Complete Summary

GUIDELINE TITLE

Use of hormonal contraception in women with coexisting medical conditions.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Use of hormonal contraception in women with coexisting medical conditions. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2006 Jun. 20 p. (ACOG practice bulletin; no. 73). [179 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American College of Obstetricians and Gynecologists (ACOG). The use of hormonal contraception in women with coexisting medical conditions. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2000 Jul. 14 p. (ACOG practice bulletin; no. 18).

**** REGULATORY ALERT ****

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

- February 28, 2008, Heparin Sodium Injection: The U.S. Food and Drug Administration (FDA) informed the public that Baxter Healthcare Corporation has voluntarily recalled all of their multi-dose and single-use vials of heparin sodium for injection and their heparin lock flush solutions. Alternate heparin manufacturers are expected to be able to increase heparin production sufficiently to supply the U.S. market. There have been reports of serious adverse events including allergic or hypersensitivity-type reactions, with symptoms of oral swelling, nausea, vomiting, sweating, shortness of breath, and cases of severe hypotension.
- January 19, 2008, Ortho Evra: The U.S. Food and Drug Administration (FDA) modified the prescribing information to include results of a new epidemiology study that found that users of the birth control patch were at higher risk of developing serious blood clots, also known as venous thromboembolism (VTE), than women using birth control pills.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Unintended pregnancy

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Counseling
Risk Assessment
Treatment

CLINICAL SPECIALTY

Family Practice
Obstetrics and Gynecology

INTENDED USERS

Advanced Practice Nurses
Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To help clinicians and women with coexisting medical conditions make sound decisions regarding the selection and appropriateness of various hormonal contraceptives, including the levonorgestrel intrauterine system

TARGET POPULATION

Women of reproductive capability who have one or more of the following coexisting medical conditions or risk factors:

- Age older than 35 years
- Tobacco smoking
- Hypertension
- Lipid disorders
- Diabetes
- Migraine headaches
- Fibrocystic breast changes, fibroadenoma, or family history of breast cancer *BRCA1* or *BRCA2*
- Uterine leiomyomata
- Breastfeeding postpartum
- Concomitant medications
- Scheduled for surgery
- History of venous thromboembolism (VTE)
- Hypercoagulable conditions
- Anticoagulation therapy
- Obesity
- Systemic lupus erythematosus (SLE)
- Sickle cell disease
- Depression
- Human immunodeficiency virus (HIV) (acquisition, transmission, and progression)

INTERVENTIONS AND PRACTICES CONSIDERED

1. Combination oral contraceptives and combination contraception by transdermal and vaginal ring systems
2. Other forms of contraception, including progestin-only oral contraceptives (depot medroxyprogesterone acetate [DMPA] injections, progestin-only pills, and the levonorgestrel intrauterine system) and implants for women with contraindications to combination oral contraceptives

MAJOR OUTCOMES CONSIDERED

- Effectiveness of contraception
- Patient morbidity

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' (ACOG's) own internal resources and documents were used to conduct a literature search to locate relevant articles published between July 1971 and February 2006. 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 ACOG 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

Review of Published Meta-Analyses
Systematic Review

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

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

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 recommendations (A-C) are defined at the end of "Major Recommendations."

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

- A history of benign breast disease or a positive family history of breast cancer should not be regarded as contraindications to oral contraceptive use.

- Combination oral contraceptives are safe for women with mild lupus who do not have antiphospholipid antibodies.
- Combination contraceptives are not recommended for women with a documented history of unexplained venous thromboembolism or venous thromboembolism associated with pregnancy or exogenous estrogen use, unless they are taking anticoagulants.
- Combination oral contraceptives should be prescribed with caution, if ever, to women who are older than 35 years and are smokers.
- Use of the levonorgestrel intrauterine system is appropriate for women with diabetes without retinopathy, nephropathy, or other vascular complications.

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

- Healthy, nonsmoking women doing well on a combination contraceptive can continue their method until the ages of 50 to 55 years, after weighing the risks and benefits.
- Progestin-only oral contraceptives and depot medroxyprogesterone (DMPA) can be initiated safely at 6 weeks postpartum in lactating women and immediately postpartum in nonbreastfeeding women.
- Combination contraceptives are not recommended as the first choice for breastfeeding women because of the possible negative impact of contraceptive doses of estrogen on lactation. However, use of combination contraceptives by well-nourished breastfeeding women does not appear to result in infant development problems; therefore, their use can be considered once milk flow is well established.
- Women with well-controlled and monitored hypertension who are aged 35 years or younger are appropriate candidates for a trial of combination contraceptives, provided they are otherwise healthy, show no evidence of end-organ vascular disease, and do not smoke.
- The use of combination contraceptives by women with diabetes should be limited to such women who do not smoke, are younger than 35 years, and are otherwise healthy with no evidence of hypertension, nephropathy, retinopathy, or other vascular disease.
- The use of combination contraceptives may be considered for women with migraine headaches if they do not have focal neurologic signs, do not smoke, are otherwise healthy, and are younger than 35 years. Although cerebrovascular events rarely occur among women with migraines who use combination oral contraceptives, the impact of a stroke is so devastating that clinicians should consider the use of progestin-only, intrauterine, or barrier contraceptives in this setting.
- Because of the increased risk of venous thrombotic embolism, combination contraceptives should be used with caution in women older than 35 years who are obese.
- In women with depressive disorders, symptoms do not appear to worsen with use of hormonal methods of contraception.
- If oral contraceptives are continued before major surgery, heparin prophylaxis should be considered.

