Royal College of Obstetricians and Gynaecologists

Setting standards to improve women's health

Clinical Governance Advice
No. 1d
February 2010

DEVELOPMENT OF RCOG GREEN-TOP GUIDELINES: CONSENSUS METHODS FOR ADAPTATION OF GREEN-TOP GUIDELINES

This is the second edition of Clinical Governance Advice No 1. It replaces the first edition entitled *Guidance for the Development of RCOG Green-top Guidelines* published in January 2000. This second edition has been separated into the following series of four documents:

Clinical Governance Advice No 1a: Policies and Processes.
Clinical Governance Advice No 1b: Producing a Scope.
Clinical Governance Advice No 1c: Producing a Clinical Practice Guideline.
Clinical Governance Advice No 1d: Consensus Methods for Adaptation of Green-top Guidelines.

1. Introduction

The Royal College of Obstetricians and Gynaecologists (RCOG) produces a series of clinical Green-top Guidelines. The procedure for developing these guidelines has evolved from being one of informal consensus opinion to being evidence based. Clinical guidelines are an increasingly familiar part of clinical practice. Their principal aim is to improve the effectiveness and efficiency of clinical care through the identification of good clinical practice and desired clinical outcomes. This 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 Clinical Excellence (NICE)[1,2] and the Scottish Intercollegiate Guideline Network (SIGN).[3]

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

This document outlines tools that can be used to adapt RCOG Green-top and other guidelines.

2. Adaptation of clinical guidelines

RCOG Green-top Guidelines are developed by stakeholders representing health care in the UK. Rigorous guideline development carries significant resource implications and clinicians often wish to adopt existing guidelines from authoritative sources, rather than developing their own guidelines *de novo*. The adoption of existing guidelines has advantages: it removes the need for the time- and skill-dependent steps of literature search and critical appraisal. However, guidelines developed for use in the UK health service may not be directly transferable to other settings: recommendations may refer to services and interventions which are unavailable or inappropriate in the target setting. An example would be Green-top Guideline No. 39, *Management of HIV in Pregnancy*. This guideline is not automatically transferable to obstetric practice in developing countries. Advice about delivery by caesarean section and avoidance of breastfeeding would not

be appropriate in many countries, where following it might result in increased morbidity and mortality to mother and baby.

The same principles can also be used for the adaptation and implementation of Green-top Guidelines to unusual UK settings (UK overseas territories for example). In the UK, every effort should be made to achieve the same standards but adaptation may be needed in such settings as remote and rural areas, isolated islands and in military and humanitarian practice.

Valid guideline development is founded on three fundamental principles:[1-3]

- guidelines must be **evidence-based** (based on a structured literature search and critical appraisal of the published scientific literature)
- individual recommendations must be **evidence-linked** (linked to the type and quality of evidence on which they are based using an accepted grading scheme)
- compilation of recommendations must involve a **multidisciplinary** group (representing all stakeholders potentially affected by the guideline).

There have been various formal consensus methods described in the literature.[4] One particular approach has been developed for **adapting** a clinical guideline for use in a setting other than that for which it was originally developed.[5] This approach, known as the Rand version of the nominal group technique is theoretically based and uses local stakeholder groups.[6] This has considerable advantages over simply **adopting** a guideline developed elsewhere. Clinicians, policy makers and service users from the intended setting can bring their local perspectives to the final wording of recommendations, ensuring that these accord with local culture and with available services and interventions. In this approach to guideline adaptation, the benefits of literature search and critical appraisal conducted within the resources of the 'parent' guideline development organisation (in this case the RCOG) are combined with the benefits of input from a multidisciplinary group representing the intended users. One must, however, be aware that guideline adaptation can result in significantly different clinical practice occurring in different settings, despite being initially based on the same parent guideline.[7] This is to be expected and does not necessarily imply that the process is incorrect but simply that there is a need for considerable modifications in certain settings.

