Clinical Governance Advice No. 1 – Development of RCOG Green-top Guidelines

May 2015

Minor updates: June 2015 – these are highlighted in yellow
Contents

Introduction 3

Part one: Policies and processes 4
1. Selection of guideline topics 4
2. Selection of guideline lead developers 7
3. Guideline development 7
4. Guideline criteria 7
5. Patient and public involvement 8
6. Peer review process 8
7. Support structure for guideline lead developers 8
8. Parallel patient information 8
9. Publishing and archiving 8
10. Citations 8
References 8
Appendix I. Proposal form for a new guideline 9

Part two: Producing a scope 12
1. Content of the scope 12
2. Identification of the evidence 12
3. Stakeholder involvement 12
4. Approval of the scope 12
5. An example of a scope 12

Part three: Producing a clinical practice guideline 15
1. Preparing the work plan 15
2. Formulation of clinical questions 16
3. Identification of evidence 18
4. Reviewing and grading of evidence 19
5. Development and grading of practice recommendations 21
6. Development of auditable topics 23
7. Development of recommendations for future research 23
8. Drafting the guideline 23
References 25

Part four: Adaptation and implementation 26
References 25
This is the third edition of Clinical Governance Advice (CGA) No. 1. It replaces the first edition entitled Guidance for the Development of RCOG Green-top Guidelines published in January 2000 and the second edition, which saw the four aspects of the process divided into four separate documents:

- CGA No. 1a: Policies and Processes
- CGA No. 1b: Producing a Scope
- CGA No. 1c: Producing a Clinical Practice Guideline
- CGA No. 1d: Adaptation and Implementation (2010).

This third edition is a single document divided into two parts:

- CGA No. 1a–c: Developing a Clinical Green-top Guideline

Introduction

The Royal College of Obstetricians and Gynaecologists (RCOG) produces a series of clinical Green-top Guidelines. Clinical guidelines are an increasingly familiar part of clinical practice, with a principal aim to improve the effectiveness and efficiency of clinical care through the identification of good practice and desired outcomes.

Green-top Guidelines provide systematically developed recommendations to assist clinicians in making evidence-based decisions about appropriate treatment for specific conditions. They are concise documents, providing specific recommendations on focused areas of clinical practice.

The procedure for developing these guidelines has evolved from being one of informal consensus opinion to being evidence-based. This Clinical Governance Advice guidance has been updated in line with the methodology used in the development of the national guidelines produced by the National Institute for Health and Care Excellence (NICE)\(^1\) and the Scottish Intercollegiate Guidelines Network (SIGN).\(^2\) Since 2010, the development process for Green-top Guidelines has been accredited by NICE\(^3\) and, as such, the procedure must be followed as stated.

The aim of this document is to assist and guide those developing Green-top Guidelines and to support implementation.
**Part one: Policies and processes**

**1. Introduction**

This section outlines the policies and processes used in the production of Green-top Guidelines. It covers the following topics:

- selection of guideline topics
- selection of guideline lead developers
- guideline development
- guideline criteria
- patient and public involvement
- peer review process
- support structure for guideline lead developers
- parallel patient information
- publishing and archiving
- citations

An overview of the guideline development pathway is presented in Figure 1.

**1.1 Governance**

The RCOG body responsible for Green-top Guidelines is the Guidelines Committee (GC). This is comprised of:

- clinicians, both generalists and specialists
- a patient/lay representative to ensure proactive involvement at all stages (via the RCOG Women’s Network)
- a Department of Health and Scottish Government representative to ensure that national policy is considered
- a National Institute for Health and Care Excellence (NICE) representative to ensure synergy with the NICE programme.
- Clinical Effectiveness Team

Vacancies on the GC will be advertised on the RCOG website allowing the entire membership to apply in a fair and open process as and when they arise. The RCOG membership is also informed of vacancies by membership emails. The Guidelines Committee is supported by RCOG staff and accountable to the Clinical Quality Board of the RCOG.

**2. Selection of guideline topics**

The Guidelines Committee selects topics from a range of sources including self-volunteered topics, a response to identified needs and areas where new evidence is available. Specialist societies, other Royal Colleges, the RCOG Women’s Network and other relevant stakeholders also suggest guideline topics in the relevant subspecialty areas.

All individuals wishing to suggest a topic must complete a pro forma (Appendix I) to enable the GC to establish need and prioritise. Topics, once formally proposed, are assessed against the criteria below. For topics to be suitable for guideline development they must satisfy all or most of the following criteria:
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 a wide variation in clinical practice and service delivery
areas where new high quality clinical evidence has been published
areas where there are resource implications
areas where there are implications across the primary/secondary care interface
areas where there is a frequent risk of litigation.

2.1 New guidance

Once the guideline topic has been approved by the GC and the Clinical Quality Board (CQB), the guideline lead developers will be selected and a scope requested. Topics are expected to have a narrower remit than NICE clinical guidelines and so it may be necessary for some guideline topics to be divided (and in some circumstances combined) at the scoping phase to give suitably concise advice. Equally, some guideline topics may be better suited for NICE guidelines and these topics will be fed through the NICE topic selection process. During this initial phase, there will be consultation with NICE, NHS, the Department of Health (DH), specialist societies and other Royal Colleges to ensure that there is no avoidable overlap in the work planned.

