Royal College of Obstetricians & Gynaecologists

Guideline Development and Adaptation

Global Health Toolkit No. 5

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Introduction

The development of evidence based guidelines is seen as increasingly important in advanced health care systems. However, they are just one part of a wider system of clinical governance and their role is limited if used in isolation.

Clinical Governance or risk management is a framework for the health organisation to demonstrate accountability for continually improving the quality of their services, safeguarding high standards of care and creating an environment in which excellence in clinical care will flourish.

The **elements of risk management** are:

- Risk identification – having a system for reporting adverse events or near misses and audit of clinical practice
- Risk analysis – analysing the error or deficiency of practice
- Risk control – guideline development aiming to reduce risk or error and standardise practice
- Risk rescue – training and drills

Good clinical guidelines can:

- change the way healthcare is delivered
- improve outcomes for patients and/or quality of care
- ensure efficient use of healthcare resources
- allow development of standards to assess clinical practice

However, development and adaptation of guidelines requires additional resources or expertise that may be limited in some healthcare settings. The RCOG has an advanced and robust process for guideline development and promotes the importance of evidence based medicine. As such, the College has produced a toolkit to give step by step guidance to develop and implement guidelines as part of a needs-based improvement programme.

This toolkit provides a practical guide to the development and adaptation of evidence-based clinical guidelines. It can be used for guidelines for public health promotion, screening, diagnosis or treatment. It is ***not*** a guide to the development of protocols, care pathways, standard operating procedures or clinical practice standards. It provides advice on the development pathway that is most appropriate to the host country - new guidance, adaptation or adoption.

While the toolkit is mainly aimed at guidelines in sexual and reproductive health, it is sufficiently generic that it could also be used in other specialties. It is intended to be used by teams of clinicians, nursing and midwifery staff, policy makers, managers and consumers.

For the purposes of this toolkit the term "local" refers to the host country or region that is undertaking guideline development of adaptation.

1. Initial Steps in Guideline Development and Adaptation

1.1 Initial Steps in Guideline Development and Adaptation

The steps in this phase all need to occur prior to starting work on the guideline itself. This stage can take from 3- 6 months but is one of the most important steps in the whole process.

1.2 Who should have overall control of guideline development?

A national body or steering committee should be responsible for guideline development within a particular country or region. For example, the National Collaborating Centre (NCC) is a body responsible for supporting guideline development in the UK. They should develop a programme for guideline development based on the health needs of their country and use a structured system to prioritise and select topics for development. There are no set criteria for this body but it must have representation from the policy makers and Government bodies and from the specialist societies and clinical groups. Involvement of service users would be considered advantageous.

Recommendation: Agree membership of a steering group responsible for the development of a guidelines' programme for the country or region. Detail what will be provided by the body and its role and responsibilities.

Recommendation: Secure central funding and resources for a guideline' programme.

Guideline Adaptation: A steering group is required for adaptation. It will prioritise and allocate resources for guideline adaptation and will remain responsible for publication, dissemination and implementation of the adapted document.

1.3 How are topics selected and prioritised for guideline development?

Ideally, guidelines should be commissioned by a central body that will have an on-going programme of work. Topics may be suggested by a variety of routes. For example, mortality and morbidity data suggesting inequalities in healthcare, variation in outcomes or poor performance compared to other areas. Topics may also be generated from adverse events via an incident reporting system or be self suggested by professional societies, clinicians or service users/patients. Finally, the need may be generated by the publication of new evidence or research. When a topic is being considered for development useful questions to ask are:

- Why are you developing the guideline?
- Why are you developing it now?
- Is anyone else already doing it?
- Is there support for development available

Suggested selection criteria are shown in **Table 1a** and worked examples are attached in **Appendix 1A**.

Table 1a: Criteria to consider in topic selection

Factors to Consider when selecting topics for guideline development
▪ Topics where there is a high rate of mortality, morbidity or disability ▪ Topics where improved standards of care would reduce rates of mortality, morbidity or disability ▪ Topics where there is uncertainty, as evidenced by a wide variation in clinical practice and service delivery ▪ Topics where there are resource implications ▪ Areas where new high-quality clinical evidence has been published
Other questions to consider include: ▪ Are there available resources to implement change? ▪ Is this an area where there is a frequent chance of litigation or an area of high patient complaints?

The topic can then be selected by multidisciplinary consensus and, once agreed, a Chair selected to lead the steering group and a time frame allocated.

Recommendation: Develop or adopt a tool to select and prioritise topics for development including an agreed scoring system.

Guideline Adaptation: These criteria are valid when prioritising a guideline for adaptation.

1.4 Does every topic need a new guideline to be developed?

Once a topic is selected for guideline development, the steering committee will need to recommend whether the need is to:

- Adopt a guideline
  - Use existing guideline in current form
  - No changes apart from translation
  - Still cost incurred in translation, implementation and review
- Adapt a guideline
  - Consider which recommendations from an existing guideline can be applied to the country or region
  - May require review of evidence
  - Utilises a formal process and has cost implication but a shortened time scale (see section 1)
- New Development
  - No guideline currently exists or is fit for adaptation to local practice
  - *De novo* development required

Recommendation: draft terms of reference for the Guideline Development Group, making clear the roles and responsibilities of each member and outlining training requirements (**Appendix 1B**)

1.5 Who should be involved in the initial stages of guideline development?

Once the guideline has been commissioned, the lead author will need to form a Guideline Development Group (GDG) unique to their particular guideline. This is a selected multidisciplinary group and is different for each guideline.

All those who will be affected by the development and implementation of the guideline **MUST** be involved and recruited at this point. These are referred to as Stakeholders (see

glossary). This is essential to ensure that all interested groups feel included in the development process, develop a sense of ownership of the finished product and therefore take responsibility for implementation and uptake of the published guidance. The more people that can be involved at this stage, the more likely it is that guidelines become integrated into practice rather than attractive documents that sit on the shelf!

Suggested professional groups for inclusion in a GDG are listed below and actual examples of groups can be found in appendix 1C. Many of the group members will not contribute to the writing of the guideline but have important contributions at different stages:

Table 1b: Members of a Guideline Development Group for Sexual and Reproductive Health

Members of the Guideline Development Group	**Role in the Group**
▪ Policy makers/ Government ministers or Officials ▪ Insurers ▪ Healthcare managers/Hospital administrators ▪ Health Economist	▪ Ensure resources are provided to support the guideline ▪ Ensure the full impact of implementation is understood
▪ Clinicians in the specialty e.g. gynaecologist ▪ Allied clinicians e.g. paediatrics, emergency room specialists, primary care ▪ Specialist Societies	▪ All key questions are answered ▪ All key evidence has been considered ▪ Recommendations are achievable in practice
▪ Allied health professionals o Nursing and midwifery o Pharmacy o Laboratory technicians or staff	▪ All key questions are answered ▪ Recommendations are achievable in practice
▪ Service users such as patients or their representatives	▪ Ensure all key questions are answered ▪ Ensure recommendations are acceptable to the target population
Other members that can be considered for Inclusion: o Universities and academic institutes o Research organisations o International parties e.g. RCOG	All key evidence has been considered

Guideline Adaptation: A guideline adaptation group (GAG) still needs to be formed although the number of members will be smaller – usually 6-8. Policy makers, clinicians, allied professionals and service users should all be included. Examples are shown in **Appendix 1C**.

1.6 What resources are needed to develop a National Guideline?

- **People** - a Guideline development group of 10-12 members. A central body should provide full technical and managerial support for the GDG including any training required and a venue for meetings.
- **Time** - expect to need around 4 one day meetings to formulate key questions, review evidence, write the recommendations and revise the initial draft. There will be considerable preparation and reading required prior to each meeting
- **IT** - The process will benefit enormously from use of a professional systematic review organisation or from access to a technical team who can search, assess and synthesise the evidence for the GDG. Access to electronic communication will also simplify the process considerably and may help to shorten the time frame or reduce the number of face to face meetings required.
- **Financial cost** - as well as support for the guideline development there will be an on-going cost for implementation, audit and review and updating the guidelines. A central body should be responsible for dissemination and launch as well as review and archiving.

Guideline Adaptation: Much of the work in adaptation can be done remotely if a consensus process is used thereby reducing the need for face to face meetings and the travel costs incurred.

As the literature search may in some cases be completely avoided or in others considerably reduced, there will be less need for systematic review teams.

Additional tools to support implementation will still be required but may already exist. Similar costs for publication and dissemination will be incurred

1.7 How long does it take to develop a national guideline?

Creating a new guideline from start to finish can be expected to take between 2 and 3 years. This does not include the time taken in selecting appropriate topics but starts from when the guideline is commissioned. The table below shows the stages and the approximate time -scales.

Table 1c: Time taken to Develop a Guideline *de Novo*

	Compose group	Producing Scope	Writing the Guideline	Consultation/ Peer Review	Implementation
Time for each step	6 months	3 months	12 months	10 months	3 months
Cumulative timeline	6 months	9 months	1 year 9 months	25 months	28 months

Guideline Adaptation: will take considerably less time as the majority of the literature has already been identified and analysed but it is still likely to take from 12-18 months

Table 1d:Time taken to Adapt an Existing Guideline

	Compose group	Producing Scope	Writing the Guideline	Consultation/ Peer Review	Implementation
Time for each step	3 months	3 months	6 months	3 months	1 month
Cumulative timeline	3 months	6 months	1 year	15 months	16 months

2. Developing a Framework for the Guideline – The Guideline Scope

2.1 What is meant by the Scope for the Guideline?

The scope of a guideline is the term used to describe a framework that is agreed at the start of the development by the guideline development group (GDG). It sets out the purpose of the guideline and identifies the broad areas to be covered as well as those that will not be covered. It details the target patient group and the target professional groups. It includes the key questions that the guideline will answer and once set these key questions will inform the search criteria for the literature review. It should be a short document of 4 pages or less but can take up to 6 months to agree and finalise. Once the scope is agreed is cannot be changed. For example no new questions can be added.

Recommendation: At the first meeting of the GDG, a draft scope should be developed.

2.2 What is the importance of reviewing the literature at this stage?

When considering the important clinical questions that the guideline should answer, it may be necessary to do a short literature search to ensure that there is sufficient evidence to answer the question. There is little point in asking the guideline to answer a question, even if very relevant, when there is no evidence on which to base the recommendations. However, where no evidence exists, this may form the basis for recommendations on future research.

2.3 What should be included in the guideline scope?

Table 2a shows suggested headings for the Scope and **Appendix 2A** contains a template for a guideline scope plus worked examples. **Appendix 2B** contains examples of finalised scopes from the RCOG.

Table 2a: Content of the Guideline Scope

Section in Scope	Suggested content
Rationale	The overall aim of the guideline and the purpose of developing it. Should include expected benefits and mention of possible risks including financial
Target professional group	The healthcare professionals the guideline should be used by The healthcare settings the guideline is aimed at **Example:** all healthcare professionals involved in the provision of intrapartum care in secondary and tertiary care settings. Does not apply to primary care and community settings
Target patient group	The patient groups that the guidelines can be applied to The patient groups that might be excluded from the guideline **Example:** all women with a breech presentation at term. Excludes women less than 37 weeks gestation and babies with a known fetal abnormality
Clinical condition	A strict definition of the clinical condition to which the guideline refers **Example:** The investigation and management of postmenopausal women with known ovarian cysts

Key Questions	These are the important clinical questions that the GDG think are relevant to the topic. Questions should be limited to a maximum of 15. If the number of questions exceeds this, the guideline should be split into different topics. **Example:** The topic preterm labour is likely to be a large topic and could be split into 3 or 4 documents: prevention and prediction of preterm birth; cervical cerclage; use of tocolytics; mode of delivery of the preterm infant Questions should be based on diagnosis, interventions and outcomes but should be very specific. **Example:** which microbiological swab gives the best detection rate of gonococcus? **(diagnosis)** **Example:** what is the advantage of salpingectomy over salpingotomy for an ectopic pregnancy? **(intervention)** **Example:** Which urinary incontinence procedures give the best results for stress incontinence at 6 month follow up? **(outcome)**
What is the expected impact of the guideline?	This should describe the expected benefit to patients and the healthcare system from introduction of the guideline **Example**: more women will receive day case surgery for urinary incontinence with reduced patient stays and quicker return to normal activity but with improved long term outcomes. There will be reduced in-patient activity**.**

2.4 Who needs to comment on the scope?

The scope is decided by the GDG but must go through a consultation process involving all stakeholders including service users. Consultation can be increased by arranging a scoping workshop. The GDG should then respond to the comments and amend the scope if necessary.

Recommendation: Once the draft scope is agreed, arrange a scoping workshop and invite all stakeholders and user groups. This will ultimately assist with implementation by publicising the development of the guideline, involve stakeholders early, highlight additional areas to be included and identify new and emerging evidence

The GDG will need to meet again after the scoping workshop and consultation period to respond to the comments. Once agreed the final scope should be published and the stakeholder comments made available to aid transparency in the process. An example of a comment sheet is given in Appendix 2C.

3. Finding and Grading the Evidence

Once the scope of the guideline has been agreed the next step is to identify high quality evidence to answer the key questions outlined in the scope. The aim of this step is to identify the best available evidence and to grade it. Following on from this the GDG can extract the evidence statements and hence develop the recommendations which form the basis of the guideline (see section 4). Expect this phase to take up to 9 months. Once the scope has been approved the GDG do not need to meet again until this phase is completed.

Guideline adaptation: The majority of this phase will not be required for guideline adaptation as for a guideline to be suitable for adaptation if must include a comprehensive review of the literature. If no guideline can be identified which contains evidence from high quality studies, adaptation should not be undertaken and a full de novo guideline development should occur. However, it is essential that all members of the guideline adaptation group (GAG) should have a thorough understanding of this phase in order to be able to adequately assess and interpret the guideline that is being adapted.

3.1 What is the search strategy?

The 'search strategy' comprises the fields and terms used to search a medical database to identify studies which specifically address the key questions. A separate search should be undertaken for each key question. The search should be as inclusive as possible and should include quantitative and qualitative studies and not be restricted by the publication language. The strategy should include details of:

- The databases searched
- The publication years included
- Language limitation
- Restrictions of study types included
- MeSH terms (MEdical Subject SubHeading) and keywords used

This strategy should be included in the final document so that the search is transparent and reproducible.

3.2 Which databases should the search include?

It is extremely difficult to perform a full literature search without undertaking an electronic search. Table 3a shows databases that may be interrogated to identify systematic reviews and primary studies.

Table 3a: Databases suitable to include in electronic search

Type of Study	Database
Systematic Reviews	Cochrane Database of Systematic Reviews (CDSR) & Cochrane Central
Randomised Controlled Trials	• Embase • Medline/Pubmed • Cumulative Index to Nursing and Allied Health Literature (CINAHL) • MIDIRS • Database of Abstracts of Reviews of Effects and Technology Assessments (DARE) • NHS Economic Evaluations Database (NEED)
Clinical Trials	• Registries of clinical trials and systematic review protocols (PROSPERO) • Ethics committees registers
Grey Literature	• Hand search for abstracts from proceedings of meetings • Hand search on reference lists • Personal communications

Guideline Adaptation: **Appendix 3A** shows the databases that may be searched to identify existing guidelines

3.3 Who is the best person to undertake a literature search?

Depending on the topic, this can be a very complex and time consuming process and a full literature review is best performed by a medical librarian or an information specialist. Internet access and good IT skills are essential and full technical support will be required.

Recommendation: The Steering Group should provide the services of professional team or expert in searching and summarising the literature.

Guideline Adaptation: A full literature search will not be required but a limited search will need to be undertaken to ensure there has not been significant new evidence since the publication of the guideline being considered for adaptation. On occasions it may also be necessary to review the original papers used in the guideline development to understand the strength of the evidence on which the recommendations are based. It should not be necessary to employ information specialists for this purpose.

3.4 What type of studies should be included in the literature search?

The search may be restricted to randomised controlled trials or systematic reviews if there are sufficient such studies published and a large volume of evidence. However, if evidence is poor, observational studies may be used in isolation if there are no higher quality studies available. For each key question, a framework for the search should be used and the PICO model is recommended.