3. Introducing a clinical guideline

To avoid adapting or absorbing guidelines which are not strictly required in the local context, the following criteria have been outlined:[8]

- topic of sufficient importance to the local setting
- sufficiently complex to require more than one recommendation
- evidence that actual care is at variance with evidence about appropriate care
- up-to-date, locally valid guidelines do not already exist
- adequate body of research about the topic concerned (in particular about the local situation).

These criteria may help those contemplating adapting guidelines to decide whether the effort is necessary. One must also be aware of the possibility that clinical questions that are relevant to some settings, but not the UK, may need to be added to a guideline. Once a decision has been reached to adapt a particular Green-top guideline, one must be aware of the local implications at each stage of the process. These are outlined in Table 1.[6,9] This paper focuses primarily on the specific stage of adapting and implementing an existing guideline to non-UK settings but these processes can be used in the adaptation of guidelines to various scenarios. It should be considered in conjunction with Clinical Governance Advice No. 1a, 1b and 1c.

Once agreement is reached on a Green-top guideline that is considered suitable for local adaptation, the approach shown in sections 4–8 may be used.

Table 1. Framework to aid decisions by policy makers and clinicians regarding introducing new or adapted Green-top clinical guidelines

Stage of guideline introduction	Activities
Selection of clinical topic	Consider: local burden of disease; availability of effective and efficient healthcare interventions; evidence of variation in practice; evidence of current suboptimal performance; receptivity and preparedness to change; availability of resources to implement changes
Availability of existing guideline	Consider the availability of existing guidelines (in this case Green-top guideline) and feasibility of its adaptation to local context. Remember that the resources required to develop a robust guideline *de novo* are substantial
Guideline adaptation	Consider using Rand methodology (formal consensus method with a local stakeholder group)[6]
	If no existing guideline available and resources permit, develop *de novo* using a published methodology (AGREE: Appraisal of Guidelines for Research and Evaluation in Europe)[3]
Dissemination and implementation	Seek resources for implementation: explore sources of funding through partnerships and stakeholders
	Identify available intervention options based on available resources and expertise
	Identify the most likely barriers to implementation across all levels of healthcare organisation (individual, team, organisational and environmental)
	Seek the 'best fit' between barriers and likely interventions
Consider resource implications of change	Policy makers and clinicians should be alert to the potential impact on different budgets of changes in practice resulting from adoption of guideline recommendations
	Suggest an economic impact assessment that includes dissemination of guideline, training, implementation including staff time and audit post introduction of guideline
Evaluate impact	Guideline introducers should design a means of evaluating the impact of guideline introduction, for example by means of clinical audit[10]
	Consider designating a specific centre to audit that the guideline is successfully in practice

4. Recruitment of local stakeholder group

The local guideline adaptation group should comprise representatives of disciplines similar to those included in the parent guideline development group. For a guideline addressing an obstetric or gynaecological topic, the group might include senior and trainee obstetricians, midwives, neonatologists, gynaecology or neonatal nurses, anaesthetists, and representatives of a service-user group, as well as those organisations likely to implement the changes (Ministry of Health Representatives and/or non-governmental organisation representatives). An overview of formal consensus methods indicates that a group size of between six and twelve participants is optimal.[4]

5. Consensus questionnaire

The Rand consensus method includes private decision-making by individual participants using mailed questionnaires.[4,5] An example of a consensus questionnaire developed for the adaptation of the RCOG Green-top guideline No. 21, *Management of Tubal Pregnancy*, is shown in Appendix 1. Participants are sent the questionnaire in advance of a group meeting and asked to score their level of agreement with each guideline recommendation in terms of suitability for use in their own setting. Scoring on a nine-point Likert scale has proved to be practicable.[5]

