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Guideline Summary NGC-8216

Guideline Title

Standards of medical care in diabetes. I. Classification and diagnosis of diabetes.

Bibliographic Source(s)

American Diabetes Association (ADA). Standards of medical care in diabetes. I. Classification and diagnosis of diabetes. Diabetes Care 2011 Jan;34(Suppl 1):S12-3.

Guideline Status

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

Scope

Disease/Condition(s)

- Diabetes mellitus (type I, type II, gestational, and diabetes due to other causes)
- Prediabetes

Guideline Category

Diagnosis

Evaluation

Prevention

Risk Assessment

Screening

Clinical Specialty

Endocrinology

Family Practice

Geriatrics

Internal Medicine

Nursing

Obstetrics and Gynecology

Pediatrics

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Dietitians

Health Care Providers

Health Plans

Hospitals

Managed Care Organizations

Nurses

Patients

Physician Assistants

Physicians

Public Health Departments

Guideline Objective(s)

- To provide information on the classification of diabetes and recommendations for the diagnosis of diabetes mellitus

- To provide clinicians, patients, researchers, payers, and other interested individuals with the components of diabetes care, general treatment goals, and tools to evaluate the quality of care

Target Population

- Children and adults with:
  - Type 1 diabetes
  - Type 2 diabetes
  - Other specific types of diabetes due to other causes, e.g., genetic defects in beta-cell function, genetic defects in insulin action, diseases of the exocrine pancreas (such as cystic fibrosis), and drug- or chemical-induced diabetes (such as in the treatment of acquired immunodeficiency syndrome [AIDS] or after organ transplantation)
- Women with gestational diabetes mellitus (GDM)
- Children and adults at increased risk for diabetes (prediabetes)
  - Impaired glucose tolerance (IGT)
  - Impaired fasting glucose (IFG)

Interventions and Practices Considered

Diagnosis/Evaluation

1. Hemoglobin A1C using a method certified by the National Glycohemoglobin Standardization Program (NGSP) and standardized or traceable to the Diabetes Control and Complications Trial (DCCT) reference assay
2. Fasting plasma glucose (FPG)
3. Two-hour plasma glucose during a 75-g oral glucose tolerance test (OGTT)
4. Random plasma glucose
5. Evaluation of symptoms

Major Outcomes Considered

Sensitivity and specificity of diagnostic tests

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Not stated

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

American Diabetes Association's Evidence Grading System for Clinical Practice Recommendations

A

Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted multicenter trial
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

Compelling nonexperimental evidence (i.e., "all or none" rule developed by the Centre for Evidence-Based Medicine at Oxford)

Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted trial at one or more institutions
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

B

Supportive evidence from well-conducted cohort studies, including:

- Evidence from a well-conducted prospective cohort study or registry
- Evidence from a well-conducted meta-analysis of cohort studies

Supportive evidence from a well-conducted case-control study

C

Supportive evidence from poorly controlled or uncontrolled studies, including:

- Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results
- Evidence from observational studies with high potential for bias (such as case series with comparison to historical controls)
- Evidence from case series or case reports

Conflicting evidence with the weight of evidence supporting the recommendation

E

Expert consensus or clinical experience

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

Not stated

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Published cost analyses were reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

The recommendations were reviewed and approved by the Professional Practice Committee and, subsequently, by the Executive Committee of the Board of Directors.

Recommendations

Major Recommendations

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary. The recommendations that follow are based on the previous version of the guideline.

Classification and Diagnosis

Diagnosis of Diabetes

Table: Criteria for the Diagnosis of Diabetes
Glycosylated hemoglobin (A1C) ≥6.5%. The test should be performed in a laboratory using a method that is National Glycohemoglobin Standardization Program (NGSP) certified and standardized to the Diabetes Control and Complications Trial (DCCT) assay.* or
Fasting plasma glucose (FPG) ≥126 mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least 8 h.* or
Two-hour plasma glucose ≥200 mg/dL (11.1 mmol/L) during an oral glucose tolerance test (OGTT). The test should be performed as described by the World Health Organization, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.* or
In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dl (11.1 mmol/L).

*In the absence of unequivocal hyperglycemia, results should be confirmed by repeat testing.

Categories of Increased Risk for Diabetes (Prediabetes)

In 1997 and 2003, the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus recognized an intermediate group of individuals whose glucose levels, although not meeting criteria for diabetes, are nevertheless too high to be considered normal. This group was defined as having impaired fasting glucose (IFG) (FPG levels of 100 mg/dL to 125 mg/dL [5.6 mmol/L to 6.9 mmol/L]) or impaired glucose tolerance (IGT) (2-h PG values in the OGTT of 140 mg/dL to 199 mg/dL [7.8 mmol/L to 11.0 mmol/L]). It should be noted that the World Health Organization (WHO) and a number of other diabetes organizations define the cutoff for IFG at 110 mg/dL (6.1 mmol/L).

Individuals with IFG and/or IGT have been referred to as having prediabetes, indicating the relatively high risk for the future development of diabetes. IFG and IGT should not be viewed as clinical entities in their own right but rather as risk factors for diabetes as well as cardiovascular disease (CVD).

Table. Categories of Increased Risk for Diabetes (Prediabetes)**
FPG 100–125 mg/dL (5.6–6.9 mmol/L): IFG or
2-h PG on the 75-g OGTT 140–199 mg/dL (7.8–11.0 mmol/L): IGT or
A1C 5.7% to 6.4%

**For all three tests, risk is continuous, extending below the lower limit of the range and becoming disproportionately greater at higher ends of the range.

Clinical Algorithm(s)

None provided

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is not specifically stated for each recommendation.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

The recommendations included are diagnostic and therapeutic actions that are known or believed to favorably affect health outcomes of patients with diabetes.

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

- Evidence is only one component of clinical decision-making. Clinicians care for patients, not populations; guidelines must always be interpreted with the needs of the individual patient in mind. Individual circumstances, such as comorbid and coexisting diseases, age, education, disability, and, above all, patients' values and preferences, must also be considered and may lead to different treatment targets and strategies. Also, conventional evidence hierarchies, such as the one adapted by the American Diabetes Association, may miss some nuances that are important in diabetes care. For example, while there is excellent evidence from clinical trials supporting the importance of achieving glycemic control, the optimal way to achieve this result is less clear. It is difficult to assess each component of such a complex intervention.
- While individual preferences, comorbidities, and other patient factors may require modification of goals, targets that are desirable for most patients with diabetes are provided. These standards are not intended to preclude clinical judgment or more extensive evaluation and management of the patient by other specialists as needed.

Implementation of the Guideline

Description of Implementation Strategy

While numerous interventions to improve adherence to the recommended standards have been implemented, a major contributor to suboptimal care is a delivery system that too often is fragmented, lacks clinical information capabilities, often duplicates services, and is poorly designed for the delivery of chronic care. The Chronic Care Model (CCM) includes

six core elements for the provision of optimal care of patients with chronic disease: 1) delivery system design (moving from a *reactive* to a *proactive* care delivery system, where planned visits are coordinated through a team-based approach; 2) self-management support; 3) decision support (basing care on consistent, effective care guidelines); 4) clinical information systems (using registries that can provide patient-specific and population-based support to the care team); 5) community resources and policies (identifying or developing resources to support healthy lifestyles); and 6) health systems (to create a quality-oriented culture). Alterations in reimbursement that reward the provision of quality care, as defined by the attainment of evidence-based quality measures, will also be required to achieve desired outcome goals. Redefinition of the roles of the clinic staff and promoting self-management on the part of the patient are fundamental to the successful implementation of the CCM. Collaborative, multidisciplinary teams are best suited to provide such care for people with chronic conditions like diabetes and to facilitate patients' performance of appropriate self-management.

A rapidly evolving literature suggests that there are three major strategies to successfully improve the quality of diabetes care delivered by a team of providers. National Diabetes Education Program (NDEP) maintains an online resource (www.betterdiabetescare.nih.gov) to help health care professionals design and implement more effective health care delivery systems for those with diabetes.

Three specific objectives are outlined below.

Objective 1

Provider and team behavior change: Facilitate timely and appropriate intensification of lifestyle and/or pharmaceutical therapy of patients who have not achieved beneficial levels of blood pressure, lipid, or glucose control.

- Clinical information systems including registries that can prospectively identify and track those requiring assessments and/or treatment modifications by the team.
- Electronic medical record-based clinical decision support at the point of care, both personalize and standardize care and can be used by multiple providers.
- Use of checklists and/or flow sheets that mirror guidelines.
- Detailed treatment algorithms enabling multiple team members to "treat to target" and appropriately intensify therapy.
- Availability of care or disease management service by nurses, pharmacists, and other providers using detailed algorithms often catalyzing reduction in A1C, blood pressure, and low-density lipoprotein (LDL) cholesterol.

Objective 2

Patient behavior change: Implement a systematic approach to support patients' behavior change efforts as needed including 1) healthy lifestyle (physical activity, healthy eating, nonuse of tobacco, weight management, effective coping, medication taking and management); 2) prevention of diabetes complications (screening for eye, foot, and renal complications; immunizations); and 3) achievement of appropriate blood pressure, lipid, and glucose goals.

- Delivery of high-quality diabetes self-management education (DSME), which has been shown to improve patient self-management, satisfaction, and glucose control.
- Delivery of ongoing diabetes self-management support (DSMS) to ensure that gains achieved during DSME are sustained. National DSME standards call for an integrated approach that includes clinical content and skills, behavioral strategies (goal-setting, problem solving), and addressing emotional concerns in each needed curriculum content area. Provision of continuing education and support (DSMS) improves maintenance of gains regardless of the educational methodology.
- Provision of automated reminders via multiple communication channels to various subgroups of diabetic patients.

Objective 3

Change the system of care: Research on the comprehensive CCM suggests additional strategies to improve diabetes care, including the following:

- Basing care on consistent, evidence-based care guidelines
- Redefining and expanding the roles of the clinic staff
- Collaborative, multidisciplinary teams to provide high-quality care and support patients' appropriate self-management
- Audit and feedback of process and outcome data to providers to encourage population-based care improvement strategies
- Care management, one of the most effective diabetes quality improvement strategies to improve glycemic control
- Identifying and/or developing community resources and public policy that support healthy lifestyles
- Alterations in reimbursement that reward the provision of appropriate and high-quality care and accommodate the need to personalize care goals, providing additional incentives to improve diabetes care

The most successful practices have an institutional priority for quality of care, expanding the role of teams and staff, redesigning their delivery system, activating and educating their patients, and using electronic health record tools. Recent initiatives such as the Patient Centered Medical Home show promise in improving outcomes through coordinated primary care and offer new opportunities for team-based chronic disease care.

It is clear that optimal diabetes management requires an organized, systematic approach and involvement of a coordinated team of dedicated health care professionals working in an environment where patient-centered high-quality care is a priority.

Implementation Tools

Personal Digital Assistant (PDA) Downloads

Quick Reference Guides/Physician Guides

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

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

American Diabetes Association (ADA). Standards of medical care in diabetes. I. Classification and diagnosis of diabetes. Diabetes Care 2011 Jan;34(Suppl 1):S12-3.

Adaptation

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

Date Released

1988 (revised 2011 Jan)

Guideline Developer(s)

American Diabetes Association - Professional Association

Source(s) of Funding

American Diabetes Association (ADA)

Guideline Committee

Professional Practice Committee

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

All members of the Professional Practice Committee are required to disclose potential conflicts of interest.

Conflict of interest disclosures for the 2010 Professional Practice Committee Members are available from the American Diabetes Association (ADA) Web site (see "Availability of Companion Documents" field).

Guideline Status

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

Guideline Availability

Electronic copies of the updated guideline: Available from the American Diabetes Association (ADA) Web site.

Print copies: Available from the American Diabetes Association, 1701 North Beauregard Street, Alexandria, VA 22311.

Availability of Companion Documents

The following are available:

- Introduction. Diabetes Care 34:S1-S2, 2011.
- Summary of revisions for the 2011 clinical practice recommendations. Diabetes Care 34:S3, 2011.
- Executive summary: standards of medical care in diabetes. Diabetes Care 34:S4-S10, 2011.
- Professional Practice Committee Members (includes conflict of interest disclosure). Diabetes Care 34:S97-S98,

2011.

Electronic copies: Available from the American Diabetes Association (ADA) Web site.

Print copies: Available from the American Diabetes Association, 1701 North Beauregard Street, Alexandria, VA 22311.

The following are also available:

- Diagnosis and classification of diabetes mellitus. Diabetes Care 2011 Jan; 34(Suppl 1):S62-S69, 2011. Electronic copies: Available from the ADA Web site.
- 2011 Standards of medical care in diabetes. Clinical practice recommendations. Slide set. American Diabetes Association; 2011 Jan. 130 p. Electronic copies: Available from the ADA Web site.
- 2011 Standards of medical care in diabetes. Clinical practice recommendations. Personal Digital Assistant (PDA). American Diabetes Association; 2011 Jan. Electronic copies: Available for download from the ADA Web site.

Patient Resources

None available

NGC Status

This summary was completed by ECRI on April 2, 2001. The information was verified by the guideline developer on August 24, 2001. This summary was updated by ECRI on March 14, 2002, July 29, 2003, May 26, 2004, July 1, 2005, March 16, 2006 and April 24, 2007. This summary was updated by ECRI Institute on March 14, 2008. The updated information was verified by the guideline developer on May 15, 2008. This summary was updated by ECRI Institute on May 19, 2010. The information was verified by the guideline developer on May 25, 2010. This summary was updated by ECRI Institute on February 24, 2011.

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