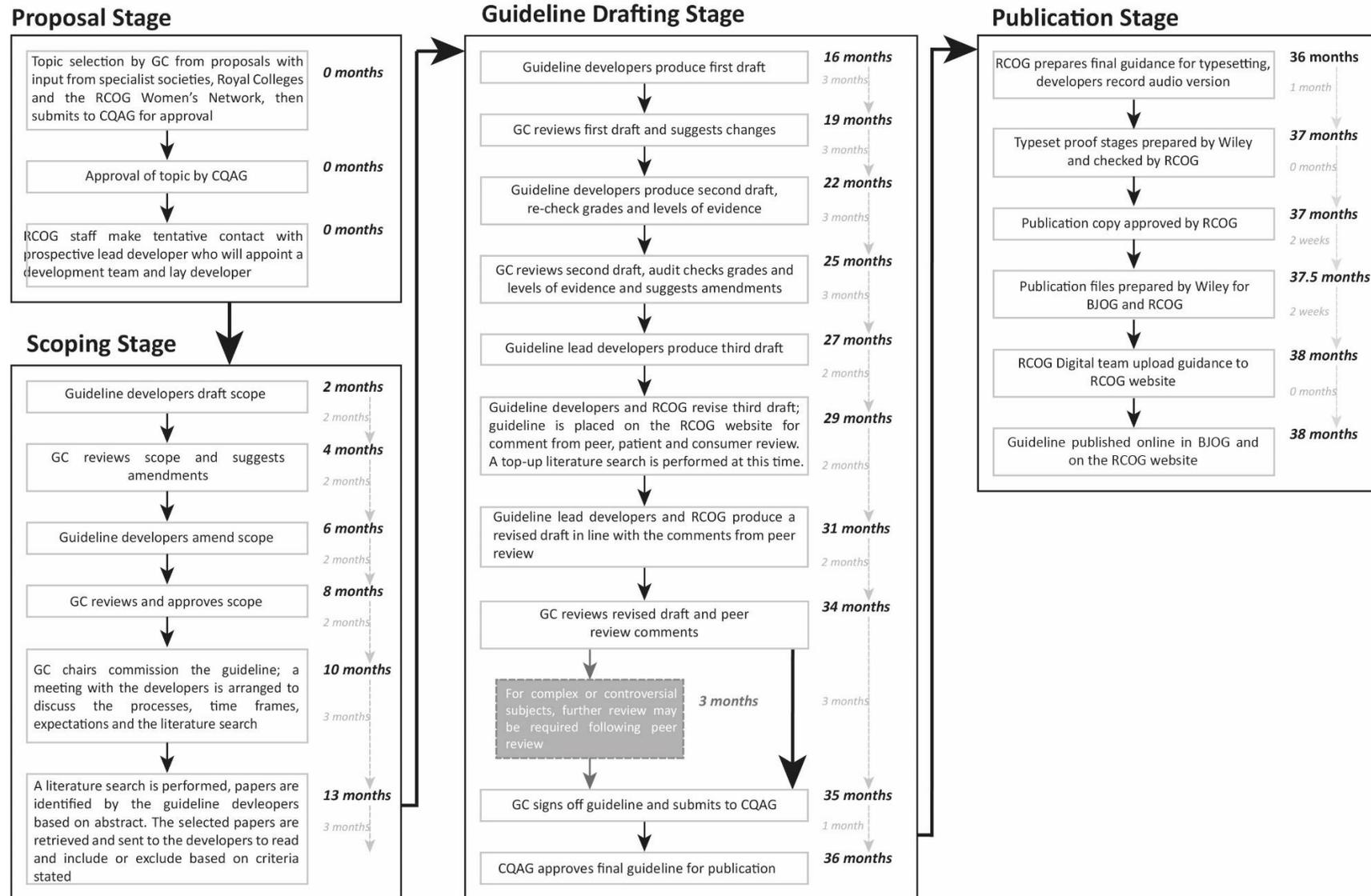
When they arise, vacancies on the Committee are advertised on the RCOG website and in a Membership email to Members and Fellows, allowing the entire membership to apply in a fair and open process.

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, the RCOG Head of Quality Improvement and the Guidance Editorial Manager, who select candidates to be approved by the RCOG Council. Committee terms are 3 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 3 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 1 year, after which they are expected to take over as co-chairs. Applicants for the role of shadow chair must have previously sat on the GC but do not have to be current members of the Committee. Applications are reviewed by the existing GC co-chairs, the Senior Director of Clinical Quality, the Vice President, Clinical Quality and the Guidance Editorial Manager. Shortlisted candidates will be put forward to the RCOG Council for approval.

2. Green-top Guideline development

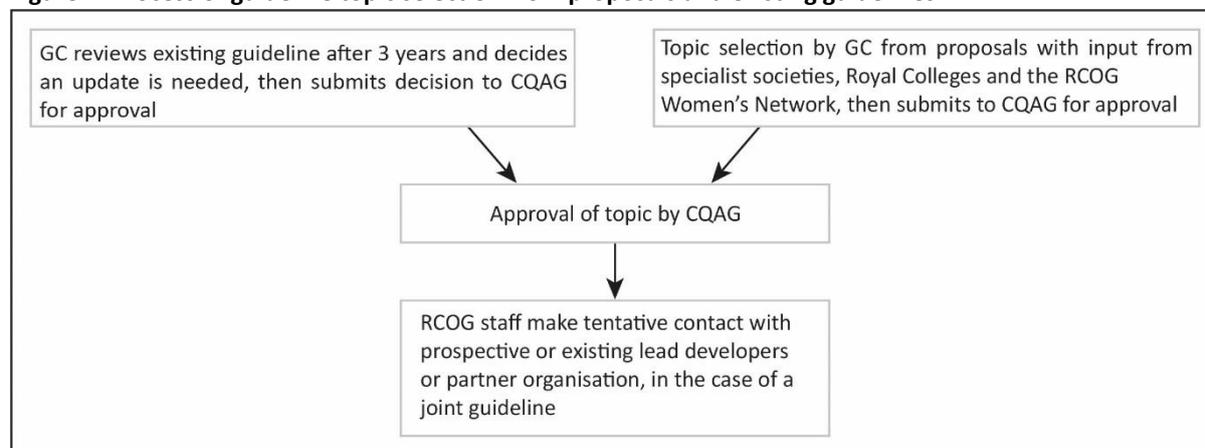
Figure 1. Guideline development pathway



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 are proposed to the GC from numerous sources including the RCOG membership, specialist societies, other Royal Colleges and the RCOG Women’s Network. The process for proposing a guideline is open to everyone.

Anyone wanting to suggest a topic must complete a proposal form ([Appendix 3](#)), which includes the overall objective(s) of the guidance. This enables the GC to establish and prioritise needs. Once formally proposed, the following aspects will be considered to determine if the topic is suitable for a guideline:

- areas where there are high rates of mortality, morbidity or disability
- areas where improved clinical quality of care would reduce rates of mortality, morbidity or disability
- areas where there is uncertainty, as evidenced by wide variation in clinical practice and service delivery
- areas where novel high-quality evidence has been published
- areas where there are resource implications
- areas where there are implications at the primary/secondary care interface
- areas where there is frequent risk of litigation

2.1.1 Proposing a new guideline

Topics that are determined suitable for a guideline are first approved by the GC and then reviewed by the CQAG to ensure they fit with the RCOG’s existing guidance. 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 suitably concise. Equally, some guideline topics may be better suited for NICE guidelines; these could be submitted to NICE to undergo their topic selection process. During this initial phase, there is

consultation with NICE, NHS England and the relevant bodies across the devolved nations, specialist societies and other Royal Colleges to ensure that there is no overlap in the work planned.

2.1.2 Update of existing guideline

Once published, GTGs are valid for 3 years. At the 3-year point, the GC considers the evidence-base and changes to practice to establish need and priority for updates using the same considerations as for topic proposals. The GC reviews the available evidence and may consult with the developers of the previously published edition. Guidelines can be archived ([see section 7](#)), revised or have their revision date extended by 1–2 years if it is felt 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 [Figure 3](#), which also describe the ways of working underlying each one.