2.2 Revision of existing guidelines

Guidelines are valid for 3–5 years depending on changes in evidence and practice. At the 3-year point, evidence, practice and need are established and they are prioritised using the same criteria. The GC review all available evidence and consult with the developers of the previously published draft. The Guidelines are either archived, have their revision date extended if there is a valid reason, or revised. The process for revision is the same as for developing a new guideline.

2.3 Alternative forms of guidance

Some topics may be better suited to a form of guidance other than a Green-top Guideline. The three main types of guidance document produced by the RCOG are outlined below.

Guidelines provide recommendations derived from researched clinical questions that are directly pertinent to clinical practice in obstetrics and gynaecology, for example, the management of premenstrual syndrome, and are known as ‘Green-top Guidelines’.

Statements provide an overview of relevant evidence in areas that have some influence or effect on day-to-day clinical practice, e.g. birth in water, but do not provide specific recommendations.

The RCOG Guidelines Committee produces guidelines and statements.

Scientific Impact Papers (SIPs) are brief opinion papers for areas that are new, emerging, controversial or lacking in evidence, such as air travel in pregnancy. These are produced by the RCOG Scientific Advisory Committee.
**Figure 1. Guideline development pathway**

Cumulative timescale (approx.)

0 months  GC selects topics with input from specialist societies, RCOG Women’s Network and Royal Colleges and submits to Clinical Quality Board for approval

0 months  Clinical Quality Board to approve topic and guideline lead(s)

0 months  RCOG staff to make tentative contact with prospective guideline lead(s) to seek their agreement and recruit a guideline lead developer

2 months  Guideline lead(s) draft scope

4 months  GC reviews and suggests amendments

6 months  Guideline lead(s) amend scope

8 months  GC reviews and approves scope

10 months  Chair of GC commissions guideline from guideline lead(s). A meeting is also held with the guideline lead(s) to discuss the processes, timeframe, expectations and the literature search

13 months  A literature search is performed. Papers are identified by the guideline leads based on a list of abstracts. RCOG staff retrieve the full articles and send to guideline lead(s) to read and include or exclude by criteria stated

Guideline lead(s) produce first draft  17 months

GC reviews first draft and suggests amendments  19 months

Guideline lead(s) produce second draft and re-check of grades and evidence levels  22 months

GC reviews second draft, audit checks evidence levels and grades, and suggests amendments  25 months

Guideline lead(s) produce third draft  27 months

Guideline lead(s) and RCOG revise third draft and guideline is sent out for peer review, patient and public review and placed on RCOG website for comment. RCOG staff will perform a top-up literature search at this time.  29 months

Guideline lead(s) and RCOG produce revised draft in line with peer review and patient and public comments  31 months

GC reviews revised draft and peer review comments  34 months

For complex or controversial subjects, further review may be required following peer review (plus 3 months)

GC signs off guideline and submits to Clinical Quality Board  35 months

Clinical Quality Board approves final guideline for publication  36 months
3. Selection of guideline lead developers

Guideline lead developers are proposed by members of GC or self-nominated. Developers are experts in their field with appropriate methodological expertise in guideline development, and have credibility with stakeholders within the area of the guideline. They will need to be approved by the GC and the CQB. Additional secondary developers may be proposed by the guideline lead and will require approval by the GC. The responsibility for both the content and production of the guideline will remain with the guideline lead developer who will draft the guideline within the expected time frame. Agreement will also be sought on the proposed order of developers in the published documents which should reflect the individual’s contribution to the guideline process. A declaration of conflict of interests form is completed by all developers and GC members at the start and end of the process; these conflicts are printed at the back of the guideline. This form will include recording 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. Some clinical experts may lack the necessary skills for drafting guidelines. The GC and the RCOG will provide in-house support to allow future and existing guideline leads to develop these skills. This process applies mainly to new guidelines. In the case of a revision, if the previous guideline leads decline or are unable to update the existing guideline, or if they are felt to be inappropriate by either the specialist society or GC, then new or additional guideline leads will be sought. Equally, if in the rare occasion the GC feel that the guideline is not developing at the reasonable pace needed, new developers will be sought.

4. Guideline development

The development of guidelines involves more than the collation and reviewing of evidence. Even with high quality data from systematic reviews of randomised controlled trials, a value judgement is needed when comparing one therapy to another. This will therefore introduce the need for consensus.

RCOG Green-top Guidelines are drafted by nominated developers in contrast to other guideline groups, such as NICE and SIGN, who use larger guideline development groups. Equally, in contrast to other guideline groups, the topics chosen for development as Green-top Guidelines are concise enough to allow development by a smaller group of individuals.

In agreeing the precise wording of evidence-based guideline recommendations and in developing consensus-based ‘good practice points’, GC will employ an informal consensus approach through group discussion. In line with current methodologies the entire development process will follow strict guidance and be both transparent and robust. The RCOG acknowledges that formal consensus methods have been described but these require further evaluation in the context of clinical guideline development. It is envisaged that this will not detract from the rigour of the process but will prevent undue delays in development.

5. Guideline criteria

Guidelines produced by the RCOG satisfy the basic criteria laid out in the Appraisal of Guidelines for Research and Evaluation in Europe (AGREE) guidelines. The key features of such guidelines are:

- a multidisciplinary working group
- a well-described systematic review of the literature
• graded recommendations with explicit links to the evidence
• quality control, e.g. input by an independent advisory board or by independent peer review.

Further guidance is available from the SIGN website.²

6. Patient and public engagement

As outlined above, there is proactive engagement from patient/lay representatives from the outset. This will mainly be via the RCOG Women’s Network and the appointed representative who sits on the GC. Once the guideline has been finalised there will be further peer review by patients, the RCOG Women’s Network and other relevant stakeholder organisations.