3.5 What is the PICO framework?

The **P**atient, **I**ntervention, **C**omparison and **O**utcome or PICO framework is a series of questions aimed at increasing the specificity of the literature search. Interventions themselves are further grouped into interventions regarding:

- Diagnosis
- Prognosis
- Intervention
- Service delivery & training

This framework is applied to each key question in the scope. Examples are shown in **table 3c**.

Table 3c: Use of the PICO framework

PICO	Definition	Example 1: tubal pregnancy	Example 2: induction of labour
Patient	Type of patients relevant to the question. Also implies which patients are excluded	Women with a tubal pregnancy (excludes cornual and cervical ectopics)	Women at term (excludes women less than 37 weeks).

Intervention	what policy, treatment or procedure is being considered	**Diagnosis** : BHCG versus BHCG + progesterone **Intervention**: Laparoscopy	**Prognosis**: chance of remaining undelivered by 42 weeks Service delivery: out-patient induction of labour
Comparison	What is the intervention being compared to (may be placebo or usual care)	Salpingectomy versus salpingotomy	**Induction** versus expectant management
Outcome	Most clinically important measure	Subsequent intrauterine pregnancy rate	Live birth rate; failed induction; admission to the neonatal unit

These criteria are then used in the literature search to generate the most applicable evidence but may need to be adjusted or expanded if no evidence is found.

3.6 How is the quality of a study assessed?

Ideally each study should be assessed by 2 people independently; however, this may not be possible if resources are limited. Tools exist that can be applied to each different study type and are given in **Appendix 3B**.For each key question, the study type with the least chance of bias should be used.

Guideline adaptation: Different tools exist to assess the quality of existing guidelines in order to aid decisions about adaptation. The most robust of these is AGREE II (see section 5)

3.7 What is the next step in development?

Once the literature has been reviewed, the evidence should be collated into tables (see **Appendix 3C**) and the evidence statements generated.

Recommendation: Once the literature review is complete, arrange a meeting of the GDG to develop the evidence statements

3.8 What are the evidence statements?

The evidence statements are a summary of the scientific information extracted from the primary studies and systematic reviews. The information should include details of the relative effects of the intervention or treatment with the confidence intervals so that the readership can decide whether the size of the effect is sufficiently large to allow implementation into clinical practice. Evidence on the harmful effects and costs must also be presented.

The statements must then be graded so that the strength of the evidence can be judged.

An example of an evidence statement regarding ectopic pregnancy is shown:

"*Laparoscopic procedures were associated with shorter operation times, less intraoperative blood loss; shorter hospital stays and lower analgesics requirements. There was no difference in the overall tubal patency rates (RR 0.89, 95% CI 0.74-1.1) between the two approaches"* Evidence level 1a (implying the evidence is derived from randomised controlled trials).

3.9 How should the evidence be graded?

There are a number of different methods currently in use that assign a ranking or hierarchy to the different study types. The most commonly used system is that described by the Agency for Health Care Policy and Research (AHCPR) and is shown in **Table 3d**. The main limitation of this method is that it does not account for the quality of the study so that a small RCT would rank higher than a large observational study. In addition there is no adjustment for bias in a study or for the use of indirect evidence. For example an RCT on the risk of postoperative venous thromboembolism applied to women after Caesarean section is indirect evidence and does not account for the effect of pregnancy.

A newer method is the GRADE system - Grading of Recommendations Assessment, Development and Evaluation. In this method, the study type automatically assigns a ranking of high, low or very low. Adjustment can then be made for the quality of the study as shown in **Table 3e** giving a further ranking of medium.

Table 3d: Grading the evidence

Level	Evidence Base
1++	High quality meta-analyses, systematic reviews of RCTs or RCTS with a very low risk of bias
1+	Well conducted meta-analyses, systematic reviews of RCTs or RCTs with a low risk of bias

1-	Meta-analyses, systematic reviews of RCTs or RCTs 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

Table 3e: GRADE method for grading evidence

Type of evidence	**Grade**
Randomised controlled trials and systematic reviews	High
Observational studies	Low
Any other evidence	Very Low
Decrease grade if: ▪ Serious (-1) or very serious (-2) limitation to study quality ▪ Important inconsistency (-1) ▪ Some (-1) or major (-2) uncertainty about directness ▪ Imprecise or sparse data (-1) ▪ High probability of reporting bias (-1)	

Once the evidence statements have been derived the guideline writing can finally begin!

4. Writing the Guideline

Once the literature has been reviewed and the evidence statements derived, this phase involves drafting the guideline recommendations. These should be directly linked to the evidence. Once all the information is available this phase should be completed within three months. It will require a meeting of the GDG to draft the guideline.

4.1 What format should the guideline take?

In a guidelines development programme, the Steering Group should decide on the preferred format for the guideline and provide a template. Section headings should be common to all guidelines and an example is shown in **Appendix 4**.

Question and answer formats are very popular as they are easy to read and are easy to convert into a patient version or a lay summary. A summary of the recommendations is usually given at the start of the document. Consideration should also be given to the media in which the guideline will appear and how it will be disseminated e.g. printed booklet or document, electronic document, electronic document that can be printed out.

Recommendation: Agree a standard format for all guidelines within a development programme. Agree the different media in which the documents will be published

4.2 What is the difference between the evidence statements and the recommendations?

Evidence statements are conclusions drawn from the literature. Recommendations suggest how this should be incorporated into clinical practice. For example:

Evidence statement: laparoscopic management of ectopic pregnancy is associated with shorter operation times, less intraoperative blood loss, shorter hospital stays and lower analgesics requirements compared to laparotomy

Recommendation: all women who are haemodynamically stable should be offered laparoscopic management of a confirmed ectopic pregnancy

Evidence statement: active management of the third stage of labour is associated with a reduced risk of postpartum haemorrhage but with a slight increased risk of retained placenta

Recommendation: all women should be offered active management of the third stage of labour to reduce the risk of postpartum haemorrhage

4.3 What information needs to be included as part of the recommendation?

Recommendations should be clear and concise and focus on the actions that need to be taken. They should include:

- information on the strength of the recommendation (see below)
- the expected outcomes of implementing the recommendations e.g. improving cure rates of cervical cancer
- consideration of the relative value of the different outcomes e.g. the prevention of stillbirth would be of more importance than an increased length of hospital stay when considering induction of labour
- a balance between benefit and harm from an intervention e.g., active management of the third stage of labour is associated with a reduced risk of postpartum haemorrhage but with a small increased risk of retained placenta
- resource implications for implementation of the guideline
- take into account any legal issues
- e.g. nifedipine and atosiban are both effect in delaying delivery in preterm labour. While there is a considerable cost advantage to the use of nifedipine it is unlicensed for this indication
- consideration of issues of equality and discrimination
- priorities for future research
- auditable standards that can be used to assess the success of implementation e.g. the number of women having laparoscopic management of ectopic pregnancy

4.4 How is the strength of the recommendation assessed?

The strength of the recommendation will reflect the evidence on which it is based. The system most commonly used is derived from the AHCPR and relates to the number and quality of studies that support the recommendation.

In addition to this, some recommendations may be described as good clinical practice (GCP) They are likely to be issues for which there is not, nor is there likely to be, any research evidence but may refer to as an intervention regarded as sound clinical practice and agreed on the basis of the clinical knowledge and expertise of the GDG.

Strength of recommendation	**Quality of Evidence**
A	At least one meta-analysis, systematic review 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 Explorated 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 Explorated evidence from studies rated as 2^{++}
D	Evidence level 3 or 4 OR Extrapolated evidence from studies rated as 2^+
GPP	

4.5 What happens if there is insufficient evidence to make a recommendation?

Where there is insufficient evidence on which to make a recommendation this should be clearly stated and recommendations made on the priority for future research

4.6 What should be included in the provenance section?

The provenance section gives details of the ownership of the guideline. It should include:

- the authors names and contact details
- the name of the person responsible for review
- the date of publication and the date a review or update is required
- the dates of any reviews or amendments
- a version number

4.7 What is the next stage of development?

Once the guideline has been drafted, it should be circulated to all stakeholders and comments invited. The CDG should review and respond to all the comments and amend the guideline as appropriate. New questions cannot be added at this stage. Once the amendments have been made, the final document is ready for publication and dissemination.

5. Adaptation of Guidelines

Adaptation is a systematic approach to considering the use and/or modification of guidelines produced in one cultural and organisational setting for application in a different context. Adaptation will be undertaken by a guideline adaptation group (GAG). While using less technical and financial resources, adaptation will still take 12-16 months to complete.

Other sections of the toolkit highlight those areas where different or alternative steps are necessary for guideline adaptation as opposed to de novo development.

5.1 Why decide to adapt a guideline?

De novo guideline development carries significant resource implications in terms of time and skill-dependent steps of literature search and critical appraisal. Hence clinicians or guideline developers may choose to utilise existing guidelines from authoritative sources. Unfortunately, guidelines developed for use in one country e.g.UK, may not be directly transferable to other settings or local needs, hence requiring 'adaptation' to maintain local relevance. The adapted guidelines can then be:

- introduced at national level for all the hospitals
- can be used for all hospitals in a region
- can be used at an individual hospital

The task of the steering group is to prioritise topics for guideline development and make a decision as to whether adaptation is the most appropriate method to undertake. The advantages and disadvantages are summarised in **Table 5a**.

Table 5a: Advantages of guideline adaptation

Advantages	**Disadvantages**
Shorter time scale – particularly important if it is a high profile "hot" topic	More up to date information may not be included
Recommendations can reflect circumstances in the targeted setting including health needs, policies and resources.	Clinical questions that are important locally may not have been covered in the original guideline
Requires less technical skills as a full search and review of the literature is not required	Does not involve all stakeholders in the process leading to barriers to implementation

Less financial resources will be required	Existing guidelines may be used in different healthcare systems making adaptation unfeasible
	No suitable guidelines may be found; existing guidelines may not be evidence based

5.2 Which aspects of the process are the same as new guideline development?

Guideline development	Guideline adaptation
Requires steering group	Requires steering group
Formal process for topic selection: large working group, over an extended period of time.	Formal process for topic selection but smaller group with shorter time scales
Guideline development group – large, includes medical librarian or information specialist reviewed	Guideline adaptation group – 6-10 members, no information specialist required
Literature search: extended and systematic review of literature to make recommendations with highly skilled working group and high technical specifications.	E search for peer reviewed guidelines on the topic; i.e. RCOG, NICE, SIGN etc Literature review not required or limited
Grading of the evidence	Grading of the existing guideline (AGREE method)
Peer review and consultation with stakeholders	Peer review and consultation with stakeholders
Dissemination	Dissemination

5.3 Which guidelines are suitable for adaptation?

Adaptation should be considered when:

- there is evidence that actual care varies from hospital to hospital
- the topic is of sufficient importance to the local setting
- up to date, locally valid guidelines do not already exist but international guidelines are available

- the topic is sufficiently complex to require development of a new and locally relevant guideline.

For example: European guidelines on management of HIV in pregnancy are not automatically transferable to obstetric practice in developing countries. Advice about delivery by caesarean section and avoidance of breastfeeding may not be appropriate in many countries where these might result in increased morbidity and mortality to mother or baby.

For example: UK guidance on intrapartum care may need to be modified depending on equipment and facilities available to clinical staff in some developing countries.

Recommendation: once a decision has been made to adapt a guideline, a systematic search of guideline databases should be undertaken to identify documents suitable for adaptation (see section 3)

The quality of existing guidelines can be assessed using the Appraisal of Guidelines Research and Evaluation Europe tool (AGREE II) which critically assesses the methodology of the development of the source guideline. Some extracts from this tool are shown in appendix 5A and a simpler purpose designed tool is given in **Appendix 5B**).

AGREE Instrument

- The Instrument provides a tool to assess the quality of clinical practice guidelines.
- This toolkit uses 23 items to support and assess the 6 quality domains
  - Scope and Purpose
  - Stakeholder involvement
  - Rigour of Development
  - Quality of Presentation
  - Applicability
  - Editorial Independence
- An overall assessment allows the assessors to make a judgement on the guideline as a whole.
- Rating Scale is 1 (Strongly disagree) -7 (strongly agree) but the panel has to decide on a cut off point or rank the guidelines.
- Each member of the GAG completes the ratings independently
- no minimum score but the numerical values can be used to compare the quality and applicability of different guidelines.

This process may identify a guideline which is suitable for ***adoption*** rather than adaptation.

Adoption of a guideline is the acceptance of a guideline as a whole after an assessment of its quality and content i.e. no changes are made and the document is used in its entirety.

It is then translated into the local language(s). The GAG must arrange dissemination and implementation as for a new or adapted guideline.

5.4 What are the methods for guideline adaptation?

Robust tool kits can be used for guideline adaptation to ensure good quality and evidence based recommendations are implemented. The ADAPTE method is used for creating a guideline whose recommendations are adapted from a number of different sources or existing guidelines.

ADAPTE: Guideline Adaptation (www. adapte.org)

- allows the GAG to set out the scope of the new document
- ensure that all questions relevant to the local population are answered
- 3 Phase Approach:
  - o Set up phase: Identify necessary skills and resources
  - o Adaptation phase: set up topic, search the guideline, assess quality of evidence and applicability, discuss adaptation and draft guideline.
  - o Final phase: Obtain feedback from stakeholders, consult with developers of source guidelines, establish review process and create final document.

A far simpler method is the RAND consensus method which identifies and utilises a single source document whereby each recommendation is reviewed and a decision made as to whether it is locally applicable (see **Appendix 5C** for more details).

RAND's Consensus methodology (RCOG approach – APPENDIX 5C)

- Clinicians, policy makers and service users from the intended setting can bring their local perspectives to the final wording of recommendations , ensuring that these are in accord with the local culture, available services and interventions.
- Rating rate in RAND is 1(Strongly disagree) – 9 (Strongly agree).
- private decision making by individual participants using mailed questionnaires
- ratings are divided into 3 bands and the recommendations accepted or not depending on the criteria agreed in advance:
  - oaccepted if majority rate in highest band rejected if majority rate in lowest band
  - ono agreement if middle band: requires discussion at face to face meeting and review of evidence

Recommendation: The steering group should decide which method (s) are to be used for adaptation and a formal assessment tool and scoring system agreed.

Recommendation: arrange a meeting of the GAG after completion of the consensus questionnaire to discuss recommendations where there is no agreement and draft modifications

5.5 When might adaptation not be possible?

Adaptation may not be possible where:

- There are no existing evidence based guidelines of sufficient quality
- There is insufficient evidence in existing guidelines that can be applied to the local setting because of:
    - a lack of resources
    - a different health care system or accessibility to patients
    - policies or legal restrictions
- There are too few recommendations that can be adapted into local practice

In this situation, the GAG may need to consider whether to commission a new guideline to be developed from the start or whether to discuss with policy makers and managers a change of policy or funding to allow the adaptation to proceed.

5.6 What happens once the adapted guideline has been drafted?

The adapted guideline will need to be circulated to all stakeholders, the comments actioned and implementation progressed as described in sections 6 and 7.

6. Implementation of Guidelines

Once the recommendations have been agreed, the final document undergoes a peer review to ensure the guideline is relevant, supported by robust scientific data and contains realistic expectations of the health service providers and commissioners. The next step is the editorial process to ensure that document is easy to read and navigate and the referencing format adhered to.

The guideline is now ready to launch!

Guideline adaptation: once a guideline has been written, the process for implementation is the same as for a new guideline

6.1 What needs to be included in the final guideline?

The Steering group should decide which media or formats the final guideline will be available in. The final published document should contain:

- a summary of the recommendations at the beginning.
- the scope and what is covered and who the guideline is aimed at. (e.g. secondary care, tertiary care)
- clear statements of recommendations supported by robust data. Evidence should be appropriately graded and good practice points highlighted.
- A balanced opinion between benefit and harm of an intervention and resource implications.
- auditable standards
- further research relevant to the topic

Consideration should be given to how information will be disseminated electronically and the guideline formatted accordingly for health professionals as well as patients/lay persons.