If a joint guideline is produced:

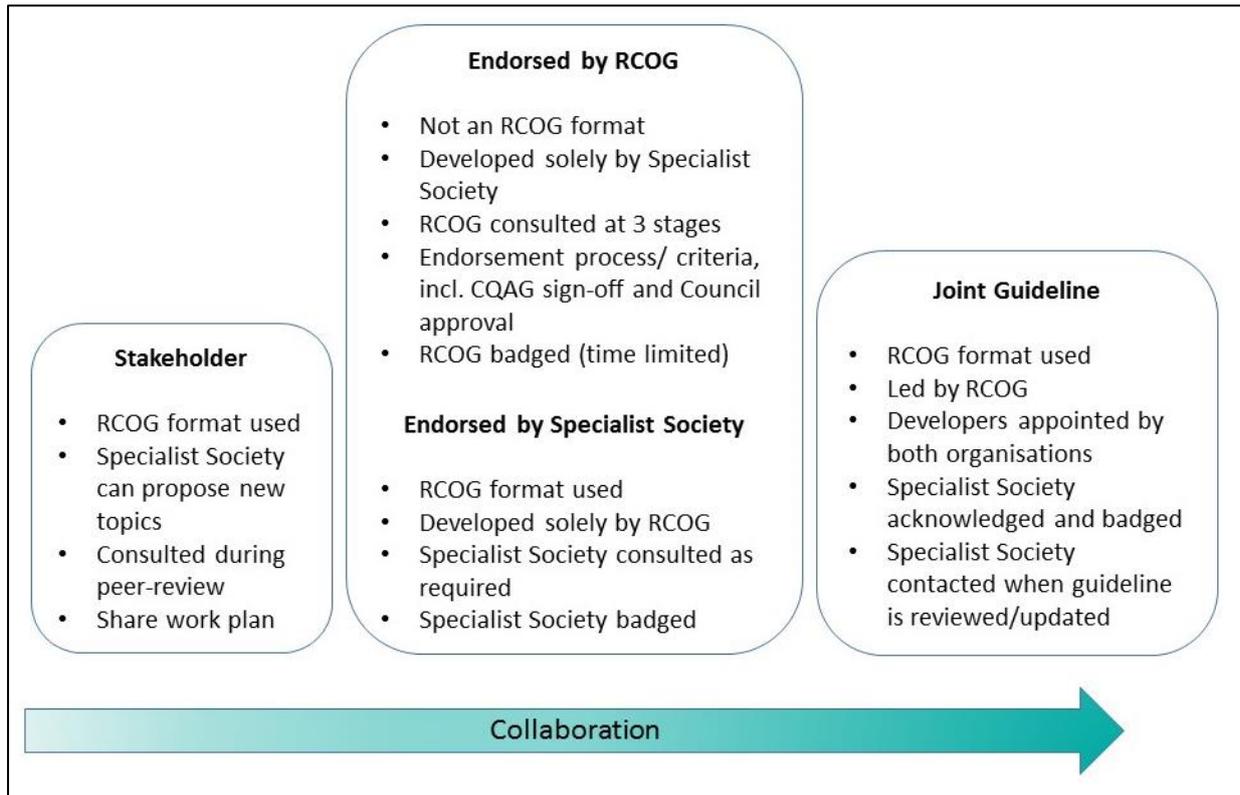
- The development will be led by the RCOG, according to the methodology outlined in this guide.
- The guideline will be published in BJOG, though will be co-badged and the contributing organisation acknowledged.
- The responsibility to determine if an update is needed lies with the RCOG.

2.1.4 Endorsement

The RCOG may be approached to endorse a guideline published by another organisation, for example the *Evidence-Based Guideline on Laparoscopy in Pregnancy* produced by the British Society for Gynaecological Endoscopy. The process for endorsement is outlined in [Figure 3](#) and more information on this is available on the RCOG website.²

The RCOG may 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 as outlined in [Figure 3](#).

Figure 3. GTG collaboration options



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 can be experts in their field, those with a particular interest in the area and/or typical users of GTGs, with 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 ([Appendix 4](#)). 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 ([Appendix 4](#)).

A lay developer should be sought for each guideline; they may be nominated by the guideline lead developer(s) or support can be provided by RCOG staff to identify an appropriate person. The Patient and Public Involvement (PPI) team at the RCOG can suggest individuals or organisations which may be able to help identify a suitable lay developer. The role can also be advertised on the RCOG website if a suitable lay developer is not identified by the developers or PPI team. A role description for lay

developers has been developed to ensure their role and responsibility within the development team is clear ([Appendix 4](#)). The appointment of the lay developer(s) must be approved by the GC.

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.

All developers should complete a declaration of interest form both at the beginning and end of the development process; please see [section 2.5](#) for details.

2.2.2 Update of existing guideline

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

Lay developers will be sought for all updates; if a previous edition had a lay developer, they will be considered before a new lay developer is sought. If the previous lay developer was nominated by a patient group or charity, the organisation (not the individual) will be approached. Should the previous lay developer (or organisation) decline or if there was no previous lay developer, one will be identified following the same process as for new guidelines.

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, including lay developers, should meet the criteria for authorship set out by the International Committee for Medical Journal Editors.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.

If deemed appropriate by the GC, the developers of the most recent edition of the guideline will be asked to resume their roles.

If the original developers decline, are unable to update the existing guideline, or if the GC or partnering organisation (in the case of joint guidance) believe other individuals are better placed to update the guideline, new or additional guideline lead developers will be sought. The developers can be recruited by advertising the role on the RCOG website.

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 Editorial Team and the GC. This includes RCOG staff performing the primary literature search and retrieving and distributing 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; consensus will be reached on GC comments. The guideline lead developers are encouraged to consult with the GC lead reviewers, GC co-chairs and the Guidance Editorial Manager on 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, peer reviewers and other 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 and GC members who receive reimbursement for expenses for attending GC meetings. Please see more information on travel expense rules on the RCOG website.⁴

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 College, charities, voluntary and private sector organisations
- Consultancies, directorship 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 Editorial 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 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 that the GC will work closely with a wide range of stakeholder groups including the RCOG membership, relevant specialist societies, other Royal Colleges, NICE, the Scottish Intercollegiate Guideline Network (SIGN), the RCOG Women's Network and other stakeholders when planning its guideline development programme.

This may involve the development of joint guidelines for specific topics. However, for the purpose of developing RCOG GTGs, prior to the formal development phase the scope requires approval by the GC only.

2.7 Patient and public engagement

The RCOG Guidance Team meaningfully and proactively engages with patient/lay representatives from the outset supported by the College's Patient and Public Involvement team. In addition to the appointment of a lay developer, there are two representatives of the RCOG Women's Network on the GC. Furthermore, 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 if patient information is required at the start of the guideline development process. It is then the responsibility of the PIC to commission and develop the accompanying Patient Information Leaflet (PIL) and any other patient materials.

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 the Committee's comments and then reviewed by the GC again for final approval.

Following approval of the scope, the RCOG library staff or Guidance Editorial Manager will perform the detailed literature search for the guideline. After a review of the abstracts is undertaken and

returned by the developers, the relevant full text versions of the papers will be provided for consideration and filtered by the guideline developers.

On receipt of the papers, the developers will be expected to produce a first draft of the guideline within the indicated timeframe.

The guideline document will be reviewed by the GC who will suggest amendments; the developers are expected to make changes in line with the GC comments. After suggested changes have been made the document will be sent out for peer review. In most circumstances, the suggested changes to the first draft will warrant further review by the GC before going out to peer review.

The guideline will be revised by the developers in line with the peer review comments and reviewed and approved by GC prior to submission to the CQAG. This entire process should ensure that guidelines commissioned by the GC are ready for publication within 36 months.

3.2 Revision of existing guideline

Existing GTGs will be reviewed and, if appropriate, updated 3 years' post-publication. An exception to this would be if a guideline was found to substantially conflict with recently published evidence.