7. Peer review process

The peer review process occurs after an initial review by GC and is transparent and robust. A broad and unbiased range of peer reviewers are invited to comment. The draft guideline is also placed on the RCOG website in a prominent position as an open access document; this enables anyone to comment. Stakeholder registration is not required. 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. This form will include recording 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 GC will review the revised draft and the table of comments. An audit trail of the comments, amendments and various drafts is retained 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.

8. Support structure for guideline lead developers

Guideline developers are supported by RCOG staff and the GC. This includes performing the main literature search and retrieving and distributing relevant papers. Individual guidelines are assigned to specific members of the GC who will act as lead committee reviewers. The guideline leads are encouraged to consult with these GC members and the Clinical Effectiveness Manager. Furthermore, it is hoped that both the GC and the RCOG will be able to assist potential developers to enhance the requisite skills to be able to develop future guidelines.

9. Parallel patient information

The GC has identified the need for parallel patient information to be developed during the guideline development process. The Patient Information Committee will develop this information. The guideline development and patient information development processes will be closely aligned through the Director of Clinical Quality who is a member of both Committees.
10. Publishing and archiving

Published guidelines will be available in electronic format. When a guideline is updated or replaced, all previous versions will be archived. However, for litigation purposes, copies will be available through the RCOG library.

11. Citations

An example of a Green-top Guideline citation is given below:


12. Conflicts of Interest

All those involved in the development of the Green-top Guidelines, including the Guidelines Committee, Guidelines Co-Chairs, guideline developers, peer reviewers and other external reviewers, are unpaid volunteers and receive no direct funding for their work in producing the guideline. The only exception is for Guidelines Committee members who only receive reimbursement of travel expenses for attending Guidelines Committee meetings for standard RCOG activities; this is as per standard RCOG rules. Please see [more information here](http://www.nice.org.uk/aboutnice/accreditation/index.jsp) for travel expenses rules. This statement is also added to the back of guidelines.

All those involved in the development of the Green-top Guidelines, including the Guidelines Committee, Guidelines Co-Chairs, guideline developers, peer reviewers and other external reviewers, should not have any conflicts of interests. Any declared conflicts of interest are reviewed by the Co-Chairs and if a second opinion is required, it is obtained from the Clinical Quality Board to whom the Guidelines Committee reports. All declared conflicts of interest (including any from the Guidelines Co-Chairs) are updated and discussed at each Guidelines Committee meetings and these are considered whilst reviewing the guideline to ensure an unbiased and transparent process. All declared conflicts of interest are documented at the end of the guideline.

References


**Appendix I. Proposal form for a new guideline**

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

<table>
<thead>
<tr>
<th>1. Proposed Title of Clinical Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Proposer's Contact Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
</tr>
<tr>
<td>----</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Subject Area(s) <em>(please tick the appropriate box(es) which relate to subject area(s) the Guideline will support)</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Acute gynaecology</td>
</tr>
<tr>
<td>□ Antenatal care</td>
</tr>
<tr>
<td>□ Basic clinical skills</td>
</tr>
<tr>
<td>□ Clinical governance</td>
</tr>
<tr>
<td>□ Colposcopy</td>
</tr>
<tr>
<td>□ Early pregnancy</td>
</tr>
<tr>
<td>□ Ethics and law</td>
</tr>
<tr>
<td>□ Fetal medicine</td>
</tr>
<tr>
<td>□ Gynaecological oncology</td>
</tr>
<tr>
<td>□ General gynaecology</td>
</tr>
<tr>
<td>□ History/biography</td>
</tr>
<tr>
<td>□ Hysteroscopy</td>
</tr>
<tr>
<td>□ Labour and delivery</td>
</tr>
<tr>
<td>□ Laparoscopy</td>
</tr>
<tr>
<td>□ Maternal medicine</td>
</tr>
<tr>
<td>□ Medical education</td>
</tr>
<tr>
<td>□ Menopause</td>
</tr>
<tr>
<td>□ Paediatric and adolescent gynaecology</td>
</tr>
<tr>
<td>□ Postoperative care</td>
</tr>
<tr>
<td>□ Postpartum and neonatal problems</td>
</tr>
<tr>
<td>□ Professional development</td>
</tr>
<tr>
<td>□ Research</td>
</tr>
<tr>
<td>□ Sexual and reproductive health</td>
</tr>
<tr>
<td>□ Subfertility</td>
</tr>
<tr>
<td>□ Surgery</td>
</tr>
<tr>
<td>□ Teaching, appraisal and assessment</td>
</tr>
<tr>
<td>□ Ultrasound</td>
</tr>
<tr>
<td>□ Urogynaecology and pelvic floor problems</td>
</tr>
<tr>
<td>□ Women’s health</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Background</th>
</tr>
</thead>
<tbody>
<tr>
<td>General - Please provide a brief background to the clinical topic</td>
</tr>
</tbody>
</table>
Define the aspects of the clinical topic which the proposed guideline will address (e.g. screening, investigation, referral, management).

