



Complete Summary

GUIDELINE TITLE

Male and female condoms.

BIBLIOGRAPHIC SOURCE(S)

Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. Male and female condoms. London (UK): Faculty of Family Planning and Reproductive Health Care; 2007 Jan. 17 p. [144 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
CONTRAINDICATIONS
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 (STIs)

GUIDELINE CATEGORY

Counseling
Evaluation
Prevention
Risk Assessment

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 male and female condoms to prevent pregnancy and/or reduce the risk of sexually transmitted infections

TARGET POPULATION

Men and women seeking male and female condoms to prevent pregnancy and/or reduce the risk of sexually transmitted infections

INTERVENTIONS AND PRACTICES CONSIDERED

Counseling

1. Counseling on factors to consider when choosing a condom
 - Latex sensitivity
 - Lubrication (with or without spermicide)
 - Lubrication (oil based/non-oil based)
 - Expiration date
2. Education on condom use, prevention of pregnancy and transmission of sexually transmitted infections (STIs)

Prevention

1. Male and female condoms (latex or polyurethane)
2. Considerations for condom failure
 - Progestogen-only emergency contraception
 - Testing for STIs
 - Post-exposure prophylaxis for possible human immunodeficiency virus (HIV) exposure

MAJOR OUTCOMES CONSIDERED

- Failure rate, unintended pregnancy rate
- Transmission rate of sexually transmitted infections (STIs)

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 was identified using a systematic literature review, and electronic searches were 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 were performed using relevant medical subject headings (MeSH) terms and text words. The Cochrane Library was searched for systematic reviews, meta-analyses and controlled trials relevant to male and female condoms for contraception and in the prevention of sexually transmitted infections. Previously existing guidelines from the 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 were also searched.

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

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

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 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 must take 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.

What Factors Should Be Considered When Choosing a Type of Condom?

Medical Eligibility Criteria: Sensitivity to Latex Proteins

1. Men or women with sensitivity to latex proteins should avoid the use of latex condoms (**Grade C**).
2. Men and women with sensitivity to latex may use male or female polyurethane condoms or deproteinised latex male condoms (**Grade C**).
3. For men and women who have symptoms of local genital irritation associated with latex condom use, a clinical history should be taken to identify any cause. Further investigation may be warranted and referral considered (**Good Practice Point**).

Condoms Lubricated with Spermicide or Non-Spermicide

4. The use of condoms lubricated with spermicide is not generally recommended (**Grade B**).

Condom Quality

5. Condoms should be checked for relevant safety markings and a valid expiry date before use (**Good Practice Point**).

Use of Lubricant

6. When using lubricant with latex condoms a non-oil-based preparation is recommended (**Grade B**).
7. The use of lubricant is recommended for anal sex to reduce the risk of condom breakage (**Grade B**).
8. It is not recommended that lubricant be applied to the penis under a male condom as this is associated with slippage (**Grade B**).

Condom Size, Shape and Thickness

9. The use of a stronger (thicker) condom instead of standard condoms does not reduce the risk of breakage and is not generally recommended (**Grade C**).

How Effective Are Condoms at Preventing Pregnancy?

How Good Is the Evidence Available on Condoms in Preventing Pregnancy?

10. Men and women can be advised that when used consistently and correctly, male condoms are up to 98% effective at preventing pregnancy (**Grade C**).
11. Men and women can be advised that pregnancy rates are similar for latex and non-latex condoms (**Grade A**).

Contraceptive Efficacy of Female Condoms

12. Men and women can be advised that when used consistently and correctly, female condoms are 95% effective at preventing pregnancy (**Grade C**).

How Effective Are Condoms at Preventing the Transmission of Sexually Transmitted Infections (STIs)?

What Factors Influence the Transmission of STIs?

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

How Effective Are Condoms in Preventing the Transmission of Specific STIs?

Human Immunodeficiency Virus (HIV)

14. The consistent and correct use of male latex condoms is recommended to reduce the risk of HIV transmission (**Grade A**).
15. The consistent and correct use of female condoms and non-latex male condoms may be recommended to reduce the risk of HIV transmission (**Good Practice Point**).

Chlamydia Trachomatis

16. The consistent and correct use of condoms is recommended to reduce the risk of *C. trachomatis* transmission (**Grade B**).

Neisseria Gonorrhoeae

17. The consistent and correct use of male condoms is recommended to reduce the risk of *N. gonorrhoeae* transmission (**Grade B**).

Trichomonas Vaginalis

18. The consistent and correct use of condoms is recommended to reduce the risk of transmission of *T. vaginalis* (**Grade B**).

Genital Herpes

19. The consistent and correct use of male condoms is recommended to reduce the risk of transmission of herpes simplex virus (HSV) (**Grade B**).
20. The consistent and correct use of female condoms may be advised to help reduce the risk of transmission of HSV (**Good Practice Point**).

Syphilis

21. The consistent and correct use of male condoms is recommended to reduce the risk of syphilis transmission (**Grade B**).
22. The consistent and correct use of female condoms may be advised to reduce the risk of syphilis transmission (**Good Practice Point**).

Human Papilloma Virus (HPV)

23. The consistent and correct use of condoms is recommended to reduce the risk of transmission of genital HPV (**Grade B**).
24. Male latex condoms, when used consistently and correctly, can increase the rate of HPV clearance and cervical intraepithelial neoplasia regression (**Grade B**).
25. The consistent and correct use of female condoms may be advised to reduce the risk of transmission of genital HPV (**Good Practice Point**).