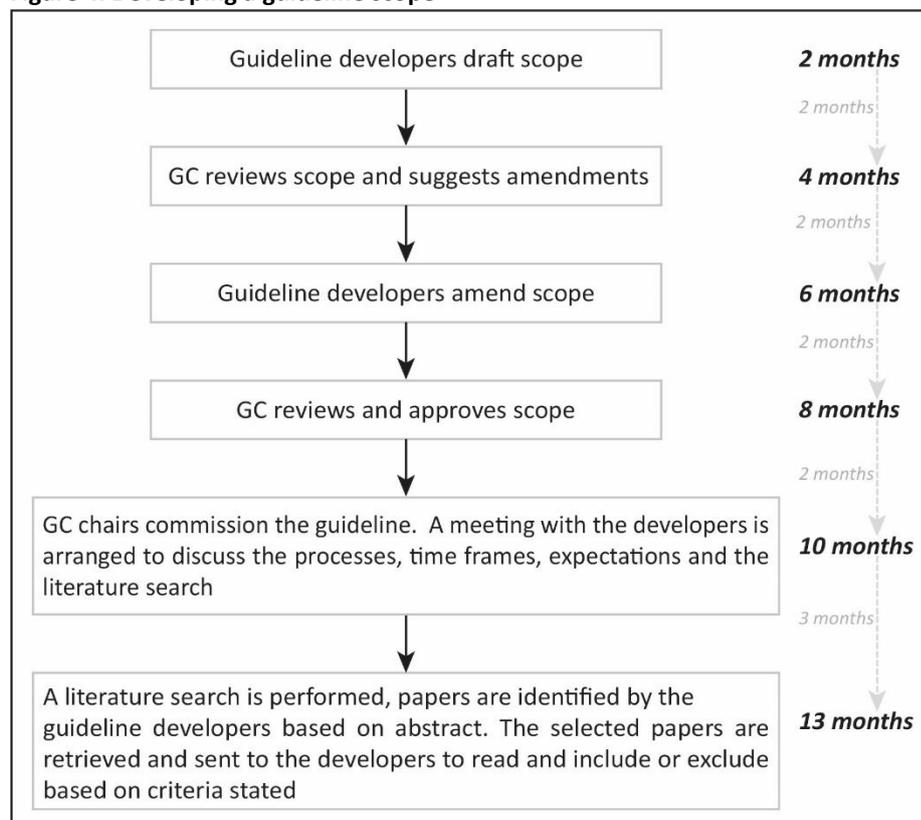
The process of updating a guideline follows the same methodology as newly-commissioned GTGs. Developers of existing guidelines will not be expected to start a revision unless requested by the GC.

The guideline lead developer(s) of the original GTG will be considered by the GC and, if appropriate, will be offered the opportunity to revise the guideline. If this offer is declined, or the GC request a new lead developer or additional developers, these will be identified by advertising the roles of lead and co-developer(s) on the RCOG website.

A new scope will be required for a GTG due for revision. This may well 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. The update of a guideline should also be considered an opportunity to add to and/or revise the clinical questions, in which case developers should refer to the guidance for developing clinical questions in [section 4.2](#) of this guide. 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.

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:
 - the population to be included or excluded,
 - the healthcare setting,
 - the interventions and treatments to be included and excluded.
- Overview of the clinical questions to be addressed.

The overview of the clinical questions involves identifying the broad areas to be examined. From these, the focused clinical questions can be developed.

An example of a proposed guideline scope is outlined in [Appendix 5](#); this example is based on GTG No. 73 *Women Presenting with Suspected Preterm Prelabour Rupture of Membranes from 24⁺⁰ Weeks of Gestation*.

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 – including lay developer – 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 a predefined subject area will be suitable for development as a single clinical practice guideline. This will be dependent in part on the number of clinical questions developed for the scope.

Clinical questions within GTGs will cover a wide range of areas including, identifying women at risk of a particular condition or outcome, diagnosis, optimal care and follow-up, including the role of specific interventions and multidisciplinary team composition. In addition, there is often the need to address communication needs, service delivery, user experience, 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 within the scope of the guideline. 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/populations:** 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

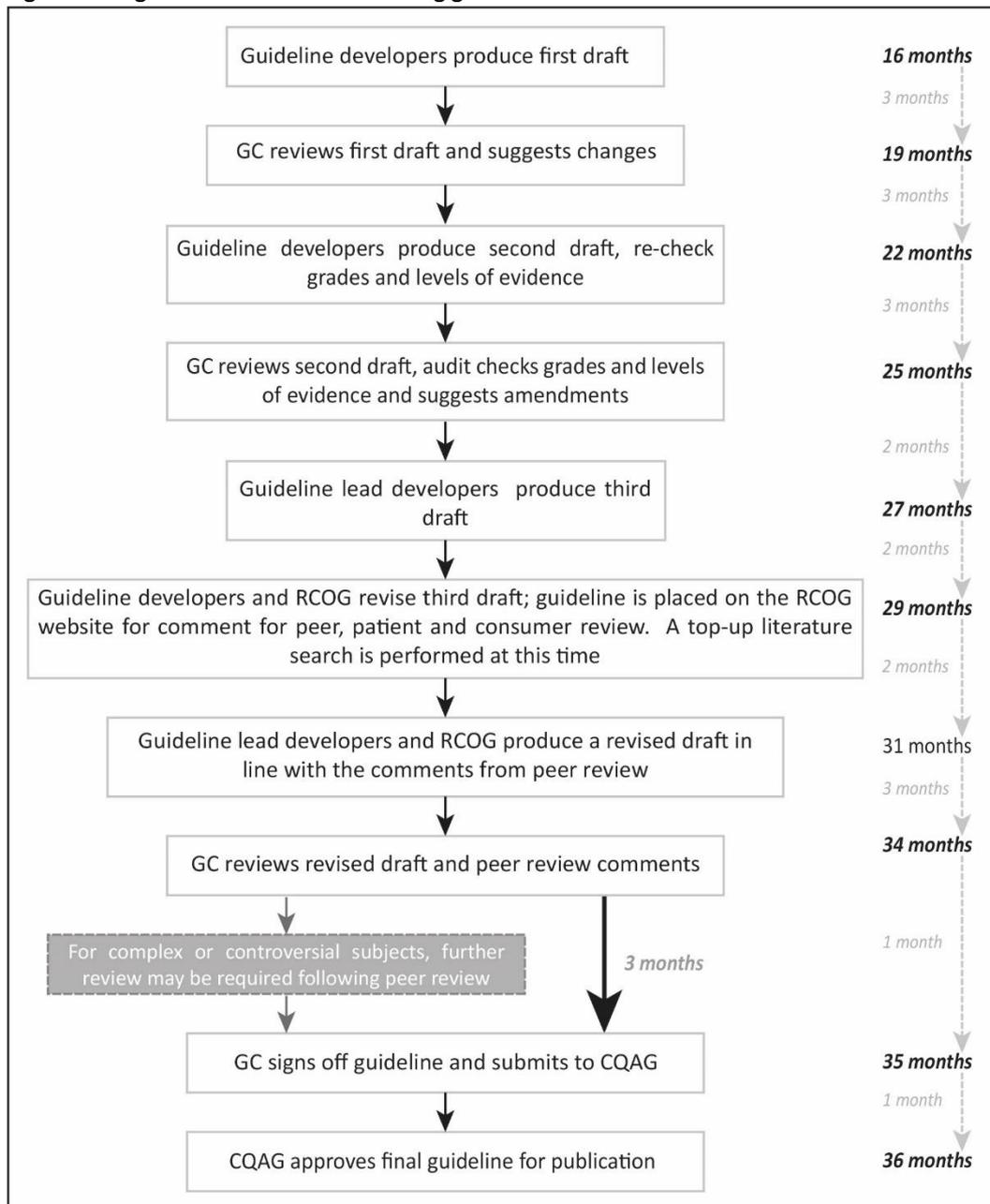
Once the clinical questions have been developed, developers should use the individual facets of each question – both the type of question and the specific population, intervention, comparison and any outcomes specified – to develop inclusion and exclusion criteria they will apply to the retrieved papers. 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, e.g. 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 and tabulated. The guideline lead developer will be expected to amend the scope in line with these comments and submit a final draft to the RCOG for GC 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 Editorial 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 offer to 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 6](#)). This is to ensure that the search strategy is documented and can be shown to meet the quality required for a GTG.

The full details of the databases to be searched and methods used for individual searches are not detailed here. 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 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

Guidelines are often not published in peer-reviewed journals and therefore will not be indexed in either MEDLINE or Embase. Searching for guidelines on the following databases via the internet will allow access to guidelines where the methodological quality can be appraised:

NICE Evidence Search: www.evidence.nhs.uk
RCOG: www.rcog.org.uk
Trip (formerly Turning Research into Practice): www.tripdatabase.com
eGuidelines.co.uk: www.eguidelines.co.uk
Scottish Intercollegiate Guidelines Network (SIGN): www.sign.ac.uk

The review of other guidelines will be helpful in the planning and drafting of a GTG.

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 7](#)).

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.

Using an example question from GTG No. 73 *Care of Women Presenting with Suspected Preterm Prelabour Rupture of Membranes from 24⁺⁰ Weeks of Gestation*, the assessed evidence is reviewed and recommendations graded using the above system:

Question: Should antibiotics be given?

