



Complete Summary

GUIDELINE TITLE

Female barrier methods.

BIBLIOGRAPHIC SOURCE(S)

Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. Female barrier methods. London (UK): Faculty of Family Planning and Reproductive Health Care; 2007 Jun. 17 p. [106 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

- Unintended pregnancy
- Sexually transmitted infections

GUIDELINE CATEGORY

Counseling
Evaluation
Prevention

CLINICAL SPECIALTY

Family Practice
Internal Medicine

Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Patients
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide evidence-based recommendations and good practice points for clinicians on the use of female barrier methods to prevent pregnancy and/or reduce the risk of sexually transmitted infections

TARGET POPULATION

Women seeking female barrier methods to prevent pregnancy and/or reduce the risk of sexually transmitted infections

INTERVENTIONS AND PRACTICES CONSIDERED

1. Assessment of medical eligibility criteria for use of female barrier methods
2. Medical and sexual history
3. Vaginal examination
4. Assessment of sexually transmitted infection risk
5. Diaphragm and cervical cap (with spermicide)
6. Female condom
7. Contraceptive sponge
8. Assessment at initial fitting and follow-up for diaphragm and cervical cap
9. Providing instructions for correct use of barrier methods
10. Counseling and educating women about the risks and benefits of contraceptive use
11. Advance provision of emergency hormonal contraception

MAJOR OUTCOMES CONSIDERED

- User acceptability and satisfaction
- Failure rates, unintended pregnancy
- Rate of sexually transmitted infection in women using the female condom
- Rate of need for emergency contraception

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Evidence is identified using a systematic literature review and electronic searches are performed for: MEDLINE (CD Ovid version) (1996–2006); EMBASE (1996–2006); PubMed (1996–2006); The Cochrane Library (to 2006) and the US National Guideline Clearing House. The searches are performed using relevant medical subject headings (MeSH), terms and text words. The Cochrane Library is searched for systematic reviews, meta-analyses and controlled trials relevant to female barrier methods for contraception and in the prevention of sexually transmitted infections. Previously existing guidelines from the Faculty of Family Planning and Reproductive Health Care (FFPRHC), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization and the British Association for Sexual Health and HIV, and reference lists of identified publications, are also searched. Similar search strategies have been used in the development of other national guidelines.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Ia Evidence obtained from meta-analysis of randomized controlled trials

Ib Evidence obtained from at least one randomized controlled trial

IIa Evidence obtained from at least one well-designed, controlled study, without randomisation

IIb Evidence obtained from at least one other type of well-designed quasi-experimental study

III Evidence obtained from well-designed non-experimental descriptive studies, correlational studies, and case studies

IV Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Selected key publications are appraised using standard methodological checklists similar to those used by the National Institute for Health and Clinical Excellence (NICE). All papers are graded according to the Grades of Recommendations Assessment, Development and Evaluation (GRADE) system. Summary evidence tables are available on request from the Clinical Effectiveness Unit.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Draft One Guidance document is written, providing recommendations and good practice points based on the literature review. The Clinical Effectiveness Unit has overall responsibility for writing the Guidance document. The Multidisciplinary Group and other peer reviewers should highlight inconsistencies and errors or where the text is incomprehensible.

A Multidisciplinary Group Meeting is held, comprising stakeholders and including service user representation, representation from the Faculty of Family Planning and Reproductive Health Care (FFPRHC) Education Committee and, where possible, representation from the FFPRHC Clinical Effectiveness Committee and FFPRHC Council. A one-day meeting is held in Aberdeen with the Multidisciplinary Group to discuss the Draft One Guidance document.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendations

A: Evidence based on randomised controlled trials (RCTs)

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point: Where no evidence exists but where best practice is based on the clinical experience of the Multidisciplinary Group

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The Draft Two Guidance document is peer reviewed by the Multidisciplinary Group and the Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Effectiveness Council (CEC). All written feedback on the Draft Two Guidance document is tabulated and the Clinical Effectiveness Unit (CEU) response to these comments is outlined. The Draft Three Guidance document is prepared based on written feedback and is sent to the Multidisciplinary Group and the FSRH CEC. In addition, two independent reviewers are identified by the CEC to provide feedback at this stage. Only minor comments can be accepted at this stage. The Final Guidance document is published by the FSRH. Proofreading of the Guidance is then performed by three members of the CEU team independently and comments collated and sent back by the Unit Director. A portable document format (pdf) version of the Guidance is made available on the FSRH website.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendation grades (**A to C, Good Practice Point**) are defined at the end of the "Major Recommendations" field.

