The Royal College of Midwives (RCM)

Manual for producing midwifery practice guidelines

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The Royal College of Midwives (RCM) Manual for producing midwifery practice guidelines prepared by members of the RCM Working Group for NHS Evidence Accreditation of RCM guidelines

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Introduction

The Royal College of Midwives (RCM) has a fundamental role in promoting the midwifery profession and supporting midwifery practice. To this end, RCM has developed a process of guideline development, and produces evidence-based guidelines and related material for national utilization and dissemination.

Clinical Guidelines are recommendations for the care of individuals by health care professionals that are based on the best available evidence (NICE 2009). Clinical guidelines are defined as ‘systematically developed statements to assist practitioner and patient decisions about appropriate care for specific clinical circumstances’ (Woolf et al 1999).

Midwifery practice guidelines can be used as a conceptual framework for evidence-based decision-making for individual women, practitioners and for organisations by making clear of the benefits, harms and, if possible, costs of different care options. There must be a focus on how the context impact on what constitutes as evidence and how that evidence is utilised. Taking cognisance of the work involved in developing evidence based guidelines the RCM aims to improve midwifery practice and encourage a uniform national standard of practice, by producing quality evidence based documents which will have local applicability.

It is not the intention to repeat existing guideline work, however midwifery practice guideline topics may evolve from these, and cover broader issues, expanding on the relevance and implications for midwifery practice. The midwifery practice guidelines are developed to ensure there is guidance for all aspects of the maternity pathway, particularly where NICE guidance does not offer detail on appropriate midwifery practice.

One of the key principles of midwifery-led care is the right of pregnant women to be provided with good information and to be involved in decisions about their own care and that of their babies. There will be a range of reasons why obstetric opinion may be required during labour for some women. This may be followed by transfer to consultant-led care, or agreement made by all parties that midwifery-led care should continue. These guidelines are developed for women who meet generally agreed criteria, i.e. women in good general health following a straightforward pregnancy and without problems in a previous pregnancy or labour, who enter spontaneous labour at term, expecting one baby in a cephalic presentation. It is expected that where concern exists about the woman, or the condition of the fetus, or progress of labour, then referral for an obstetric opinion will take place. It is also anticipated that use of epidural pain relief will be associated with following a different care pathway, as labour may no longer be physiological.

In all situations, it is important that women understand who has responsibility for their care, that they remain informed and involved in decisions about them and their babies. Record keeping should reflect discussions that take place about options for care, and should provide a full and accurate picture of events to enable smooth and safe transfer of care, where that is required.
Systematic approach

The process for developing the midwifery practice guidelines ensures an objective, professional, quality and evidence based document is available to the midwifery profession. The process is underpinned by the following guiding principles.

Guiding principles

- The guidelines should be based on best available evidence
- Sound critical analysis should be used to synthesise the evidence
- The process for developing and evaluating the papers should incorporate outcomes valued by users
- The guidelines should be flexible and adaptable so individual user and local circumstances can be taken into consideration
- There should be evidence of user involvement and other appropriate professionals

The following standardised approach forms the guidance for those involved in the writing of these documents. Each paper will carry a date of publication, a proposed date for revision and an acknowledgement of authors and peer reviewers, including documentation of their affiliations.

Process

1. Suitability screen

The suitability screen is the first step to ensure that the agreed topic is relevant to practice and to assess the level of existing guidance in that area of practice. The steps include:

- Outcome of a brief literature search to identify whether there is adequate literature to make evidence based decisions about appropriate practice.
- Is there already a suitable guideline available that could be accepted or is there any guidance in production (e.g. NICE guideline) that covers the scope of the suggested topic?
- Will the topic benefit practice and how easy would it be to implement? Is it acceptable to women and midwives?
2. Purpose and Scope

The topic and a description of the users/clinical setting to which it applies should be stated in the title and/or in the first paragraph of each guideline.

The need for guidance could fall into one of the following categories:

- Areas where improved standards of care would reduce health inequalities, rates of morbidity, disability or mortality
- New innovative practices adopted
- Areas of uncertainty as evidenced by a wide variation in practice
- Areas with resource implications for midwifery practice
- Areas where there are implications across the primary/secondary care interface.

The identification of guideline topics should involve consultation with practising midwives and lay members of organisations who work with users of the maternity services.

3. Literature searching and assessing the evidence

A structured and systematic search strategy must be evident in finding the data for the development of the guidelines.