Erythromycin should be given for 10 days following the diagnosis of PPROM, or until the woman is in established labour (whichever is sooner). [A]

A Cochrane review investigating the role of antibiotics for women with confirmed PPROM found that the use of antibiotics is associated with a statistically significant reduction in chorioamnionitis (RR 0.66; 95% CI 0.46–0.96). There was a significant reduction in the numbers of babies born within 48 hours (RR 0.71; 95% CI 0.58–0.87) and 7 days (RR 0.79; 95% CI 0.71–0.89). Neonatal infection, use of surfactant, oxygen therapy and abnormal cerebral ultrasound prior to discharge from hospital was also reduced. There was no significant reduction in perinatal mortality¹⁵ or on the health of the children at 7 years of age.¹⁶ The antibiotic of choice and optimal duration of treatment are not clear; erythromycin 250 mg four times a day for 10 days or until the woman is in established labour (whichever is sooner), is recommended in NICE NG25.⁵ Penicillin may be used in women who cannot tolerate erythromycin. Alternative antibiotic regimens have been investigated.^{17,18} Co-amoxiclav should be avoided as it is associated with an increased risk of neonatal necrotising enterocolitis,¹⁹ and antibiotics should not be given unless the diagnosis of PPROM is confirmed. [Evidence level 1++]

In practice there are a number of outcomes that can be examined for individual questions; for example, when looking at subsequent outcome after surgery for tubal pregnancy, one can examine both subsequent fertility rates and repeat ectopic pregnancy rates. Recommendations are often based on a value judgment on all of the outcomes. It is therefore important all developers within the team – including lay developer – are involved in the process of drafting and agreeing the recommendations.

It is expected that 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 using informal consensus methods then other, more formal methods can be used such as voting and or processes such as the Delphi technique.¹¹ In the last

instance, decisions can be referred to the GC and GC co-chairs for a final decision; such instances should be documented within the guideline.

For recommendations to change 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.¹¹ Ambiguity in the language used will result in confusion at the implementation phase.¹² 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.

An example of a derived audit criterion from GTG No. 73 *Care of Women Presenting with Suspected Preterm Prelabour Rupture of Membranes from 24⁺⁰ Weeks of Gestation* is:

Recommendation

In women who have PPRM and are in established labour or having a planned preterm birth within 24 hours, intravenous magnesium sulfate should be offered between 24⁺⁰ and 29⁺⁶ weeks of gestation. [A]

Auditable topic

- Proportion of women less than 30⁺⁰ weeks' gestation who receive magnesium sulfate within 24 hours prior to birth.

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.

An example of a recommendation for future research from GTG No. 31 *The Investigation and Management of the Small-for-Gestational-Age Fetus* is:

Research may be required to evaluate the effectiveness of/determine:

- How combinations of risk factors for a SGA neonate (historical, biochemical and ultrasound) relate to each other in the individual woman.

5.6 Videos and algorithms

Some guidelines benefit from accompanying videos or algorithms. These should be included in the scope of the guideline and produced as early as possible during the development process.

Accompanying material should be available for comment during stakeholder consultation.

5.7 Drafting the guideline

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

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

In addition, where appropriate, practice algorithms should be produced. 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.

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

1 **Should women with PPRM be offered emotional support?**

Recommendation	Evidence level	Strength	Rationale for the Recommendation
Women with PPRM and their partners should be offered additional emotional support during pregnancy and postnatally 2	4 6	GPP 3	Cohort studies have shown that post-traumatic stress disorder occurs in a substantial number of women whose pregnancy is complicated by PPRM. 4

5 Prospective cohort studies have shown that posttraumatic stress disorder is more common in women whose pregnancies were complicated by PPRM compared to uncomplicated controls (14% versus 2% antenatally, and 17% versus 3% at 6 weeks postnatal).⁴⁵ [Evidence Level 2+] 6

Women with PPRM and their partners should be offered access to additional emotional support, both during pregnancy and postnatally.

- 1 **Clinical question**
- 2 **Structured recommendation**
This statement should be directly derived from the clinical question. It should attempt to answer the question and not represent a statement.
- 3 **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.
- 5 **Summary of supporting evidence**
This should include relevant studies and examine the key population, intervention and outcomes. Discussions of the quality and directness of evidence should be included where relevant. Where possible absolute and relative values should be included.
- 6 **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.

5.8 Peer review process

The peer review process occurs after an initial review of at least two drafts by the GC and is transparent and robust.

A broad and unbiased range of stakeholder organisations and individual peer reviewers are invited to comment and 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.

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. Invited peer reviewers include specialist societies, Royal Colleges, clinicians who have published within the subject area, experts who practice in this area and relevant patient/user groups.

All peer reviewers commit formally to the process and must declare any conflicts of interest which are printed on the back of the guideline. The RCOG declaration of interest and good standing form records conflicts such as: any office held in professional bodies, specialist societies, medical Royal College, charities, voluntary and private sector organisations; consultancies, directorship or advisory positions; public appointments, research positions, contracts and secondments; any other professional, personal or non-personal interest, either financial or non-financial. The peer review process is not anonymous.

All comments are collated by the RCOG and tabulated for consideration by the guideline leads. Each comment requires discussion. 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. A list of the decisions is within the GC meeting minutes. A list of peer reviewers, together with the guideline developers is included in the published guideline.

5.9 Infographics

Guidelines will be accompanied by a graphical summary of the key recommendations selected. This will be produced by the RCOG following peer review; key recommendations should have been finalised at this point in the process.

The infographic will be sent to the developers for comment, before the GC reviews it along with the post peer review draft of the guideline. There is one round of comments submitted on this before approval. The infographic will go to CQAG for sign off with the guideline and any other accompanying materials.

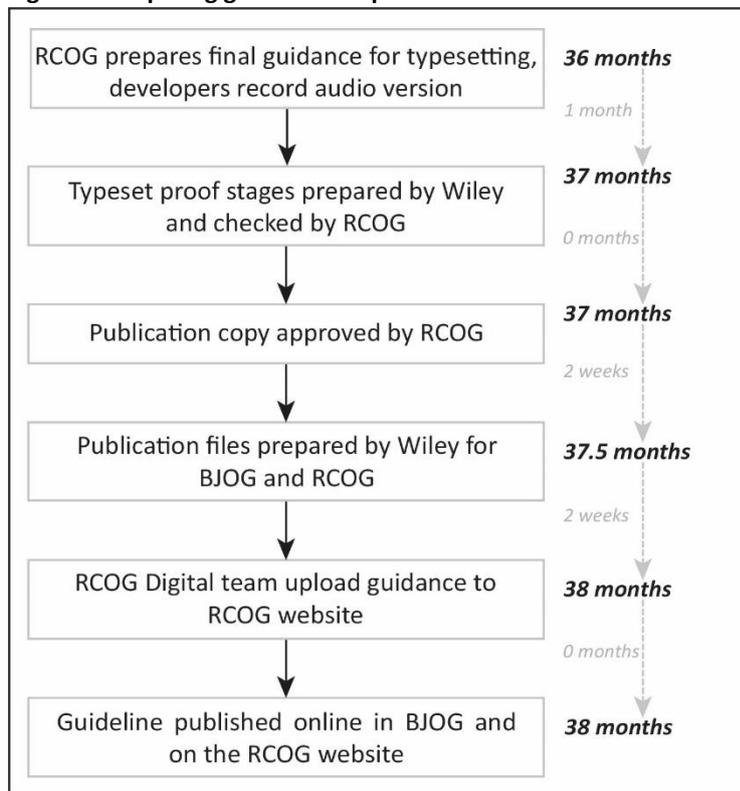
5.10 Approval

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 Editorial Manager 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.

At this stage, the guideline lead developer or a nominated developer will be asked to record an audio version of the guideline, to accompany the full text of 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 Editorial Manager 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, and is available on the BJOG and RCOG apps ([Figure 7](#)).

The full publication date of each GTG is available on the relevant RCOG webpage and on the article publication in BJOG.

For new guidelines, unless decided otherwise, a date three years from the publication date will be specified on the RCOG webpage, as well as in the guideline itself, as the date on which the guideline will be reviewed.

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 cover 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 was removed from the website and archived and redirect users to any guidance by other bodies that has replaced the archived GTG. The date the GTG was archived is recorded on the GTG landing page.

References

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14. Scottish Intercollegiate Guidelines Network. Implementation Support. [<https://www.sign.ac.uk/implementation-support.html>] Accessed 15 July 2019

Appendix 1. Terms of Reference

Guidelines Committee

Reporting mechanism

The Guidelines Committee reports to the [Clinical Quality Board](#) (CQB) and [Clinical Quality Assurance Group](#) (CQAG).