Assessing Which Women Can Use Female Barrier Methods

Medical Eligibility Criteria for Contraceptive Use

Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS)

1. The use of a diaphragm, cervical cap or contraceptive sponge (all with nonoxynol-9) by women who have HIV or AIDS, or who are at high risk of HIV infection, is not generally recommended (**Grade C**).
2. The consistent and correct use of female condoms may reduce the risk of HIV transmission (**Good Practice Point**).

Sensitivity to Latex Proteins

3. Women with sensitivity to latex proteins can use a silicone diaphragm or cervical cap or a polyurethane female condom (**Grade C**).

Toxic Shock Syndrome

4. For women with a history of toxic shock syndrome the use of a diaphragm, cervical cap or contraceptive sponge is not generally recommended (**Grade C**).

5. Women with a history of toxic shock syndrome may use a female condom (**Grade C**).
6. A diaphragm, cervical cap or contraceptive sponge should not be left *in situ* longer than recommended by the manufacturer (**Good Practice Point**).

Other Conditions That May Need to Be Considered Individually When Counselling About the Use of Female Barrier Methods

7. Women considering use of a diaphragm or cervical cap should be assessed individually to determine if use is appropriate for them (**Good Practice Point**).

How Effective Are Female Barrier Methods at Preventing Pregnancy?

Diaphragms and Cervical Caps

8. When used consistently and correctly and with spermicide, diaphragm and cervical caps are estimated to be between 92% and 96% effective at preventing pregnancy (**Grade C**).

Female Condoms

9. When used consistently and correctly, female condoms are 95% effective at preventing pregnancy (**Grade C**).

Contraceptive Sponge

10. When used consistently and correctly, the contraceptive sponge is estimated to be between 80% and 90% effective (**Grade C**).

Is the Contraceptive Efficacy of a Diaphragm or Cervical Cap Increased with Use of Spermicide?

11. Women using a diaphragm should be advised to use it with spermicide (**Grade B**).
12. Women using a cervical cap should be advised to use it with spermicide (**Good Practice Point**).

Do Female Barrier Methods Provide Any Protection Against Sexually Transmitted Infections (STIs)?

Female Condo

13. In general, evidence supports the use of female condoms to reduce the risk of STIs. However, even with consistent and correct use, transmission may occur and male condoms provide better protection (**Grade C**).

Diaphragm, Cervical Caps and Contraceptive Sponge

14. In general there is little evidence to support the use of a diaphragm or cervical cap (with spermicide) or a contraceptive sponge to reduce the risk of STIs (**Grade C**).
15. There is limited evidence that a diaphragm may reduce the risk of cervical intra-epithelial neoplasia (CIN) (**Grade C**).

What Should Health Professionals Assess at the Initial Fitting and Follow-Up of Women Using a Diaphragm or Cervical Cap?

Clinical History Taking

16. A medical history (including a sexual history) should be taken from women considering the use of a diaphragm or cervical cap (**Good Practice Point**).
17. An individual assessment of STI risk should inform decisions about the appropriateness of diaphragm and cervical cap use, the need for use of male condoms in addition if STI risk is higher, and appropriate testing for STIs (**Good Practice Point**).

Vaginal Examination at Initial Visit and Follow-Up

18. A vaginal examination by a competent health professional at initial fitting and follow-up is mandatory to ensure the safe and effective use of a diaphragm or cervical cap (**Grade C**).
19. Women having a vaginal examination for fitting a diaphragm or cervical cap should be offered a chaperone and this should be documented in the case notes (**Grade C**).
20. As a minimum, health professionals should be competent in counselling about the correct use of the method, choosing the most appropriate method and ensuring that the cervix is covered (**Good Practice Point**).
21. After the initial fitting, all women should be asked to re-attend the clinic for review after using the diaphragm or cervical cap as a secondary method of contraception (**Good Practice Point**).
22. At first follow-up, the health professional should check the woman can insert the diaphragm or cervical cap correctly to cover the cervix; that the method used is the correct size; that the woman is comfortable while using the method for the duration of its use, including during intercourse; and that she can tolerate the use of spermicide (**Good Practice Point**).

Emergency Contraception

23. Health professionals should consider the advance provision of emergency hormonal contraception to women who use a diaphragm or cervical cap (**Grade C**).

What Information Should Be Given to Women on the Use of a Diaphragm or Cervical Cap?

Information About Correct Use (i.e., Insertion and Removal, Use of Spermicide and Need for Emergency Contraception)

Note: Detailed instructions for women on use of a diaphragm or cervical cap are included in Box 2 of the original guideline document.