Significant questions likely to drive the review are:

- What is the balance of harm or benefit for the practice/intervention? (safety)
- Why are there differences in clinical outcomes? (process of service delivery)
- What is the acceptability to women of the practice/intervention? (acceptability)
- What are the respective costs? (cost effectiveness)
- What is the appropriate client group? (appropriateness)
- How will satisfaction be affected? (satisfaction)

The literature review should include as a minimum

- Searching by a librarian of the electronic databases (such as Cochrane, MEDLINE, eMBASE, MIDIRS).
- Hand searching key journals and looking for frequently cited literature.
- Search of The National Institute for Health and Clinical Excellence Guidelines and the Scottish Intercollegiate Guidelines for existing guidelines in the topic areas.

The time frame covered by the search is recommended as 1990 onwards.
Literature covering the following perspectives should be sought and reviewed:

- that of systematic reviews and prospective and published randomised controlled trials;
- that exploring women’s views;
- reports from professional bodies and government policy directives

This should include both quantitative and qualitative evidence sources, depending on the research questions.

In line with the philosophy of midwifery-led care, particular weight should be given to finding literature that incorporates women’s views. Where there is more than one treatment option supported by the evidence and there are clear preferences found in the literature reporting on women’s views, this should be documented in the recommendations.

**Inclusion criteria**

The search should be limited to

- English language papers or abstracts
- Published academic papers relevant to the topic under consideration
- Research conducted in settings and contexts relevant to UK midwifery-led care

Where there is uncertainty about the appropriateness of including a paper, this should be discussed by the authors and agreed by the guideline advisory group. The guideline advisory group should include membership from practising midwives, obstetricians and lay user groups (appendix B).

**Search Terms**

Separate search strategies should be developed for each section of the review.

Initial search terms for each discrete area should be identified by the authors. In addition, the Medline records for key papers in each area should be examined in order to determine the most appropriate Medical Subject Headings (MeSH). For each search, a combination of MeSH and keyword (free text) terms should be used to achieve comprehensiveness. The dates of the search should be documented in the guidelines and the search strategies made available on request.

There may be additional searches performed once the guideline review is underway. This is to ensure that the most up to date relevant information is incorporated. These additional searches (i.e. outside the full search strategy) will be documented in the methodology section of each guideline where relevant.

**4. Evaluating and assessing the data**

The authors of the guidelines assess the information returned from the search for inclusion or exclusion from the evidence base for the guideline topic under consideration. All papers that have abstracts should be reviewed independently by two authors and papers discarded if they do not fit the inclusion criteria. Exclusion criteria should include
- Papers published prior to 1990
- Non-English language papers
- Papers irrelevant to the topic
- Animal studies

Once any erroneous evidence has been excluded, the full texts of the remaining evidence should be obtained and assessed for quality and strength. The evaluation and assessment of data should be based on critical appraisal of the research. See appendix A for appropriate critical appraisal tools. This assessment should be performed independently by at least two members of the guideline advisory group. If there is disagreement, then the full papers are discussed with all the advisory group members to obtain consensus about the inclusion or exclusion of the evidence. Papers will be excluded at this stage if they are found to be low quality or lack applicability. The decision to include or exclude a paper should be documented on the paper itself. All papers accessed will be archived at the RCM.

5. Midwifery Practice Guideline recommendations

Any recommendations and guidance in the paper must be based on the best available evidence. There should be clear links between the evidence and the recommendations for practice. The critical appraisal process should identify any strength and limitations of the evidence base and this should be indicated in the final version of the guidelines.

The guidelines are drafted based on the evidence and then reviewed by the Guideline Advisory Group. The Guideline Advisory Group will discuss issues raised by the critical appraisal process and give opinions and comments on the evidence base. The group will assess and discuss the evidence and formulate their recommendations by informal consensus. Where necessary the advisory group can request further information be sought in a topic area. When requested, the extra information is sought and reviewed at a second Guideline Advisory Group meeting. In the event that an informal consensus cannot be reached on a recommendation, the Guideline Advisory Group can proceed to a vote, with the chair having a second deciding vote if required.

