Complete Summary

GUIDELINE TITLE

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

BIBLIOGRAPHIC SOURCE(S)

American Diabetes Association (ADA). Standards of medical care in diabetes. I. Classification and diagnosis. Diabetes Care 2008 Jan;31(Suppl 1):S12-3.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American Diabetes Association (ADA). Standards of medical care in diabetes. I. Classification and diagnosis. Diabetes Care 2007 Jan;30(Suppl 1):S4-5.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Diabetes mellitus
  - 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 (such as in the treatment of acquired immunodeficiency syndrome [AIDS] or after organ transplantation)
  - Gestational diabetes mellitus (GDM)
- Pre-diabetes

- Impaired glucose tolerance (IGT)
- Impaired fasting glucose (IFG)

GUIDELINE CATEGORY

Diagnosis

CLINICAL SPECIALTY

Endocrinology
Family Practice
Geriatrics
Internal Medicine
Obstetrics and Gynecology
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Nurses
Patients
Physician Assistants
Physicians

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, treatment goals, and tools to evaluate the quality of care

TARGET POPULATION

- Children and nonpregnant adults suspected of having diabetes mellitus
- Women diagnosed with gestational diabetes mellitus during pregnancy who require postpartum evaluation

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Fasting plasma glucose (FPG) (preferred test)
2. Evaluation of symptoms of diabetes (e.g., polyuria, polydipsia, unexplained weight loss)
3. Casual plasma glucose
4. Two-hour plasma glucose during a 75-g oral glucose tolerance test (OGTT)
5. Hemoglobin A1C (considered, but not recommended)

MAJOR OUTCOMES CONSIDERED

Sensitivity and specificity of diagnostic tests

METHODOLOGY

METHODS USED TO COLLECT/SELECT 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 non-experimental evidence (i.e., "all or none" rule developed by the Center 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

**Either all patients died before therapy and at least some survived with therapy, or some patients died without therapy and none died with therapy. Example: use of insulin in the treatment of diabetic ketoacidosis.*

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 with 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

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

Recommendations have been assigned ratings of A, B or C, depending on the quality of evidence (see "Rating Scheme for the Strength of the Evidence"). Expert opinion (E) is a separate category for recommendations in which there is as yet no evidence from clinical trials, in which clinical trials may be impractical, or in which there is conflicting evidence. Recommendations with an "A" rating are based on large, well-designed clinical trials or well done meta-analyses. Generally,

these recommendations have the best chance of improving outcomes when applied to the population to which they are appropriate. Recommendations with lower levels of evidence may be equally important but are not as well supported.

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

The recommendations were reviewed and approved in October 2007 by the Professional Practice Committee and, subsequently, by the Executive Committee of the Board of Directors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The evidence grading system for clinical practice recommendations (A through C, E) is defined at the end of the "Major Recommendations" field.

Classification and Diagnosis

Diagnosis of Diabetes

- The fasting plasma glucose (FPG) test is the preferred test to diagnose diabetes in children and nonpregnant adults. (E)
- Use of the glycated hemoglobin test (A1C) for the diagnosis of diabetes is not recommended at this time. (E)

Criteria for the Diagnosis of Diabetes	
1.	FPG $\geq$126 mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least 8 h*. **OR**
2.	Symptoms of hyperglycemia and a casual plasma glucose $\geq$200 mg/dL (11.1 mmol/L). Casual is defined as any time of day without regard to time since last meal. The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss. **OR**
3.	2-h plasma glucose $\geq$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.*

*In the absence of unequivocal hyperglycemia, these criteria should be confirmed by repeat testing on a different day.

Although the OGTT is not recommended for routine clinical use, it may be useful for further evaluation of patients in whom diabetes is still strongly suspected but who have normal FPG or impaired fasting glucose (IFG).