24. A diaphragm or cervical cap can be inserted with spermicide any time before intercourse but additional spermicide should be applied if sex is to take place and the method has been *in situ* for ≥ 3 hours or if sex is repeated with the method in place (**Grade C**).
25. Women using a diaphragm or cervical cap should be informed that the method must be left in place for at least 6 hours after the last episode of intercourse (**Grade C**).
26. Latex diaphragms and cervical caps can remain in place for a maximum of 30 hours but women should refer to the patient information leaflet for recommended duration of use for specific diaphragms and cervical caps (**Grade C**).
27. Women using a diaphragm or cervical cap should be advised in what circumstances emergency contraception may be indicated (such as if a diaphragm or cervical cap is dislodged during sex or removed within 6 hours of sex) (**Good Practice Point**).

Factors That May Influence Contraceptive Efficacy

28. Women should be advised to check the diaphragm or cervical cap regularly for tears, holes or cracks (**Grade C**).
29. Oil-based products can damage latex and women should be advised to avoid their use when using latex diaphragms or cervical caps (**Grade C**).
30. Women should be advised to follow the manufacturers' instructions regarding cleaning and caring for a diaphragm or cervical cap (**Good Practice Point**).
31. Women using diaphragms can be advised that there is no evidence that colour changes or a small change in outer ring shape has an effect on contraceptive efficacy (**Good Practice Point**).
32. There is no evidence that inserting the diaphragm dome up or dome down influences efficacy; however, the woman should check that the diaphragm covers the cervix after insertion (**Good Practice Point**).

When Should Women Attend for Advice

33. Women using a diaphragm or cervical cap should be advised to attend for a contraceptive review if they have any problems with the method, if they have lost or gained over 3 kg (7 lb) in weight, or if they have had any pregnancy (**Grade C**).

Definitions:

Grades of Recommendations

A: Evidence based on randomised controlled trials (RCTs)

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C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point: Where no evidence exists but where best practice is based on the clinical experience of the Multidisciplinary Group

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate use of barrier methods of contraception to decrease the rate of unwanted pregnancy and sexually transmitted diseases
- Advantages of female barrier methods include: no serious side effects, use is under the woman's control, they need only be used during sex, they can be inserted at a convenient time before sex, and they may provide some protection against sexually transmitted infections.

POTENTIAL HARMS

- Medical conditions for which the risks associated with use of female barrier methods may outweigh the benefits include:
 - High risk of human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS)
 - HIV infected (with and without use of highly active antiretroviral therapy [HAART])
 - AIDS and using HAART
 - History of toxic shock syndrome
 - Sensitivity to latex proteins, excluding use of non-latex condoms or diaphragms
- Perceived disadvantages of female barrier methods include: messiness, problems with insertion/removal, irritation (with diaphragm and cervical caps used with spermicide), lack of sexual spontaneity and noisiness (female condom).
- The failure rate of the diaphragm at preventing pregnancy when used correctly and with spermicide is 4% to 8%.
- The failure rate of the cervical cap at preventing pregnancy when used correctly and with spermicide is 10% to 13%.
- The failure rate of the female condom at preventing pregnancy when used correctly is 5%.
- The failure rate of the contraceptive sponge at preventing pregnancy when used correctly is 10% to 20%.
- Even with consistent and correct use of the female condom, transmission of sexually transmitted infections may occur.

QUALIFYING STATEMENTS

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This document is not intended to serve alone as a standard of medical care, as this should be determined individually based on available clinical information.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Staff Training/Competency Material

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. Female barrier methods. London (UK): Faculty of Family Planning and Reproductive Health Care; 2007 Jun. 17 p. [106 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2007 Jun

GUIDELINE DEVELOPER(S)

Faculty of Sexual and Reproductive Healthcare - Professional Association

SOURCE(S) OF FUNDING

Faculty of Sexual and Reproductive Healthcare

GUIDELINE COMMITTEE

Clinical Effectiveness Unit

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [Faculty of Sexual and Reproductive Healthcare Web site](#).

Print copies: Available from the Faculty of Sexual and Reproductive Healthcare, 27 Sussex Place, Regent's Park, London NW1 4RG

AVAILABILITY OF COMPANION DOCUMENTS

Discussion points and questions for female barrier methods developed by the Faculty of Sexual and Reproductive Healthcare are available at the end of the original guideline document.

Electronic copies: Available in Portable Document Format (PDF) from the [Faculty of Sexual and Reproductive Healthcare Web site](#).

PATIENT RESOURCES

None available

NGC STATUS

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