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

- Most women with controlled dyslipidemia can use combination oral contraceptives formulated with 35 micrograms or less of estrogen. In women with uncontrolled low-density lipoprotein (LDL) cholesterol greater than 160 mg/dL, a triglyceride level greater than 250 mg/dL, or multiple additional risk factors for coronary artery disease, alternative contraceptives should be considered.
- DMPA has noncontraceptive benefits and is appropriate for women with sickle cell disease.
- Progestin-only contraceptives may be appropriate for women with coronary artery disease, congestive heart failure, or cerebrovascular disease. However, combination oral contraceptives are contraindicated in these women.
- Short- or long-term use of DMPA in healthy women should not be considered an indication for dual-energy X-ray absorptiometry (DXA) or other tests that assess bone mineral density. In adolescents, the advantages of DMPA likely outweigh the theoretical safety concerns regarding bone mineral density and fractures. However, in the absence of long-term data in this population, consideration of long-term use should be individualized.

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 hormonal contraception in women with coexisting medical conditions

Benefits for Specific Populations

- Perimenopausal women may benefit from a positive effect on bone mineral density and a reduction in vasomotor symptoms offered by combination oral contraceptives.
- The reduced risk of endometrial and ovarian cancers associated with oral contraceptive use is of particular importance to older women of reproductive age.
- Because oral contraceptive use reduces ovarian cancer risk in *BRCA1* and *BRCA2* carriers, as it does in noncarriers, use of oral contraceptives offers important benefits for women with *BRCA1* or *BRCA2* mutations.
- Several large epidemiologic studies have observed that oral contraceptive use does not induce the growth of uterine leiomyomata and may decrease bleeding disorders in women with menorrhagia or dysmenorrhea associated with uterine leiomyomata.
- Progestin-only pills and depot medroxyprogesterone acetate (DMPA) do not impair lactation and, in fact, may increase the quality and duration of lactation.
- Two controlled studies assessing the use of DMPA in women with sickle cell disease found that the use of DMPA reduced the incidence of painful crises.

POTENTIAL HARMS

- Combination contraceptives are not recommended for women with a documented history of unexplained venous thromboembolism or venous thromboembolism associated with pregnancy or exogenous estrogen use, unless they are taking anticoagulants.
- Combination oral contraceptives should be prescribed with caution, if ever, to women who are older than 35 years and are smokers.
- Combination oral contraceptives are not recommended as the first choice for breastfeeding women because of the possible negative impact of contraceptive doses of estrogen on lactation.

- Because of the increased risk of venous thrombotic embolism, combination contraceptives should be used with caution in women older than 35 years who are obese.

CONTRAINDICATIONS

CONTRAINDICATIONS

In women with the following conditions, use of progestin-only oral contraceptives, including depot medroxyprogesterone acetate, may be safer than combination oral, transdermal, or vaginal ring contraceptives. An intrauterine device also represents an appropriate contraceptive choice for women with these conditions.

- Migraine headaches, especially those with focal neurologic signs
- Cigarette smoking or obesity in women older than 35 years
- History of thromboembolic disease
- Hypertension in women with vascular disease or older than 35 years
- Systemic lupus erythematosus with vascular disease, nephritis, or antiphospholipid antibodies
- Less than 3 weeks postpartum*
- Hypertriglyceridemia
- Coronary artery disease
- Congestive heart failure
- Cerebrovascular disease

*Use of an intrauterine device may not be an appropriate contraceptive choice.

QUALIFYING STATEMENTS

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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

Audit Criteria/Indicators

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

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ADAPTATION

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

DATE RELEASED

2000 Jul (revised 2006 Jun)

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

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GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

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

Proposed performance measures are included in the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on September 14, 2004. The information was verified by the guideline developer on December 8, 2004. This NGC summary was updated by ECRI Institute on August 2, 2007. The updated information was verified by the guideline developer on September 10, 2007. This summary was updated by ECRI Institute on February 4, 2008 following the new U.S. Food and Drug Administration advisory on Ortho Evra Contraceptive Transdermal Patch. This summary was updated by ECRI Institute on March 14, 2008 following the updated FDA advisory on heparin sodium injection.

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