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes / No</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is it a cause of mortality, or morbidity, or disability?</td>
<td>Yes / No</td>
<td>Detail:</td>
</tr>
<tr>
<td>Is it a frequent cause of litigation?</td>
<td>Yes / No</td>
<td>Detail:</td>
</tr>
<tr>
<td>Is there evidence of wide variation in clinical practice?</td>
<td>Yes / No</td>
<td>Detail:</td>
</tr>
<tr>
<td>Is there evidence of wide variation in service delivery?</td>
<td>Yes / No</td>
<td>Detail:</td>
</tr>
<tr>
<td>Is there good quality evidence available to derive recommendations?</td>
<td>Yes / No</td>
<td>Detail:</td>
</tr>
<tr>
<td>Is there recent evidence which supports changing practice?</td>
<td>Yes / No</td>
<td>Detail:</td>
</tr>
</tbody>
</table>

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?

5. Existing Evidence and Guidance

Indication of the size and strength of the evidence base which is available to support recommendations on effective practice (including existing systematic reviews in this area).

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?

6. Developers Please indicate the health care professionals and patient groups potentially involved in developing the guideline. Please state their specialist area (eg Pharmacist, Sonographer, etc) and provide their names (if possible)
and contact details (if possible).

<table>
<thead>
<tr>
<th>7. <strong>Joint Initiatives</strong></th>
<th>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?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>8. <strong>Declaration of Conflicting Interests</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9. <strong>Any other Information</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Part two: Producing a scope

1. Content of the scope

Following the selection of a topic, the development of a scope is the first stage of the guideline development process. The purpose of the scope is to provide the following:

- the background epidemiology relevant to the condition or disease
- a 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.
- an 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 (see Part three: Producing a clinical practice guideline).

2. Identification of the evidence

Some developers may request a preliminary review of the literature to assist with identifying possible clinical questions. This will aim to identify any guidelines and systematic reviews relevant to the guideline. However, it is not anticipated that the scope will be referenced.

3. Stakeholder involvement

It is anticipated that GC will work closely with the relevant specialist societies, other Royal Colleges, NICE, SIGN, the RCOG Women’s Network, the Cochrane Collaboration and other stakeholders when planning its guideline development programme. This may involve the development of joint guidance for specific topics. However, for the purpose of the development of RCOG guidelines, the scope will only require approval by GC prior to the formal development phase. In specific circumstances, where systematic reviews of randomised controlled trials would help to inform the clinical questions posed, it may be appropriate to commission a review if one is not found during the initial literature searches. This may be performed by the guideline lead developers or commissioned through one of the groups of the Cochrane Collaboration (e.g. The Pregnancy and Childbirth Group). Equally, as part of the preliminary searches, a search of published protocols on the Cochrane Library must also be carried out.

4. Approval of the scope

Following submission of the scope to GC, all committee comments will be collated and tabulated. The guideline leads will be expected to amend the scope in line with these comments and submit a final draft of the scope to the RCOG for the GC and Chair’s approval. Once approval is given, then no changes to the scope should be made without consultation with GC. The drafts of the guideline submitted to the GC will be cross-referenced to the final, agreed scope.

5. An example of a scope

An abridged example of a proposed guideline scope is outlined below. It should be noted that this is a hypothetical example based on Green-top Guideline No. 60, Cervical Cerclage.
1. Purpose and scope
2. Introduction and background epidemiology
3. Identification and assessment of evidence
4. Definitions
5. History-indicated cerclage
   5.1 When should a history-indicated cerclage be offered?
6. Ultrasound-indicated cerclage
   6.1 When should an ultrasound-indicated cerclage be offered?
      6.1.1 Women with a singleton pregnancy and no history of spontaneous mid-trimester loss
      or preterm birth
   6.1.2 Women with a singleton pregnancy and a history of spontaneous mid-trimester loss
      or preterm birth
   6.2 Who should be offered serial sonographic surveillance ± ultrasound-indicated cerclage?
7. Can cervical cerclage be recommended in any other groups considered at increased risk of
   spontaneous preterm delivery?
   7.1 Multiple pregnancies
   7.2 Uterine anomalies and cervical trauma
      7.2.1 Radical trachelectomy
8. Transabdominal cerclage
   8.1 When should a transabdominal cerclage be considered?
   8.2 Should an abdominal cerclage be performed laparoscopically?
   8.3 How should a delayed miscarriage or fetal death be managed in women with an abdominal
cerclage?
9. Rescue cerclage
   9.1 When should a rescue cerclage be considered?
10. What are the contraindications to cerclage insertion?
11. What information should be given to women before cerclage insertion?
12. Pre operative management
   12.1 What investigations should be performed before insertion of cervical cerclage?
   12.2 Should amniocentesis to detect infection be performed before rescue or ultrasound-
   indicated cerclage?
      12.2.1 Is amnioreduction before rescue cerclage recommended?
      12.2.2 Should a latency period be observed between presentation and insertion of rescue
      or ultrasound-indicated cerclage?
      12.2.3 Should routine genital tract screening for infection be carried out before cerclage
insertion?
13. Operative issues
   13.1 Should perioperative tocolysis be used for insertion of cerclage?
   13.2 Should perioperative antibiotics be given?
   13.3 What method of anaesthesia should be employed for the insertion of cerclage?
   13.4 Can cerclage be performed as a day-case procedure?
   13.5 Which technique and material should be used?
14. Adjuvant management
   14.1 Bed rest
   14.2 Sexual intercourse
   14.3 Is there a role for post-cerclage serial sonographic surveillance of cervical length?
   14.4 Is there a role for repeat cerclage when cervical shortening is seen post-cerclage?
14.5 Is fetal fibronectin testing useful following insertion of a cervical cerclage?