6. Review and updating of guidelines

The process for review of guidelines and commencing the literature searching, should begin 4 years after publication of the current edition unless evidence requires earlier review. A librarian will undertake a brief literature review every six months, of all the subjects in the midwifery led care guidelines and a copy of the contents page of the significant midwifery journals will be sent from the library to one of the key guideline developers. This enables the RCM to be alerted to any important new evidence.
7. Audit and implementation support

The membership of RCM is notified by email when a final version of a clinical guideline is posted on the main guidelines page on the website http://www.rcm.org.uk/college/policy-practice/evidence-based-guidelines/

There will be recommendations in each midwifery practice guideline that can be used as auditable standards. This will allow clinicians to assess the effects of guideline implementation on local practice.

The guidelines aim to be as useful to the practising midwife as possible. The format of the practice recommendations in a pocket sized booklet has been a significant tool in facilitating their implementation (Spiby and Munro 2009) and the guidelines should be produced in this format where possible. The RCM run education workshops and present at conferences to discuss potential barriers to implementation. The RCM undertakes national audits of the guideline recommendations periodically which inform any educational/implementation activity linked to the guidelines.

8. Peer Review

Each guideline will be subject to internal and external formal peer review.

Peer reviewing of the 2nd version of the draft guideline will be undertaken by independent expert referees. These referees should be respected and known experts in the midwifery community and members of the RCM expert reference group. There is no financial remuneration for this role.

The peer reviewers should be sent the draft and asked to comment on

- Comprehensiveness and accuracy of interpretation of evidence
- Clarity
- Value of the guideline in practice

The reviewers should be offered a month to undertake the review, and this should happen in isolation as opposed to at group meetings.

The comments received from peer reviewers should be discussed at the following guideline advisory group meeting. Each point should be addressed. Comments should be collated and responses to them documented. Any changes to the recommendations in response to the peer review are made by informal consensus. As above, in the event that an informal consensus cannot be reached, the Guideline Advisory Group can proceed to a vote, with the chair having a second deciding vote if required.

The names of author(s), any significant contributors and external peer reviewers and their affiliations must be included in the guideline.
9. Declaration of Interests

The authors and all those involved in the work of the guideline development, including peer reviewers should be asked to complete a declaration of interests form (see Appendix D). These forms are accessed by the chair of the guideline advisory group prior to the authors and stakeholders participating in each stage of the guideline development process. For any significant conflict identified the chair will inform the relevant party of whether they can be involved or if the conflict is significant enough to remove them from the guideline production process entirely. Signed copies will be returned to and retained at the London office of the Royal College of Midwives, where they can be inspected by any interested party.

RCM guidelines are not funded by any external organisation, commercial company or charity other than RCM itself. The RCM Guideline Advisory Group receives no funding apart from expenses from the RCM to cover the cost of assistance with gathering evidence, meetings, and incidental travel expenses.

Conclusion

Good quality research evidence fundamentally improves the information, evidence and quality of midwifery care as well as enhances the decision making process for women and their partners.

Evidence based policy is not simply an extension of evidence based practice, it is qualitatively different and this process and product will support professional midwifery practice and influence policy makers.
References and bibliography:


Royal College Of Midwives (RCM) (2010a) The Royal College Of Midwives’ Audit Of Midwifery Practice London : RCM

Royal College Of Midwives (RCM) (2010b) The Royal College of Midwives’ Survey of positions used in labour and birth London : RCM


Appendix A

Critical appraisal tools in evidence based guideline production

Examples of studies relevant to midwifery practice will include research designs other than Randomised Controlled Trials (RCTs) e.g. social research including cross sectional studies (surveys), case-control studies, action research, systematic review or ethnographic studies.

Different clinical or research questions use different study designs and assessing these different methodologies will need different appraisal questions, but the checklist for each study should include assessment of 3 main sections:

- Study authenticity/trustworthiness;
- Study results
- Study relevance.

Initial appraisal should be done through relevant CASP tools, and then through more detailed accepted tools, where these exist, such as CONSORT for RCTs and the tool below for qualitative studies.
## Summary Criteria for appraising qualitative research studies