Objectives

- To manage the development, updating and publication of Green-top guidelines as determined by the CQAG and CQ Board.
- To collaborate with other organisations and produce or endorse guidelines, as determined by the Board.
- To collaborate with other committees on other College activities (e.g. audits, Scientific Advisory Committee papers, scientific meetings, study groups) as determined by the Board.
- To provide comments on consultation documents, particularly most [NICE](#) guidelines, quality standards and technology evaluations.

Clinical Quality Assurance Group

Reporting mechanism

The Clinical Quality Assurance Group reports to the [Clinical Quality Board](#).

Objectives

- Develop and maintain an overall framework for the quality assurance of all clinical quality products
- Quality assurance of all CQ products as follows:
Ensure that the due process has been adhered to for all emerging CQ products, that the products meet the RCOG quality standard, and that patient safety is paramount. This includes (but is not limited to) the following prescribed QA checks:
 - Accessibility
 - Appropriate stakeholder input/collaboration
 - Conflict/duplication
 - Ethics
 - Evidence based
- Where necessary, provide QA advice to other College Committees and work in other Directorates in relation to Clinical Quality
- Ensure that relevant information is shared with the appropriate partners for input where necessary, such as specialist societies, Ethics Committee etc. The Group will have the right to co-opt appropriate advisers for specific pieces of work.
- Provide assurance to CQ Board that the totality of the College's CQ resource is integrated and coherent
- Evaluate the CQAG process and systems at 6 months and one year intervals thereafter.

Appendix 2. Guideline Committee Member Role Descriptions

Role Title	Co-Chair of the Guidelines Committee
Reporting to	Vice-President, Clinical Quality/Director of Clinical Quality
Duration and Dates of Appointment	Three years
Purpose and Description of Role	
<p>The role is to Co-Chair the RCOG Guidelines Committee.</p> <ol style="list-style-type: none"> 1. To develop and update evidence-based guidelines as determined by the Clinical Quality Assurance Group (CQAG). 2. To collaborate with other organisations and produce or endorse guidelines, as determined by CQAG. 3. To collaborate with other committees on other College activities (e.g. audits, Scientific Advisory Committee papers, scientific meetings, study groups) as determined by CQAG. 4. To provide comments on consultation documents. 	
Main Responsibilities	
<p>The responsibilities of the Co-Chairs include:</p> <ol style="list-style-type: none"> 1. Oversee the development and production of Green-Top Guidelines. 2. Represent the Guidelines Committee at the quarterly CQAG and Clinical Quality Board meetings. 3. Chair four meetings a year. 4. With the support of the Committee secretary, set the agendas and ensure that decisions taken are properly and effectively followed up and completed. 5. Deal with all enquiries and correspondence from College Officers, Fellows and Members, and outside bodies, as and when they arise. 6. Coordinate College responses, as requested by College Officers, to relevant consultation documents from external bodies. 7. Where appropriate, seek advice and opinion about particular issues from individuals and experts not represented on the Committee. 8. Decide which issues are to be dealt with immediately by the Chair and which can be held over until the next Committee meeting. 9. Recommend future membership of the Committee. 	
Key Working Relationships	
<ul style="list-style-type: none"> • Members of the Guidelines Committee • Vice President, Clinical Quality • Director of Clinical Quality • Members of the Clinical Quality Team, specifically the Editorial Managers, Editorial Assistant and Head of Quality Improvement • Executive Director of Quality, Knowledge and Projects 	

Time Commitment
<p>The Committee meets four times per year, and the Chair will also be expected to represent the Committee at the CQAG and Clinical Quality Board meetings.</p> <p>There will also be a significant commitment outside of the meetings to deal with Committee matters and responses to consultations as required.</p> <p>Travel and any accommodation costs will be covered in-line with the RCOG expenses policy.</p>
Evaluation of the Role and Succession Planning
<p>This role reflects the present requirements of the post. As duties and responsibilities change and develop the role description will be reviewed and be subject to amendment in consultation with the post holder.</p> <p>The role description will be re-evaluated at the end of the term.</p> <p>A shadow chair should be appointed 12 months before the end of the current holder's term of office; they should work closely together during this time in order to facilitate a smooth take-over period.</p>

Person Specification

Qualifications / Training
<p>Essential</p> <ul style="list-style-type: none"> • MRCOG/FRCOG • Registered with a licence to practice with GMC, in good standing • Substantive consultant in Obstetrics &/or Gynaecology in UK NHS Practice • Evidence of annual appraisal • At least one fully completed CPD cycle • Evidence of equal opportunities and diversity training within previous 3 years <p>Desirable</p> <ul style="list-style-type: none"> • Formal training or experience in healthcare management • Previous role as clinical manager such as departmental lead/clinical director
Previous Experience
<p>Essential</p> <ul style="list-style-type: none"> • Previous experience as a Guidelines Committee member
Key Skills / Attributes
<p>Essential</p> <ul style="list-style-type: none"> • Clear demonstration of a commitment to improving women's health relevant to the Guidelines Committee • Conversant with the activities and reporting structure of the Guidelines Committee • Understanding of role of the Guidelines Committee • Knowledge of the RCOG's Strategic and Operational Plans • Good communicator as evidenced by past publications and presentations

- Agreement from host organisation to be released to fulfil roles
- Flexibility
- Prepared to respond rapidly to issues as they arise
- Prepared to undertake work for the Committee, outside of the Committee meetings
- Prepared to represent the Guidelines Committee views for formal consultations
- Prior experience of a significant leadership role
- Detailed knowledge of current NHS and the Health and Social Care Act
- Up to date with membership subscriptions
- Of good standing with the College

Role Title	“Shadow” Chair of the Guidelines Committee
Reporting to	Vice-President, Clinical Quality/Senior Director of Clinical Quality
Duration and Dates of Appointment	One year
Purpose and description of role	
<p>The role is to be a “Shadow” Chair for the RCOG Guidelines Committee. To support the Chair/s of the Guideline Committee to:</p> <ol style="list-style-type: none"> 1. To manage the development, updating and publication of Green-top Guidelines as determined by the Clinical Quality Assurance Group (CQAG) and CQ Board. 2. To collaborate with other organisations and co-develop or endorse guidelines, as determined by the Board. 3. To collaborate with other committees on other College activities (e.g. audits, Scientific Advisory Committee papers, scientific meetings, study groups) as determined by the Board. 4. To provide comments on consultation documents, particularly NICE guidelines, quality standards and technology evaluations. <p>This role is to prepare “Shadow” Chair/s to take over as Chair/s of the Guidelines Committee after 12 months of supporting the Chair/s in this role and will be reviewed after 12 months.</p>	
Main responsibilities	
<p>The responsibilities of the “Shadow” Chair include:</p> <ol style="list-style-type: none"> 1. Support the Chair/s. 2. Maintain a role on the Guidelines Committee. 3. Commit to attending all four meetings per year unless in exceptional circumstances. 4. Assist the Chair/s in dealing with all enquiries and correspondence from College Officers, Fellows and Members, and outside bodies, as and when they arise. 5. Coordinate College responses, as requested by College Officers, to relevant consultation documents from external bodies as directed by the Chair/s. 6. Deputise for the Chair/s as required. 7. Take part in weekly phone calls with the Chair/s and Guidance Editorial Manager. 	
Key working relationships	
<ul style="list-style-type: none"> • Chair of the Guidelines Committee • Other Guidelines Committee members • Guidance developers, particularly the Lead Developer • Vice President, Clinical Quality • Senior Director of Clinical Quality • Members of the Clinical Quality Team, specifically the Editorial Managers, Editorial Assistant and Head of Quality Improvement • Executive Director of Education, Quality and Projects 	

Time commitment
<p>The Committee meets four times per year, and the “Shadow” Chair/s will be expected to attend all committees.</p> <p>There will also be a significant commitment outside of the meetings to deal with Committee matters and responses to consultations as required.</p> <p>Travel and any accommodation costs will be covered in-line with the RCOG expenses policy.</p>
Evaluation of the role and succession planning
<p>This role reflects the present requirements of the post. As duties and responsibilities change and develop the role description will be reviewed and be subject to amendment in consultation with the post holder.</p> <p>The role description will be re-evaluated at the end of the term.</p> <p>A new “Shadow” Chair/s should be appointed 12 months before the end of the current Chair/s term of office and they should work closely together during this time in order to facilitate a smooth take-over period.</p> <p>The expectation is for the “Shadow” Chair/s to become Chair/s unless their performance is deemed inadequate by current Co-Chairs or the Vice President for Clinical Quality. In the unlikely event of this happening alternative options will be considered.</p>