6. Aggregating the scores

The aim of the private decision-making step is to achieve consensus agreement with a proportion of guideline recommendations in order to reduce the number requiring face-to-face discussion at a group meeting. Authorities differ as to what level of agreement constitutes 'consensus'.[4] Purists would argue that consensus has not been achieved unless **all** participants are in agreement. However, pragmatic consensus rules are acknowledged as acceptable, as long as these rules are pre-agreed at the outset. With a group of 11 participants, consensus may be deemed to have been achieved if 10 of the 11 score a recommendation within a three-point band on the nine-point Likert scale. For example, for the recommendation: 'Laparoscopic salpingotomy should be considered as the primary treatment when managing tubal pregnancy in the presence of contralateral tubal disease and the desire for future fertility', if ten participants gave it an agreement score of 7, 8 or 9 and the remaining participant gave it a score of 5, then this would be deemed 'consensus agreement' with the recommendation. Conversely, for the recommendation 'Expectant management is an option for clinically stable women with minimal symptoms and a pregnancy of unknown location', if nine participants gave it an agreement score of 7, 8 or 9 and the remaining participants gave scores of 2 and 3, there is 'no consensus' and the recommendation requires face-to-face discussion.[6]

During a guideline adaptation exercise, postal questionnaires would be returned to a central point and scores aggregated as described above. This approach has been applied with groups of clinicians in the UK, Iraq and Sri Lanka. Generally, the private decision making exercise results in consensus agreement with the majority of recommendations in the original guideline; these can then be adopted for the new setting without modification. A minority of recommendations will remain for which the adaptation group have reached no consensus or a consensus of disagreement (at least ten participants giving a score of 1, 2 or 3); these require face-to-face discussion and local modification.

The formal Rand consensus method elicits private decisions using mailed questionnaires as described above. However, this approach has also been successfully adopted in a workshop format with private decision-making taking place at the beginning of the meeting, scores being aggregated on-site, and face-to-face discussion taking place thereafter.

7. Modification of contentious recommendations

Following the consensus questionnaire exercise, a limited number of recommendations will require group discussion and modification. For each of these, the evidence base for the recommendation (as presented in the original guideline) should be reviewed and options for modified wording explored. Often, necessary modifications will be easily resolved (for example, replacement of the term 'NHS' by a term that describes the local health care system; or substitution of a drug which is unavailable locally).

8. Repeat private decision-making

If time and resources permit, a second consensus questionnaire should be compiled containing all recommendations in the adapted guideline (those which achieved consensus agreement in the first survey and those for which the wording was modified at the face-to-face meeting). Participants should then score their level of agreement with each using the nine-point Likert scale to demonstrate that consensus has been achieved for all recommendations in the final adapted guideline.

In practice, the modifications required may be few in number and minor in nature. In this case, agreement on the adapted guideline may be achieved by informal consensus at the end of the face-to-face meeting.

The use of an explicit and transparent consensus process permits adaptation of a clinical guideline developed for use in one healthcare system for use in another. Such adaptation results in a valid guideline which adheres to the three fundamental principles: it is **evidence-based**, recommendations are **evidence-linked** (drawing on structured literature review and critical appraisal undertaken by the 'parent' guideline developers) and it incorporates **multidisciplinary** input from a local stakeholder group.

It may be difficult, in resource-poor settings, to achieve an entire consensus approach as described above. However, it is advised that the adaptation of guidelines should involve as many stakeholders as possible even if all that is achievable are informal discussions.This will promote local acceptance of the guideline and hence successful implementation.

