



Complete Summary

GUIDELINE TITLE

Pregestational diabetes mellitus.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Pregestational diabetes mellitus. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2005 Mar. 11 p. (ACOG practice bulletin; no. 60). [86 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Pregestational diabetes mellitus

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice

Internal Medicine
Obstetrics and Gynecology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To provide an overview of the current understanding of pregestational diabetes mellitus and to suggest management guidelines during pregnancy

TARGET POPULATION

Pregnant women with diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

Management/Counseling

1. Dietary regulation
2. Blood glucose and urine ketone self-monitoring
3. Hemoglobin A_{1c} levels
4. Family training to respond to potential hypoglycemic episodes
5. Preconceptional counseling
6. Preconceptional retinal examination, 24-hour urine collection, electrocardiography, thyroid function study
7. Assessment of diabetic ketoacidosis
8. Antepartum fetal monitoring (ultrasound, echocardiography, fetal movement counting, nonstress test, biophysical profile, contraction stress test, umbilical artery Doppler velocimetry, amniocentesis)
9. Blood glucose monitoring during labor and delivery
10. Encouragement of breastfeeding
11. Counseling on postpartum contraception options

Treatment

1. Insulin injections or continuous subcutaneous infusion
2. Limited use of oral hypoglycemic agents
3. Treatment of diabetic ketoacidosis
4. Cesarean delivery
5. Timing of delivery
6. Induction of labor (not recommended with suspected fetal macrosomia)
7. Multivitamin with folic acid

MAJOR OUTCOMES CONSIDERED

- Blood glucose levels

- Incidence of maternal morbidity (diabetes-related retinopathy, neuropathy, nephropathy, hypertension, ketoacidosis, uteroplacental insufficiency)
- Incidence of perinatal morbidity or mortality
- Incidence of obstetric complications (preterm labor, hydramnios, preeclampsia, fetal intrauterine growth restriction, primary cesarean delivery)
- Cesarean delivery 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 October 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

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

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.

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

- Suspected fetal macrosomia is not an indication for induction of labor because induction does not improve maternal or fetal outcomes.
- Antepartum fetal monitoring, including fetal movement counting, the nonstress test, the biophysical profile, and the contraction stress test when performed at appropriate intervals, is a valuable approach and can be used to monitor the pregnancies of women with pregestational diabetes mellitus.
- Adequate maternal glucose control should be maintained near physiologic levels before conception and throughout pregnancy to decrease the likelihood of spontaneous abortion, fetal malformation, fetal macrosomia, intrauterine fetal death, and neonatal morbidity.
- Patients and their families should be taught how to respond quickly and appropriately to hypoglycemia.
- Preconceptional counseling for women with pregestational diabetes mellitus has been reported to be beneficial and cost-effective and should be encouraged.
- The use of oral agents for control of type 2 diabetes mellitus during pregnancy should be limited and individualized until data regarding the safety and efficacy of these drugs become available.
- To prevent traumatic birth injury, cesarean delivery may be considered if the estimated fetal weight is greater than 4,500 g in women with diabetes.

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 management of pregestational diabetes mellitus

POTENTIAL HARMS

- Major disadvantages of insulin pump use include the increased cost of the pump and pump supplies. In addition, if the delivery of insulin is interrupted or impaired by battery failure or infection at the infusion site, diabetic ketoacidosis may develop rapidly.
- Metformin is a category B drug, and although there are more reports of its use during pregnancy, the long-term effects of in utero exposure have not been well studied. The use of all oral agents for control of type 2 diabetes mellitus during pregnancy should be limited and individualized until data regarding the safety and efficacy of these drugs become available.

- Because hypoglycemia and hypokalemia are frequent complications of diabetic ketoacidosis therapy, glucose and potassium concentrations should be monitored closely. Although maternal mortality is rare, fetal mortality has ranged from 35% of cases to, more recently, 10% of cases.

CONTRAINDICATIONS

CONTRAINDICATIONS

Angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers should be discontinued before conception and should not be used during pregnancy because of their adverse fetal effects.

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

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

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

DATE RELEASED

2005 Mar

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

None available

PATIENT RESOURCES

The following is available:

- Diabetes and pregnancy. Atlanta (GA): American College of Obstetricians and Gynecologists (ACOG); 2005.

Electronic copies: 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

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