Person Specification

Qualifications / Training
<p>Essential</p> <ul style="list-style-type: none"> • MRCOG/FRCOG • Registered with a licence to practice with GMC, in good standing • Substantive consultant in Obstetrics &/or Gynaecology in UK NHS Practice • Evidence of annual appraisal • At least one fully completed CPD cycle • Evidence of equal opportunities and diversity training within previous 3 years <p>Desirable</p> <ul style="list-style-type: none"> • Formal training or experience in healthcare management • Previous role as clinical manager such as departmental lead/clinical director
Previous experience
<p>Essential</p>

- Previous experience as a Guidelines Committee member

Key skills / attributes

Essential

- Clear demonstration of a commitment to improving women's health relevant to the Guidelines Committee
- Conversant with the activities and reporting structure of the Guidelines Committee
- Understanding of role of the Guidelines Committee
- Knowledge of the RCOG's Strategic and Operational Plans
- Good communicator as evidenced by past publications and presentations
- Agreement from host organisation to be released to fulfil roles
- Flexibility
- Prepared to respond rapidly to issues as they arise
- Prepared to undertake work for the Committee, outside of the committee meetings
- Prepared to represent the Guidelines Committee views for formal consultations
- Prior experience of a significant leadership role
- Detailed knowledge of current NHS and the Health and Social Care Act
- Up to date with membership subscriptions
- Of good standing with the College

Role Title	Member, Guidelines Committee
Reporting to	Chair, Guidelines Committee
Duration and Dates of Appointment	3 years
Purpose and description of role	
<ol style="list-style-type: none"> 1. To manage the development, updating and publication of Green-top Guidelines as determined by the Clinical Quality Assurance Group and CQ Board. 2. To collaborate with other organisations and co-develop or endorse guidelines, as determined by the Board. 3. To collaborate with other committees on other College activities (e.g. audits, Scientific Advisory Committee papers, scientific meetings, study groups) as determined by the Board. 4. To provide comments on consultation documents, particularly NICE guidelines, quality standards and technology evaluations. 	
Main responsibilities	
<ol style="list-style-type: none"> 1. Clinical guidance <ol style="list-style-type: none"> i. Review Green-top Guidelines at all stages of development, to take overall responsibility for the content, accuracy and length of the guidance. In particular, ensuring the: <ul style="list-style-type: none"> • guidance is unbiased • recommendations are realistic and can easily be implemented within the UK • language used for the guidance is clear, unambiguous and can be understood by all O&G professionals, not just the specialist • guidance addresses the scope and does not address areas outside the scope • guidance is internally consistent • guidance is externally consistent with relevant RCOG, national or international guidance, as appropriate • references and underpinning evidence to support the recommendations/statements are accurate and of the highest quality available • grading and evidence levels are in place, consistent and accurate. ii. Provide an expert view when deciding if guidance should be commissioned or not. iii. Submit tabulated comments in a timely manner for every piece of guidance, even those outside your area of expertise. iv. If acting as a lead reviewer, to review all comments from the Committee before they are sent to the developers to address. v. Liaise directly with developers as and when necessary, occasionally meeting with them if needed. vi. Suggest relevant stakeholders/interested parties to be invited to peer review guidance. 	

- vii. Distil the peer review comments to ensure they are not biased or outside the scope and respond to them as necessary.
- viii. Develop guidance implementation support tools, including but not limited to: guidance summaries, PowerPoint slides and video/audio abstracts.
- ix. Participate at press release stage.

2. External consultation documents

- i. Review clinical guidance and pathways sent to the Committee for review.
- ii. Provide a consensus opinion on behalf of the Committee.
- iii. Act as representative for specific guidance projects or other initiatives.
- iv. Ensure the external guidance is consistent with RCOG guidance.

Key working relationships

- Chair of the Guidelines Committee
- Other Guidelines Committee members
- Guidance developers, particularly the Lead Developer
- Vice President, Clinical Quality
- Senior Director of Clinical Quality
- Members of the Clinical Quality Team, specifically the Editorial Managers, Editorial Assistant and Head of Quality Improvement
- Executive Director of Education and Quality

Time commitment

The Committee meets four times per year and attendance is mandatory either in person or via video-link. There will also be a significant commitment outside of the meetings to deal with Committee matters and responses to consultations as required. Although it varies throughout the year, as an average, most committee members find it takes of 4 hours/week (consultant time - 1 Programmed Activities-PAs/week).

Travel and any accommodation costs will be covered in-line with the RCOG expenses policy.

Evaluation of the role and succession planning

This role reflects the present requirements of the post. As duties and responsibilities change and develop the role description will be reviewed and be subject to amendment in consultation with the post holder.

The role description will be re-evaluated at the end of the term. A new committee member will be appointed 3–6 months before the end of the current holder's term of office and they should work closely together during this time in order to facilitate a smooth take-over period.

Person Specification

Qualifications / Training
<p>Essential</p> <ul style="list-style-type: none"> • MRCOG/FRCOG • Registered with a licence to practise with GMC, in good standing • Substantive consultant in obstetrics and/or gynaecology in UK NHS practice • Evidence of annual appraisal • At least one fully completed CPD cycle • Evidence of equal opportunities and diversity training within previous 3 years
Previous experience
<p>Essential</p> <ul style="list-style-type: none"> • Developed or implemented guidance locally <p>Desirable</p> <ul style="list-style-type: none"> • Peer reviewed RCOG clinical guidance • Implemented RCOG clinical guidance locally • Developed RCOG clinical guidance
Key skills / attributes
<ul style="list-style-type: none"> • Clear demonstration of a commitment to improving women’s health relevant to the Guidelines Committee • Conversant with the activities and reporting structure of the Guidelines Committee • Understanding of role of the Guidelines Committee • Knowledge of the RCOG’s Strategic and Operational Plans • Good communicator as evidenced by past publications and presentations • Agreement from host organisation to be released to fulfil roles • Flexibility • Keep items discussed confidential • Prepared to respond rapidly to issues as they arise • Prepared to undertake work for the Committee outside of the Committee meetings • Prepared to represent the views of the Guidelines Committee for formal consultations • Prior experience of a significant leadership role • Detailed knowledge of current NHS and the Health and Social Care Act • Up to date with membership subscriptions • Of good standing within the College

Role title	RCOG Women's Network (WN) Representative
Committee	Guidelines Committee
Tenure	The Chair of the RCOG Women's Network and the Chair of the Guidelines Committee jointly approve the appointment of a representative on the Guidelines Committee to serve a tenure of three years. However, this will be reviewed on an annual basis. There are two Women's Network members on the Guidelines Committee.
Responsibility of Women's Network representative	
<ol style="list-style-type: none"> 1. Ensure that the patient/public view is fed into the development of clinical guidelines through membership of the Guidelines Committee. Membership involves both contributing at meetings and providing input via email between meetings. 2. Coordinate with the Women's Network to provide a wider patient/public perspective on guidelines and provide a single consensus response. 3. Provide updates to the Women's Network on the Guidelines Committee's activities. 	
Key requirements of Women's Network member	
<p>Meetings</p> <p>There are four Committee meetings per year, normally in March, June, September and November/December. The RCOG Women's Network Representative is expected to:</p> <ul style="list-style-type: none"> • attend all meetings where possible • participate in discussions during the meeting • raise any patient/public experience issues <p>Outside of meetings</p> <p>There is significant work outside of the committee meetings to comment on guideline drafts:</p> <ul style="list-style-type: none"> • read agenda papers and guideline drafts and submit comments relating to patient/public experience issues in advance of meetings • comment on additional papers in between meetings as requested and liaise with the Women's Network for wider viewpoints as needed • coordinate responses from Women's Network during the peer review process of guidelines development and provide a single response paper within the deadline • provide patient/public input into RCOG responses to external consultations as requested by Guidelines Committee secretary. 	