Viral Hepatitis

26. Male latex condoms, when used consistently and correctly, may be recommended to reduce the risk of transmission of hepatitis B (**Grade B**).
27. There is insufficient evidence to determine the efficacy of condoms in preventing transmission of hepatitis A and C. Use may be recommended during infectious episodes (**Good Practice Point**).

What Should Be Considered When There Is a Recognised or a Potential Condom Failure?

Emergency Contraceptive Use

28. Advance provision of progestogen-only emergency contraception should be offered to women relying solely on condoms for contraception (**Grade C**).

Testing for STIs

29. Men and women should be made aware of the possibility of STI when there is a potential condom failure and advised about STI testing 2 and 12 weeks later (**Grade C**).

Post-Exposure Prophylaxis for HIV

30. Men and women can be made aware of post-exposure prophylaxis for HIV following sexual exposure (PEPSE) when there is a condom failure. The decision to initiate PEPSE can only be made after consideration of the risks of exposure and likelihood of compliance with treatment (**Good Practice Point**). See table below.

Table. Recommendations for Post-Exposure Prophylaxis Following Sexual Exposure (PEPSE) (e.g., Following Unprotected Sex or Condom Failure)

HIV Risk	PEPSE Recommended	PEPSE Considered	PEPSE Not Recommended
Source is HIV positive	Receptive anal and vaginal sex Insertive anal and vaginal sex	Fellatio with ejaculation Splash of semen into the eye	Fellatio without ejaculation Cunnilingus
Source HIV status is unknown Source from a group or area with high HIV prevalence (e.g., men who have sex with men, individuals from sub-Saharan Africa)	Receptive anal sex	Receptive vaginal sex Insertive anal and vaginal sex Fellatio with ejaculation	
Source <i>not</i> from a group or area of high HIV prevalence		Receptive anal sex	Receptive vaginal sex Insertive anal or vaginal sex Fellatio with ejaculation

What Information Should Be Given About Condom Use?

31. Counselling men and women about condoms should include advice on correct use, appropriate use of lubricant, STI screening and when emergency contraception may be required (**Good Practice Point**).

Note: Detailed instructions on the use of male condoms are provided in Box 1 in the original guideline document.

Note: Detailed instructions on the use of female condoms are provided in Box 2 in the original guideline document.

Definitions:

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

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 male and female condoms to prevent unintended pregnancy and transmission of sexually transmitted infections (STIs)

POTENTIAL HARMS

Men or women with sensitivity to latex proteins should avoid the use of latex condoms. Repeat exposure may increase the risk of a reaction; most reactions due to latex allergy are clinically mild and localised to the penis or vulva (Type IV hypersensitivity); other symptoms can include pruritis, oedema of the skin, mucous membranes or subcutaneous tissues, and abdominal symptoms (cramp, nausea, vomiting and diarrhoea); the most serious clinical syndrome (Type I

hypersensitivity) can manifest with symptoms as above but the onset is quicker; people with Type I latex allergy are at risk of anaphylaxis.

- The true failure rate (method failure) for male condoms in the first year of use is 2%. The typical use failure rate (method failure plus user failure) is 15%.
- With consistent and correct use the method failure rate for female condoms is 5% while the typical use failure rate is 21%.
- In general, evidence supports the use of condoms to reduce the risk of sexually transmitted infections. However, even with consistent and correct use, transmission may still occur.

CONTRAINDICATIONS

CONTRAINDICATIONS

The only contraindication to the use of latex condoms is for people with sensitivity or allergy to latex proteins.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This document is not intended to serve alone as a standard of medical care since 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. Male and female condoms. London (UK): Faculty of Family Planning and Reproductive Health Care; 2007 Jan. 17 p. [144 references]

ADAPTATION

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

DATE RELEASED

2007 Jan

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

Clinical Effectiveness Unit (CEU): Dr Susan Brechin, (CEU Unit Director); Ms Lisa Allerton (CEU Research Assistant); Ms Gillian Stephen, (CEU Research Assistant)

Clinical Effectiveness Committee: Mrs Walli Bounds (Former Research Co-ordinator, The Margaret Pyke Centre, London/Principal Research Fellow, Department of Obstetrics and Gynaecology, University College London (now retired); Dr David Hicks (Medical Director/Consultant in Genitourinary Medicine and HIV, Central Sheffield University Hospital/Representative of the FFPRHC Clinical Effectiveness Committee); Dr Nicola Mullin (Consultant in Sexual and Reproductive Health Care, Cheshire West PCT/Representative of the FFPRHC Education Committee); Dr Alyson Elliman (Consultant in Family Planning, Croydon PCT/Honorary Secretary of the FFPRHC); Mr Martin Murchie (Senior Health Adviser, The Sandyford Initiative, Glasgow); Mr Rod Watson (Deputy Head of Health Promotion, Terrence Higgins Trust, London); Dr Lesley Bacon (Consultant in Sexual Health, Lewisham PCT)

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 male and female condoms 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

This NGC summary was completed by ECRI Institute on May 16, 2008

COPYRIGHT STATEMENT

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at <http://www.guideline.gov/about/inclusion.aspx>.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

© 1998-2008 National Guideline Clearinghouse

Date Modified: 9/29/2008