Many guideline development groups have a website where guidelines can be accessed. As well as seeing the status of guidelines in development, new guidelines can be promoted. There are links to supporting documents including the scope and the comments from stakeholders. Some organisations require membership to allow access but this will limit dissemination.

Table 6a: Different documents available in different media

Paper copy	Electronic copy
▪ Complete version ▪ Condensed version ▪ Quick reference guide	▪ On-line ▪ Distributable e.g. USBs, CD ROMs, DVDs ▪ Apps for mobile devices- may be more interactive

Recommendation: The GDG or GAG should decide what formats the guideline will be produced in and what additional materials will be produced once the scope has been finalised

6.2 How should the guideline be launched and implemented?

Change in practice through new guidelines begins with the involvement of stakeholders at the beginning of the process. It can only be facilitated if the guideline is launched and disseminated appropriately (see **table 6b**). Audit and feedback have a variable impact but provide baseline information to assist countries and organisations in developing an implementation strategy. The effectiveness of the different methods is variable or largely unproven, although computerised records and reminders have shown the most consistent effectiveness. Combination strategies are most successful with different approaches at different times likely to raise awareness most consistently.

Recommendation: the GDG or GAG should agree the implementation strategy once the draft guideline has been written in order that important launch dates and information can be circulated with the draft

Table 6b: Implementation Strategies for National guidelines

Method	**Effectiveness**
National meeting ▪ advertised well ▪ supported by specialist societies ▪ educational incentives (professional accreditation) ▪ linked to training events	Small to moderate effect Expensive Can be combined with written materials
▪ Press releases and posters o Can use mass media as well as local	Moderate effect
▪ Promotion through medical organisations and societies (e.g. RCOG) ▪ Involvement of National organisations	Moderate May be combined with training event or awareness days
▪ Opinion leaders and champions o Often identified at the scoping stage and fully committed	Variable but champions may develop own innovative implementation methods
▪ Education methods e.g. training days or educational meetings	Group education less effective than individual or targeted education
▪ Patient mediated interventions	No evidence that effective
▪ Financial incentives and penalties ▪ Policy/regulation	None of these methods effective
▪ Internet/online databases	No evidence that effective
▪ Combination of methods	All combinations more effective than any one intervention alone

Following the launch there needs to be a programme of reminders and continued incentives until the changes are embedded in clinical practice. This might include:

- monthly bulletins
- an electronic alert system for notification of new guidance e.g. from the specialist societies
- launch of additional tools at a later date, for example the audit tools
- follow up training days

Recommendation: Arrange a national launch meeting to coincide with a press release. Include consumer input and support

6.3 How long does it take for a guideline to be incorporated into clinical practice?

Despite robust strategies, the recommendations may take up to three months (sometimes longer) to be incorporated into practice. It is hence vital to continue 'championing' the guideline with health care professionals as well as patients.

6.4 What additional tools may be required to support implementation?

Information needs to be provided in a number of different formats for distribution to different groups of stakeholders

These include

- A quick reference guide or executive summary – a summary of the key recommendations and priorities for implementation
- Algorithms as a visual or easy to follow explanation of the care pathways
- Information for patients or a lay summary
- Electronic versions- for easy dissemination; provide latest updates and ensure recommendations remain current

In addition, other tools may be provided at the initial launch or as a follow up to assist uptake into clinical practice. These additional tools may help overcome some of the barriers to change and are listed in **table 6c**. Examples of the tools are shown in **Appendix 6.**

Table 6c: Implementation tools

Additional Tools
▪ Teaching aids e.g. slide sets ▪ guidance specific implementation tools e.g. dosing regimes, data collection proformas ▪ Costing tools ▪ Baseline assessment tool; spreadsheet detailing all recommendations which organisation completes to assess compliance ▪ Audit tools for quality assurance

6.5 What are the potential barriers to implementation?

Implementation can be hampered by several human or organisational barriers and these need to be carefully considered when developing and drawing up strategies for dissemination and implementation. Where implementation is resisted or slower than expected, consider focus groups to develop solutions and receive feedback.

Barriers to Guideline implementation
• Structural factors e.g. financial disincentives, national targets and regulations • Organisational factors e.g. lack of facilities or equipment, lack of reward /recognition, inappropriate skill mix • Peer group e.g. standards not in line with preferred care • Individual factors e.g. knowledge, attitudes, skills, limitations in accessing electronically • Professional - patient interaction e.g. problems with information processing

Recommendation: Once a guideline has been launched and implemented, a review or audit needs to be undertaken to ensure it is incorporated into clinical practice and that barriers to change have been overcome

7. Assessing the Impact

Once a guideline has been launched there needs to be an assessment to ensure that it is:

- being effectively utilised i.e. that we are doing what we think we are doing
- achieving the desired effect
- potential risks and harm are controlled

This can be achieved through clinical audit but can also be measured in other ways such as a reduction in incident reporting, adverse outcomes, patient complaints or litigation, or through other quality markers. Risks as well as benefits need to be assessed. For example:

- the introduction of a guideline on pre-term birth may show a reduced incidence of respiratory distress syndrome if more babies are given antenatal corticosteroids
- a guideline on thromboprophylaxis following gynaecological surgery may show a reduction in postoperative thromboembolism but may also reveal an increased risk of postoperative bleeding

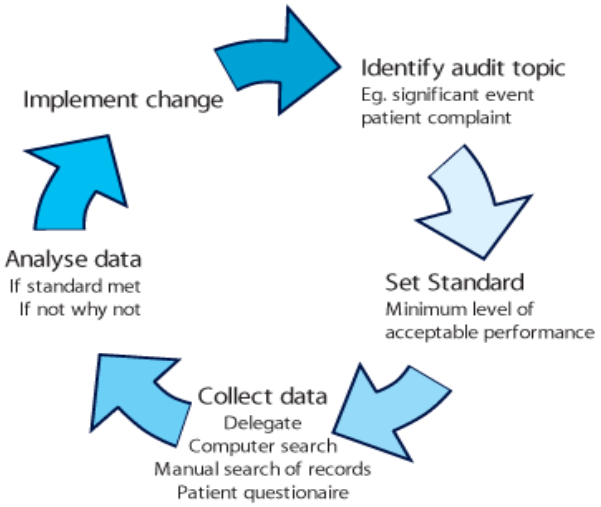
Clinical audit is an ongoing process and can be commenced 3-6 months after a guideline has been launched to allow time for implementation. An audit at this point also serves as a reminder of the guidance and can improve implementation.

Guideline adaptation: once a guideline has been implemented, the process for review and audit is the same as for a new guideline

7.1 What is clinical audit?

Clinical audit is a systematic review of care to assess whether specific standards are being met. An example from an audit on preterm labour would be the percentage of women delivering preterm who received a course of antenatal corticosteroids to promote fetal lung maturity.

Where standards are not being met there should be a plan of action to improve the standards after which a repeat audit is undertaken. Hopefully this shows improvement and the process is repeated at regular intervals to ensure this standard is maintained. This is referred to as the audit cycle.



In some countries the clinical audits required are set by an external body to assess whether the units are achieving a preset standard. Failure to achieve this standard may result in a financial penalty or loss of reputation e.g. NHS litigation authority.

Table 7a lists information that may be collected under the term “clinical audit” which are not audits

Table 7a

Data collection	Type of study
Collection of outcome data	Morbidity and mortality data Performance data
How successful a particular consultants care is	Individual performance data
How happy patients are with the care or treatment they receive	Patient satisfaction survey
How likely a treatment is to work	Research
What the best treatment is for a particular condition	Research

7.2 Who should be involved in a clinical audit?

A multi-professional group is required to undertake a clinical audit and is referred to as the clinical audit team (CAT). It usually involves:

- Senior clinician
  - Can be doctor or nurse/midwife
  - supervise writing the proforma, setting up the methodology and supervising the extraction of data.
- Junior clinicians
  - represents those who deliver the service; this helps embed practice and achieve change
  - often a training requirement
- Managers
  - find the notes and make them available for the process
  - facilitates changes recommended by audit
- Statistician
  - sets the number of notes required
  - analyses the data
  - suggests how to present the data.

Other team members may be involved from allied health professions to advise on the audit and the results. For example a microbiologist may be involved in an audit on group B streptococcus; a pharmacist may be involved in an audit on chemotherapy for ovarian cancer

The clinical audit team should develop an audit proposal. This is similar to a research proposal and should detail:

- the need for the clinical audit
- describe the Clinical Audit standards
- describe the methodology
- how results will be presented
- who will be responsible for implementing actions

Recommendation: the clinical audit team should meet and complete an audit proposal. An example is shown in **Appendix 7A**.

7.3 What are audit standards?

Well-written guidelines contain a series of recommendations linked to the evidence. These recommendations form the basis for a standard that can be measured and used to judge the performance of an individual, an hospital or a country. When assessing the impact of a new or adapted guideline, each organisation must decide which recommendations are the priorities for implementation and what is an acceptable standard bearing in mind any local factors. Examples of standards are shown in **table 7b.**

Table 7b: Standards derived from guideline recommendations

Guideline recommendation	Audit standard
Women with heavy periods do not need a hysteroscopy as a first line investigation	Less than 5% of women should have a hysteroscopy as first line investigation for heavy periods
All pregnant women should be recommended an HIV test	95% of pregnant women should have an HIV test before 20 weeks
Women with chronic pelvic pain should be offered 3-6 month trial of hormonal treatment before diagnostic laparoscopy	80% of women should have a trial of hormonal therapy for chronic pelvic pain

The CAT will set the expected or acceptable standard for each criteria based on the importance of the recommendation. Following implementation of a new guideline, the initial standard may be modest with an expectation of improvement over time. The standard may be increased in subsequent audit cycles. For example, on the introduction of guideline on screening for HIV in pregnancy, the initial standard may be 80% to allow time for training, implementation and acceptance by the population. Over the course of 2 years this standard may rise to 95%.

7.4 What methods can be used in a clinical audit?

7.4.1 Data Collection Proforma

Information should be recorded on either a paper or directly into an electronic database. Data should be anonymous and each subject allocated an audit number only. A specific proforma should be designed for each audit topic (examples are shown in **Appendix 7B**).The questions should be clearly defined with a small range of possible options; ideally yes/no answers or a drop down list of a limited number of options

For example:

1) Was an HIV test offered at booking YES / NO

2) Did the woman have an HIV test at booking?

- test not offered
- test offered but declined
- test offered and accepted

7.4.2 Sampling methods

The CAT will need to agree a sample size and sampling method as well as a time frame for the data collection.

For uncommon conditions all cases over a set time period would be collected. For example of cases over uterine rupture over a 1 year period

For common conditions the options would be:

- random sample of 5% of cases in 1 year e.g. miscarriages
- all cases in a short time period e.g. all Caesarean sections in 1 month
- 1 in 5 cases e.g. women attending for emergency contraception
- 30 sequential ectopic pregnancies
- All cases of pelvic inflammatory disease selected every Friday (convenience)

7.4.3 Data collection method

Audit data can be collected retrospectively or prospectively. The merits of each method are shown in **table 7c**.

Table 7c: Role of prospective and retrospective audit

Prospective audit	**Retrospective Audit**
Complete data set from each case Carrying out audit may generate change in practice by raising awareness Meanings and abbreviations can be clarified	Predictable time frame Auditors workload easy to organise Number of cases can be achieved Results and changes available early
Time frame uncertain as incidence varies Workload harder to manage Some cases may be missed if not all staff aware of need to identify and audit cases	Case notes may be missing; especially interesting or unusual cases Required data may not be recorded in notes Guidelines may have changed since time period chosen for audit

7.5 How is the audit recorded?

Once the audit has been completed, a report is prepared and disseminated summarising the findings and making suggestions for change where standards are not being met (**Appendix 7C**).

A system for registration and monitoring of clinical audit is recommended as it allows tracking of audits done and improvements achieved. It will make managers and policy makers aware of efforts being made, where improvement is needed and what resources are required to implement changes. Nationally collected audit data allows different organisations to compare themselves to others.

Recommendation: Set up an audit database and templates for audit notification and reporting

7.6 How are the audit results disseminated?

The results of the audit need to be shared with those providing the care as well as the managerial teams. Positive findings should be acknowledged but areas for improvement should also be recognised. Audit can be:

- Presented at a regular departmental meeting
- Presented at an educational/awareness event – useful to implement changes
- Circulated as a newsletter/ report – can be included in a risk management report every quarter; can be electronic
- Displayed on departmental notice boards
- Included in promotional posters aimed at generating change or improvement

In addition results may be presented to management or policy makers in the form of a structured report, recorded on an electronic database or given as a formal presentation during meetings at an organisational level

7.7 What is the role of an action plan?

Following the implementation of a new guideline, an initial audit is likely to show a difference between the expected and the actual results. In order to ensure that standards improve, the Clinical audit Team (CAT) should generate an action plan following the principles of the 5 “W”s :

- **Who** needs to know results of the audit?
- **What** changes are needed?
- **When** do they need to make the changes?
- **Why** do they need to change?
- **What** is needed to make the changes?

There may be a wide variety of actions arising for a clinical audit but examples are shown in T**able 7d**.

Action	Purpose
Generate posters/ notices/ algorithms	Raise awareness
Design documentation proformas	Improve documentation standards as well as acting as an aide memoire
Business case Cost benefit analysis	Identify and provide additional resources
Amend or review guidelines	Make standards achievable
Arrange training programme	Raise awareness; confirm or establish competencies

7.8 What is the purpose of re-audit?

This is a vital part of the process to :

- Identify if changes have occurred
- Identify any new issues
- Proves to the overseeing body that guidelines are being followed
- May need to be part of a continuing programme

8. Local Guideline Development and Adaptation

In countries where there are robust national guidelines produced, each local area or Unit will need to establish a process for adapting those guidelines for local use. For the purposes of this section the term “local” may be taken to mean a single department within an institution (e.g. obstetric department of a hospital), an individual organisation or hospital, a group of collaborating but similar hospitals, a regional area (e.g. West Yorkshire) or even a small country that is part of a larger area (e.g. central Asia).

8.1 Why do Guidelines need to be adapted for local use?

National or centrally produced guidelines tend to be detailed and detailed documents that run to several chapters and several hundred pages. They include sections relevant to all potentially interested parties and stakeholders. However, not all these section may be relevant to the local Unit and it may be difficult to extract the relevant data. In addition, the

part relevant to the local unit may be only a small section of a much larger document. Some examples are given in table 8a.

Table 8a: Examples of the Need for local Adaptation

Type of Guidance	Title	Local Unit	Need For Adaptation
National	Weight Management Before, During & after Pregnancy	Local Hospital/ Secondary Care	Sections are included on pre-conceptual care which are not provided by secondary care Large sections refer to provision of leisure facilities and sports programmes to improve exercise in the general population
Secondary Care	Thromboprophylaxis	Department of Obstetrics	Guidelines are generic for hospital admissions and do not account for additional risk factors and cautions in the obstetric patient
National	Intrapartum Care	Midwifery led Unit/Primary Care	Not all care described is offered in the local unit e.g. electronic fetal monitoring, induction of labour
Regional	Heavy Menstrual Bleeding	Local Hospital/ Secondary Care	Not all interventions described are offered in the local unit

Finally, local units are more likely to be able to assess the potential benefits of new guidance. For example a guideline introducing the use of tape procedures for urinary stress incontinence might initially appear to have cost implications by needing additional training and equipment but this may be offset by being able to offer more day case procedures and therefore reducing the number of hospital admissions.

8.2 How are local guidelines different to National or International Guidelines?

Local guidelines are much shorter and contain only that information which is relevant to the local unit. They may have embedded within them one or more protocols or standard operating procedures such as the procedure for transferring a patient to another Unit. They will usually be available electronically or printed out in simple format and are less likely to be supported by additional tools such as patient information and audit tools.