14.6 Should women receive supplemental progesterone following cerclage?

15. When should the cerclage be removed?

15.1 Should the cerclage be removed following PPROM?

16. Recommendations for future research

17. Auditable topics

18. Useful links and support groups

19. References

20. Appendices
Part three: Producing a clinical practice guideline

1. Preparing the work plan

1.1 New guidelines

The guideline development pathway (Part one: Policies and processes, Figure 1) outlines the stages of the work plan for a new Green-top Guideline. As shown, following approval of the topic and guideline leads, it is expected that a scope will be received by GC. Following revision and then approval of the scope by GC, the developers will be expected to produce a first draft of the guideline within the timeframe listed.

RCOG staff will perform the detailed literature searches for the guidelines and after a review of the abstracts received by the developers, the relevant full text versions of the papers will be forwarded for consideration and filtering. The first draft will then be submitted for consideration by GC.

Two GC nominated reviewers will lead on discussions regarding the clinical questions, the supporting evidence and the recommendations and consensus will be reached. The document will be sent out for peer review after GC suggested changes have been made. In many circumstances, the suggested changes to the first draft will warrant a further GC review before going out to peer review.

The guideline will be revised in line with the peer review comments and reviewed and approved by GC prior to submission to the Clinical Quality Board. This entire process should ensure that guidelines commissioned by GC are ready for publication within 36 months. For revisions of existing guidelines the process will be effectively the same.

1.2 Revision of existing guidelines

Existing Green-top Guidelines will require review, and update if appropriate, 3 years post publication. An exception to this process will be where a guideline is found to substantially conflict with recently published evidence. In these cases the guideline will be removed and only republished once an update has occurred. This process will effectively follow the same methodology as newly commissioned guidelines. Guideline leads of existing guidance will not be expected to start a revision unless requested by GC.

The guideline leads of the original guideline will be considered by the GC and the CQB and if appropriate, will be offered the opportunity to revise the guideline. If this offer is declined, or new guideline leads or additional developers are requested by the GC, then new guideline leads will need to be proposed using the mechanism highlighted in Part one: Policies and processes.

A new scope will be required for a guideline 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. Equally, it is recognised that as this methodology comes into use some guidelines will require revision that have not previously gone through this process. Literature searches will only be performed from the date of the searches in the previous guideline where existing clinical questions are being re-examined. For new clinical questions full searches will be required. Furthermore, new clinical questions may well be generated through ongoing feedback through the RCOG Women’s Network.
2. Formulation of clinical questions

The clinical questions define the areas to be examined within the guideline. They provide the framework for the systematic review of the available evidence. The exact number of questions within each guideline will depend on the subject area being examined. During the scoping phase of a guideline 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 will cover a wide range of areas but invariably fall into three categories:

- diagnosis
- intervention
- prognosis.

In addition there is often the need to examine issues of service delivery and training. The range and type of questions posed will depend on the nature of the subject area.

2.1 Questions about diagnosis

Issues relating to diagnosis are increasingly common within guidelines. All diagnostic tests need to be assessed against clinical quality which relate to accuracy, reliability, acceptability and safety. Hence clinical questions on these tests need to reflect these areas and need to have structure.

Clinical questions on diagnosis need to examine defined outcomes in defined patient groups. The focus is on the ability of the test to detect or exclude a condition. The most appropriate study design to address these questions are test accuracy studies incorporating an independent, blind comparison with a reference standard among an appropriate population of consecutive patients.

An example derived from the management of red cell antibodies in pregnancy guideline would be:

**Question:** How should pregnancies at risk of fetal anaemia be monitored?

**Patient/population:** Pregnant women whose pregnancies are at risk of fetal anaemia

**Diagnostic test:** Middle cerebral artery peak systolic velocity Doppler measurement

**Reference standard:** Middle cerebral artery peak systolic velocity Doppler measurement greater than 1.5 MoMs is 100% sensitive in diagnosing fetal anemia

**Other outcomes:** False positive rate 12%

**Study type:** Prospective cohort study

2.2 Questions about interventions

The majority of clinical questions within guidelines are usually about interventions. A useful way of approaching and formatting these types of questions is to use the patient intervention comparison and outcome (PICO) framework.¹

**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: What is/are the main alternative/s to compare with the intervention?
Outcome: What are the important outcomes for the patient?

In the majority of cases these questions are best answered by randomised controlled trials; however, for some of the rarer outcomes or for examining the adverse effects of an individual treatment, well-conducted cohort studies may be more appropriate.

An example of clinical question formulation using the example within the scope above would be as follows

Question: Should perioperative tocolysis be used for insertion of cerclage?

Patient/population: Women who are pregnant who require an ultrasound-indicated cerclage
Subgroup: Those who require ultrasound-indicated cerclage
Interventions: Perioperative tocolysis (indometacin for 48 hours after cerclage)
Comparison: Pregnant women who had ultrasound-indicated cerclage without tocolysis
Outcomes: Preterm (< 35 weeks of gestation) birth rate
Study type: Retrospective cohort

2.3 Questions about prognosis/screening

Questions relating to the prognosis of a particular condition are of central importance to a guideline. Often the issues relate to screening for or early intervention in relation to a particular condition or may involve advice on behaviour modification which may change the outcome. The study design most appropriate for answering these types of question is randomised controlled trials or cohort studies.

An example from the cervical cerclage guideline:

Question: Is fetal fibronectin testing useful following insertion of a cervical cerclage?