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<th>Stages</th>
<th>Essential criteria</th>
<th>Specific prompts</th>
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</table>
| **Scope & Purpose** | Clear statement of and rationale for research question/aims/purposes Study thoroughly contextualised by existing literature | • Clarity of focus demonstrated  
• Explicit purpose given, such as descriptive/explanatory intent, theory building, hypothesis testing  
• Link between research and existing knowledge demonstrated  
• Evidence of systematic approach to literature review and/or to location of literature to contextualise the findings |
| **Design**      | Method/design apparent, and consistent with research intent Data collection strategy apparent and appropriate | • Rationale given for use of qualitative design  
• Discussion of epistemological/ontological grounding  
• Rationale explored for specific qualitative method e.g. ethnography, grounded theory, phenomenology  
• Discussion of why particular method chosen is mostappropriate/sensitive/relevant for research question/aims  
• Setting appropriate  
• Were data collection methods appropriate for type of data required and for specific qualitative method  
• Were they likely to capture the complexity/diversity of experience and illuminate context in sufficient detail?  
• Was triangulation of data sources employed if appropriate? |
| **Sampling strategy** | Sample and sampling method appropriate | • Selection criteria detailed, and description of how sampling was undertaken  
• Justification for sampling strategy given  
• Thickness of description likely to be achieved from sampling  
• Any disparity between planned and actual sample explained |
| **Analysis**    | Analytic approach appropriate                           | • Approach made explicit e.g. thematic distillation, constant comparative method, grounded theory  
• Was it appropriate for the qualitative method chosen?  
• Was data managed by software package or by hand and why?  
• Discussion of how coding systems/conceptual frameworks evolved  
• How was context of data retained during analysis  
• Evidence that the subjective meanings of participants were portrayed  
• Evidence of more than one researcher involved in stages if appropriate to epistemological/theoretical stance  
• Did research participants have any involvement in analysis e.g. member checking  
• Evidence provided that data reached saturation or discussion/rationale if it did not  
• Evidence that deviant data was sought, or discussion/rationale if it was not |
| **Interpretation** | Context described and taken account of in interpretation Clear audit trail given Data used to support interpretation | • Description of social/physical and interpersonal contexts of data collection  
• Evidence that researcher spent time ‘dwelling with the data’, interrogating it for competing/alternative explanations of phenomena  
• Sufficient discussion of research processes such that others can follow ‘decision trail’  
• Extensive use of field notes entries/verbatim interview quotes in discussion of findings  
• Clear exposition of how interpretation led to conclusions |
| Reflexivity                          | Researcher reflexivity demonstrated | • Discussion of relationship between researcher and participants during fieldwork  
• Demonstration of researcher’s influence on stages of research process  
• Evidence of self awareness/insight  
• Documentation of effects of the research on researcher  
• Evidence of how problems/complications met were dealt with |
|-------------------------------------|------------------------------------|---------------------------------------------------------------------|
| Ethical Dimensions                  | Demonstration of sensitivity to ethical concerns | • Ethical committee approval granted  
• Clear commitment to integrity, honesty, transparency, equality and mutual respect in relationships with participants  
• Evidence of fair dealing with all research participants  
• Recording of dilemmas met and how resolved in relation to ethical issues  
• Documentation of how autonomy, consent, confidentiality, anonymity were managed |
| Relevance and Transferability       | Relevance and transferability evident | • Sufficient evidence for typicality/specificity to be assessed  
• Analysis interwoven with existing theories and other relevant explanatory literature drawn from similar settings and studies  
• Discussion of how explanatory propositions/emergent theory may fit other contexts  
• Limitations/weaknesses of study clearly outlined  
• Clearly resonates with other knowledge and experience  
• Results/conclusions obviously supported by evidence  
• Interpretation plausible and ‘makes sense’  
• Provides new insights and increases understanding  
• Significance for current policy and practice outlined  
• Assessment of value/empowerment for participants  
• Outlines further directions for investigation  
• Comment on whether aims/purposes of research were achieved |

Appendix B

Current membership of the Guideline Advisory Group

Pauline Cooke, Consultant Midwife, Imperial College Healthcare NHS Trust

Elizabeth Duff, Senior Policy Adviser, National Childbirth Trust

Christine Harding, Consultant Midwife Trainee, Oxford University Hospitals NHS Trust

Kathryn Hardy, Midwife, Risk Management Project Lead, Northumbria Healthcare NHS Foundation Trust

Mervi Jokinen, Practice and Standards Development Advisor, The Royal College of Midwives

Jane Munro, Quality and Audit Development Advisor, The Royal College of Midwives

Sue Townend, Consultant Midwife & Supervisor of Midwives, Calderdale & Huddersfield NHS Foundation Trust

Helen White, Consultant Midwife for Intrapartum Care, Oxford University Hospitals NHS Trust