National guidelines on the other hand contain information to cover all eventualities and are more generic in recommending the best treatment or intervention but will not give specific information on drug doses and regimes. They are formally published in bound volumes and include additional information for service users and other supporting documents.

Local guidelines adhere to the local format so that all users are familiar with the layout and how to access the information. They will also contain:

- specific information for the local unit where appropriate such as named personnel, contact telephone numbers, ward or departmental details

- details of requesting and referral systems and proformas that may be required

- specific drug protocols e.g. the regime for magnesium sulphate including the administration pump to be used

- an assessment of the impact of introducing the guideline particularly considering financial implications. However, good clinical guidelines may result in cost savings by more efficient use of available resources.

- an evidence base referencing the original document and any additional references utilised. The grading system may be absent or simplified.

- a provenance section detailing the author, review date and version number to assist archiving

8.3 Who should be responsible for Guidelines Locally?

Local guidelines should be administered and governed by a central committee comprising multi -professional workers and at least one service user. Commissioners and insurers may be asked to contribute but a librarian/information specialist and health economist will not usually be involved in local guidelines. The central committee will have responsibility for checking the quality of the guidelines, ensuring consistency and avoiding duplication. Whilst they will ensure there is a need for the guidelines, they are not experts in every area and will not be able to advise on the content. This is the role of peer review with widespread review by those responsible for applying them. Administrative or clerical support will be required but variable in depending on the local areas commitment to the process.

The central committee will also take responsibility for archiving guidelines which are amended or updated. Where the guideline process is well established they will also advise departments of the publication of new national guidance and request review and comments on them.

In addition, each specialty in the local area should have a group of staff allocated to guideline development. They will be responsible for selecting topics, commissioning authors and for arranging widespread consultation and peer review. They will also be multi-professional and meet at least 4 times a year. The local committee reports to the central committee but also to the Risk Management Group.

Guidelines will need to be approved by an operational group within the specialty before being presented to the central committee for final sanctioning and publication.

Recommendation: Develop a local Clinical Guideline Committee comprising medical, nursing and allied staff as well as service users. Consult a pharmacist for all guidance including drugs and a microbiologist for all guidance involving antibiotic use.

8.4 Can guidelines be adopted for local use?

Whilst in some instances the majority of the recommendations included in a national guideline can be incorporated into local practice, they will normally need some adaptation to fit the local services and the local population and at the very least will need to be condensed into a more accessible form. Local guidelines will normally be only 10-20 pages excluding appendices. In order to assess how many of the recommendations fit local practice it is useful to use a baseline assessment tool (see Appendix 6C) which is used to assess the "gap" between the recommendations and current practice. If the gap is small, adoption may be feasible but in most cases further development or formal adaptation will be required.

Recommendation: When new national guidance is published, the specialty guideline committee should undertake a baseline assessment (gap analysis) within 6 months and advise the central committee and Risk Management group of any develop requirements

8.5 What is the best process for adapting guidelines for local use?

Local adaptation should be done using a formal process as described in section 5 using the most appropriate tool. It will involve a small group of people (6-10) and be done in face to face meetings. Prior to adaptation, the specialty group will need to agree the priorities for guideline development (see section 1). A checklist may be applied to assist in development and ensuring quality (see Appendix 8A).

8.6 What is the best process for developing guidelines for local use?

Development of a new local guideline will be similar to national development (see sections 1-4) but on a much smaller scale. As such, the number of topics developed at any time should be restricted as should the breadth of the topic under development.

For example, the department of gynaecology at a tertiary hospital may agree to develop 2 new and update 1 existing guideline in a 6 month period. When considering guidelines on the management of urinary incontinence, this may be subdivided into a number of topics

such as: investigation of incontinence; management of the overactive bladder; medical management of stress urinary incontinence; surgical management of stress urinary incontinence etc. In addition, careful consideration should be given to what is a guideline, what is a protocol and what is a new technology as the latter 2 can be developed much more easily.

For example the use of a tape procedure for urinary incontinence is a protocol that describes in a stepwise fashion how to undertake the procedure. It can be quickly and easily developed by a clinician familiar with undertaking the procedure and is very specific to the local unit. In contrast, the surgical management of stress urinary incontinence is a guideline and will need to examine the evidence for the use of a number of different procedures and make recommendations as to which are best suited to the local population and how this is balanced with effectiveness and cost pressures. This will involve more detailed research and input from a wide range of interested parties.

8.7 What is the best process for implementing guidelines for local use?

Once the guidelines have been agreed and ratified they should be introduced in a similar way to any other new guidance (see section 6). This will involve dissemination at departmental and local meetings, inclusion in newsletters and bulletins and email promotion. It should include reminders at regular intervals particularly in advance of audit. Clinical educators may have a specific role in promoting new guidance in their own clinical areas.

8.8 What is the next stage?

Once guidelines have been implemented locally, a period of time should be allowed for them to be incorporated into routine practice after which an audit should be carried out to assess adherence. Local guidelines may need further adjustment after implementation and in light of the audit and it is usual to have a date for review and update of no more than 2 years

9. Quality Assurance (QA)

9.1 QA provided by RCOG

The RCOG will undertake to quality assure its own work and that of any representatives acting on its behalf. The RCOG will ensure that anyone acting on its behalf is fully competent to undertake the work required. Any output from work undertaken will be reviewed by the RCOG Education Quality Assurance Committee.

The RCOG may also seek input and advice on QA matters from other organisations in relation to specific and specialised work, for example NICE International, other NGOs, the Health Quality Improvement Partnership. Authorisation will be sought from the 'host' country before taking action.

9.2 QA provided by the 'host' country

The RCOG requires the 'host' country (or an institution within it) to agree appropriate quality assurance governance arrangements, to be agreed between the parties. Where no appropriate QA governance exists, the RCOG will assist the host country with establishing such governance and advising on the types of people to undertake this work.

10.Risk management

The RCOG will need to undertake a risk assessment with the host country, in terms of risk to success of the project, personal security risk to RCOG representatives, and financial risk to the RCOG of undertaking any piece of work. The outcomes of a risk assessment will differ with each proposal, as will mitigation, acceptance or rejection of risk. Use a standard RCOG risk assessment template and adapt as required.

Below is a simple list of the most likely areas of risk for consideration:

Personal/physical security of RCOG representatives
Financial risk to the RCOG – is the host country covering the RCOG's costs; does the project require external fundraising; what are payment terms
The RCOG cannot identify a suitably qualified person to undertake the Needs Assessment
The data quality provided by the host country does not permit robust analysis
There is no political or senior 'ownership' of the project in the host country
There is senior 'ownership' in the host country but that is not shared by stakeholders lower down the organisational structure
There is resistance or outright obstruction when trying to access patients or former patients
Recommendations from the HNA/TNA are rejected by the host country
The host country is unable or unwilling to make changes or undertake

recommendations due to resource implications
Cultural differences between clinicians lead to differences of opinion as to priorities
Political priorities changes during the project (funding may cease; health or training priorities may change)

Risk factors must be owned by not only the project lead(s) but by the RCOG as a whole, through the appropriate governance route. Changes to risks should be captured as they occur and dealt with immediately.

10 Definitions, Glossary and Abbreviations

DEFINITIONS

Clinical Guideline: is a systematically developed, evidence-based guidance that assists in decision-making about the appropriate healthcare for a specific clinical condition: a detailed explanation to guide you in deciding on which course of action to take

Clinical Protocol: a list of things that **must** be done in specific situations or to achieve a specific outcome: a set of rules from which deviations are not allowed.

NB This is **NOT** the same as an abbreviated or local form of a national guideline

Standard Operating Procedure : set of written instructions applied to an activity undertaken at an organisational rather than a clinical level

Care Pathway: list of steps in the care of patients over time for a specific clinical problem with expected progress and outcomes: may include referral, investigation and treatment

Public Health Guidance: guidance on the promotion and protection of good health and the prevention of disease: applies to professionals outside of healthcare

Clinical Practice Standards: a specific and measurable target representing the minimum care that would be expected: measure of the ***quality*** of care provided: not evidence based: focused on safety and providing a good patient experience

Care Bundle: a set of interventions that, when used together, significantly improve patient outcomes: usually multidisciplinary and based on evidence or research

GLOSSARY OF TERMS

Adoption (of guidance): use existing guideline in current form: must include all elements: translation allowed

Adaptation (of guidance): use some, but not all, recommendations from an existing guideline: change or omit some recommendations to be more suited to "local" practice

Scope: a clear outline of the aspects of care that the document will cover

Clinical Audit: a process of systematic review of care against explicit criteria: a quality improvement process that seeks to improve patient care.

NB This is **NOT** the same as collecting and reviewing outcome data

Stakeholder: a person, group or organisation who is, or who may be affected by the guidance

Healthcare Commissioner: an appointed person responsible for procuring healthcare services within a particular area: may be a group of people.

In the UK this is currently led by the **NHS Commissioning Board (NCB)** which is responsible for managing the more local Clinical Commissioning Groups (CCGs).

Primary Care: the first level of care or the entry point to the health care system: usually a general practitioner or family doctor but may be other healthcare providers such as nurses and midwives

Secondary Care: care provided by medical specialists with access to a range of investigation and treatment methods including in-patient care: usually, but not always, hospital based

Community Care: care provided close to the woman's home or outside of hospital

Service user or consumer: a woman or her family or other representatives, who are currently or have previously been in contact with the healthcare services being described

NICE (National Institute of Clinical Excellence): UK based organisation which produces independent, evidence-based guidance on the most effective ways to prevent, diagnose and treat disease and ill health, reducing inequalities and variation. They are aimed at all those involved in the provision of healthcare.

SIGN (Scottish Intercollegiate Guidelines Network): independent organisation developing evidence based clinical practice guidelines for the National Health Service (NHS) in Scotland:

derived from a systematic review of the literature with the aim of translating new knowledge into action to improve patient-important outcomes.

Key Questions: the main questions that the guideline should address. They are set out at the stage of the scope and are not added to after the scope has been agreed

Abbreviations

GAG	Guideline adaptation group
GDG	Guideline development group

11 Evidence Base

References & Useful Links

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Adaptation of clinical guidelines: a framework Fervers et al: Int J Qual Health Care (June 2006) 18 (3): 167-176.

Developing a methodology for drawing up guidelines on best medical practice. Council of Europe (2002)

APPPENDIX 1A: TOPIC SELECTION TOOL

For each topic suggested, consider how well it matches each of the selection criteria listed

Criteria	Topic match
Is this an area associated with high mortality?	
Is this an area associated with high morbidity?	
In all likelihood would an improvement in care reduce mortality?	
In all likelihood would an improvement in care reduce morbidity?	
What is the incidence of the problem in the local population?	
What is the evidence for current suboptimal care/treatment?	
Is there a currently accepted treatment/management?	
Is treatment/management standardised across the country?	
Is there more than 1 treatment/management in use?	
Are there resource implications if treatment/management is changed? Consider people, equipment, skill and costs	
Are there resource implications if treatment/management is NOT changed?	
Is this an important area for the specialty?	
Is this an area associated with high complaints or claims?	
Has any new evidence been published recently?	
Is any new evidence expected in the next 6 months?	
Has funding been obtained for development?	

The group recommendation could be:

- Priority for development
- Strong support but not priority
- Some support but does not fulfil all criteria
- Weak support
- Development not supported

Alternatively a score and weighting could be applied to each of the criteria although this must be agreed by the Steering body prior to application of the criteria.

APPPENDIX 1A: TOPIC SELECTION TOOL

Considering the topic of Prevention and Treatment of Anaemia in Pregnancy

Criteria	Topic match
Is this an area associated with high mortality?	No - death of mother of baby unlikely
Is this an area associated with high morbidity?	No - low level morbidity in mother and infant
In all likelihood would an improvement in care reduce mortality?	Unlikely
In all likelihood would an improvement in care reduce morbidity?	Possible reduction in some postnatal illnesses
What is the incidence of the problem in the local population?	High incidence √
What is the evidence for current suboptimal care/treatment?	Access to blood transfusion limited. Currently poor uptake of iron therapy. √
Is there a currently accepted treatment/management?	Cheap, available and acceptable to women √
Is treatment/management standardised across the country?	Not at present
Is there more than 1 treatment/management in use?	Several regimes exist including prophylactic treatment of all pregnant women √
Are there resource implications if treatment/management is changed? Consider people, equipment, skill and costs	Cost of treatment cheap and acceptable with minimal side effects and risks. Could be safely prescribed by healthcare assistants.
Are there resource implications if treatment/management is NOT changed?	No measurable effect
Is this an important area for the specialty?	No
Is this an area associated with high complaints or claims?	No
Has any new evidence been published recently?	No
Is any new evidence expected in the next 6 months?	No
Has funding been obtained for development?	Yes √

Overall this topic matches only 5 of the criteria. Compare this to the next example

APPPENDIX 1A: TOPIC SELECTION TOOL

Considering the topic of HIV infection in pregnancy

Criteria	Topic match
Is this an area associated with high mortality or morbidity?	While mortality low, maternal and neonatal infection could cause significant morbidity √
In all likelihood would an improvement in care reduce mortality?	Diagnosis and early treatment of HIV will significantly reduce mortality √
Would an improvement in care reduce morbidity?	Diagnosis and early treatment will significantly reduce morbidity √
What is the incidence of the problem in the local population?	True incidence unknown in pregnant population as there is no screening programme
What is the evidence for current suboptimal care/treatment?	Many women undiagnosed and untreated. Where diagnosis known there is poor availability of drugs √
Is there a currently accepted treatment/management?	Agreed treatment for pregnancy √
Is care standardised across the country?	Not at present
Is there more than 1 treatment/management in use?	Yes
Are there resource implications if treatment/management is changed? Consider people, equipment, skill and costs	Low cost of screening test High costs associated with staff to undertake screening in pregnancy, cost of medication and cost of expertise to care for women - high
Are there resource implications if treatment/management is NOT changed?	Continued vertical transmission of HIV which will have long term burden of disease Increasing maternal morbidity and mortality due to late diagnosis and treatment √
Is this an important area for the specialty?	Yes √
Is this an area associated with high complaints/ claims?	No
Has any new evidence been published recently?	Yes
Is any new evidence expected in the next 6 months?	Yes
Has funding been obtained for development?	No

This topic matches 7 of the criteria and would have a higher priority for development to the previous guideline. However, as new evidence is expected in the next 6 months, the guideline will be deferred for now.

Appendix 1B

Roles and Responsibilities of the different groups in Guideline Development

- Steering Group
  - Oversee Development programme
  - Select topic & commission guideline
  - Suggest workplan or timeframe
  - Approve/ratify guidelines ensuring consistency & transparency
  - Dissemination & Launch of the guidelines
  - Archiving
- Guideline Development Group
  - Find & review the evidence
  - Write the guidance
  - Amend the guidance in response to comments
  - Update the guidance as requested by the steering committee
  - Ensure guidelines adhere to boundaries set out in the initial brief
  - Incorporation of feedback
- Peer review/Consultation
  - Ensure no evidence missed
  - Ensure recommendations reflect evidence
  - No patient groups missed/disadvantaged
- Supporting Body
  - Ensure adheres to format
  - Check for accuracy and consistency
  - Ensure no patient groups missed/disadvantaged

Appendix 1C

Example of members of a Guideline Development Group

Heavy Menstrual Bleeding (NICE)
• Two gynaecologists • One obstetrician • Two primary care physicians • One gynaecology specialist nurse practitioner • One radiologist • One epidemiologist • One clinical director • Two patient or carer members representing women's interests • Technical team e.g.. systematic reviewer, health economist

Example of members of a Guideline Adaptation Group

Tubal Pregnancy
• One gynaecologists • One primary care physician • One gynaecology nurse • One emergency department practitioner • One radiologist • One service user • One biochemist/laboratory technician

APPENDIX 2A:Tool for Developing the Guideline Scope

This is a suggested template to help develop the guideline scope and should be completed by the CDG. It is followed by a worked example. It can be used for most topics and can also be used in adaptation to review what questions the GDG need an adapted guideline to answer (see final page).

Composition of Guideline Development Group

Target Patient Group: Target Professional Group:

Interventions

Outcomes

APPENDIX 2A:Tool for Developing the Guideline Scope

Key Questions -

Diagnosis / Intervention / Prognosis

APPENDIX 2A:Tool for Developing the Guideline Scope

Breech Presentation

Composition of Guideline Development Group

Two obstetricians

A midwife or specialist nurse

A primary care physician

A sonographer

A policy maker

A medical librarian

A service user

Target Patient Group: all women with a term breech presentation. Excludes preterm breech; excludes women with prelabour rupture of the membranes

Target Professional Group: all healthcare professionals providing antenatal and intrapartum care

Interventions

Diagnosis : ultrasound diagnosis of breech presentation and what should be reported; pelvimetry not considered

Interventions: external cephalic version; mode of delivery

Outcomes

Maternal	Fetal
Mode of delivery	Condition at birth
Maternal complications	Long term outcome
Effect on long term fertility	

APPENDIX 2A:Tool for Developing the Guideline Scope

Key Questions
Diagnosis / Intervention / Prognosis
When should a persistent breech presentation be suspected?
What investigations are required to assist decision making with a confirmed breech presentation?
What is the role of external cephalic version (ECV)?
What factors affect the likely success of ECV?
Should tocolytics be given for ECV?
What is the optimum mode of delivery of a breech presentation in a primip?
What is the optimum mode of delivery in a multip?
What are the maternal complications of a vaginal breech delivery compared to a planned Caesarean section?
What are the fetal complications of a vaginal breech delivery compared to a planned Caesarean section?
What are the long term outcomes of babies born by vaginal breech delivery?

***APPENDIX 2B: The Management of Tubal Pregnancy Final* Scope**

Background epidemiology
The incidence of ectopic pregnancy has remained static in recent years (11.1/1000 pregnancies) and nearly 32 000 ectopic pregnancies are diagnosed in the UK within a 3-year period. There were 13 maternal deaths resulting from ectopic pregnancy in the UK during the period 1997–99.
Tubal pregnancy can be managed by laparotomy, operative laparoscopy, medically and, occasionally, by observation alone. Management must be tailored to the clinical conditions and future fertility requirements of the woman.

Population to be studied and setting
Pregnant women with suspected tubal pregnancy managed within a secondary care setting, including outpatient management.
The guideline will not cover the diagnosis of tubal pregnancy.

Interventions to be studied
Comparison of conservative, all surgical and medical treatments for the management of tubal pregnancy.

Clinical areas to be examined
Q: Which surgical technique is preferable (laparotomy or laparoscopy) for the management of tubal pregnancy?

Q: Which surgical technique is preferable (laparotomy or laparoscopy) for the management of tubal pregnancy in the woman who is haemodynamically unstable?

Q: Should salpingectomy or salpingotomy/salpingostomy be used for the management of a confirmed tubal pregnancy in the presence of a normal contralateral tube? Which method should be used when the contralateral tubal is damaged/absent?

Q: Which medical treatment should be offered for the management of suspected tubal pregnancy and in which patient group should it be used?

Q: Is expectant management of women with suspected tubal pregnancy appropriate and if so in which patient groups should it be used?

Preliminary review of evidence
Several systematic reviews of randomised controlled trials comparing various treatments are available, as well as a small number of high-quality cohort studies. Outcomes considered include future pregnancy and fertility rates, recurrence of ectopic pregnancy and operative complications. There are notable gaps in the evidence base (no direct comparison of laparoscopic salpingectomy to salpingotomy), resulting in the need for indirect comparisons. This will make the drawing of firm conclusions difficult.

APPENDIX 2C: Sickle Cell Disease in Pregnancy – Final Stage

Scope

Background Epidemiology

The haemoglobinopathies are the most common inherited disorders worldwide and in the UK. For sickle cell disease alone, there are between 12,000 and 15,000 people with this condition in the UK, and an incidence of over 300 new births per year. Incidence of haemoglobinopathy in pregnancy is unknown in the United Kingdom but mortality in pregnancy is quoted as 0.2-0.45% of pregnancies. Sickle cell disease is associated with an increased mortality and morbidity both in pregnant mothers and in the infants due to an increased rate of pre-eclampsia, eclampsia, premature labour, miscarriages, stillbirth and intra-uterine growth restriction. Perinatal mortality has decreased over recent decades but is still up to 5%. The development of guidelines in this area is complicated as there is a great phenotypic variation between women with SCD, partly due to different genotypes (ie Homozygous sickle cell disease (HbSS), tends to be more severe than the compound heterozygotes, HbSC disease and HbS Bthalassaemia), but even within the same genotypes there can be significant variation in severity of disease.

There is considerable geographical variation across the UK with high incidence areas including Greater London, Birmingham and Manchester, and low prevalence areas including Wales, Scotland and much of rural England. This complicates management and the development of services as it leads to a large variation in experience across the UK, and makes service planning difficult.

Clinical need for the guidelines

a.We do not know the true figure of the prevalence of Haemoglobinopthy in pregnancy. It is estimated to be 120 per year. Despite the low rate, in each triennium, the death associated with haemoglobinopthy is 2-4 mothers. Thus, the morbidity mortality ratio associated with the condition is very high.
b. Haemoglobinopathy in pregnancy is associated with risks to the mother and the developing fetus: As above
c. The guideline will build on existing clinical guidelines for routine care during the antenatal, intrapartum and postnatal periods. It will focus on areas where additional (or different) care should be offered to women with sickle cell disease and their newborn babies.

Population to be covered and setting

The guideline will study pregnant women with sickle cell disease. It will look at pre-conceptual, antenatal, intrapartum and post natal care in the primary and secondary care settings and advise about contraceptive methods for women with sickle cell.
It will also look at

- The place of invasive prenatal testing
- Advice about partner testing and if there is no partner around
- What is the place for genetic counseling?

Population that will *not* be covered:

a. Aspects of routine antenatal, intrapartum and postnatal care that apply equally to women with and without major haemoglobinopathies, including whether or not to screen for haemoglobinopathies.
b. Aspects of routine care of women with major haemoglobinopathies that do not change during the pre-conception, antenatal, intrapartum and postnatal periods
c. Investigation and management of comorbidities (eg renal disease)
d. Management of complications of pregnancy (for example pre-eclampsia)

Interventions to be studied

Comparison of conservative and medical treatments for the management of sickle cell in pregnancy

Clinical areas to be examined

What is the optimum pre-conceptual care for this group of patients; are there any interventions which are of benefit at the pre-conceptual stage. This will include genetic counseling and consideration of patients on hydroxycarbamide, ACE inhibitors or regular transfusion therapy.
Are there any prognostic indicators which can be used for stratifying risk in pregnancy
What is the optimum antenatal care for pregnant women with sickle cell disease. This will include:

- Should this group of patients be looked after in the community, district general hospitals or tertiary referral centres, and what should be the frequency of medical and midwifery review throughout pregnancy.
- What investigations should be carried out during pregnancy, and what should be there frequency. This will include ultrasounds scans to monitor growth and uterine Doppler flow, echocardiograms, full blood counts, renal function and ophthalmology review.
- What model of midwifery care should they receive? Traditional or caseload.
- What medications should be taken during pregnancy; this will include the role of folic acid, penicillin prophylaxis, aspirin and anticoagulation?
- What is the role of blood transfusion during pregnancy?
- What is the optimal management of acute painful crisis during pregnancy?
- Who should provide care?
- What is the best intrapartum management for women with sickle cell disease? This will include the timing of delivery and the role of operative intervention
- What is the best postpartum management for women with sickle cell disease; this will include the role of post partum anticoagulation.
- What should be the best advice for contraception?

Preliminary review of evidence

There are no systematic reviews in this area, and small numbers of randomized controlled trials looking at particular interventions (eg transfusion therapy in SCD). There are a small number of cohort studies, the majority of which are retrospective, and several international guidelines and recommended standards of care. There are notable gaps in the evidence, which will make the drawing of firm conclusions difficult.

References

Smith JA, Espeland M, Bellevue R et al. Pregnancy in sickle cell disease: experience of the cooperative study of sickle cell disease. Obstet Gynecol 1996; 87:199-203

Khare M, Bewley S. Management of pregnancy in SCD. Practical management of haemoglobinopathies. Ed Blackwell Publishing 2004.

APPENDIX 2D: Guideline comments example

Comments on Sickle Cell Disease in Pregnancy Sept 2009

Comments Table

Name of Reviewer	Section	Comments	Developers Response
British Maternal and Fetal Medicine Society	4.1	Worth mentioning the effects of pregnancy on SCD ie worsening of anaemia, increased risk of crises and chest syndrome and increased infections rates esp UTI, as well as the effects of SCD on pregnancy as listed	Actioned
Dr MB Department of Maternal, Newborn, Child and Adolescent Health. WHO Geneva	4.1	Is there any specific impact of SCD on infant psychomotor development?	I have not seen any publication on impact of SCD on infants psychomotor response. But we could consider a study with WHO to look into this specific question
Dr KR, Manchester Royal Infirmary..	4.2	Suggest include reminder for women considering IVF to ensure partner is screened as well. Echo screening is usually done every 2-3 years in the routine clinic. Rather than repeat unnecessarily you should say ensure Echo has been performed in the last year and is normal.	Actioned
British Maternal and Fetal Medicine Society	4.3	Are they suggesting ALL women should have penicillin prophylaxis? Should be continued if already on it but individualised if not unless guidance has changed recently – not all SCD are hyposplenic.	yes
Dr MB Department of Maternal, Newborn, Child and Adolescent Health. WHO Geneva	09/07/2014	Penicillin prophylaxis: Can this (More applicable to pediatric population) be applied to adult population? For how long?	In pregnancy, we know maternal immunity is reduced, we also know that acute chest syndrome often starting of as pneumonia in pregnancy has a significant mortality attached to it. So during pregnancy we recommend that penicillin prophylaxis be used, but we could quite easily do RCT on this in pregnancy and I will add this to the research question.
OAA	4.3	What advice for penicillin allergic patients? (see also # 9)	Actioned Erythromycin
British Maternal and Fetal Medicine Society	4.5	Penultimate paragraph, last sentence – suggest change to '…it should be stopped and a level 3 ultrasound performed to look for structural abnormality, but termination is not indicated based on drug exposure alone.'	Actioned
OAA	5.6	Regional analgesia may be very useful in some situations	Actioned
Dr MB Department of Maternal, Newborn, Child and Adolescent Health, WHO Geneva	5.6.4	Blood transfusion is not indicated in the management of an uncomplicated pain episode.	We agree and we have added a statement that the decision to transfuse should be made by an experienced haematologist or obstetrician
Dr AS NHS Sickle Cell and Thalassaemia Screening Programme	7.1	In pregnancies….early testing for SCD should be offered Samples need to be sent to laboratories who are experienced in the routine analysis of sickle cell disease of newborn samples which will usually be a regional centre	actioned
RCOG Consumers' Forum	7.1	I think the authors may like to consider making it clearer that breastfeeding is not contraindicated, whether for mother's health, baby's health, as well as in terms of medication used.	actioned
Dr IR, Medical Director, RCGP Clinical Innovation and Research Centre and GP principal	9	Auditable standard for example in primary should be highlighted such as the proportions of patients with sickle cell disease who are up to date with their vaccination status.	Actioned
Dr JP FRCOG Consumers forum professional member	General	This appears to be a really good guideline for someone like me who works in a small DGH with a low risk of SCD in our population and therefore get little exposure to such cases. The guideline is very readable, well done to the authors	Thank you
Dr IRi, Medical Director, RCGP	Page 5	With regard to the advice on low dose aspirin in pregnancy – should specify the need for care in the case of patients with aspirin sensitivity. Who will be instigating the commencement of aspirin?	actioned
Dr IR, Medical Director, RCGP	Page 7-11	Secondary care focussed - reads well. The management of a sickle cell crisis again is relevant to primary care, particularly options in the case of a 'mild' attack.	Actioned

Appendix 3A: :Databases to search for existing Guidelines

Databases of Existing Guidelines
National Guideline Clearinghouse:www.guideline.gov/ National Electronic Library for Health: www.library.nhs.uk/rss/ RCOG:www.rcog.org.uk/ Organising Medical Information Online(OMNI): http://omni.ac.uk (specify guidelines in Resource type) Turning Research into Practice (TRIP): www.tripdatabase.com E guidelines: www.eguidelines.co.uk

APPENDIX 3B: Tool for Assessing Quality of Systematic Reviews

Study identification (*Include author, title, year of publication, journal title, pages*)		
Guideline topic:	Key Question No:	
Before completing this checklist, consider: • Is the paper a systematic review or meta-analysisIs the paper relevant to key question		
Reason for rejection: 1. Paper not a systematic review/meta-analysis 2. Paper not relevant to key question 3. Other reason (please specify):		
Checklist completed by:		
In a well conducted systematic review	**In this study this criterion is::**	
1.1 The study addresses an appropriate and clearly focused question.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.2 A description of the methodology used is included.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.3 The literature search is sufficiently rigorous to identify all the relevant studies.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.4 Study quality is assessed and taken into account.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
1.5 There are enough similarities between the studies selected to make combining them reasonable.	Well covered Adequately addressed Poorly addressed	Not addressed Not reported Not applicable
2.1 How well was the study done to minimise bias? Code ++, +, or -		
2.2 **Notes.** Summarise the authors conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question		

Tool for Assessing Quality or RCTs

Study identification (*Include author, title, year of publication, journal title, pages*)		
Guideline topic:	Key Question No:	Reviewer:
Before completing this checklist, consider: 1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? 2. Is the paper relevant to key question?		
Reason for rejection: 1. Paper not relevant to key question ☐ 2. Other reason ☐ (please specify):		

In a well conducted RCT study…		***Does this study do it?***
1.1	The study addresses an appropriate and clearly focused question.	Yes ☐ Can't say ☐ No ☐
1.2	The assignment of subjects to treatment groups is randomised.	Yes ☐ Can't say ☐ No ☐
1.3	An adequate concealment method is used.	Yes ☐ Can't say ☐ No ☐
1.4	Subjects and investigators are kept 'blind' about treatment allocation.	Yes ☐ Can't say ☐ No ☐
1.5	The treatment & control groups are similar at the start of the trial.	Yes ☐ Can't say ☐ No ☐
1.6	The only difference between groups is the treatment under investigation.	Yes ☐ Can't say ☐ No ☐
1.7	All relevant outcomes are measured in a standard, valid and reliable way.	Yes ☐ Can't say ☐ No ☐
1.8	What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?	
1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).	Yes ☐ Can't say ☐ No ☐ Does not apply ☐
1.10	Where the study is carried out at more than one site, results are comparable for all sites.	Yes ☐ Can't say ☐ No ☐ Does not apply ☐
2.1	How well was the study done to minimise bias? *Code as follows:*	High quality (++)☐ Acceptable (+)☐ Unacceptable – reject 0 ☐

2.2	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?	
2.3	Are the results of this study directly applicable to the patient group targeted by this guideline?	
2.4	**Notes.** Summarise the authors' conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.	

Tool for Assessing Quality of Observational studies

Study identification (*Include author, title, year of publication, journal title, pages*)		
Guideline topic:	Key Question No:	Reviewer:

Before completing this checklist, consider:

1. Is the paper really a cohort study
2. Is the paper relevant to key question?..

Reason for rejection: 1. Paper not relevant to key question ☐ 2. Other reason ☐ (please specify):

Please note that a retrospective study (ie a database or chart study) cannot be rated higher than +.

	In a well conducted cohort study:	***Does this study do it?***
1.1	The study addresses an appropriate and clearly focused question.	Yes □ No □ Can't say □
	SELECTION OF SUBJECTS	
1.2	The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation.	Yes □ No □ Can't say □ Does not apply □
1.3	The study indicates how many of the people asked to take part did so, in each of the groups being studied.	Yes □ No □ Does not apply □
1.4	The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis.	Yes □ No □ Can't say □ Does not apply □
1.5	What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed.	
1.6	*Comparison is made between full participants and those lost to follow up, by exposure status.*	Yes □ No □ Can't say □ Does not apply □
	ASSESSMENT	
1.7	The outcomes are clearly defined.	Yes □ No □ Can't say □
1.8	The assessment of outcome is made blind to exposure status. If the study is retrospective this may not be applicable.	Yes □ No □ Can't say □ Does not apply □

1.9	Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome.	Yes □ Can't say □	No □ □
1.10	The method of assessment of exposure is reliable.	Yes □ Can't say □	No □
1.11	Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable.	Yes □ Can't say □	No □ Does not apply□
1.12	Exposure level or prognostic factor is assessed more than once.	Yes □ Can't say □	No □ Does not apply □
CONFOUNDING			
1.13	The main potential confounders are identified and taken into account in the design and analysis.	Yes □ Can't say □	No □
STATISTICAL ANALYSIS			
1.14	Have confidence intervals been provided?	Yes □	No □
2.1	How well was the study done to minimise the risk of bias or confounding?	High quality (++) □ Acceptable (+) □ Unacceptable – reject 0	
2.2	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, do you think there is clear evidence of an association between exposure and outcome?	Yes ☐ Can't say ☐	No ☐
2.3	Are the results of this study directly applicable to the patient group targeted in this guideline?	Yes □	No □
2.4	**Notes.** Summarise the authors conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.		

Appendix 4A: Guideline templates

Comments on Sickle Cell Disease in Pregnancy Sept 2009

Comments Table

British Maternal and Fetal Medicine Society	4.1	Worth mentioning the effects of pregnancy on SCD ie worsening of anaemia, increased risk of crises and chest syndrome and increased infections rates esp UTI, as well as the effects of SCD on pregnancy as listed	Actioned
Dr MB Department of Maternal, Newborn, Child and Adolescent Health. WHO Geneva	4.1	Is there any specific impact of SCD on infant psychomotor development?	I have not seen any publication on impact of SCD on infants psychomotor response. But we could consider a study with WHO to look into this specific question
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British Maternal and Fetal Medicine Society	4.3	Are they suggesting ALL women should have penicillin prophylaxis? Should be continued if already on it but individualised if not unless guidance has changed recently – not all SCD are hyposplenic.	yes
Dr MB Department of Maternal, Newborn, Child and Adolescent Health. WHO Geneva	4.3	Penicillin prophylaxis: Can this (More applicable to pediatric population) be applied to adult population? For how long?	In pregnancy, we know maternal immunity is reduced, we also know that acute chest syndrome often starting of as pneumonia in pregnancy has a significant mortality attached to it. So during pregnancy we recommend that penicillin prophylaxis be used, but we could quite easily do RCT on this in pregnancy and I will add this to the research question.
OAA	4.3	What advice for penicillin allergic patients? (see also # 9)	Actioned Erythromycin
British Maternal and Fetal Medicine Society	4.5	Penultimate paragraph, last sentence – suggest change to '…it should be stopped and a level 3 ultrasound performed to look for structural abnormality, but termination is not indicated based on drug exposure alone.'	Actioned

Appendix 4A: Guideline templates

Comments on Sickle Cell Disease in Pregnancy Sept 2009

OAA	5.6	Regional analgesia may be very useful in some situations	Actioned
Dr MB Department of Maternal, Newborn, Child and Adolescent Health. WHO Geneva	5.6.4	Blood transfusion is not indicated in the management of an uncomplicated pain episode.	We agree and we have added a statement that the decision to transfuse should be made by an experienced haematologist or obstetrician
British Maternal and Fetal Medicine Society	6.2	Increased risk of crises with protracted labour is often secondary to dehydration, so if labour is progressing and the woman has been kept appropriately hydrated then labour should be allowed to progress with appropriate supervision. Could consider adding the caveat of considering CS if labour not progressing well and delivery unlikely in the near future, and ensure good hydration. Highlight use of Pulse ox in labour	Actioned
Dr AS NHS Sickle Cell and Thalassaemia Screening Programme	7.1	In pregnancies....early testing for SCD should be offered Samples need to be sent to laboratories who are experienced in the routine analysis of sickle cell disease of newborn samples which will usually be a regional centre	actioned
RCOG Consumers' Forum	7.1	I think the authors may like to consider making it clearer that breastfeeding is not contraindicated, whether for mother's health, baby's health, as well as in terms of medication used.	actioned
Dr Imran Rafi, Medical Director, RCGP Clinical Innovation and Research Centre and GP principal	9	Auditable standard for example in primary should be highlighted such as the proportions of patients with sickle cell disease who are up to date with their vaccination status.	Actioned
Dr JP FRCOG Consumers forum professional member	General	This appears to be a really good guideline for someone like me who works in a small DGH with a low risk of SCD in our population and therefore get little exposure to such cases. The guideline is very readable, well done to the authors	Thank you
Dr IRi, Medical Director, RCGP	Page 5	With regard to the advice on low dose aspirin in pregnancy – should specify the need for care in the case of patients with aspirin sensitivity. Who will be instigating the commencement of aspirin?	actioned
Dr IR, Medical Director, RCGP	Page 7-11	Secondary care focussed - reads well. The management of a sickle cell crisis again is relevant to primary care, particularly options in the case of a 'mild' attack.	Actioned

APPRAISAL OF GUIDELINES FOR RESEARCH & EVALUATION II

AGREE II

INSTRUMENT

The AGREE Next Steps Consortium

May 2009

AGREE II INSTRUMENT

DOMAIN 1. SCOPE AND PURPOSE

1. The overall objective(s) of the guideline is (are) specifically described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

2. The health question(s) covered by the guideline is (are) specifically described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 2. STAKEHOLDER INVOLVEMENT

4. The guideline development group includes individuals from all relevant professional groups.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

5. The views and preferences of the target population (patients, public, etc.) have been sought.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

6. The target users of the guideline are clearly defined.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 3. RIGOUR OF DEVELOPMENT

7. Systematic methods were used to search for evidence.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

8. The criteria for selecting the evidence are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

9. The strengths and limitations of the body of evidence are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 3. RIGOUR OF DEVELOPMENT continued

10. The methods for formulating the recommendations are clearly described.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

11. The health benefits, side effects, and risks have been considered in formulating the recommendations.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

12. There is an explicit link between the recommendations and the supporting evidence.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 3. RIGOUR OF DEVELOPMENT continued

13. The guideline has been externally reviewed by experts prior to its publication.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

14. A procedure for updating the guideline is provided.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 4. CLARITY OF PRESENTATION

15. The recommendations are specific and unambiguous.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

16. The different options for management of the condition or health issue are clearly presented.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

17. Key recommendations are easily identifiable.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 5. APPLICABILITY

18. The guideline describes facilitators and barriers to its application.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

19. The guideline provides advice and/or tools on how the recommendations can be put into practice.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

20. The potential resource implications of applying the recommendations have been considered.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 5. APPLICABILITY continued

21. The guideline presents monitoring and/or auditing criteria.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

DOMAIN 6. EDITORIAL INDEPENDENCE

22. The views of the funding body have not influenced the content of the guideline.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

23. Competing interests of guideline development group members have been recorded and addressed.

1 Strongly Disagree	2	3	4	5	6	7 Strongly Agree

Comments

OVERALL GUIDELINE ASSESSMENT

For each question, please choose the response which best characterizes the guideline assessed:

1. Rate the overall quality of this guideline.

1 Lowest possible quality	2	3	4	5	6	7 Highest possible quality

2. I would recommend this guideline for use.

Yes	
Yes, with modifications	
No	

NOTES

Appendix 5B: Tool to Assess Scope for Guideline Adaptation

Guideline Adaptation - Review/Comment on Existing Guideline

Background/ Epidemiology
Is the epidemiology relevant and succinct? Is the justification for the guideline stated? Are the overall objectives specifically described? Are expected changes described?

Is the Target Patient Group clear? Is the Target Professional Group?

Interventions
What interventions have been considered?

Outcomes
What outcomes have been considered?

Key Questions (use the model Diagnosis / Intervention / Prognosis)

How do the key questions fit into the model?

Are all your important areas covered by the key questions? Is anything missing?

Miscellaneous

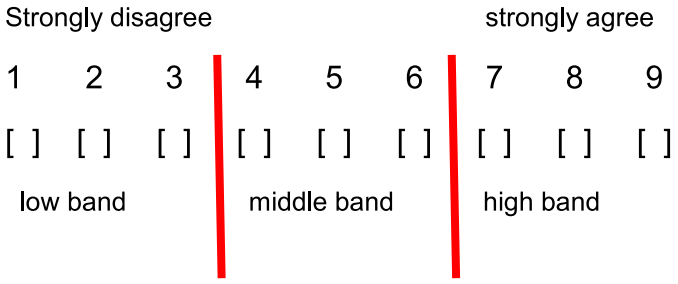
Has there been consideration of the economic impact?

Has equality and diversity been considered?

Have any additional tools been suggested? Are any required e.g. patient information leaflets; audit tool

Appendix 5C: Explanation and Example of Rand Consensus Method

The scoring system is agreed in advance and a consensus questionnaire sent to all members of the GAG who complete it independently. They use a 9 point scale to state their level of agreement with each recommendation. E.g.



The ratings are divided into 3 bands and the recommendations accepted or not depending on the criteria agreed in advance. The score bands and implications are shown in table 5b and worked examples are shown in Appendix 5C

Table 5b: Scoring system for the Rand consensus method

Majority Score*	Status	Action
7-9	Agreement	Accept recommendation in source guideline
4-6	No agreement	Discuss in more detail at a face to face meeting. May involve review of the original literature and consideration of modifying the recommendation
1-3	Disagreement	***Either*** do not include in guideline ***OR*** consider if the recommendation can be adapted to local use by modifying some element e.g. substitute alternative drug or treatment .
No majority score band	No agreement	Discuss in more detail at a face to face meeting. May involve review of the original literature and consideration of modifying the recommendation

*majority is usually taken to mean more than 50% of GAG i.e. if 7 out of 10 members score 7 or above this would be a majority acceptance; if only 5 out of 10 score 7 or above this would not be a majority and would not lead to agreement

If the recommendations are modified, the consensus questionnaire is resent to all members again but contains only those recommendations on which agreement has not been reached. A further face to face meeting of the GAG will be required to draft the adapted guideline

Appendix 5D: Rand Consensus Methodology – RCOG Model

Adapting a Guideline for Use in Non-UK settings
Severe Pre-eclampsia / Eclampsia

	Strongly disagree							Strongly agree	
1) The guidelines are current and up to date	1 [ ]	2 [ ]	3 [ ]	4 [ ]	5 [ ]	6 [ ]	7 [ ]	8 [ ]	9 [ ]
2) The guidelines are evidence based	1 [ ]	2 [ ]	3 [ ]	4 [ ]	5 [ ]	6 [ ]	7 [ ]	8 [ ]	9 [ ]
3) The guidelines have been adequately peer reviewed	1 [ ]	2 [ ]	3 [ ]	4 [ ]	5 [ ]	6 [ ]	7 [ ]	8 [ ]	9 [ ]
4) The target patient population is clearly defined	1 [ ]	2 [ ]	3 [ ]	4 [ ]	5 [ ]	6 [ ]	7 [ ]	8 [ ]	9 [ ]
5) No patient groups that are important locally have been excluded	1 [ ]	2 [ ]	3 [ ]	4 [ ]	5 [ ]	6 [ ]	7 [ ]	8 [ ]	9 [ ]
6) The healthcare settings described are available in the local setting	1 [ ]	2 [ ]	3 [ ]	4 [ ]	5 [ ]	6 [ ]	7 [ ]	8 [ ]	9 [ ]
7) The evidence presented is applicable to the local patient population	1 [ ]	2 [ ]	3 [ ]	4 [ ]	5 [ ]	6 [ ]	7 [ ]	8 [ ]	9 [ ]
8) The evidence for the recommendations is strong	1 [ ]	2 [ ]	3 [ ]	4 [ ]	5 [ ]	6 [ ]	7 [ ]	8 [ ]	9 [ ]
9) All key questions that are important locally are covered in the guideline	1 [ ]	2 [ ]	3 [ ]	4 [ ]	5 [ ]	6 [ ]	7 [ ]	8 [ ]	9 [ ]
10) Areas for further research are suggested	1 [ ]	2 [ ]	3 [ ]	4 [ ]	5 [ ]	6 [ ]	7 [ ]	8 [ ]	9 [ ]
11) Auditable standards are suggested and are achievable in the local setting	1 [ ]	2 [ ]	3 [ ]	4 [ ]	5 [ ]	6 [ ]	7 [ ]	8 [ ]	9 [ ]
12) Additional tools e.g. flowcharts, summaries are included	1 [ ]	2 [ ]	3 [ ]	4 [ ]	5 [ ]	6 [ ]	7 [ ]	8 [ ]	9 [ ]

Royal College of Obstetricians and Gynaecologists

Setting standards to improve women's health

Adapting a Guideline for Use in Non-UK settings

Severe Pre-eclampsia / Eclampsia

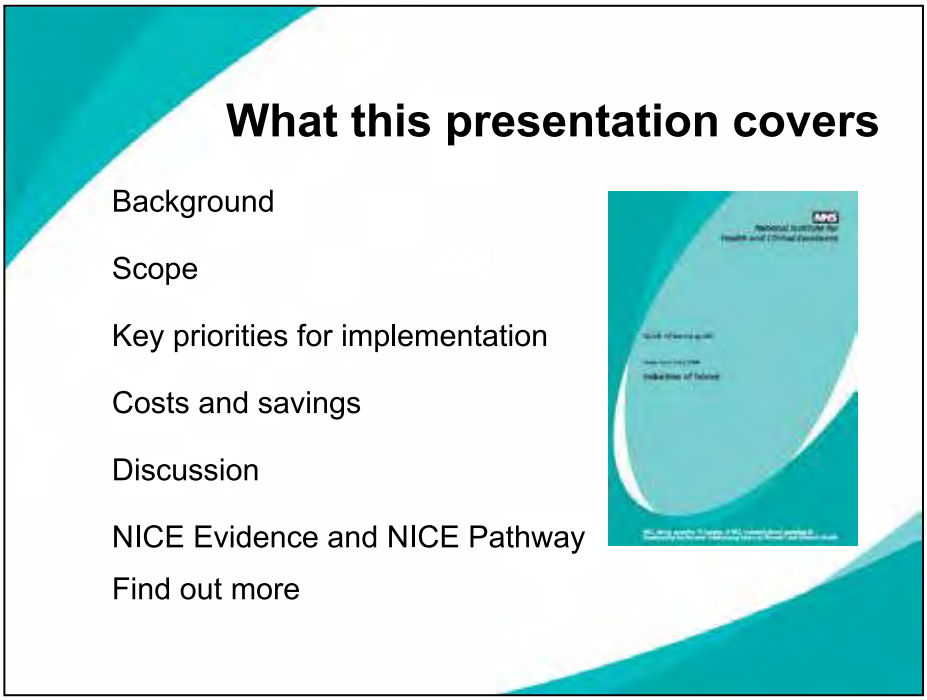
Participant Name …….

Indicate your level of agreement with each recommendation FOR USE IN YOUR COUNRTY by placing an X in the appropriate box whereby 1= STRONGLY DISAGREE and 9= STRONGLY AGREE

	Strongly disagree 1	2	3	4	5	6	7	8	Strongly agree 9
1) Senior obstetricians, anaesthetists and experienced midwives should be involved in the assessment of women with severe PET (**GPP)**	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
2) On a visual urine dipstick assessment, 2+ can be taken as evidence of proteinuria. Ideally a protein creatinine ratio or a 24 hour urine collection is required to confirm it. **(Grade C)**	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
3) The blood pressure should be checked every 15 minutes until the woman is stable and then every 4 hours if managed conservatively **(GPP)**	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
4) Assessment should include a full blood count, liver function and renal function tests repeated daily. Clotting studies are not required if the clotting is above $100x10^6$/l **(GPP)**	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
5) Close fluid balance with a catheter and hourly urometer is advisable in the acute phase and in the immediate postpartum period **(GPP)**	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
6) In the acute setting, an initial fetal assessment with CTG should be undertaken **(Grade B)**	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
7) Women in labour with severe PET should have continuous fetal monitoring **(Grade B)**	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
8) If conservative management is planned, then fetus requires ultrasound measurements of size, liquor volume and umbilical artery Doppler **(Grade A)**	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
9) Antihypertensive treatment should be commenced if the maternal blood pressure is over 160mmHg systolic or 110mmHg diastolic **(Grade C)**	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
10) Labetalol (oral or iv), nifedipine (oral) or hydralazine (iv) can be used **(Grade A)**	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
11) Magnesium sulphate should be considered for women where there is concern about the risk of eclampsia **(Grade A)**	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

	1	2	3	4	5	6	7	8	9
12) Magnesium sulphate is the treatment of choice for control of seizures. A 4g loading dose followed by 1g/hour **(Grade A)**	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
13) Fluid restriction to avoid fluid overload is advised in the intrapartum and postpartum period. Total fluids should be limited 80ml/hour **(Grade C)**	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
14) Regarding delivery, if less than 34 weeks, corticosteroids should be given **(Grade A)**	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
15) The third stage of labour should be managed with oxytocin (im or iv). Ergometrine should not be used for haemorrhage prevention as it can further increase blood pressure **(GPP)**	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
16) Women with persisting hypertension and proteinuria at 6 weeks postpartum may have renal disease and should have further investigations **(Grade C)**	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

APPENDIX 6A

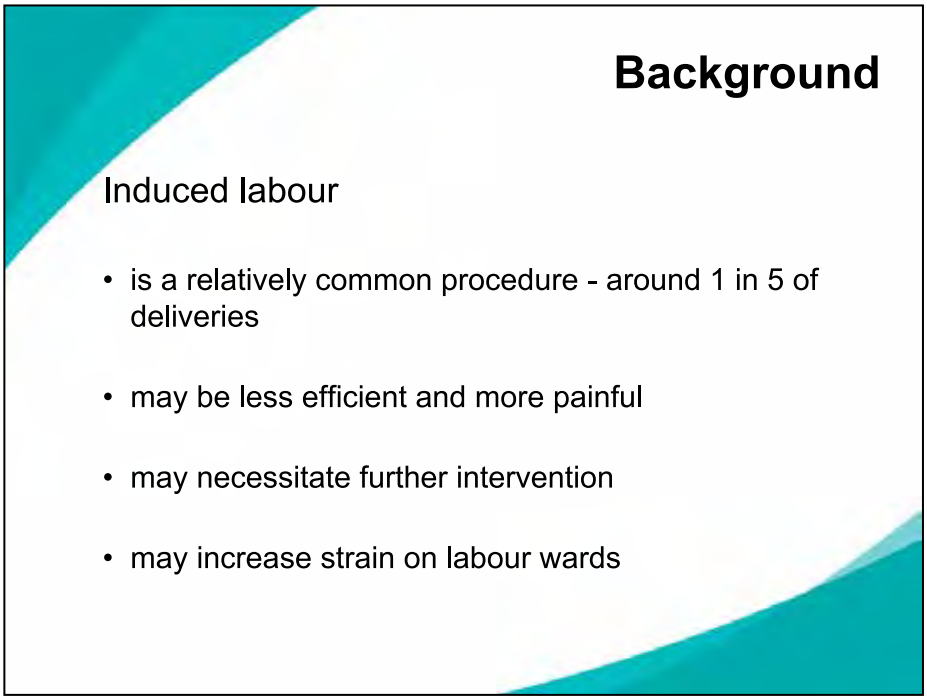


NOTES FOR PRESENTERS:
In this presentation we will start by providing some background to the guideline and why it is important.

The NICE guideline contains seven key priorities for implementation,.

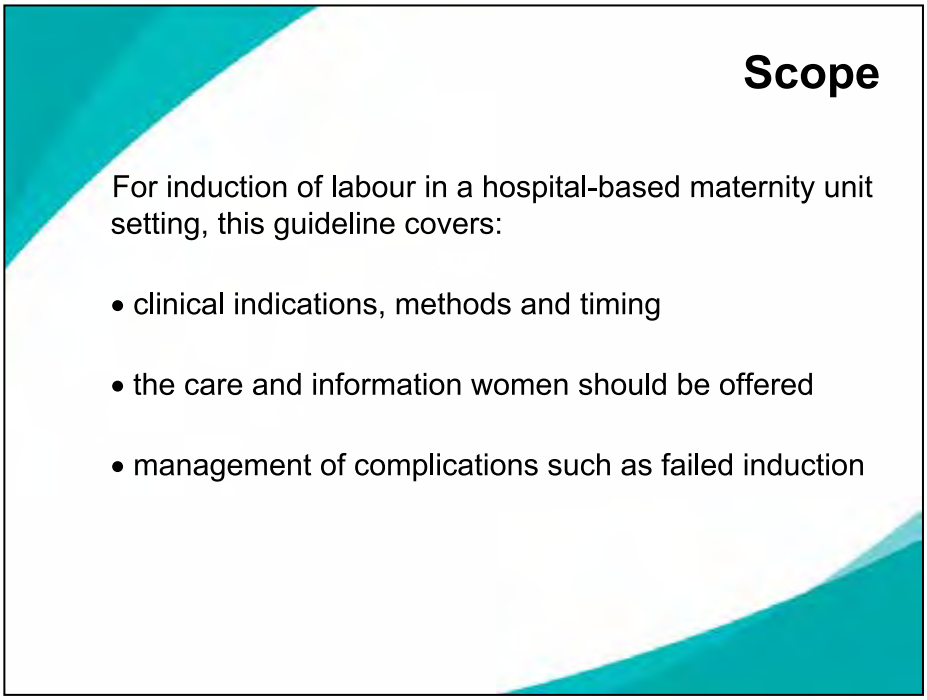
The key priorities for implementation cover the following areas:
• Information and decision-making
• Prevention of prolonged pregnancy
• Preterm prelabour rupture of membranes
• Vaginal Prostaglandin E2 (Vaginal PGE_2)
• Failed induction

Costs and savings that are likely to be incurred in implementing the guideline are summarised, followed by a suggested list of questions to help prompt discussion.
Following this we will highlight the NICE Pathway and look at NHS Evidence and how this resource may help with keeping up to date with the latest evidence base.
Information on finding out more about the support provided by NICE is given at the end of this presentation.



NOTES FOR PRESENTERS:
Key points to raise:
Induced labour has an impact on the birth experience of women. It may be less efficient and is usually more painful than spontaneous labour, and epidural analgesia and assisted delivery are more likely to be required.
Induction of labour is a relatively common procedure. In 2010/11, about one in every five deliveries in the UK was induced (21.3%)*, continuing the upward trend (20.8% in 2009/10)*. This includes induction for all medical reasons. When labour was induced using pharmacological methods (whether or not surgical induction was also attempted), less than two thirds of women gave birth without further intervention, with about 15% having instrumental births and 22% having emergency caesarean sections.
Induction of labour has a large impact on the health of women and their babies and so needs to be clearly clinically justified.
Induction of labour can place more strain on labour wards than spontaneous labour. Traditionally, induction is carried out during the daytime when labour wards are often already busy. This updated guideline reviews the policy and methods of induction, and the care to be offered to women being offered and having induction of labour.

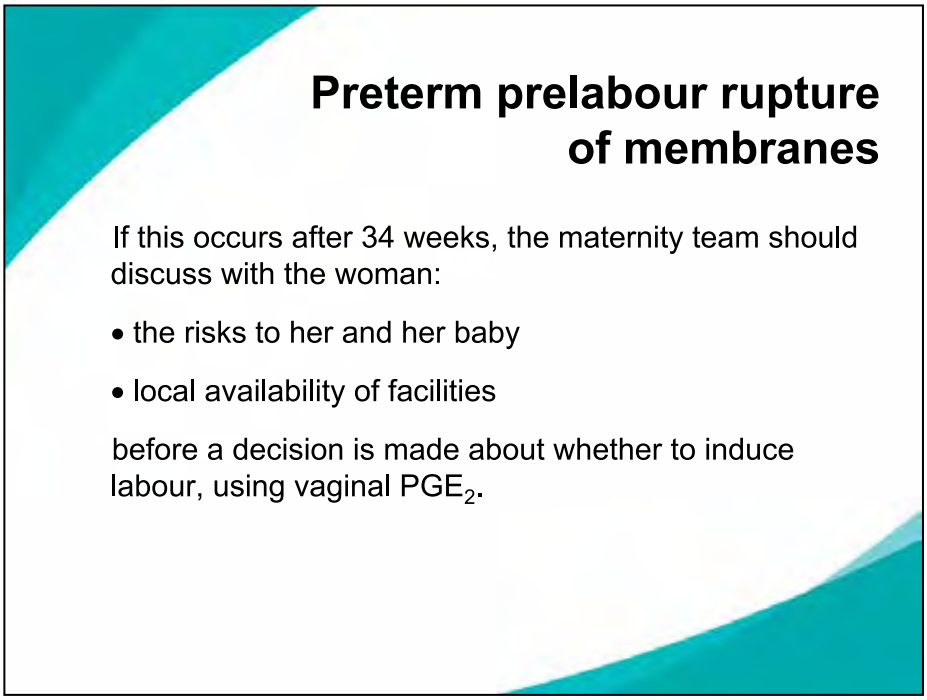
* from The NHS Maternity Statistics, England: 2010-11 can be found on the Information Centre website at http://www.ic.nhs.uk/statistics-and-data-collections/hospital-care/maternity/nhs-maternity-statisticsengland-2010-11



NOTES FOR PRESENTERS:
Key points to raise:
This guideline covers induction of labour in the following clinical circumstances:
•prolonged pregnancy
•preterm prelabour rupture of membranes
•prelabour rupture of membranes
•fetal growth restriction
•suspected macrosomia
•previous caesarean section
•history of precipitate labour
•maternal request
•breech presentation
•intrauterine fetal death

Women with uncomplicated pregnancies should be given every opportunity to go into spontaneous labour.

Additional Information:
This guideline does not cover induction of labour for the following groups:
•women with diabetes
•women with multifetal pregnancy
•women having augmentation (rather than induction) of labour.



NOTES FOR PRESENTERS:
Key points to raise:
If a woman has preterm prelabour rupture of membranes, induction of labour should not be carried out before 34 weeks unless there are additional obstetric indications (for example, infection or fetal compromise).

Additional information:
Vaginal PGE_2 has been used in UK practice for many years in women with preterm rupture of membranes. However, the summary of product characteristics (SPC) (July 2008) advises that the use of vaginal PGE_2 is not recommended in women with preterm rupture of membranes. Informed consent on the use of vaginal PGE_2 in this situation should therefore be obtained and documented.

Recommendation 1.2.2.2 in full:
If a woman has preterm prelabour rupture of membranes after 34 weeks, the maternity team should discuss the following factors with her before a decision is made about whether to induce labour, using vaginal prostaglandin E2 (PGE_2)[1]:

- risks to the woman (for example, sepsis, possible need for caesarean section)
- risks to the baby (for example, sepsis, problems relating to preterm birth)
- local availability of neonatal intensive care facilities.

NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Questionnaire for women: Induction of labour

Implementing the NICE guidance on Induction of labour (CG70)

Published: 2008
Updated: 2014

Induction of labour questionnaire for women

This questionnaire has been developed to help maternity services collect information from the women who have used their services about the care they received. The NICE guideline on induction of labour provides recommendations on the support and information that should be offered to pregnant women, whether they are being informed about the possibility of induction or being offered induction.

The questionnaire aims to collect information from the woman's perspective and can provide valuable data on activity in the service and on the service's performance against the guideline. The appropriate sample would be women who had a relatively straightforward induction of labour after 34 weeks of pregnancy. You may want to provide a copy of the Understanding NICE Guidance booklet when giving the questionnaire to women. This will help explain some of the interventions and actions being asked about in the questionnaire.

The questionnaire can be used along with any clinical audit of the service based on the guideline and national priorities such as the CQC review of maternity services and NHSLA. Once women's experiences have been collected they may be useful as evidence for statement 2 of the Induction of Labour quality standard (QS60, 2014). NICE has produced Audit support which can be used with this questionnaire to obtain information about the provision of induction of labour and improve the care of women who have labour induced.

Additional questions can be added if you would like to collect further information from women who have used your service and had labour induced. A section has been included at the end of the questionnaire so that women can add any further comments they may have about their experience.

Induction of labour questionnaire for women

This questionnaire is designed to find out about the treatment you received when you had your baby in our maternity service, and to help us improve the care we give women in the future. It is based on the NICE guideline on induction of labour, which describes how induction should be carried out. If you would like to see the guideline please ask <local contact> for a copy or visit the website at http://www.nice.org.uk/CG070.

		Yes	No	Not applicable / can't remember
What information did you receive to help you make your decisions?				
1	At your 38 week antenatal appointment, did your midwife or doctor offer you information on: *If you were induced before 38 weeks please go to question 3*			
	• The possible risks to you and your baby if your pregnancy were to last longer than 42 weeks?			
	• The options available to help you go into labour, such as: (tick all that apply)			
	- membrane sweeping[1]			
	◊ were you told what a membrane sweep is?			
	◊ were you told that membrane sweeping would make it more likely that you would go into labour?			
	◊ were you told that the procedure may cause some pain or vaginal bleeding?			
	- having your labour induced between 41 and 42 weeks of pregnancy			
	- expectant management, which involves the midwife or obstetrician keeping an eye on you and your baby until you go into labour naturally?			
2	Do you feel that you were: (tick all that apply)			
	• given enough time to discuss your options with your partner or family before making a decision?			
	• encouraged to look at a variety of sources of information?			
	• invited to ask your doctor or midwife questions?			
	• encouraged to think about what your options were?			
	• supported by your healthcare team in the decision you made?			

[1] (This involves a doctor or midwife placing a finger into the cervix and making a circular, sweeping movement to separate the membranes that surround the baby, or massaging the cervix).

Induction of labour questionnaire for women

		Yes	No	Not applicable / can't remember
Did your waters break early?				
3	Did your waters break between 34 and 37 weeks of pregnancy? *If yes, answer question 4. If no, go to question 5.*			
4	If labour had not started within 24 hours of your waters breaking, did your doctor or midwife discuss the following with you before a decision was made about whether to induce your labour: (tick all that apply)			
	• what the risks of induction were to you?			
	• what the risks of induction were to your baby?			
	• the availability of neonatal intensive care facilities in your area?			
Did you have your labour induced at full term (from 37 weeks)?				
5	Did your waters break after 37 weeks of pregnancy? *If yes, answer question 6. If no, go to question 7.*			
6	When you were offered induction, were you given information on: (tick all that apply)			
	• why you were being offered induction?			
	• when, where and how labour could be induced?			
	• what support and pain relief would be available?			
	• what the options would be if you decided not to go ahead with induction?			
	• the risks and benefits of inducing labour, and the specific risks and benefits relating to the proposed method of induction?			
	• what your options would be if inducing your labour didn't work?			
7	Before you were given the option of induction, were you offered one or more membrane sweeps?			

Induction of labour questionnaire for women

		Yes	No	Not applicable / can't remember
What information and support were you offered on pain relief?				
8	Was it explained to you that induced labour is likely to be more painful than spontaneous labour?			
9	Were you informed of the different pain relief options?			
10	Were you: (tick all that apply)			
	• offered pain relief, such as entonox (gas and air), pethidine or epidural?			
	• encouraged to use your own coping strategies for pain relief?			
	• given the opportunity to labour in water?			
Did your induction fail?				
11	If you didn't go into labour after induction, did your midwife or doctor discuss your options with you?			
12	Were you offered: • a further attempt at inducing your labour			
	• or caesarean section?			
Do you have any comments about your experience?				

Thank you for completing this questionnaire.

Please return it to <local contact>.