References

1. National Institute for Health and Clinical Excellence. *The Guideline Development Process. An Overview for Stakeholders, the Public and the NHS.* 2nd ed. London: NICE; 2006 [www.nice.org.uk/page.aspx?o=guidelinesprocess].
2. National Institute for Health and Clinical Excellence. *The Guidelines Manual 2006*. London: NICE; 2006 [www.nice.org.uk/page.aspx?o=308639].
3. Scottish Intercollegiate Guidelines Network. *A Guideline Developer's Handbook*. SIGN Publication 50. Edinburgh: SIGN; 2004 [www.sign.ac.uk/guidelines/fulltext/50/index.html].
4. Murphy MK, Black NA, Lamping DL, McKee CM, Sanderson CFB, Askham J, *et al*. Consensus development methods, and their use in clinical guideline development. *Health Technol Assess* 1998;2:1–88.
5. Glasier A, Brechin S, Raine R, Penney G. A consensus process to adapt the World Health Organization Selected Practice Recommendations for UK use. *Contraception* 2003;68:327–33.
6. Penney GC. Adopting and adapting clinical guidelines for local use. *The Obstetrician & Gynaecologist* 2007;9:48–52.
7. Wabitsch R, Margolis, CZ, Malkin JE, Abu-Saad, K, Waksman J. Evaluating the process of tailoring the global HIV/AIDS practice guidelines for use in developing countries. *Int J Qual Health Care* 1998;10:147–54.
8. Baker R, Feder G. Clinical guidelines: where next? *Int J Quality Health Care* 1997;9:399–404.
9. Grimshaw JM, Thomas RE, MacLennan G, Fraser C, Ramsay CR, Vale L, *et al*. Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technol Assess* 2005;21:149.
10. Kongnyuy EJ, van den Broek N. Audit for maternal and newborn health services in resource-poor countries. *BJOG* 2009;116:7–10.

APPENDIX I: An example of a consensus questionnaire for adaptation of an RCOG Green-top Guideline for setting-specific use.

Adapting RCOG Guideline 21 for Use in Non-Uk Settings

The Management of Tubal Pregnancy

Participant Name: .....

Please indicate your level of **agreement** with each recommendation **FOR USE IN PRACTICE IN YOUR COUNTRY** by placing an **x** in the appropriate box. Please use the 9 point scale where 1 = strongly disagree and 9 = strongly agree:

	Strongly Disagree 1	2	3	4	5	6	7	8	Strongly Agree 9
1. A laparoscopic approach to the surgical management of tubal pregnancy, in the haemodynamically stable patient, is preferable to an open approach. (**Grade A**)	☐	☐	☐	☐	☐	☐	☐	☐	☐
2. Management of tubal pregnancy in the presence of haemodynamic instability should be by the most expedient method. In most cases this will be laparotomy. (**Grade C**)	☐	☐	☐	☐	☐	☐	☐	☐	☐
3. In the presence of a healthy contralateral tube there is no clear evidence that salpingotomy should be used in preference to salpingectomy. (**Grade B**)	☐	☐	☐	☐	☐	☐	☐	☐	☐
4. Laparoscopic salpingotomy should be considered as the primary treatment when managing tubal pregnancy in the presence of contralateral tubal disease and the desire for future fertility. (**Grade B**)	☐	☐	☐	☐	☐	☐	☐	☐	☐
5. Medical therapy should be offered to suitable women, and units should have treatment and follow-up protocols for the use of methotrexate in the treatment of ectopic pregnancy. (**Grade B**)	☐	☐	☐	☐	☐	☐	☐	☐	☐
6. If medical therapy is offered, women should be given clear information (preferably written) about the possible need for further treatment and adverse effects following treatment. Women should be able to return easily for assessment at any time during follow-up. (**Grade B**)	☐	☐	☐	☐	☐	☐	☐	☐	☐
7. Women most suitable for methotrexate therapy are those with a serum hCG below 3000 iu/l, and minimal symptoms. (**Grade B**)	☐	☐	☐	☐	☐	☐	☐	☐	☐

Adaptation of clinical guidelines for use in non-UK settings

8. Outpatient medical therapy with single-dose methotrexate is associated with a saving in treatment costs. (**Grade A**)

Strongly Disagree 1 2 3 4 5 6 7 8 9 Strongly Agree

9. Expectant management is an option for clinically stable women with minimal symptoms and a pregnancy of unknown location. (**Grade C**)