Naomi Whitelaw, Consultant Obstetrician and Gynaecologist, Milton Keynes Hospital NHS Foundation Trust
Appendix C
Outline of guideline development process

DEVELOPMENT PHASE

- Establish importance of topic area
- By scoping of topic area, reacting to externally identified issues, consulting with practitioners, service users, managers, policy makers, commissioners

- Establish key sub-elements of the topic
- As above

- Determine which designs are best to answer each of these sub-elements
- Use Petticrew and Roberts (2003) taxonomy

- Determine which quality tools will be used to assess each of the included designs, and if any studies will be excluded on the grounds of quality
- Use CASP as initial screening tool, then use design-specific tools

SEARCH PHASE

- Construct a search strategy for each sub-element
  - Consider:
    - Inclusion, exclusion
    - Date range (and rationale for this)
    - Sources to search
  - Keywords to use
    - Whether grey literature will be included
  - Which journals/books to hand search

Undertake the search

ANALYSIS PHASE

- Agree on which studies should be included (topic, quality)
  - Use the relevant quality inclusion tools for each study as appropriate

- Analyse the data for each sub-element separately
  - Synthesise studies with sufficient heterogeneity within each sub-element

GUIDELINE CONSTRUCTION PHASE

- Highlight significant practice points for each sub-element, prioritising those findings with the best quality evidence
- Decide in the guideline advisory group how to summarise the overall impression of all the sub-elements together
Appendix D
Template for guidelines

Title:

Provide a summary of all practice points from throughout the guideline. Ensure the language is unambiguous and clear.

Describe with references throughout how the evidence found and included answers the questions asked for this guideline topic. Ensure that the evidence is explained and any/all information about risks/benefits identified are described.

If there are any findings from the research into the topic which identify some practices that may improve women’s experience and outcomes:

Please document them here.

References

List in accordance with RCM style

This updated guideline was authored by Name(s), role(s), organisation(s) with contributions on specific guidelines from:

Name(s), Role(s) and organisation(s)

The development of this guideline has been under the auspices of the Guideline Advisory Group and the final ratification and sign off has been undertaken by the Director of Learning Research and Practice Development, Professional Midwifery Lead
Sources

Describe which databases etc were searched including dates of search.

The search was undertaken by name(s), role(s) and organisation(s).

Search Terms

Separate search strategies were developed for each section of the review. Initial search terms for each discrete area were identified by the authors. For each search, a combination of MeSH and keyword (free text) terms was used.

Journals hand-searched by the authors were as follows:

- List in bulleted format
Appendix E

The Royal College of Midwives
15 Mansfield Street, London W1G 9N

Declaration of Interests

The Royal College of Midwives is committed to open declaration of competing interests in the development of guidelines. Accordingly all persons involved in the development of college guidelines are requested to declare all competing interests on the enclosed form.

Competing interests are defined as any interest of the person, their partners or close relatives or their department/employer/business which may potentially influence the content, including recommendations of RCM guidelines. Generally, but not exclusively these situations might include:

- Sponsorship or payment of expenses by commercial organisations
- Donations, sponsorships or similar from pharmaceutical firms or equipment manufacturers
- Consultancies and fees paid
- Holding of shares in commercial organisations
- Membership of any national body, charity or pressure group
- Editorial responsibility including payment for publications

All of those contributing to the development of guidelines are asked to complete and sign the declaration of personal interests attached.

Please return the completed form by post or scan and email to:

Jane Munro
The Royal College of Midwives
15 Mansfield Street
London W1G 9NH

Email: Jane.Munro@rcm.org.uk
## Declaration of Interests

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>Do you or any member of your immediate family receive sponsorship or paid consultancy work within commercial organisations related to midwifery?</td>
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<tr>
<td></td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>Do you or any members of your immediate family have any commercial interest such as personal shares with any company related to midwifery?</td>
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<td>Yes</td>
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<td>Does your department or unit receive financial support from commercial organisations related to midwifery?</td>
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<td>Yes</td>
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<tr>
<td>Are you a consultant to or member of any national body, charity or pressure group whose work is related to midwifery?</td>
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<td></td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
Do you receive fees for commissioned articles for publication or are you paid for editorial work for any publication related to midwifery?

No       Yes

If yes please provide details

Date:

Confirmation: By returning this form to RCM, I confirm that the information stated above is true and correct

Please print your name: Signature: