Complete Summary

GUIDELINE TITLE

Gestational diabetes mellitus (GDM). Evidence-based nutrition practice guideline.

BIBLIOGRAPHIC SOURCE(S)

American Dietetic Association (ADA). Gestational diabetes mellitus (GDM). Evidence based nutrition practice guideline. Chicago (IL): American Dietetic Association (ADA); 2008. Various p. [234 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previously published version: American Dietetic Association. Nutrition practice guidelines for gestational diabetes mellitus. Chicago (IL): American Dietetic Association; 2001 Sep. Various p.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
CONTRAINDICATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Gestational diabetes mellitus

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Counseling
Diagnosis
Evaluation

Management
Prevention
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Nursing
Nutrition
Obstetrics and Gynecology

INTENDED USERS

Advanced Practice Nurses
Dietitians
Health Care Providers
Nurses
Pharmacists
Physician Assistants
Physicians
Students

GUIDELINE OBJECTIVE(S)

Overall Objective

To provide medical nutrition therapy (MNT) guidelines for gestational diabetes mellitus that assist in the normalization and maintenance of glycemia, and reduce the risk of adverse maternal and neonatal outcomes

Specific Objectives

- To define evidence-based diabetes nutrition recommendations for registered dietitians (RDs) that are carried out in collaboration with other healthcare providers
- To guide practice decisions that integrate medical, nutritional and behavioral strategies
- To reduce variations in practice among RDs
- To promote self-management strategies that empower the pregnant women with gestational diabetes mellitus to take responsibility for day-to-day management
- To provide the RD with data to make recommendations to adjust MNT or recommend other therapies to achieve desired outcomes
- To develop guidelines for interventions that have measurable clinical outcomes
- To define the highest quality of care within cost constraints of the current healthcare environment

TARGET POPULATION

Pregnant women at risk for or withÂ gestational diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Screening for gestational diabetes mellitus (GDM) or impaired glucose tolerance (IGT)
2. Risk assessment
3. Referral to a registered dietitian
4. Nutritional assessment
    - Food/nutrition-related history including food intake, physical activity, and medications
    - Anthropometric measurements (body mass index [BMI], weight gain)
    - Biochemical data, medical tests and procedures—relevant laboratory values (e.g., blood glucose monitoring and ketone testing)
    - Nutrition-focused physical findings including caloric intake, macronutrient and micronutrient intake
    - Client History

Management/Treatment

1. Individualized prescription for medical nutrition therapy based on:
    - Dietary interventions such as use of non-nutritive sweeteners, promotion of breastfeeding, alcohol consumption
    - Physical activity interventions
    - Behavioral interventions
    - Pharmacotherapy such as insulin, insulin analogs, and glyburide
2. Monitoring and evaluation
3. Prevention of GDM recurrence

MAJOR OUTCOMES CONSIDERED

- Glycemic control
- Insulin use
- Fetal growth
- Hospital admission
- Perinatal complications
- Weight loss after delivery
- Recurrent gestational diabetes
- Type 2 diabetes mellitus

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches of PubMed and CENTRAL databases, and hand searches of other relevant literature were performed on the following topics:

- The provision of medical nutrition therapy (MNT) for pregnant women with impaired glucose tolerance or gestational diabetes mellitus
- Caloric intake
- Macronutrient and micronutrient intake
- Physical activity
- Promotion of breastfeeding
- Blood glucose monitoring and ketone testing
- Indications for pharmacologic therapy
- Monitoring and evaluation
- Prevention of gestational diabetes mellitus recurrence and type 2 diabetes

General Exclusion Criteria

As a general rule, studies are excluded if the:

- Study sample size is less than 10 in each treatment group
- Drop-out rate was >20%

Inclusion Criteria

- Study design preferences: randomized controlled trials or clinical controlled studies, large nonrandomized observational studies, and cohort and case-control studies
- Limited to articles in English

The American Dietetic Association (ADA) has determined that for narrowly focused questions dealing with therapy or treatment, six well designed randomized controlled trials that demonstrate similar results is sufficient to draw a conclusion.

No one study design was preferred for all questions. The preferred study design depended on the type of question. The ADA uses the following principles in the table below for identifying preferred study design.

Type of Question	Preferred Study Designs (in Order of Preference)
Diagnosis questions	Sensitivity & specificity of diagnostic test Cross-sectional study
Etiology, causation, or harm questions	Prospective cohort Case control study Cross-sectional study

Type of Question	Preferred Study Designs (in Order of Preference)
Therapy and prevention questions	Randomized controlled trial Nonrandomized trial
Natural history and prognosis questions	Cohort study

NUMBER OF SOURCE DOCUMENTS

352 considered

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Grading the Strength of the Evidence for a Conclusion Statement or Recommendation Conclusion Grading Table

Strength of Evidence Elements	Grade I Good/Strong	Grade II Fair	Grade III Limited/Weak	Grade IV Expert Opinion Only	Grade Grade Assigna
Quality • Scientific rigor/validity • Considers design and execution	Studies of strong design for question Free from design flaws, bias and execution problems	Studies of strong design for question with minor methodological concerns OR Only studies of weaker study design for question	Studies of weak design for answering the question OR Inconclusive findings due to design flaws, bias or execution problems	No studies available Conclusion based on usual practice, expert consensus, clinical experience, opinion, or extrapolation from basic research	No evidence that pertains question being address
Consistency Of findings across studies	Findings generally consistent in direction and size of effect or degree of association,	Inconsistency among results of studies with strong design OR	Unexplained inconsistency among results from different studies OR	Conclusion supported solely by statements of informed nutrition or medical	NA

Strength of Evidence Elements	Grade I Good/Strong	Grade II Fair	Grade III Limited/Weak	Grade IV Expert Opinion Only	Grade Grade Assigna
	and statistical significance with minor exceptions at most	Consistency with minor exceptions across studies of weaker designs	Single study unconfirmed by other studies	commentators	
Quantity • Number of studies • Number of subjects in studies	One to several good quality studies Large number of subjects studies Studies with negative results having sufficiently large sample size for adequate statistical power	Several studies by independent investigators Doubts about adequacy of sample size to avoid Type I and Type II error	Limited number of studies Low number of subjects studies and/or inadequate sample size within studies	Unsubstantiated by published studies	Relevan studies have no been do
Clinical Impact • Importance of studies outcomes • Magnitude of effect	Studied outcome relates directly to the question Size of effect is clinically meaningful Significant (statistical) difference is large	Some doubt about the statistical or clinical significance of effect	Studies outcome is an intermediate outcome or surrogate for the true outcome of interest OR Size of effect is small or lacks statistical and/or clinical significance	Objective data unavailable	Indicate area for future research
Generalizability To population of interest	Studied population, intervention and outcomes are free from	Minor doubts about generalizability	Serious doubts about generalizability due to narrow or different	Generalizability limited to scope of experience	NA

Strength of Evidence Elements	Grade I Good/Strong	Grade II Fair	Grade III Limited/Weak	Grade IV Expert Opinion Only	Grade Grade Assigna
	serious doubts about generalizability		study population, intervention or outcomes studied		

This grading system was based on the grading system from: *Greer N, Mosser G, Logan G, Wagstrom Halaas G. A practical approach to evidence grading. Jt Comm. J Qual Improv. 2000; 26:700-712*. In September 2004, The ADA Research Committee modified the grading system to this current version.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Step 1: Formulate the question

Specify a question in a defined area of practice; or state a tentative conclusion or recommendation that is being considered. Include the patient type and special needs of the target population involved, the alternatives under consideration, and the outcomes of interest.

Step 2: Gather and classify evidence reports

Conduct a systematic search of the literature to find evidence related to the question, gather studies and reports, and classify them by type of evidence. Classes differentiate primary reports of new data according to study design, and distinguish them from reports that are a systematic review and synthesis of primary reports.

Step 3: Critically appraise each report

Review each report for relevance to the question and critique for scientific validity. Abstract key information from the report and assign a code to indicate the quality of the study by completing quality criteria checklist.

Step 4: Summarize evidence in a narrative and an overview table

Combine findings from all reports in a table that pulls out the important information from the article worksheets. Write a brief narrative that summarizes and synthesizes the information abstracted from the articles that is related to the question asked.

Step 5: Develop a conclusion statement and grade the strength of evidence supporting the conclusion

Develop a concise conclusion statement (the answer to the question), taking into account the synthesis of all relevant studies and reports, their class and their quality ratings. Assign a grade to indicate the overall strength or weakness of evidence informing the conclusion statement.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The expert work group, which includes practitioners and researches with a depth of experience in the specific field of interest, develops the disease-specific guideline. The guideline development involved the following steps:

Review Evidence Based Conclusions

The work group meets to review the materials resulting from the evidence analysis, which may include conclusion statements, evidence summaries, and evidence worksheets.

Formulate Recommendations for the Guideline Integrating Conclusions from Evidence Analysis

The work group uses an expert consensus method to formulate recommendations, taking into account the following:

- Recommendations for what the dietitian should do and why
- Rating of recommendations based on strength of supporting evidence
- Label of Conditional (clearly define a specific situation) or Imperative (broadly applicable to the target population without restraints on the pertinence)
- Risks and Harms of Implementing the Recommendations, including potential risks, harms, or adverse consequences
- Conditions of Application, including organizational barriers or conditions that may limit application
- Potential Costs Associated with Application
- Recommendation Narrative
- Recommendation Strength Rationale, evidence strength and methodological issues
- Minority Opinions, when the expert working group cannot reach consensus on a recommendation
- Supporting Evidence

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Criteria for Recommendation Rating

Statement Rating	Definition	Implication for Practice
Strong	A **Strong** recommendation means that the workgroup believes that the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation), and that the quality of the supporting evidence is excellent/good (grade I or II)*. In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Practitioners should follow a **Strong** recommendation unless a clear and compelling rationale for an alternative approach is present.
Fair	A **Fair** recommendation means that the workgroup believes that the benefits exceed the harms (or that the harms clearly exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade II or III)*. In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Practitioners should generally follow a **Fair** recommendation but remain alert to new information and be sensitive to patient preferences.
Weak	A **Weak** recommendation means that the quality of evidence that exists is suspect or that well-done studies (grade I, II, or III)* show little clear advantage to one approach versus another.	Practitioners should be cautious in deciding whether to follow a recommendation classified as **Weak**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.
Consensus	A **Consensus** recommendation means that Expert opinion (grade IV)* supports the guideline recommendation even though the available scientific evidence did not present consistent results, or controlled trials were lacking.	Practitioners should be flexible in deciding whether to follow a recommendation classified **Consensus**, although they may set boundaries on alternatives. Patient preference should have a substantial influencing role.

Statement Rating	Definition	Implication for Practice
Insufficient Evidence	An **Insufficient Evidence** recommendation means that there is both a lack of pertinent evidence (grade V)* and/or an unclear balance between benefits and harms.	Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Insufficient Evidence** and should exercise judgment and be alert to emerging publications that report evidence that clarifies the balance of benefit versus harm. Patient preference should have a substantial influencing role.

*Conclusion statements are assigned a grade based on the strength of the evidence. Grade I is good; grade II, fair; grade III, limited; grade IV signifies expert opinion only and grade V indicates that a grade is not assignable because there is no evidence to support or refute the conclusion. The evidence and these grades are considered when assigning a rating (Strong, Fair, Weak, Consensus, Insufficient Evidence - see chart above) to a recommendation.

Adapted by the American Dietetic Association from the American Academy of Pediatrics, Classifying Recommendations for Clinical Practice Guideline, Pediatrics. 2004;114;874-877.

COST ANALYSIS

Medical nutrition therapy (MNT) education can be considered cost effective when considering the benefits of nutrition interventions on the onset and progression of comorbidities versus the cost of the intervention.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Each guideline is reviewed internally and externally using the AGREE (Appraisal of Guidelines for Research and Evaluation) instrument as the evaluation tool. The external reviewers consist of a multidisciplinary group of individuals (may include dietitians, doctors, psychologists, pharmacists, nurses, etc). The review is done electronically. The guideline is adjusted by consensus of the expert panel and approved by American Dietetic Association's Evidence-Based Practice Committee prior to publication on the Evidence Analysis Library (EAL).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Ratings for the strength of the recommendations (Strong, Fair, Weak, Consensus, Insufficient Evidence), conclusion grades (I-V), and statement labels (Conditional versus Imperative) are defined at the end of the "Major Recommendations" field.

Gestational Diabetes Mellitus (GDM): Screening for GDM

GDM: Screening for GDM

All pregnant women should be screened forÂ GDM and/or impaired glucose tolerance (IGT); however, depending on level of risk, timing of screening will differ. Research indicates the similarities between GDM and IGT, and both are associated with increased risks of poor maternal/neonatal outcomes if left untreated.

Strong, Imperative

Recommendation Strength Rationale

- Conclusion Statements wereÂ **Grades I andÂ II**Â

GDM: Pregnant Women at Risk for GDM

GDM: Pregnant Women at Risk for GDM

For pregnant women at average or high risk forÂ GDM, the registered dietitian (RD) should monitor weight gain, nutritional intake and physical activity. Research indicates that obesity, excessive weight gain prior to pregnancy and increased saturated fat intake are associated with the development of glucose abnormalities in pregnancy and increased risk of gestational diabetes. In addition, regular physical activity during pregnancy reduces the risk ofÂ GDM.

Weak, Conditional

Recommendation Strength Rationale

- Conclusion Statements wereÂ **Grade II**

GDM: MNT for Pregnant Women with IGT or GDM

GDM: MNT for Women with GDM

TheÂ RD should initiateÂ MNT within one week after diagnosis ofÂ GDM, and include a minimum of three nutrition visits. Research indicates that MNT results in improved maternal and neonatal outcomes, especially when diagnosed and treated early.

Strong, Imperative

GDM: MNT for Pregnant Women with IGT

For women withÂ IGT during pregnancy, theÂ RD should initiate the same recommendations ofÂ MNT as those forÂ GDM. Research indicates thatÂ IGT andÂ GDM carry similar risks of adverse outcomes.

Strong, Imperative

Recommendation Strength Rationale

- Conclusion Statements wereÂ **Grades I and II**Â

GDM: Assessment of Food Intake, Physical Activity and Medications

GDM: Assess Food Intake, Physical Activity and Medications

TheÂ RD should assess dietary intake and physical activity of pregnant women, including those withÂ GDM. Evaluation of a pregnant woman's dietary pattern, augmented by questions about medications, special concerns, conditions, and/or food preferences that might affect her dietary adequacy or needs, provides the basis forÂ MNT.

Consensus, Imperative

Recommendation Strength Rationale

The American Dietetic Association (ADA) Gestational Diabetes Mellitus Expert Work Group concurs with the clinical recommendations from the Committee on Nutritional Status During Pregnancy and Lactation, Institute of Medicine.

GDM: Assessment of Body Mass Index (BMI) and Weight Gain

GDM: Assessment of BMI and Weight Gain

TheÂ RD should assess body mass index (based on actual or estimated prepregnancy weight) as a baseline to determine recommended weight gain in pregnant women, including those withÂ GDM.Â BMI is a better indicator of maternal nutritional status than is weight alone.

Consensus, Imperative

Recommendation Strength Rationale

The ADA Gestational Diabetes Mellitus Expert Work Group concurs with the clinical recommendations from the Committee on Nutritional Status During Pregnancy and Lactation, Institute of Medicine.

GDM: Caloric Intake

GDM: Caloric Intake for Normal and Underweight Women

TheÂ RD should encourage normal and underweight women withÂ GDM to consume adequate calories to promote appropriate weight gain while preventing hyperglycemia and ketonuria, with guidance from the Dietary Reference Intakes (DRI) for pregnant women. Research indicates that low or inadequate weight gain

during pregnancy is associated with an increased risk of preterm delivery, regardless of prepregnancy BMI levels.

Fair, Conditional

GDM: Caloric Intake for Overweight/Obese Women with GDM

Since weight loss in pregnancy is not recommended, the RD should encourage a modest energy restriction to slow weight gain in women with GDM who are also overweight/obese. Caloric restriction (~70% of theÂ DRI for pregnant women) results in considerable slowing of maternal weight gain in obese women withÂ GDM, without causing maternal or fetal compromise and/or ketonuria.

Fair, Conditional

Recommendation Strength Rationale

- Conclusion Statements wereÂ **Grades II andÂ III**

GDM: Macronutrient and Micronutrient Intake

GDM: Carbohydrate Intake

The RD should encourage pregnant women, including those with GDM, to consume a minimum of 175 g of carbohydrate per day based on theÂ DRI for pregnant women for provision of glucose to the fetal brain and to prevent ketosis. Total carbohydrate intake should be less than 45% of energy to prevent hyperglycemia in women with GDM. Carbohydrate intake affects postprandial blood glucose levels; increased postprandial blood glucose levels are associated with increased incidence of large-for-gestational age infants and increased rate of Cesarean sections. Research is limited regarding fiber intake and glycemic index in women with GDM.

Fair, Imperative

GDM: Protein and Fat Intake

The RD should encourage pregnant women, including those with GDM, to consume adequate protein and fat based on the DRI for pregnant women. Research is limited regarding protein and fat intake in women with GDM.

Fair, Imperative

GDM: Vitamin and Mineral Supplementation

If usual dietary intake does not meet the DRI for pregnant women, including those with GDM, the RD should encourage vitamin and mineral supplementation to prevent nutritional deficiencies.

Consensus, Conditional

Recommendation Strength Rationale

- Conclusion Statement was **Grade II**

GDM: Physical Activity

GDM: Physical Activity

Unless contraindicated, the RD should encourage women with GDM to participate in physical activity for 30 minutes per day for a minimum of three times per week. Research indicates that regular physical activity during pregnancy aids with improved glycemic control and reduces the common discomforts of pregnancy, without a negative effect on maternal or neonatal outcomes.

Fair, Conditional

Recommendation Strength Rationale

- Conclusion Statement wasÂ **Grade II**

GDM: Blood Glucose Monitoring and Ketone Testing

GDM: Blood Glucose Monitoring

The RD should advise women with GDM to monitor their blood glucose, including fasting and postprandial levels. Several studies report a correlation between elevated fasting and postprandial blood glucose values with poor maternal and neonatal outcomes.

Fair, Imperative

GDM: Ketone Testing

The RD should recommend ketone testing for women with GDM who have insufficient calorie and/or carbohydrate intake and/or weight loss. Two of three studies regarding ketonemia and ketonuria with poor metabolic control during a diabetic pregnancy report a positive association with lower intelligence quotient (IQ) in offspring.

Fair, Conditional

Recommendation Strength Rationale

- Conclusion Statement was **Grade II**

GDM: Use of Non-Nutritive Sweeteners

GDM: Use of Non-Nutritive Sweeteners

If women with GDM choose to consume products containing non-nutritive sweeteners, theÂ RD should inform them that only U.S. Food and Drug Administration (FDA)-approved non-nutritive sweeteners should be consumed and that moderation is encouraged. Research in this area is extremely limited.

Consensus, Conditional

Recommendation Strength Rationale

- Conclusion Statement wasÂ **Grade IV**

GDM: Promotion of Breastfeeding

GDM: Promotion of Breastfeeding

Unless contraindicated, the RD should encourage breastfeeding in women withÂ GDM. Research indicates that even short duration of breastfeeding results in long-term improvements in glucose metabolism and may also reduce the risk of type 2 diabetes in children.

Weak, Conditional

Recommendation Strength Rationale

- Conclusion Statement wasÂ **Grade III**

GDM: Alcohol Consumption

GDM: Alcohol Consumption

The RD should advise pregnant women, including those with GDM, to avoid the consumption of alcohol, including alcohol used in cooking. No amount of alcohol consumption can be considered safe during pregnancy. Alcohol use during pregnancy increases the risk of alcohol-related birth defects, including growth deficiencies, facial abnormalities, central nervous system impairment, behavioral disorders, and impaired intellectual development.

Consensus, Imperative

Recommendation Strength Rationale

The ADA Gestational Diabetes Mellitus Expert Work Group concurs with the clinical recommendations from the National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control, Department of Health and Human Services, in coordination with the National Task Force on Fetal Alcohol Syndrome and Fetal Alcohol Effect.

GDM: Pharmacological Therapy for Treatment of GDM

GDM: Pharmacological Therapy for Treatment of GDM

When optimal blood glucose levels have not been maintained with MNT and/or the rate of fetal growth is excessive, the RD should advise the healthcare team about the initiation of pharmacological therapy for treatment of women with GDM. Research indicates that pharmacological therapy, such as the use of insulin, insulin analogs and glyburide, improves glycemic control and reduces the incidence of poor maternal and neonatal outcomes.

Strong, Conditional

Recommendation Strength Rationale

- Conclusion Statement wasÂ **Grade II**

GDM: Monitor and Evaluate MNT Effectiveness

GDM: Monitor and Evaluate MNT Effectiveness

TheÂ RD should monitor and evaluate blood glucose, weight, food intake, physical activity and pharmacological therapy (if indicated) in women with GDM at each visit. Research indicates that MNT results in improved maternal and neonatal outcomes.

Strong, Imperative

Recommendation Strength Rationale

- Conclusion Statement wasÂ **Grade II**

GDM: Prevention of GDM Recurrence/Type 2 Diabetes

GDM: Weight Loss after Delivery

For women with GDM who are overweight/obese or with above recommended weight gain during pregnancy, the RD should advise weight loss after delivery. Research indicates that the risks of recurrent GDM or development of type 2 diabetes can be reduced with weight loss.

Strong, Conditional

Recommendation Strength Rationale

- Conclusion Statements were **Grade I**

Note: The recommendations listed below were originally developed for other ADA evidence-based nutrition practice guidelines, but have been integrated into the Gestational Diabetes Evidence-based Nutrition Practice Guideline and may provide additional guidance for the practitioner.

Diabetes Mellitus (DM): Fiber and Diabetes

DM: Fiber Intake and Glycemia

Recommendations for fiber intake for people with diabetes are similar to the recommendations for the general public (DRI: 14 g per 1000 kcal). While diets containing 44 to 50 g of fiber daily are reported to improve glycemia, more usual fiber intakes (up to 24 g daily) have not shown beneficial effects on glycemia. It is unknown if free-living individuals can daily consume the amount of fiber needed to improve glycemia.

Strong, Imperative

DM: Fiber Intake and Cholesterol

Include foods containing 25 to 30 g of fiber per day, with special emphasis on soluble fiber sources (7 to 13 g). Diets high in total and soluble fiber, as part of cardioprotective nutrition therapy, can further reduce total cholesterol by 2 to 3% and low-density lipoprotein (LDL) cholesterol up to 7%.

Strong, Imperative

Recommendation Strength Rationale

- Conclusion Statement for Fiber and DiabetesÂ is **Grade I**
- Conclusion Statements for Fiber and congestive heart disease (CHD)Â were **Grades I, II and III**

(DM): Carbohydrate

DM: Carbohydrate Intake Consistency

In persons on either MNT alone, glucose-lowering medications or fixed insulin doses, meal and snack carbohydrate intake should be kept consistent on a day-to-day basis. Consistency in carbohydrate intake results in improved glycemic control.

Strong, Conditional

DM: Carbohydrate Intake and Insulin Dose Adjustment

In persons with type 1 or type 2 diabetes who adjust their mealtime insulin doses or who are on insulin pump therapy, insulin doses should be adjusted to match carbohydrate intake (insulin-to-carbohydrate ratio). This can be accomplished by comprehensive nutrition education and counseling on interpretation of blood glucose patterns, nutrition-related medication management and collaboration with the healthcare team. Adjusting insulin dose based on planned carbohydrate intake improves glycemic control and quality of life without any adverse effects.

Strong, Conditional

Recommendation Strength Rationale

- Conclusion Statement wasÂ **Grade I**

DM: Glycemic Index and Diabetes

DM: Glycemic Index (GI)

If the use of glycemic index is proposed as a method of meal planning, the RD should advise on the conflicting evidence of effectiveness of this strategy. Studies comparing high versus low GI diets report mixed effects on A1C.

Fair, Conditional

Recommendation Strength Rationale

- Conclusion statementÂ was **Grade II**

Definitions:

Conditional versus Imperative Recommendations

Recommendations can be worded as conditional or imperative statements. Conditional statements clearly define a specific situation, while imperative statements are broadly applicable to the target population without restraints on their pertinence. More specifically, a conditional recommendation can be stated in if/then terminology (e.g., if an individual does not eat food sources of omega-3 fatty acids, then 1 g of EPA and DHA omega-3 fatty acid supplements may be recommended for secondary prevention).

In contrast, imperative recommendations "require," "must," or "should achieve certain goals," but do not contain conditional text that would limit their applicability to specified circumstances. (e.g., portion control should be included as part of a comprehensive weight management program. Portion control at meals and snacks results in reduced energy intake and weight loss).

Level of Evidence

Strength of Evidence Elements	**Grade I** **Good/Strong**	**Grade II** **Fair**	**Grade III** **Limited/Weak**	**Grade IV** **Expert Opinion Only**	**Grade** **Grade I Assigna**
Quality • Scientific rigor/validity • Considers design and execution	Studies of strong design for question Free from design flaws, bias and execution problems	Studies of strong design for question with minor methodological concerns OR	Studies of weak design for answering the question OR Inconclusive findings due to	No studies available Conclusion based on usual practice, expert consensus, clinical experience,	No evidence that pertains question being addresse

Strength of Evidence Elements	Grade I Good/Strong	Grade II Fair	Grade III Limited/Weak	Grade IV Expert Opinion Only	Grade Grade Assigna
		Only studies of weaker study design for question	design flaws, bias or execution problems	opinion, or extrapolation from basic research	
Consistency Of findings across studies	Findings generally consistent in direction and size of effect or degree of association, and statistical significance with minor exceptions at most	Inconsistency among results of studies with strong design OR Consistency with minor exceptions across studies of weaker designs	Unexplained inconsistency among results from different studies OR Single study unconfirmed by other studies	Conclusion supported solely by statements of informed nutrition or medical commentators	NA
Quantity • Number of studies • Number of subjects in studies	One to several good quality studies Large number of subjects studies Studies with negative results having sufficiently large sample size for adequate statistical power	Several studies by independent investigators Doubts about adequacy of sample size to avoid Type I and Type II error	Limited number of studies Low number of subjects studies and/or inadequate sample size within studies	Unsubstantiated by published studies	Relevan studies have no been do
Clinical Impact • Importance of studies outcomes • Magnitude of effect	Studied outcome relates directly to the question Size of effect is clinically meaningful	Some doubt about the statistical or clinical significance of effect	Studies outcome is an intermediate outcome or surrogate for the true outcome of interest OR	Objective data unavailable	Indicate area for future research

Strength of Evidence Elements	Grade I Good/Strong	Grade II Fair	Grade III Limited/Weak	Grade IV Expert Opinion Only	Grade Grade Assigna
	Significant (statistical) difference is large		Size of effect is small or lacks statistical and/or clinical significance		
Generalizability To population of interest	Studied population, intervention and outcomes are free from serious doubts about generalizability	Minor doubts about generalizability	Serious doubts about generalizability due to narrow or different study population, intervention or outcomes studied	Generalizability limited to scope of experience	NA

This grading system was based on the grading system from: *Greer N, Mosser G, Logan G, Wagstrom Halaas G. A practical approach to evidence grading. Jt Comm. J Qual Improv. 2000; 26:700-712*. In September 2004, The ADA Research Committee modified the grading system to this current version.

Criteria for Recommendation Rating

Statement Rating	Definition	Implication for Practice
Strong	A **Strong** recommendation means that the workgroup believes that the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation), and that the quality of the supporting evidence is excellent/good (grade I or II)*. In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Practitioners should follow a **Strong** recommendation unless a clear and compelling rationale for an alternative approach is present.
Fair	A **Fair** recommendation means that the workgroup believes that	Practitioners should generally follow a **Fair** recommendation

Statement Rating	Definition	Implication for Practice
	the benefits exceed the harms (or that the harms clearly exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade II or III)*. In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	but remain alert to new information and be sensitive to patient preferences.
Weak	A **Weak** recommendation means that the quality of evidence that exists is suspect or that well-done studies (grade I, II, or III)* show little clear advantage to one approach versus another.	Practitioners should be cautious in deciding whether to follow a recommendation classified as **Weak**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.
Consensus	A **Consensus** recommendation means that Expert opinion (grade IV)* supports the guideline recommendation even though the available scientific evidence did not present consistent results, or controlled trials were lacking.	Practitioners should be flexible in deciding whether to follow a recommendation classified **Consensus**, although they may set boundaries on alternatives. Patient preference should have a substantial influencing role.
Insufficient Evidence	An **Insufficient Evidence** recommendation means that there is both a lack of pertinent evidence (grade V)* and/or an unclear balance between benefits and harms.	Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Insufficient Evidence** and should exercise judgment and be alert to emerging publications that report evidence that clarifies the balance of benefit versus harm. Patient preference should have a substantial influencing role.

*Conclusion statements are assigned a grade based on the strength of the evidence. Grade I is good; grade II, fair; grade III, limited; grade IV signifies expert opinion only and grade V indicates that a grade is not assignable because there is no evidence to support or refute the conclusion. The evidence and these grades are considered when assigning a rating (Strong, Fair, Weak, Consensus, Insufficient Evidence - see chart above) to a recommendation.

Adapted by the American Dietetic Association from the American Academy of Pediatrics, Classifying Recommendations for Clinical Practice Guideline, Pediatrics. 2004;114;874-877.

CLINICAL ALGORITHM(S)

Algorithms are provided in the original guideline document for:

- Gestational Diabetes Nutrition Guideline
- Gestational Diabetes Nutrition Assessment
- Gestational Diabetes Nutrition Diagnosis
- Gestational Diabetes Nutrition Intervention
- Gestational Diabetes Nutrition Monitoring and Evaluation

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").

The guideline contains conclusion statements that are supported by evidence summaries and evidence worksheets. These resources summarize the important studies (randomized controlled trials [RCTs], clinical trials, observational studies, cohort and case-control studies) pertaining to the conclusion statement and provide the study details.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

A priority aim and benefit of implementing the recommendations in this guidelineÂ is to improve a pregnant woman's ability to achieve optimal nutrition through healthful food choices and a physically active lifestyle during her pregnancy. In addition, implementation of these recommendations will:

- Assist in the normalization and maintenance of glycemia in pregnant women, and reduce the risk of adverse maternal and neonatal outcomes, andÂ reduce variations in practice among registered dietitians
- Promote self-management strategies that empower the pregnant women with gestational diabetes mellitus to take responsibility for day-to-day management

POTENTIAL HARMS

Overall Risk/Harm Considerations

When using these recommendations:

- Review the individual's age, socioeconomic status, cultural issues and other health conditions.
- Consider a referral to a behavioral specialist if psychosocial issues are a concern.

- Consider a referral to social services to assist individuals with financial arrangements if economic issues are a concern.
- Use clinical judgment when evaluating pregnant women with gestational diabetes mellitus.

In addition to the above, a variety of barriers may hinder the application of these recommendations.

Recommendation-Specific Risks/Harms

Screening for Gestational Diabetes Mellitus (GDM)

- International consensus of the screening and diagnostic criteria have not been established.
- Misdiagnosis due to false-positives is possible.
- Screening may result in psychological stress for some individuals.
- Screening may cause gastrointestinal upset and other symptoms in some individuals.

Physical Activity

Physical activity may cause hypoglycemia in women using pharmacological therapy.

Caloric Intake

Caloric restriction may result in non-adherence.

Macronutrient and Micronutrient Intake

Some individuals may not tolerate vitamin and/or mineral supplementation.

Blood Glucose Monitoring and Ketone Testing

- Frequent glucose self-monitoring may cause pain and discomfort
- Individuals should know of proper disposal of hazardous waste

Use of Non-Nutritive Sweeteners

Nonnutritive sweeteners are generally safe when consumed during pregnancy within the acceptable daily intake (ADI) levels established by the Food and Drug Administration (FDA), with the exception of saccharin due to slowed fetal clearance and aspartame in women with phenylketonuria.

Pharmacological Therapy for Treatment of GDM

- Use of pharmacological therapy may result in hypoglycemia
- All medications taken in pregnancy should be reviewed for FDA-approved Pregnancy classification

Fiber Intake

Excessive fiber intake can potentially have undesirable gastrointestinal side effects.

Carbohydrate Intake

- Although total carbohydrate content of meals and snacks is the first priority, macronutrient content and total energy intake cannot be ignored as excessive energy intake may lead to weight gain, even if glycemic control is maintained.
- Diets too low in carbohydrate eliminate many foods that are important sources of vitamins, minerals, fiber and energy.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Contraindications to exercise during pregnancy may include but are not limited to: pregnancy-induced hypertension, premature rupture of membranes, intrauterine growth retardation, preterm labor or history of preterm labor, incompetent cervix/cervical cerclage, and persistent second or third trimester bleeding.
- The American Medical Association suggests avoiding saccharin during pregnancy due to possible slow fetal clearance
- Contraindications to breastfeeding include:
    - Human immunodeficiency virus (HIV) infection
    - Use of some medications
    - Substance abuse

Clinical judgment is crucial in application of these guidelines. Careful consideration should be given to the application of these guidelines for patients with significant medical comorbidities.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This American Dietetic Association Evidence-Based Nutrition Practice Guideline is meant to serve as a general framework for handling clients with particular health problems. It may not always be appropriate to use these nutrition practice guidelines to manage clients because individual circumstances may vary. For example, different treatments may be appropriate for clients who are severely ill or who have co-morbid, socioeconomic, or other complicating conditions. The independent skill and judgment of the health care provider must always dictate treatment decisions. These nutrition practice guidelines are provided with the express understanding that they do not establish or specify particular standards of care, whether legal, medical, or other.
- While the guideline represents a statement of best practice based on the latest available evidence at the time of publishing, they are not intended to

overrule professional judgment. Rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance.Â The independent skill and judgment of the health care provider must always dictate treatment decisions. These nutrition practice guidelines are provided with the express understanding that they do not establish or specify particular standards of care, whether legal, medical or other.
- This guideline recognizes the role of patient preferences for possible outcomes of care, when the appropriateness of a clinical intervention involves a substantial element of personal choice or values.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The publication of this guideline is an integral part of the plans for getting the American Dietetic Association Medical Nutrition Therapy (ADA MNT) evidence-based recommendations on gestational diabetes to all dietetics practitioners engaged in, teaching about or researching gestational diabetes, as quickly as possible. National implementation workshops at various sites around the country and during the ADA Food Nutrition Conference Expo (FNCE) are planned. Additionally, there are recommended dissemination and adoption strategies for local use of the ADA Gestational Diabetes Evidence-Based Nutrition Practice Guideline.

The guideline development team recommended multi-faceted strategies to disseminate the guideline and encourage its implementation. Management support and learning through social influence are likely to be effective in implementing guidelines in dietetic practice. However, additional interventions may be needed to achieve real change in practice routines.

Implementation of the gestational diabetes guideline will be achieved by announcement at professional events, presentations and training. Some strategies include:

- **National and local events**: State dietetic association meetings and media coverage will help launch the guideline
- **Local feedback adaptation**: Presentation by members of the work group at peer review meetings and opportunities for continuing education units (CEUs) for courses completed
- **Education initiatives**: The guideline and supplementary resources will be freely available for use in the education and training of dietetic interns and students in approved Commission on Accreditation of Dietetics Education (CADE) programs
- **Champions**: Local champions will be identified and expert members of the guideline team will prepare articles for publications. Resources will be provided that include PowerPoint presentations, full guidelines and pre-prepared case studies.
- **Practical Tools**: Some of the tools that will be developed to help implement the guideline include specially-designed resources, such as clinical algorithms, slide presentations, training and toolkits.

Specific distribution strategies include:

Publication in full: The guideline is available electronically at the ADA Evidence Analysis Library website (www.adaevidencelibrary.com) and announced to all ADA Dietetic Practice Groups. The ADA Evidence Analysis Library will also provide downloadable supporting information and links to relevant position papers.

IMPLEMENTATION TOOLS

Clinical Algorithm
Slide Presentation

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
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Dietetic Association (ADA). Gestational diabetes mellitus (GDM). Evidence based nutrition practice guideline. Chicago (IL): American Dietetic Association (ADA); 2008. Various p. [234 references]

ADAPTATION

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

DATE RELEASED

2008

GUIDELINE DEVELOPER(S)

American Dietetic Association - Professional Association

SOURCE(S) OF FUNDING

American Dietetic Association

GUIDELINE COMMITTEE

Expert Work Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, the American Dietetic Association (ADA) has adopted the policy of revealing relationships workgroup members have with companies that sell products or services that are relevant to this topic. Workgroup members are required to disclose potential conflicts of interest by completing the ADA Conflict of Interest Form. It should not be assumed that these financial interests will have an adverse impact on the content, but they are noted here to fully inform readers.

None of the work group members listed above disclosed potential conflicts of interest.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previously published version: American Dietetic Association. Nutrition practice guidelines for gestational diabetes mellitus. Chicago (IL): American Dietetic Association; 2001 Sep. Various p.

GUIDELINE AVAILABILITY

Electronic copies: Available to members from the American Dietetic Association Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Executive summary of recommendations. Chicago (IL): American Dietetic Association; 2009. Electronic copies: Available from the American Dietetic Association Web site.
- American Dietetic Association gestational diabetes mellitus evidence-based nutrition practice guideline. Slide set. Chicago (IL): American Dietetic

Association; 2009. Electronic copies: Available for purchase from the American Dietetic Association Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on April 29, 2003. The information was verified by the guideline developer on August 6, 2003. This summary was updated by ECRI Institute on February 9, 2010. The information was verified by the guideline developer on March 9, 2010.

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