Patient/population: Pregnant women at high risk of preterm birth
Treatment: Fetal fibronectin testing
Outcomes: Prediction of delivery before 30 weeks of gestation
Study type: Retrospective cohort

2.4 Service delivery

National guidance does not often include discussion on service delivery. RCOG Green-top Guidelines are increasingly a forum for examining the implementation of best practice. This may involve examination of a research base where changes in service delivery have been assessed. This is best examined using randomised controlled trials, but other study types are often used for practical reasons.
An example from the cervical cerclage guideline:

**Question:** Can cerclage be performed as a day-case procedure?

**Patient/population:** Pregnant women receiving cerclage

**Setting:** Outpatient

**Comparison:** Inpatient

**Outcomes:** Short-term complications, pregnancy outcome

**Study type:** Retrospective cohort

### 2.5 Inclusion/exclusion criteria

Once the clinical questions have been developed, it will be possible to use the individual facets of each question to develop focused searches. Equally, to streamline this process, it is important that sets of exclusion criteria are used; for example, when looking at issues relating to early pregnancy complications in relation to tubal pregnancy, studies relating to miscarriage would need to be excluded.

### 3. Identification of evidence

Retrieval 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 will offer to perform the searches for the full guideline. Alternatively, if the literature search is carried out by the guideline leads, then the search strategy **must** be sent to RCOG in a pro forma provided for this purpose. This is to ensure that the search strategy is documented and that it can be shown to meet the quality required for a Green-top Guideline.

The full details of the databases to be searched and methods used for individual searches are not detailed here. RCOG staff and the guideline lead will liaise to develop the clinical questions and hence develop the searches accordingly.

#### 3.1 Searching for guidelines

During the scoping exercise for guideline production both pre-existing guidelines and systematic reviews will be sought. To avoid duplication of effort, the first step should be 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 and accepted methodology should be considered. Guidelines will be reviewed using Appraisal of Guidelines for Research and Evaluation in Europe (AGREE) criteria.²

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.

- **National Guideline Clearinghouse:** [www.guideline.gov](http://www.guideline.gov)
- **NICE Evidence Search:** [www.evidence.nhs.uk](http://www.evidence.nhs.uk)
- **RCOG:** [www.rcog.org.uk](http://www.rcog.org.uk)
The reviewing of these guidelines will be useful in planning the full guideline production.

3.2 Searching for systematic reviews

Following the search for 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.

3.3 Searching for randomised controlled trials and observational studies

A wide range of biomedical databases will be searched. These will include MEDLINE and EMBASE. The full details of these searches will not be published with the guidelines, but the main MeSH terms and keywords used and the databases searched will be stated. Equally the volume of literature retrieved and details of numbers of rejections and inclusions will also be documented. When reviewing literature reference lists key articles will also be searched and acknowledged experts in the field may also be contacted. Once lists of abstracts have been retrieved, these will be screened by the authors before the selected full text articles are reviewed and assessed for suitability.

Unpublished literature will not be included. Grey literature i.e. conference proceedings will only be included when sufficient information is available to appraise its quality.

3.4 Document retrieval

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

4. Reviewing and grading of evidence

Previous Green-top Guidelines have used levels of evidence developed by the US Agency for Health Care Policy and Research (AHCPR, now the US Agency for Health Research and Quality, AHRQ). The synthesis of recommendations from evidence using these hierarchies has limitations. Firstly there were no allowances made for study quality. Hence a small potentially biased randomised controlled trial would be given a higher rating (1-) compared with a large well-conducted cohort study addressing the same question (2+).

Similarly, in some instances no directly applicable evidence may be available to answer clinical questions within guidelines. An example of this would be extrapolating the benefits of low-molecular-weight heparin for the prevention of deep vein thrombosis and pulmonary embolus from the non-pregnant to the pregnant population. Using current evidence hierarchies there would be no adjustment made for this indirect comparison.

SIGN developed a method of grading evidence that incorporated aspects of study quality and evidence that is being applied indirectly. There is thus consistency across results. The Grading of
Recommendations, Assessment, Development and Evaluation (GRADE) Working Group have taken a similar line but have moved away from hierarchies for grading evidence and recommendations. For development of RCOG guidelines the use of hierarchies will be maintained with adoption of SIGN methodology.

For this process to work efficiently, the clinical questions developed in the scope must specify the patient groups and outcomes. Equally the study type needed to address the question must be considered. For many therapies randomised controlled trials or systematic reviews of randomised controlled trials will be sought. However, in some instances randomised controlled trials may not be feasible. Observational data may provide better evidence, as is generally the case for rare outcomes.

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, randomised controlled trials 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 ([http://www.sign.ac.uk/methodology/checklists.html](http://www.sign.ac.uk/methodology/checklists.html)). 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 (Figure 2). Where evidence is felt to warrant ‘down-grading’, for whatever reason, the rationale must be stated.

Evidence felt to be of poor quality can be excluded. Any study with a high chance of bias (either 1– or 2) should be excluded from the guideline and recommendations should not be based on this evidence. This prevents recommendations being based on poor quality randomised controlled trials when higher quality observational evidence is available.

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 are considered by the Guideline development group when forming the clinical recommendations, and by the committee when reviewing the guideline. The committee is a multidisciplinary group that includes end users, who are aware of potential barriers to implementation. The recommendations may be altered in line with this specialist advice.

Whilst we don’t undertake a cost-benefit analysis in our guidelines, 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 then this is highlighted in the guideline.

