Complete Summary

GUIDELINE TITLE

Management of herpes in pregnancy.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Management of herpes in pregnancy. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2007 Jun. 10 p. (ACOG practice bulletin; no. 82). [68 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American College of Obstetricians and Gynecologists (ACOG). Management of herpes in pregnancy. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 1999 Oct. 10 p. (ACOG practice bulletin; no. 8).

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SCOPE

DISEASE/CONDITION(S)

Genital herpes simplex virus (HSV) infection in pregnancy

GUIDELINE CATEGORY

Diagnosis
Management

CLINICAL SPECIALTY

Infectious Diseases
Obstetrics and Gynecology
Pediatrics

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To outline the spectrum of maternal and neonatal infection, including risks of transmission, and provide management guidelines supported by appropriately conducted outcome-based research

TARGET POPULATION

Pregnant women with genital herpes simplex virus infection

INTERVENTIONS AND PRACTICES CONSIDERED

1. Confirmation of the diagnosis of herpes simplex virus (HSV) infection

   Note: Routine antepartum genital HSV cultures in asymptomatic patients with recurrent disease are not recommended; routine screening of pregnant women for HSV is also not recommended.

2. Antiviral therapy such as acyclovir, famciclovir and valacyclovir
3. Cesarean delivery in women with first-episode herpes simplex virus (HSV) infection and active genital lesions, as well as in women with recurrent HSV and active genital lesions or prodromal symptoms
4. Expectant management in patients with preterm labor or preterm premature rupture of membranes and active HSV
5. Invasive procedures, such as amniocentesis, percutaneous umbilical cord blood sampling, transabdominal chorionic villus sampling, and fetal scalp monitoring in patients with recurrent HSV and no active lesions

MAJOR OUTCOMES CONSIDERED

- Mortality rates in neonatal herpes simplex virus (HSV) infection
- Vertical transmission rates
- Sensitivity and specificity of diagnostic tests

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 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 January 1985 and October 2006. The search was restricted to articles published in the English language. Priority was given to the 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

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

Several analyses have evaluated the cost effectiveness of various screening protocols for pregnant patients to reduce the incidence of neonatal herpes simplex virus (HSV) infection. The results from these analyses are highly variable—estimates of the cost to prevent one case of neonatal herpes range from $200,000 to $4,000,000. A number of factors influence these cost estimates, including the costs of testing and counseling, effectiveness of antiviral therapy, the probability of lesions or shedding at delivery in asymptomatic women in whom HSV has been diagnosed only by the screening test, and the likelihood of neonatal herpes with vaginal delivery. Currently, there is no evidence of cost-effectiveness of screening strategies from clinical trials or well-designed cohort studies in pregnancy.

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" field.

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

- Women with active recurrent genital herpes should be offered suppressive viral therapy at or beyond 36 weeks of gestation.
- Cesarean delivery is indicated in women with active genital lesions or prodromal symptoms, such as vulvar pain or burning at delivery, because these symptoms may indicate an impending outbreak.

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

- In women with premature rupture of membranes, there is no consensus on the gestational age at which the risks of prematurity outweigh the risks of herpes simplex virus (HSV).
- Cesarean delivery is not recommended for women with a history of HSV infection but no active genital disease during labor.
- Routine antepartum genital HSV cultures in asymptomatic patients with recurrent disease are not recommended.
- Routine HSV screening of pregnant women is not recommended.

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 could also 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

- *Acyclovir* therapy started at 36 weeks of gestation may decrease viral shedding, prevent neonatal herpes, reduce the need for cesarean delivery, and decrease clinical recurrences of herpes simplex virus infection. Several trials demonstrating similar efficacy of valacyclovir have been published.
- Because of their increased bioavailability, *valacyclovir* and *famciclovir* require less frequent dosing to achieve the same therapeutic benefits as acyclovir.

POTENTIAL HARMS

Although neutropenia is a recognized, transient complication of acyclovir treatment of neonatal herpes simplex virus infection, it has not been reported following maternal suppressive therapy. The acyclovir concentrations at which neutropenia occurred were approximately 5 to 30 times higher than were observed in umbilical vein plasma in a pharmacokinetic study of valacyclovir in pregnancy

CONTRAINDICATIONS

CONTRAINDICATIONS

If a woman with herpes simplex virus has an obvious lesion on the breast, breastfeeding is contraindicated.

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

Foreign Language Translations
Patient Resources

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

Getting Better
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

1999 Oct (revised 2007 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 - Obstetrics

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

The following is available:

- Genital herpes. Atlanta (GA): American College of Obstetricians and Gynecologists (ACOG); 2008. Available from the American College of Obstetricians and Gynecologists (ACOG) Web site. 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.

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NGC STATUS

This NGC summary was completed by ECRI on January 14, 2005. This summary was updated by ECRI Institute on July 21, 2008. The updated information was verified by the guideline developer on August 11, 2008.

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