Complete Summary

GUIDELINE TITLE

Neural tube defects.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Neural tube defects. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2003 Jul. 11 p. (ACOG practice bulletin; no. 44). [81 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American College of Obstetricians and Gynecologists (ACOG). Neural tube defects. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2001 Mar.

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SCOPE

DISEASE/CONDITION(S)

Neural tube defects, including:

- Cranial defects (anencephaly, exencephaly, encephalocele, and iniencephaly)
- Spinal defects (spina bifida, meningocele, meningomyelocele, myeloschisis, holorachischisis, and craniorachischisis)

GUIDELINE CATEGORY

Diagnosis
Management
Prevention
Risk Assessment
Screening

CLINICAL SPECIALTY

Medical Genetics
Neurological Surgery
Neurology
Obstetrics and Gynecology
Pediatrics
Preventive Medicine

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To provide guidelines on screening for and primary prevention of neural tube defects and for management of delivery of fetuses with neural tube defects

TARGET POPULATION

- Pregnant women diagnosed with fetal neural tube defects
- Fetuses and newborn infants with neural tube defects

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Screening

1. Maternal serum alpha-fetoprotein (MSAFP) evaluation
2. Amniocentesis
3. Ultrasound

Management

1. Delivery at a facility with personnel capable of handling all aspects of neonatal complications
2. Fetal surgery (considered but not recommended)

Prevention

Periconceptional folic acid supplementation

MAJOR OUTCOMES CONSIDERED

- Risk factors for neural tube defects
- Effectiveness of periconceptional folic acid supplementation for preventing neural tube defects
- Predictive value of serum alpha-fetoprotein levels in screening for neural tube defects

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 January 1985 and January 2003. 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

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.

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 the "Major Recommendations."

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

- Periconceptional folic acid supplementation is recommended because it has been shown to reduce the occurrence and recurrence of neural tube defects (NTDs).
- For low-risk women, folic acid supplementation of 400 micrograms per day currently is recommended because nutritional sources alone are insufficient. Higher levels of supplementation should not be achieved by taking excess multivitamins because of the risk of vitamin A toxicity.
- For women at high risk of NTDs or who have had a previous pregnancy with an NTD, folic acid supplementation of 4 mg per day is recommended.
- Maternal serum alpha-fetoprotein (AFP) evaluation is an effective screening test for NTDs and should be offered to all pregnant women.

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

- Women with elevated serum alpha-fetoprotein levels should have a specialized ultrasound examination to further assess the risk of NTDs.
- The fetus with an NTD should be delivered at a facility that has personnel capable of handling all aspects of neonatal complications

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

- The ideal dose for folic acid supplementation has not been appropriately evaluated in prospective clinical studies. A 400 microgram supplement currently is recommended for women capable of becoming pregnant.
- The route of delivery for the fetus with an NTD should be individualized because data are lacking that any one route provides a superior outcome.

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

Overall Benefits

Appropriate diagnosis, management, and prevention of neural tube defects

Benefits of Folic Acid

A double-blind, placebo-controlled, randomized trial showed that periconceptional folic acid supplementation decreased the risk of a first occurrence of a neural tube defect. The efficacy of periconceptional folic acid supplementation for preventing both recurrence and occurrence of neural tube defects has since been confirmed by many other studies.

POTENTIAL HARMS

- *Risks of folic acid supplementation*. The risks of higher levels of folic acid supplementation are believed to be minimal. Folic acid is considered nontoxic even at very high doses and is rapidly excreted in the urine. There have been concerns that supplemental folic acid could mask the symptoms of pernicious anemia and thus delay treatment. However, folic acid cannot mask the neuropathy typical of this diagnosis. Currently, 12% of patients with pernicious anemia present with neuropathy alone. With folic acid supplementation, this proportion may be increased, but there is no evidence that initiating treatment after the development of a neuropathy results in irreversible damage. A small number of women taking seizure medication (diphenylhydantoin, aminopterin, or carbamazepine) may have lower serum drug levels and experience an associated increase in seizure frequency while taking folic acid supplement. Monitoring drug levels and increasing the dosage as needed may help to avert this complication.
- Some over-the-counter multivitamin supplements and most prenatal vitamins contain 400 micrograms of folic acid. Higher levels of supplementation should be achieved by taking an additional folic acid supplement and not by taking excess multivitamins. In particular, vitamin A is potentially teratogenic at high doses, and pregnant women should not take more than the 5,000 IU per day, which is typically found in one multivitamin/mineral supplement.

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.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

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

DATE RELEASED

2001 (revised 2003 Jul)

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

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on February 4, 2004. The information was verified by the guideline developer on July 26, 2004.

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