Complete Summary

GUIDELINE TITLE

Intrauterine device.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Intrauterine device. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2005 Jan. 10 p. (ACOG practice bulletin; no. 59). [74 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

SCOPE

DISEASE/CONDITION(S)

- Unintended pregnancy
- Menorrhagia

DISCLAIMER

GUIDELINE CATEGORY

Management Technology Assessment

CLINICAL SPECIALTY

Obstetrics and Gynecology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To present evidence regarding the safety and efficacy of copper T380A and the levonorgestrel intrauterine system

TARGET POPULATION

Women and adolescent girls of child-bearing capability who desire contraception, especially:

- Multiparous and nulliparous women at low risk for sexually transmitted diseases
- Women who desire long-term reversible contraception
- Women with diabetes, thromboembolism, menorrhagia/dysmenorrhea, breast cancer, liver disease, or who are breastfeeding for which an intrauterine device may be an optimal method of contraception

INTERVENTIONS AND PRACTICES CONSIDERED

Use of Intrauterine Devices (IUDs)

- 1. Copper T380A
- 2. Levonorgestrel intrauterine system
- 3. Difficulties associated with IUD insertion and removal
- 4. Routine use of prophylactic antibiotics at time of insertion (not recommended)
- 5. Treatment options for asymptomatic patients with actinomyces identified on a Pap test
- 6. Use of copper T380A for emergency contraception
- 7. Use of levonorgestrel intrauterine system for menorrhagia
- 8. Removal of IUDs from pregnant women and after menopause
- 9. Counseling concerning risk factors for sexually transmitted diseases and pelvic inflammatory disease

MAJOR OUTCOMES CONSIDERED

- Pregnancy rates
- Incidence of complications, eg, pelvic inflammatory disease
- Contraception continuation rate

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

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and September 2004. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

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

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- **I**: Evidence obtained from at least one properly designed randomized controlled trial.
- **II-1**: Evidence obtained from well-designed controlled trials without randomization.
- **II-2**: Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- **II-3**: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- **III**: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

METHODS USED TO ANALYZE THE EVIDENCE

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician—gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

COST ANALYSIS

In an economic analysis, the levonorgestrel intrauterine system was shown to be the most cost-effective reversible method of contraception after 5 years of continuous use. As with the copper T380A, return to fertility is rapid after removal of the device.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

Conclusions

Pelvic inflammatory disease (PID) complicating intrauterine device (IUD) insertion is uncommon, and the risk of PID decreases to the background risk after the first 20 days after insertion.

Nulligravid and multiparous women at low risk of sexually transmitted diseases (STDs) who desire long-term reversible contraception are good candidates for IUDs.

Summary of Recommendations

The following recommendations are based on good and consistent scientific evidence (Level A):

- Routine use of prophylactic antibiotics at the time of IUD insertion confers little benefit.
- The copper T380A is very effective for postcoital emergency contraception and is most effective if inserted within 5 days after unprotected intercourse.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- IUDs may be offered to women with a history of ectopic pregnancy.
- The levonorgestrel intrauterine system may be an acceptable alternative to hysterectomy in women with menorrhagia.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- The Food and Drug Administration (FDA) recommends that IUDs be removed from pregnant women when possible without an invasive procedure.
- An IUD placed for contraception should be removed in a woman who has become menopausal.
- Contraception counseling should include information about risk factors for sexually STDs and PID.

Definitions:

Grades of Evidence

I: Evidence obtained from at least one properly designed randomized controlled trial.

- **II-1**: Evidence obtained from well-designed controlled trials without randomization.
- **II-2**: Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- **II-3**: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- **III**: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Levels of Recommendations

- **Level A** Recommendations are based on good and consistent scientific evidence.
- **Level B** Recommendations are based on limited or inconsistent scientific evidence.
- **Level C** Recommendations are based primarily on consensus and expert opinion.

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").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of the intrauterine device

POTENTIAL HARMS

- Some women may experience hormone-related effects, such as headache, nausea, breast tenderness, and depression, with the levonorgestrel intrauterine system.
- Difficulties that may occur at intrauterine device (IUD) insertion include vasovagal reaction, the need for cervical dilation, severe pain, inability to insert the IUD, and uterine perforation. Overall, these conditions rarely occur.

 Complications that may occur in IUD users who become pregnant include an increased risk of spontaneous abortion and an increased risk of septic abortion.

CONTRAINDICATIONS

CONTRAINDICATIONS

Contraindications to Intrauterine Device (IUD) Use

- Pregnancy
- Pelvic inflammatory disease (current or within the past 3 months)
- Sexually transmitted diseases (current)
- Puerperal or postabortion sepsis (current or within the past 3 months)
- Purulent cervicitis
- Undiagnosed abnormal vaginal bleeding
- Malignancy of the genital tract
- Known uterine anomalies or fibroids distorting the cavity in a way incompatible with IUD insertion
- Allergy to any component of the IUD or Wilson's disease (for coppercontaining IUDs)

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Foreign Language Translations Patient Resources

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Intrauterine device. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2005 Jan. 10 p. (ACOG practice bulletin; no. 59). [74 references]

ADAPTATION

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

DATE RELEASED

2005 Jan

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Gynecology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following is available:

• The intrauterine device. Atlanta (GA): American College of Obstetricians and Gynecologists (ACOG); 2007.

Electronic copies: Available from the <u>American College of Obstetricians and Gynecologists (ACOG) Web site</u>. Copies are also available in Spanish.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI Institute on October 10, 2007. The information was verified by the guideline developer on December 3, 2007.

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: 10/13/2008