Person Specification

Experience and knowledge
<p>Essential</p> <ul style="list-style-type: none">• Understanding of current NHS and women’s health issues <p>Desirable</p> <ul style="list-style-type: none">• Experience of the process of reviewing and developing clinical guidelines• Understanding of the methodology for developing clinical guidelines
Qualities /skills/attributes
<p>Essential</p> <ul style="list-style-type: none">• Commitment to dedicate the necessary time to the tasks assigned by the Committee• Commitment to ensuring that the guidelines development process fully considers the end users’ needs at all times• Willingness to work closely with the other Network member on the GC• Ability to take into consideration the views of other Committee members• Skills to analytically appraise complex information and make suggestions• Committed to regularly communicating the work of the Committee into the RCOG Women’s Network• Excellent organisational skills• Assertiveness

Guidelines Committee Remit

1. To develop and update guidelines and other guidance documents as determined by the Clinical Quality Board.
2. To collaborate with other organisations and produce or endorse guidelines, as determined by the Clinical Quality Board.
3. To collaborate with other committees on other College activities (e.g. audits, Scientific Advisory Committee papers, scientific meetings, study groups) as determined by the Clinical Quality Board.
4. To provide comments on consultation documents.

Appendix 3. Proposal form for a new guideline

NEW RCOG GUIDELINE PROPOSAL

Please submit the completed proposal form to Clinical Effectiveness (clinicaleffectiveness@rcog.org.uk) for consideration. Please provide a comprehensive overview to assist the Committee in making a decision.

1. Proposed Title of Clinical Guideline			
2. Proposer's Contact Details			
Name:			
Address:			
Email:			
Mobile Telephone:			
3. Subject Area(s) (please tick the appropriate box(es) that relate to subject area(s) the Guideline will support)			
<input type="checkbox"/> Acute gynaecology	<input type="checkbox"/> Medical education		
<input type="checkbox"/> Antenatal care	<input type="checkbox"/> Menopause		
<input type="checkbox"/> Basic clinical skills	<input type="checkbox"/> Paediatric and adolescent gynaecology		
<input type="checkbox"/> Clinical governance	<input type="checkbox"/> Postoperative care		
<input type="checkbox"/> Colposcopy	<input type="checkbox"/> Postpartum and neonatal problems		
<input type="checkbox"/> Early pregnancy	<input type="checkbox"/> Professional development		
<input type="checkbox"/> Ethics and law	<input type="checkbox"/> Research		
<input type="checkbox"/> Fetal medicine	<input type="checkbox"/> Sexual and reproductive health		
<input type="checkbox"/> Gynaecological oncology	<input type="checkbox"/> Subfertility		
<input type="checkbox"/> General gynaecology	<input type="checkbox"/> Surgery		
<input type="checkbox"/> History/biography	<input type="checkbox"/> Teaching, appraisal and assessment		
<input type="checkbox"/> Hysteroscopy	<input type="checkbox"/> Ultrasound		
<input type="checkbox"/> Labour and birth	<input type="checkbox"/> Urogynaecology and pelvic floor problems		
<input type="checkbox"/> Laparoscopy	<input type="checkbox"/> Women's health		
<input type="checkbox"/> Maternal medicine			
4. Type of Guidance (please tick the appropriate box)			
<input type="checkbox"/> Green-top Guideline	<input type="checkbox"/> Scientific Impact Paper	<input type="checkbox"/> Good Practice Paper	<input type="checkbox"/> Consent Advice
<i>Please provide a brief summary to help describe why this type of guidance is the best fit for this topic:</i>			
Would this guideline benefit from having a Patient Information Leaflet?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Would this guideline benefit from having an accompanying lay summary?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

5. Background		
General - Please provide a brief background to the clinical topic Please consider: 1. (Clinical) Need for the guidance 2. Population/groups that will be covered 3. Population/groups that will not be covered 4. Target audience 5. (Clinical) Issues that will be covered 6. (Clinical) Issues that will not be covered		
Define the aspects of the topic which the proposed guideline will address (<i>e.g. screening, investigation, referral, management</i>).		
Is it a cause of mortality, or morbidity, or disability?	Yes / No	Detail:
Is it a frequent cause of litigation?	Yes / No	Detail:
Are there any ethical considerations relating to this guidance?	Yes / No	Detail:
Is there evidence of wide variation in clinical practice?	Yes / No	Detail:
Is there evidence of wide variation in service delivery?	Yes / No	Detail:
Is there good quality evidence available to derive recommendations?	Yes / No	Detail:
Is there recent evidence which supports changing practice?	Yes / No	Detail:
Detail any aspects that are areas of concern for patients, carers and/or the organisations that represent them.		
Will the guideline apply to primary or secondary care, or both?		
6. Existing Evidence and Guidance		
Indication of the size and strength of the evidence base which is available to support recommendations on effective practice (<i>including existing systematic reviews in this area</i>).		
Are there any existing guidelines relevant to this condition? (Give source and date of publication). Please comment on their quality and whether they are still valid.		
If there are other existing guidelines, how will this guideline differ?		

7. Submitted research/articles	
Please indicate if you have similar articles already submitted to other publications, e.g. TOG, BJOG. Please state title and journal.	
7. Developers Please indicate the health care professionals and patient groups potentially involved in developing the guideline. Please state their specialist area (e.g. Pharmacist, Sonographer, etc.) and provide their names (if possible) and contact details (if possible).	
8. Joint Initiatives Do you propose this is a joint initiative with another organisation? If so, who, why, have they been approached, and are they accredited by NICE?	
9. Declaration of Conflicting Interests	
10. Any Other Information	

Appendix 4. Guideline Development Team Role Descriptions

Role title	Lead Developer of Green-top Guideline no. XX [insert title]
Reporting to	Guidelines Committee
Duration and dates of appointment	Up to 36 months
Purpose and description of role	
<p>The RCOG is seeking an expert in the field of XX, specifically XX. They will be recruited to update Green-top Guideline no. XX [insert title], which is now due for update in line with the new evidence.</p>	
Main responsibilities	
<p>Applicants must have appropriate methodological expertise in guideline development, experience of critically appraising the evidence and have an amount of credibility with stakeholders within the outlined area of expertise.</p> <p>The lead developer is responsible for nominating a team of co-developers and leading on the update of the [insert title] guideline. The lead developer will be responsible for the content and production of the guideline; critically appraising the current literature to develop evidence-based recommendations; and to draft and review the guideline within the expected time lines outlined by the RCOG.</p>	
Key working relationships	
<ul style="list-style-type: none"> • Guidance Editorial Manager, RCOG • Guidelines Committee Chair • Guidelines Committee Lead Reviewers 	
Time commitment	
<p>The development of a guideline from scoping to publication can take anywhere between 24 and 36 months.</p> <p>The volume of work will vary depending on the stage of development, and the review by the Guidelines Committee and external stakeholders following consultation.</p> <p>You will be expected to produce a series of drafts for review by the Guidelines Committee, addressing committee comments at each stage. A detailed process map can be found at the back of this document.</p> <p>Travel is not required for this role, and will be completed remotely via e-mail and telephone.</p> <p>This role is not remunerated.</p>	

Evaluation of the role and succession planning

Developers who are no longer able to fulfil their commitments may resign from their role via formal notification to the Guidance Editorial Manager, RCOG. Ideally, a notice period of 3 months will be required to allow sufficient time to identify a replacement developer.

If in the rare occasion the Guidelines Committee feel that the guideline is not developing at the reasonable pace needed, new developers will be sought.

This role reflects the present requirements of the post. As duties and responsibilities change and develop the role description will be reviewed and be subject to amendment in consultation with the post holders.

Additional information

The RCOG Clinical Governance Advice No. 1 *Development of RCOG Green-top Guidelines* is available to assist and guide the development of Green-top Guidelines. We have achieved NICE accreditation for this method.

You can gain 5 CPD credits for developing a national guideline.

The Green-top Guidelines are now published in BJOG.

Person Specification

Qualifications / Training

Essential

- Member or Fellow of the RCOG, or respective College.
- GMC Registered Medical Practitioner and in good standing with the GMC.
- In active clinical practice, out of programme for experience/research, or retired within the previous three years.
- Up to date with continuing professional development.
- Have the necessary commitment and time to take part in the full development process.
- Normally resident in the UK.
- Able to demonstrate detailed knowledge of national and professional service standards, publications and their application.
- Demonstrate commitment to risk management.

Previous Experience

Essential

- Developed or implemented guidance locally.

Desirable

- Published scientific material.

Key Skills

- Good communicator and excellent writing skills as evidenced by past publications and presentations.

- Ability to gather data, analyse, critique and synthesise complex information, as evidenced by relevant experience and/or academic qualifications.
- An understanding of research methods including critical appraisal, systematic reviewing and meta-analysis.
- Prepared to respond rapidly to issues as they arise.
- Prepared to commit to the workload and time required to develop this guideline.
- Prior experience of a leadership role.
- Detailed knowledge of current NHS.