Strongly Disagree 1 2 3 4 5 6 7 8 9 Strongly Agree

10. Expectant management is an option for clinically stable asymptomatic women with an ultrasound diagnosis of ectopic pregnancy and a decreasing serum hCG, initially less than serum 1000 iu/l (**Grade C**)

Strongly Disagree 1 2 3 4 5 6 7 8 9 Strongly Agree

11. When salpingotomy is used for the management of tubal pregnancy, protocols should be in place for the identification and treatment of women with persistent trophoblast. (✔)

Strongly Disagree 1 2 3 4 5 6 7 8 9 Strongly Agree

12. All NHS trusts should provide an early pregnancy assessment unit with direct access for general practitioners and accident and emergency departments. Available facilities for the management of suspected ectopic pregnancy should include:
    - diagnostic and therapeutic algorithms
    - transvaginal ultrasound
    - serum hCG estimations

(✔)

Strongly Disagree 1 2 3 4 5 6 7 8 9 Strongly Agree

13. Clinicians undertaking the surgical management of ectopic pregnancy must have received appropriate training. Laparoscopic surgery requires appropriate equipment and trained theatre staff. (✔)

Strongly Disagree 1 2 3 4 5 6 7 8 9 Strongly Agree

14. Nonsensitised women who are rhesus negative with a confirmed or suspected ectopic pregnancy should receive anti-D immunoglobulin. (✔)

Strongly Disagree 1 2 3 4 5 6 7 8 9 Strongly Agree

15. Women should be carefully advised, whenever possible, of the advantages and disadvantages associated with each approach used for the treatment of ectopic pregnancy. They should participate fully in the selection of the most appropriate treatment. (✔)

Strongly Disagree 1 2 3 4 5 6 7 8 9 Strongly Agree

Grades of recommendations

A	Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation. (Evidence levels Ia, Ib)
B	Requires the availability of well controlled clinical studies but no randomised clinical trials on the topic of recommendations. (Evidence levels IIa, IIb, III)
C	Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (Evidence level IV)

Good practice point

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

APPENDIX II

Clinical guidelines are: 'systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions'. Each guideline is systematically developed using a standardised methodology. Exact details of this process can be found in Clinical Governance Advice No. 1: *Development of RCOG Green-top Guidelines* (available on the RCOG website at **http://www.rcog.org.uk/womens-health/clinical-guidance/development-rcog-green-top-guidelines-policies-and-processes**). These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution and variations in local populations. It is hoped that this process of local ownership will help to incorporate these guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research may be indicated.

The evidence used in this guideline was graded using the scheme below and the recommendations formulated in a similar fashion with a standardised grading scheme.

Classification of evidence levels

1++ High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias

1- Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias

2++ High-quality systematic reviews of case–control or cohort studies or high-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal

2+ Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal

2- Case–control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal

3 Non-analytical studies; e.g. case reports, case series

4 Expert opinion

Grades of recommendations

A At least one meta-analysis, systematic reviews or randomised controlled trial rated as 1++ and directly applicable to the target population; or
A systematic review of randomised controlled trials 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 point

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

This Clinical Governance Advice was based on the work of **Ms G Penney FRCOG, Aberdeen**, which has been amended by **Ms C Bearfield, Research Fellow RCOG, London** and **Miss AE Makins MRCOG, Oxford**, for use in this Advice on behalf of the Guidelines Committee of the Royal College of Obstetricians and Gynaecologists.

This advice was peer reviewed by: Dr V Argent FRCOG, Eastbourne; Dr AD Falconer FRCOG, Chair, RCOG International Committee, London; Mr D Fraser, Norfolk and Norwich University Hospital; Mr T Kelly MRCOG, Brighton; Dr CE Lennox, Lanarkshire.

The GAC lead reviewers are: Mr M Griffiths FRCOG, Bedforshire, and Mr P Hilton FRCOG, Newcastle.

The final version is the responsibility of the Guidelines Committee of the RCOG.

The review date of this Clinical Governance Advice will commence in 2013 unless otherwise stated