Appendix 6C

Baseline assessment tool for NICE quality standard on Hypertension in pregnancy (QS35)

Number of recommendations applicable to the organisation	0
Number of recommendations met	0
Percentage of recommendations met	

Quality statement	Is the recommendation relevant to the organisation?	Current activity/evidence	Recommendation met?	Actions needed to implement recommendation	Is there a risk associated with not implementing this recommendation?	Is there a cost or saving?	Deadline	Organisation lead
1. Women of childbearing potential with treated hypertension are given information annually about safe antihypertensive treatment during pregnancy.								
2. Pregnant women at increased risk of pre-eclampsia at the booking appointment are offered a prescription of 75 mg of aspirin to take daily from 12 weeks until birth.								
3. Women with hypertension in pregnancy have a blood pressure target set below 150/100 mmHg or, if they also have target organ damage, below 140/90 mmHg.								
4. Pregnant women with severe hypertension are admitted for a full assessment, carried out by a healthcare professional trained in managing hypertension in pregnancy.								
5. Women with a diagnosis of pre-eclampsia are admitted to hospital and monitored daily.								
6. Women with pre-eclampsia have an agreed consultant obstetrician-led plan for the timing and mode of birth.								
7. Women who have had hypertension in pregnancy have a plan for ongoing antihypertensive management included in their postnatal care plan, which is communicated to their GP when they are transferred to community care after the birth.								
8. Women who have had gestational hypertension or pre-eclampsia discuss future pregnancy and lifetime cardiovascular risks during a medical review at their 6–8 week postnatal medical check.								

Appendix 7A
Clinical Audit Notification Form

Audit Title	**Referrals for Menorrhagia from Primary Care**

Name of Person Undertaking the Audit (if different from above)	**Position**	**Contact Details** (Telephone/Bleep/Email)
Dr A	Junior Doctor	
Name of Audit Sponsor (must be full-time member of staff)	**Position**	**Directorate / Specialty**
Professor B	Consultant O & G	O & G

Is the project:- National ☐ Regional ☐ Local (involving hospital only **X**

Does it relate to any of the following?

Mandatory Health Records Audit ☐ Clinical Risk ☐
Consent – mandatory audit ☐ Other Integrated care pathway ☐
Royal Colleges / Chartered Society Guidance ☐ ☐
NICE Guideline (Please Specify) **NICE CG 44 Heavy Menstrual Bleeding**

Local Hospital Policy, guideline or protocol ☐
Please specify _____

What professions are involved?

Medical **X** Nursing ☐ Allied Health Professionals ☐ Multi-Professional ☐

What is the main aim of the Audit? eg. to improve, to reduce	**To ensure women with menorrhagia referred to secondary care have been offered appropriate initial treatment in primary care**
What are the specific objectives of the Audit? (e.g. what standards are you are auditing against?)	**NICE recommend that women with menorrhagia in whom there are no contraindications to hormonal therapy are offered the levonorgestrel intrauterine system (Mirena IUS)** • **No. of women who have an IUS in situ** • **No. of women in whom IUS has failed** • **No. of women who refused IUS**

Start Date __01/09/09 _ **Estimated Completion Date** __30/11/09

Please complete this page for completed audits

Summary of findings :
29 new referrals to gynae out-patients with menorrhagia

- **Only 2 had IUS in-situ; 3 had been unable to tolerate IUS; 4 had been referred for IUS to be fitted; 7 had refused IUS in primary care**
- **15/29(52%) had not been offered an IUS**

Recommended service changes :
Circulation of menorrhagia pathway to GPs to improve awareness
Patient education with recommendation of use of patient information leaflet

Lead for Service Changes: Mr Griffin-Jones
Status of the Changes

Completed ☐ Ongoing X Other (please state) _____

Lessons for Others

Re-audit planned: **Yes** ☐ **No** ☐ **Is a Re-audit** ☐

Date of re-audit: Sept 2010

Appendix 7B

VBAC Audit

Name of person completing form: (Please print)	

Designation		**Date**		**Unit**	**LGI / SJUH**
Unit Number		**Date of Delivery:**			
Mode of Delivery	**SVD / VENOUSE / FORCEPS / LSCS**				

Documented antenatal discussion on mode of delivery/plan for place of labour	**Yes**	**No**	**N/A**	**Comment**
Documented individual management plan for labour				
Documented plan for early labour				
Plan for labour should this not commence as planned- discussed with consultant obstetrician				
Documented plan for monitoring of fetal heart in labour				

Actions taken in response to Audit	**Yes**	**No**	**Comments**
IR1 form completed			
Further investigation required (IR2)			
Midwifery Supervision input required			
Other action taken (please state)			

DATA COLLECTION - 'Take 5 Charts'
PRESCRIBING STANDARDS AUDIT TOOL

Ward number & Site…….. **Division** ……..

Month ……..…… **Directorate** ……..…….

	Patient				
	1	2	3	4	5
No. of drugs prescribed on main chart (include prns and stats)					

General Prescribing Standards	1	2	3	4	5
Allergy box completed fully, signed and dated Y / N					
Ward annotated correctly on chart Y / N					
No. of occasions prescribers identity not clear.					
No. of occasions the word units is abbreviated (ie u, iu)					

Antimicrobial Prescribing	1	2	3	4	5
No. of antimicrobials prescribed on chart					
How many antimicrobials do not have an indication on the chart?					
How many antimicrobials do not have duration or a review date stated on the chart?					

Administration route of anti-microbials	1	2	3	4	5
Parenteral (Infusion or injection)					
Number of parenterals given for greater than 48hrs					
In your opinion, how many of the parenteral antimicrobial prescriptions could have been given orally?					

VTE prophylaxis	1	2	3	4	5
Has a thromboprophylaxis risk assessment been completed					
Has thromboprophylaxis been prescribed.					

High Risk Medicines -Opiates - Max doses of prn opiates	1	2	3	4	5
Is a prn morphine prescribed Y / N					
Is a max dose in 24 hrs prescribed Y / N					

Send completed documents to Helen-M Smith, Pharmacy Office at SJUH (or fax 66833) for collation. Data will be provided back to Clinical Directors.

Appendix 7C: Example of an action plan relating to an audit of ectopic pregnancy

Area of weakness	Action	Who	When	Colour	Reporting
Delay in diagnosis	Lecture series for emergency department (ED)	Gynae consultant	Every 3 months	Red	ED and Women's management group
Delay in urinary HCG result	Implement point of care HCG testing	ED manager	Dec 1st	Red	ED management group
Delay in gynae staff response	Employ more gynaecologists	Women's management team	July	Green	Trust board

CLINICAL AUDIT REPORT

Women who decline blood products

May 2010

CONTENTS

BACKGROUND

The risk of maternal death in women who decline blood transfusion is 44 times higher than those who do not (CI:9-211)[1]. The last audit of this cohort of parturient at this hospital was carried out in 2001[2].

CLINICAL AUDIT DESIGN

The cohort under investigation is defined as parturients delivering at this hospital from 1st May 2009 until 30th April 2010, who object to any blood product at any point antenatally. These patients were identified using our maternity database (Healthware). In addition, any qualifying patients identified opportunistically who had not been identified on Healthware were included.

Women are routinely asked about whether or not they would accept blood as part of the pre-formatted booking questionnaire.

The notes for these patient were tracked and retrieved.

Each set of notes were examined to determine whether the patient had an individual management plan documented antenatally.

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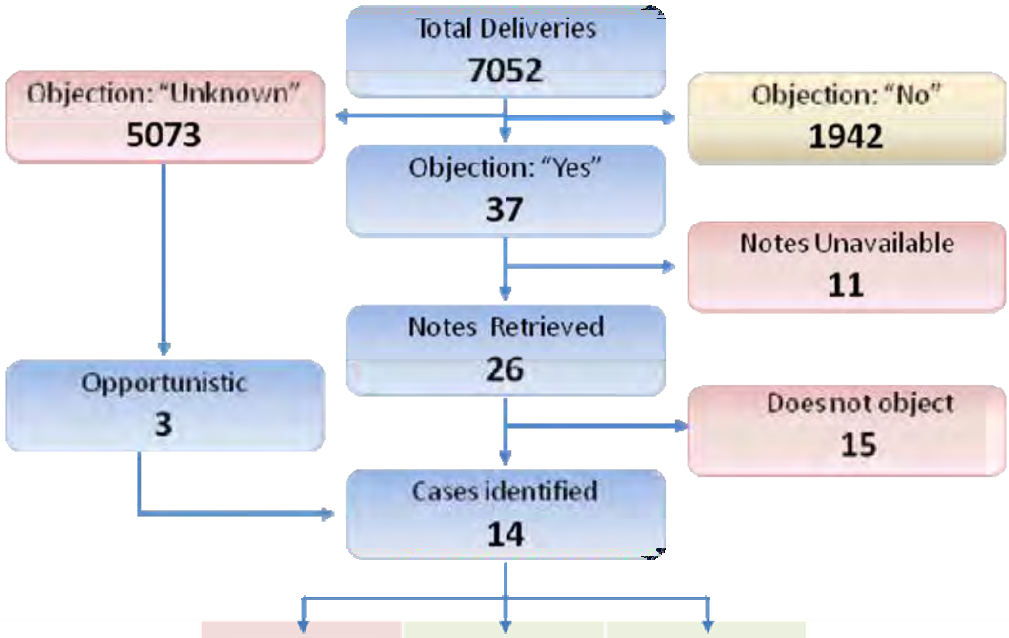
[1] Are women who are Jehovah's Witness at risk of maternal death? A Singla et al. American Journal of Obstetrics and Gynaecology 185(4) 893-5. Oct 2001.

[2] Audit of the Obstetric Management of Jehovah's Witness Patients. I Agbaje. GSTT Women's Services, Dec 2001.

FINDINGS



Appropriate Midwife Referral	2/2	4/5	6/7	**12/14**
Discussion with Obstetric Team	1/2	5/5	7/7	**13/14**
Individual Management Plan	0/2	5/5	7/7	**12/14**
Discussion of Blood Products	1/2	1/5	6/7	**8/14**
Patient Signature Regarding Objection	0/2	0/5	4/7	**4/14**
Specific Antenatal Management	0/2	0/5	5/7	**5/14**
Considered Objection Intrapartum	1/2	1/5	6/7	**8/14**
Specific intrapartum Management	0/2	1/5	4/7	**5/14**
Specific PPH Management	0/1	0/2	3/4	**3/7**
Specific Postnatal Management	0/2	0/5	3/7	**3/14**

There were only 14 women identified who's notes were available, and who expressed an objection to receiving blood products antenatally.

13 out of 14 women were referred to a consultant obstetrician to discuss blood (and products), when they would be used and the potential consequences of declining blood

Five women on further discussion agreed to have blood in life saving circumstances

Seven had a documented plan and in one no specific plan was made and in one a plan was made intrapartum

Of these, there was only 1 case where this had apparently not been considered by the obstetric team at any time. **13/14 had clearly documented in the notes whether they would, or would not accept blood products if necessary to save their life**.

ANALYSIS OF PROBLEMS AND RECOMMENDATIONS

Identification of cases

The electronic data system has inadequate data to reliably identify cases. The 'Objects to blood transfusions' field is not compulsory, and consequently about ⅔ of women have it left as 'Unknown'.

A better system for identification of cases.

Adherence to policy

The individual care plans were sometimes not as thorough as they could have been.. It seemed, however, that many of the obstetric doctors who saw these women antenatally and during labour either did not know about the policy, did not have time to refer to the policy, or at least did not adhere to the policy.

A checklist to be completed for all women who decline blood

ACTION TO ACHIEVE IMPROVEMENT NEEDED

Action point	Who is responsible	When it should be done	Completed
Checklists for action that should be taken antenatally, intrapartum in the event of a PPH, and postpartum.	Consultant A	March 2011	
Change to electronic data base	Manager A	April 2012	

APPENDIX 8A: Clinical Guideline Assurance Checklist

Protocol Title: TEMPLATE

IDENTIFICATION OF NEED	YES	NO	EVIDENCE/COMMENTS
Why has this guideline been developed? Has the need/requirement for this guideline been established by the specialty or Directorate ?			
Is the need/requirement for this guideline responding to a Patient Safety Alert, NICE guidance, other national best practice, external agency report, SUI or other ? .			
IMPLEMENTATION AND COMMUNICATION			
Explain how the guideline will be communicated and implemented			
AUDIT AND MONITORING			
Please describe how this guideline will be monitored for compliance			
Does the documentation define clear criteria, standards, targets or outcome measures to facilitate audit or aide assessment of the effects of implementation?			
RISK/BENEFIT AND COST/BENEFIT	**YES**	**NO**	**EVIDENCE/COMMENTS**
Is there a description of the health (or other) benefits anticipated as a result of the implementation of this guideline?			
Is there a description of the possible harm or risk that may result from implementation?			
GUIDELINE DEVELOPMENT AND PEER REVIEW	**YES**	**NO**	**EVIDENCE/COMMENTS**
Is there a clear description of the individuals and groups who were involved in developing it?			
Were the guidelines internally peer reviewed during the production process? Please indicate the disciplines/specialties consulted during the development of this guideline			
What were the review methods and results of the review			
Please describe the steps taken to address comments/criticisms arising from peer review?			
Does this guideline have implications for diagnostics/therapeutics? If so has it been discussed and agreed with the relevant discipline			
CLARITY	**YES**	**NO**	**EVIDENCE/COMMENTS**
Is the guidance easy to read and follow?			
REVIEWS	**YES**	**NO**	**EVIDENCE/COMMENTS**
Is a review date specified? Who is responsible for the review (include post/title)			

Clinical Protocol Assurance Checklist

Title: Protocol for the Generation and Use of Customised Fetal Growth Charts

IDENTIFICATION OF NEED	YES	NO	EVIDENCE/COMMENTS
Why has this guideline been developed? Has the need/requirement for this guideline been established by the specialty or Directorate ?	√		Commissioned by obstetric department due to clinical need
Is the need/requirement for this guideline responding to a Patient Safety Alert, NICE guidance, other national best practice, external agency report, SUI or other ? .		√	
IMPLEMENTATION AND COMMUNICATION			
Explain how the guideline will be communicated and implemented	√		Disseminated via Maternity services forum, supervisors meetings, team leaders meetings and maternity services newsletter
AUDIT AND MONITORING			
Please describe how this guideline will be monitored for compliance	√		According to maternity services audit plan - see section “Monitoring Compliance”
Does the documentation define clear criteria, standards, targets or outcome measures to facilitate audit or aide assessment of the effects of implementation?	√		
RISK/BENEFIT AND COST/BENEFIT	**YES**	**NO**	**EVIDENCE/COMMENTS**
Is there a description of the health (or other) benefits anticipated as a result of the implementation of this guideline?	√		Improved detection of fetal growth restriction Reduced intervention is babies that are normally grown for a particular woman
Is there a description of the possible harm or risk that may result from implementation?	√		Increase requirements for ultrasound scans estimated at increase of 5%
GUIDELINE DEVELOPMENT AND PEER REVIEW	**YES**	**NO**	**EVIDENCE/COMMENTS**
Is there a clear description of the individuals and groups who were involved in developing it?	√		See provenance
Were the guidelines internally peer reviewed during the production process? Please indicate the disciplines/specialties consulted during the development of this guideline	√		Circulated to: all Consultant obstetricians; sonographers; radiologists; midwifery teamleaders
What were the review methods and results of the review			Reviewed by authors after peer review
Please describe the steps taken to address comments/criticisms arising from peer review?			Amended/revised in light of comments received from peer review
Does this guideline have implications for diagnostics/therapeutics?		√	
CLARITY	**YES**	**NO**	**EVIDENCE/COMMENTS**
Is the guidance easy to read and follow?	√		
REVIEWS	**YES**	**NO**	**EVIDENCE/COMMENTS**
Is a review date specified? Who is responsible for the review (include post/title)	√		J Williams; October 2014

Also in the Toolkit series:

- Curriculum Design
- Developing a Subspecialty Training Programme
- Establishing a Training Centre for Courses
- Exam Preparation
- Guideline Development and Adaptation
- Health and Training Needs Assessment
- Service Review and Audit

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