When recommendations are formulated, the evidence is considered to account for each individual benefit of the recommendations, as well as the side effects and risks of each clinical scenario.

All guidelines are extensively peer-reviewed by a wide range of users and groups where the recommendations are commented upon.

Figure 2: Evidence grading system
<table>
<thead>
<tr>
<th>Levels of Evidence</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1++</td>
<td>High quality meta analyses, systematic reviews of RCTs or RCTs with a very low risk of bias</td>
</tr>
<tr>
<td>1+</td>
<td>Well conducted meta analyses, systematic reviews of RCTs or RCTs with a low risk of bias</td>
</tr>
<tr>
<td>1–</td>
<td>Meta analyses, systematic reviews of RCTs or RCTs with a high risk of bias</td>
</tr>
<tr>
<td>2++</td>
<td>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</td>
</tr>
<tr>
<td>2+</td>
<td>Well conducted case control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal</td>
</tr>
<tr>
<td>2–</td>
<td>Case control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal</td>
</tr>
<tr>
<td>3</td>
<td>Non-analytical studies e.g. case reports, case series</td>
</tr>
<tr>
<td>4</td>
<td>Expert opinion</td>
</tr>
</tbody>
</table>

Two examples are given below, on some of the common problems encountered with available evidence.

Example 1. From Green-top Guideline No. 60.

The insertion of a history- or ultrasound-indicated cerclage in women with multiple pregnancies is not recommended, as there is some evidence to suggest it may be detrimental and associated with an increase in preterm delivery and pregnancy loss.[B]

In a meta-analysis, subgroup examination of 39 twin pregnancies demonstrated a doubling in delivery rates before 35 weeks of gestation with the use of ultrasound-indicated cerclage compared with expectant management in women with a cervical length less than 25 mm (RR 2.15; 95% CI 1.15–4.01). In a prospective cohort study of 147 twin pregnancies identified 37 women with cervical length less than 25 mm between 18 and 26 weeks of gestation, of whom 21 underwent insertion of McDonald cerclage and 12 did not. Insertion of cervical cerclage was not associated with any significant improvement in preterm delivery at 34 weeks of gestation or less (42.9% in the cerclage group versus 50% in the non-cerclage group). Small numbers and lack of randomised design limit the conclusions that can be drawn from this study. Furthermore, those women who underwent cerclage had a significantly shorter mean cervical length compared with those who did not. Evidence level 2++

A prospective cohort study of 147 twin pregnancies identified 37 women with cervical length less than 25 mm between 18 and 26 weeks of gestation, of whom 21 underwent insertion of McDonald cerclage and 12 did not. Insertion of cervical cerclage was not associated with any significant improvement in preterm delivery at 34 weeks of gestation or less (42.9% in the cerclage group versus 50% in the non-cerclage group). Small numbers and lack of randomised design limit the conclusions that can be drawn from this study. Furthermore, those women who underwent cerclage had a significantly shorter mean cervical length compared with those who did not. Evidence level 2++

There is only one RCT of history-induced cerclage in twin pregnancies. This study examined the effect of cerclage (n = 25) versus no cerclage (n = 23) in twins conceived following ovulation induction, and demonstrated that cerclage was not effective in prolonging gestation or improving fetal outcome. Several studies of cervical cerclage have included a subgroup of multiple pregnancies; however, they were of insufficient number to enable conclusions to be drawn regarding the effect of cerclage in...
preventing preterm birth. In an IPD meta-analysis,\textsuperscript{24} data for multiple gestations were available in 66 mothers from three randomised studies.\textsuperscript{11,25,26} The use of cervical cerclage in multiple gestations was associated with a substantial increase in pregnancy loss or death before discharge from hospital (OR 5.88; 95% CI 1.14–30.19); however, the results should be interpreted with caution owing to the relatively small number of women included. Evidence level 1+

Although there is 1++ evidence in the form of meta-analyses the grade of evidence is B as the meta-analyses were all small.

Example 2. From Green-top Guideline No. 43

6. What is the risk of stillbirth for pregnancies complicated by obstetric cholestasis?

In a hospital setting, the current additional risk of stillbirth in obstetric cholestasis above that of the general population has not been determined but is likely to be small. [B]

Stillbirth is the major concern for those involved in the management of obstetric cholestasis. Perinatal mortality of six deaths from 56 cases (107/1000) was described from a single Australian centre between 1965 and 1974.\textsuperscript{12} When the same hospital re-reported their results a decade later, the perinatal mortality rate was lower, at 35/1000.\textsuperscript{15} When more recent studies are considered, the perinatal mortality rate from obstetric cholestasis is 11/1000 (17 fetal or neonatal deaths from all causes in 1538 pregnancies beyond 24 weeks of gestation and live births).\textsuperscript{8–10,15–17,19–21} When only studies between 2001 and 2011 are considered, the perinatal mortality rate is 5.7/1000 (four deaths in 697 pregnancies).\textsuperscript{8,20,21} Where the data are unclear, neonatal deaths have been assumed to occur in the first week of life; if this is an incorrect assumption, the perinatal mortality rate is falsely elevated. It seems most likely that some of this fall in the perinatal mortality rate is secondary to general improvements in obstetric and neonatal care and in women’s overall health and socio-economic status. The contributions of active management, case selection (it is possible that more recent series include less severe cases) and reporting bias are unknown. These rates are comparable to whole population figures over the same time period: for England and Wales in 1980, the perinatal mortality rate was 13.4, 8.3 in 2002\textsuperscript{22} and 5.4 in 2008.\textsuperscript{23} This fall should be balanced against the increase in case ascertainment over this period of time, which may include milder forms of the disease. Evidence level 2+

There are no randomised controlled trials evaluating the risk of stillbirth in pregnancies diagnosed with obstetric cholestasis. The evidence comes from cohort studies.