Role title	Co-Developer of Green-top Guideline no. XX [insert title]
Reporting to	Guidelines Committee
Duration and dates of appointment	Up to 36 months
Purpose and description of role	
<p>The RCOG is seeking experts in the field of XX, specifically XX. They will be recruited to support the lead developer in updating Green-top Guideline no. XX [insert title], which is now due for update in line with the new evidence.</p>	
Main responsibilities	
<p>Applicants must have appropriate methodological expertise in guideline development, experience of critically appraising the evidence and have an amount of credibility with stakeholders within the outlined area of expertise.</p> <p>Co-developers are responsible for supporting the lead developer in updating the [insert title] guideline. Co-developers will be responsible for supporting the lead developer in producing content for the guideline; critically appraising the current literature to develop evidence-based recommendations; and to assist in drafting and reviewing the guideline within the expected time lines outlined by the RCOG.</p>	
Key working relationships	
<ul style="list-style-type: none"> • Guidance Editorial Manager, RCOG • Guidelines Committee Chair • Guidelines Committee Lead Reviewers 	
Time commitment	
<p>The development of a guideline from scoping to publication can take anywhere between 24 and 36 months.</p> <p>The volume of work will vary depending on the stage of development, and the review by the Guidelines Committee and external stakeholders following consultation.</p> <p>As a team of developers, you will be expected to produce a series of drafts for review by the Guidelines Committee, addressing committee comments at each stage. A detailed process map can be found at the back of this document.</p> <p>Travel is not required for this role, and will be completed remotely via e-mail and telephone.</p> <p>This role is not remunerated.</p>	

Evaluation of the role and succession planning

Developers who are no longer able to fulfil their commitments may resign from their role via formal notification to the Guidance Editorial Manager, RCOG. Ideally, a notice period of 1 month will be required to allow sufficient time to identify a replacement co-developer.

In the rare occasion the Guidelines Committee feel that the guideline is not developing at the reasonable pace needed, new developers will be sought.

This role reflects the present requirements of the post. As duties and responsibilities change and develop the role description will be reviewed and be subject to amendment in consultation with the post holders.

Additional information

The RCOG Clinical Governance Advice No. 1 *Development of RCOG Green-top Guidelines* is available to assist and guide the development of Green-top Guidelines. We have achieved NICE accreditation for this method.

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The Green-top Guidelines are now published in BJOG.

Person Specification

Qualifications / Training

Essential

- Member or Fellow of the RCOG, or respective College.
- GMC Registered Medical Practitioner and in good standing with the GMC.
- In active clinical practice, out of programme for experience/research, or retired within the previous three years.
- Up to date with continuing professional development.
- Have the necessary commitment and time to take part in the full development process.
- Normally resident in the UK.
- Able to demonstrate detailed knowledge of national and professional service standards, publications and their application.
- Demonstrate commitment to risk management.

Previous Experience

Essential

- Developed or implemented guidance locally.

Desirable

- Published scientific material.

Key Skills

- Good communicator and excellent writing skills as evidenced by past publications and presentations.
- Ability to gather data, analyse, critique and synthesise complex information, as evidenced by relevant experience and/or academic qualifications.
- An understanding of research methods including critical appraisal, systematic reviewing and meta-analysis.
- Prepared to respond rapidly to issues as they arise.
- Prepared to commit to the workload and time required to develop this guideline.
- Prior experience of a leadership role.
- Detailed knowledge of current NHS.

Role title	Lay developer of Green-top Guideline no. XX [insert title]
Reporting to	Guidelines Committee
Duration of appointment	Duration of guideline development process (likely 36 months)
Tenure, time commitment and ways of working	
<p>[Amend the below as needed]</p> <p>The tenure of the LR role will be the duration of the guideline development process up to publication, likely to be 36 years. A detailed process map can be found at the back of this document; the full development process can be found on the RCOG website.</p> <p>The development group predominantly work electronically, however, they may communicate via teleconference once or more during the development of the guideline.</p> <p>A regular “check-in” will be available between the Lead Developer (LD) and the LR to ensure the involvement is working well for all. The Guidance Editorial Manager will also be available to answer questions and offer additional support as needed.</p> <p>It is estimated that around 5–10 hours per month will be required although this is variable depending on various stages of the development process.</p> <p>If the LR is no longer able to fulfil their commitments, they may resign from their role via formal notification to the Guidance Editorial Manager. Ideally, the notice period will be 1 month to allow enough time to find a replacement LR.</p> <p>In accordance with RCOG policy on guideline development, on the rare occasion the developers or Guidelines Committee feel the LR role is not being fulfilled to its potential, the situation will be reviewed by the Guidelines Committee Chairs and the Women’s Network representatives on the Committee. If the situation cannot be resolved satisfactorily, a replacement LR will be sought.</p>	
Key responsibilities	
<p>[Amend the below as needed]</p> <ul style="list-style-type: none"> • Bring recent lived experience – [and/or] insight from others who have lived experience of xxxxxxxxx - to all stages of the guideline development from end to end to ensure women and their families remain at the heart of the guidance • Work collaboratively with the Guideline Development Group members • Work collaboratively with the Patient Information Committee as needed 	
Key requirements of the LR	
<p>[Amend the below as needed]</p> <p>The LR will:</p> <ul style="list-style-type: none"> • Critically review the guideline and comment on all drafts • Ensure the emotional/human aspect of care is fully considered and addressed throughout • Review clinical evidence and methodology (if they choose) 	

- Review accompanying patient information materials
- Respond to requests in a timely manner in line with agreed deadlines

Key relationships

The LR will work closely with:

- The Lead Developer
- Guidance Editorial Manager
- Other development group colleagues
- Women’s Network representatives on the RCOG Guidelines Committee
- Ensure the wording of the guideline reflects patient-centred care and terminology
- [Add additional if needed]

Appointment process

[Amend the below if needed]

Applications will be shortlisted, based on suitability outlined by the applicant against the role description and person specification. Shortlisted candidates may be invited to a telephone interview to further assess their suitability.

Expenses

Travel is not required for this role. To avoid phone charges for teleconferences, the College will facilitate these if requested. If travel is required, the RCOG should be contact to agree arrangements before any provisions are made. Any out of pocket expenses will be reimbursed in accordance with the RCOG expenses policy.

Person Specification

Skills, experience and attributes

Essential

- Willing to engage in discussion with a range of other people including healthcare professionals around potential topics within the guideline
- Confidence to share views and experiences, to listen and appreciate other opinions
- Can take a balanced and analytical viewpoint
- Works effectively as part of a team
- Cooperative in understanding challenges and limitations
- Not be a healthcare professional
- Be emotionally resilient
- Commitment to dedicate the necessary time to the role
- Commitment to keep all work confidential
- Commitment to principles of equality & diversity

Desirable

- Have some knowledge or experience of the process for developing clinical guidance

To be discussed and agreed

- Recent lived experience of xxx
- Understanding of the needs of women with recent experience of xxx

[Insert additional or delete as needed]

Appendix 5: An example of a scope

Green-top Guideline no. 73, Care of Women Presenting with Suspected Preterm Prelabour Rupture of Membranes

Guideline content

1. Background and scope
 2. Identification and assessment of evidence
 3. Diagnosis
 - 3.1. How is the diagnosis of PPRM made?
 4. Assessment
 - 4.1. What is required antenatally to identify infection?
 - 4.2. Should neonatologists be involved in the woman's care?
 5. Management
 - 5.1. Should antibiotics be given?
 - 5.2. What is the role of antenatal corticosteroids?
 - 5.3. What is the role of magnesium sulfate for neuroprotection of the baby?
 - 5.4. Should tocolytic agents be used?
 - 5.5. Can women be monitored at home?
 - 5.6. Is there a role for amnioinfusion in PPRM?
 6. Birth
 - 6.1. When is the appropriate time to deliver the baby?
 7. Care in a subsequent pregnancy following PPRM
 - 7.1. Who should care for woman in a subsequent pregnancy?
 8. Key recommendations
 9. Recommendations for future research
 10. Auditable topics
 11. Useful links and support groups
- References

Appendix 6: 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/>)

Date:

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 7: Explanation of guidelines and evidence levels

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

- A** 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
- B** A body of evidence including studies rated as 2++ directly applicable to the target population, and demonstrating overall consistency of results; or
Extrapolated evidence from studies rated as 1++ or 1+
- C** A body of evidence including studies rated as 2+ directly applicable to the target population, and demonstrating overall consistency of results; or
Extrapolated evidence from studies rated as 2++
- D** Evidence level 3 or 4; or
Extrapolated evidence from studies rated as 2+

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 ✓. 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.