



Complete Summary

GUIDELINE TITLE

Fetal lung maturity.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Fetal lung maturity. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2008 Sep. 10 p. (ACOG practice bulletin; no. 97). [44 references]

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

- Fetal lung maturity
- Neonatal respiratory distress syndrome (RDS)
- Pregnancy

GUIDELINE CATEGORY

Counseling
Diagnosis
Evaluation
Management
Prevention
Risk Assessment

CLINICAL SPECIALTY

Obstetrics and Gynecology
Pediatrics

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To review commonly used tests to determine fetal lung maturity

TARGET POPULATION

Pregnant women, including those with pregestational and gestational diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

1. Tests and techniques to assess fetal lung maturity:
 - Fluorescence polarization with TDx-FLM II
 - Lecithin/sphingomyelin ratio using thin layer chromatography
 - Phosphatidyl-glycerol using thin layer chromatography or antisera with AminoStat-FLM
 - Lamellar body counts using commercial hematology counter
 - Optical density at 650nm (spectrophotometric reading)
 - Foam stability index (ethanol added to amniotic fluid, solution shaken, presence of stable bubble at the meniscus noted)
2. Amniocentesis of both twins versus one twin for twin gestations
3. Corticosteroid administration
4. Use of both gestational age and results of fetal lung maturity testing to predict probability of respiratory distress syndrome
5. Use of amniotic fluid collected vaginally versus fluid collected by transabdominal amniocentesis
6. Interpretation of test results in pregnant women with diabetes

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of tests for assessment of fetal lung maturity
- Predictive value and utility of fetal lung maturity testing for neonatal respiratory distress syndrome (RDS)
- Complications of amniocentesis

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 October 2007. 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

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" field.

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

- Testing for fetal lung maturity should not be performed, and is contraindicated, when delivery is mandated for fetal or maternal indications.
- Fetal pulmonary maturity should be confirmed before scheduled delivery at less than 39 weeks of gestation unless fetal maturity can be inferred from historic criteria.
- The probability of neonatal respiratory distress syndrome (RDS) is dependent on both the fetal lung maturity test result and the gestational age at which the fetal lung maturity test was performed.
- Fluorescence polarization assays (TDx FLM II) using a defined mature profile of 55 mg/g or greater is appropriate for the determination of risk of neonatal RDS in pregnancies of women with diabetes mellitus.
- Fetal lung maturity test results from amniotic fluid collected vaginally compared with those from fluid collected by transabdominal amniocentesis demonstrate that when results from fluid collected vaginally are mature, the results are reliable.
- Complications from third-trimester amniocentesis for fetal lung maturity are uncommon when performed with ultrasound guidance.

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

- In general, the same threshold values for fetal lung maturity tests that predict low risk of neonatal RDS in pregnancies of women who do not have diabetes mellitus apply to pregnancies of women who have diabetes mellitus, whether it is gestational diabetes mellitus or pregestational diabetes mellitus.
- Data suggest that amniocentesis of both twins be performed when the gestation is between 30 0/7 weeks and 32 6/7 weeks of gestation. Amniocentesis of one twin appears to be sufficient when gestation is greater than 32 6/7 weeks.
- Prior to elective delivery, fetal lung maturity testing in twins with well defined gestational ages at 38 0/7 weeks or greater may not be necessary.

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

The status of fetal lung maturation can assist the clinician in determining when delivery should occur.

POTENTIAL HARMS

Complications for third semester amniocentesis in one reported study were isolated events but included fetal heart rate abnormalities, placental bleeding, placental abruption, and uterine rupture.

CONTRAINDICATIONS

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Testing for fetal lung maturity should not be performed, and is contraindicated, when delivery is mandated for fetal or maternal indications.

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
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

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

DATE RELEASED

2008 Sep

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

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

Proposed performance measures are included in the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on January 5, 2008. The information was verified by the guideline developer on January 23, 2009.

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Date Modified: 2/23/2009