5. Development and grading of practice recommendations

The evidence from the above system is used to derive the grade of the recommendation. The system below developed by SIGN, allows for the quality of the evidence used and the directness of its application to be incorporated into the grading of the recommendation. In general where evidence has a low risk of confounding or bias, or the evidence is being extrapolated, this results in the subsequent grade of the recommendation being one lower than would have been using previous methodology.

This new set of grading has also been expanded from A–C to A–D. Increasing the number of available grades has a number of advantages. It allows the differentiation between cohort and case–control
studies from non-analytical studies e.g. case series and case reports. It also allows for those studies where there is concern over the introduction of bias or the evidence is being applied indirectly to have the grade of recommendation downgraded.

Figure 3: Grades of recommendation

A  At least one meta analyses, 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 ✓. 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.

Using an example question from the preterm prelabour rupture of membranes guideline, the assessed evidence is reviewed and recommendations graded using the above system.

Question: Are prophylactic antibiotics recommended?
Erythromycin should be given for 10 days following the diagnosis of PPROM. [A]

Twenty-two trials involving over 6000 women with PPROM before 37 weeks of gestation were included in a meta-analysis. The use of antibiotics following PPROM is associated with a statistically significant reduction in chorioamnionitis (RR 0.57; 95% CI 0.37–0.86). 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 0.80; 95% CI 0.71–0.90). Neonatal infection was significantly reduced in the babies whose mothers received antibiotics (RR 0.68; 95% CI 0.53–0.87). There was also a significant reduction in the number of babies with an abnormal cerebral ultrasound scan prior to discharge from hospital (RR 0.82; 95% CI 0.68–0.98). There was no significant reduction in perinatal mortality, although there was a trend for reduction in the treatment group. Evidence level 1++

A meta-analysis with over 6000 women directly applicable to the population showed that the use of antibiotics following a diagnosis of preterm prelabour rupture of membranes is associated with a statistically significant reduction in chorioamnionitis and babies born within 48 hours and 7 days, as well as a significant reduction in neonatal infection and abnormal cerebral ultrasound prior to discharge.

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.

For recommendations to change practice, they need to be accurate and easy to understand. The recommendations should be clear on who the recommendation is aimed at, what and how practice should change and ideally some time frame over when this change should occur. Ambiguity in the language used will result in confusion at the implementation phase. Therefore, where possible the recommendations should echo the precision of the original clinical question.

6. Development of auditable topics

Both NICE and SIGN have structure for developing audit on the back of guideline production. The RCOG have produced comprehensive advice concerning understanding audit. This document outlines all aspects of the audit process and authors of Green-top Guidelines 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 the scope above would be:

**Recommendation**

It is good practice to offer a first-trimester ultrasound scan and screening for aneuploidy before the insertion of a history-indicated suture to ensure both viability and the absence of lethal/major fetal abnormality. Before ultrasound-indicated or rescue cerclage, it is good practice to ensure an anomaly scan has been performed recently. [GPP]

**Auditable topic**

Proportion of women receiving aneuploidy screening before history-indicated cerclage insertion.
7. Development of recommendations for future research

During the development of 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 the investigation and management of the small-for-gestational-age fetus guideline (Green-top Guideline No. 31) would be:

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.

8. Drafting the guideline

As well as developing consistent methodology for Green-top Guidelines, it is anticipated that these documents will have a recognisable style. This will allow ease of navigation and aid familiarity.

Guidelines will 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 specific practice recommendations and a synthesis of the evidence
- Recommendations for future research
- Auditable topics
- Useful links and support groups.

In addition where appropriate, it is anticipated that practice algorithms will be produced. These represent a further distilled version of the recommendations and should aid integration and implementation of the evidence into clinical practice.

Although these documents will be concise, in some cases discussion of evidence pertinent to specific clinical questions may be complex. Inclusion of a summary of recommendations will aim to alert readers to the key findings.

Guidelines are not expected to provide long detailed discussions concerning the evidence base. The recommendations will be based on and supported by pertinent supporting text.

An example taken from the cervical cerclage Green-top Guideline of a clinical question, followed by a specific practice recommendation and grade, together with a synthesis of the reviewed evidence and grade is shown in Figure 4 below.

Figure 4. Example of a clinical question, recommendation and supporting evidence
Should an abdominal cerclage be performed laparoscopically? 

There is no evidence to support a laparoscopic approach over laparotomy in the insertion of an abdominal cerclage.

One small study making a retrospective comparison in 19 women demonstrated a viable infant in nine of 12 women who received a laparoscopic procedure compared with five of seven who received an abdominal procedure. Evidence level 3

Clinical Question

Structured recommendation (see section 6)

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

Recommendation grade (see section 6)

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

Summary of supporting evidence (see section 5)

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

Evidence level (see section 5)

This will reflect directly 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.

References


Part four: Adaptation and implementation

Please note this is currently being revised and the new version will not be available for a further year. In the meantime, the previous version can be found at https://www.rcog.org.uk/en/guidelines-research-services/guidelines/clinical-governance-advice-1d/