Diagnosis of Pre-Diabetes

Hyperglycemia not sufficient to meet the diagnostic criteria for diabetes is categorized as either IFG or impaired glucose tolerance (IGT), depending on whether it is identified through the FPG or the OGTT:

- IFG = FPG 100 mg/dL (5.6 mmol/L) to 125 mg/dL (6.9 mmol/L)
- IGT = 2-h plasma glucose 140 mg/dL (7.8 mmol/L) to 199 mg/dL (11.0 mmol/L)

IFG and IGT have been officially termed "pre-diabetes."

Definitions:

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

A

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- Evidence from a meta-analysis that incorporated quality ratings in the analysis
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**Either all patients died before therapy and at least some survived with therapy, or some patients died without therapy and none died with therapy. Example: use of insulin in the treatment of diabetic ketoacidosis.*

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- 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 with 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

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 the "Major Recommendations" field).

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 more extensive evaluation and management of the patient by other specialists as needed.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

In recent years, numerous health care organizations, ranging from large health care systems such as the U.S. Veteran's Administration to small private practices, have implemented strategies to improve diabetes care. Successful programs have published results showing improvement in process measures such as measurement of A1C, lipids, and blood pressure. Successful interventions have been focused at the level of health care professionals, delivery systems, and patients. Features of successful programs reported in the literature include:

- Improving health care professional education regarding the standards of care through formal and informal education programs.
- Delivery of diabetes self-management education (DSME), which has been shown to increase adherence to standard of care.
- Adoption of practice guidelines, with participation of health care professionals in the process. Guidelines should be readily accessible at the point of service, such as on patient charts, in examining rooms, in "wallet or pocket cards," on Personal Digital Assistants (PDAs), or on office computer systems. Guidelines should begin with a summary of their major recommendations instructing health care professionals what to do and how to do it.
- Use of checklists that mirror guidelines have been successful at improving adherence to standards of care.
- Systems changes, such as provision of automated reminders to health care professionals and patients, reporting of process and outcome data to providers, and especially identification of patients at risk because of failure to achieve target values or a lack of reported values.
- Quality improvement programs combining continuous quality improvement or other cycles of analysis and intervention with provider performance data.
- Practice changes, such as clustering of dedicated diabetes visits into specific times within a primary care practice schedule and/or visits with multiple health care professionals on a single day and group visits.
- Tracking systems either with an electronic medical record or patient registry have been helpful at increasing adherence to standards of care by prospectively identifying those requiring assessments and/or treatment modifications. They likely could have greater efficacy if they suggested

specific therapeutic interventions to be considered for a particular patient at a particular point in time.
- A variety of non-automated systems, such as mailing reminders to patients, chart stickers, and flow sheets, have been useful to prompt both providers and patients.
- Availability of case or (preferably) care management services, usually by a nurse. Nurses, pharmacists, and other non-physician health care professionals using detailed algorithms working under the supervision of physicians and/or nurse education calls have also been helpful. Similarly dietitians using medical nutrition therapy (MNT) guidelines have been demonstrated to improve glycemic control.
- Availability and involvement of expert consultants, such as endocrinologists and diabetes educators.

Evidence suggests that these individual initiatives work best when provided as components of a multifactorial intervention. Therefore, it is difficult to assess the contribution of each component; however, it is clear that optimal diabetes management requires an organized, systematic approach and involvement of a coordinated team of health care professionals.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

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. Diabetes Care 2008 Jan;31(Suppl 1):S12-3.

ADAPTATION

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

DATE RELEASED

1988 (revised 2008 Jan)

GUIDELINE DEVELOPER(S)

American Diabetes Association - Professional Association

SOURCE(S) OF FUNDING

The American Diabetes Association (ADA) received an unrestricted educational grant from LifeScan, Inc., a Johnson and Johnson Company, to support publication of the 2008 Diabetes Care Supplement.

GUIDELINE COMMITTEE

Professional Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Irl Hirsch, MD, Chair; Martin Abrahamson, MD; Andrew Ahmann, MD; Lawrence Blonde, MD; Silvio Inzucchi, MD; Mary T. Korytkowski, MN, MD, MSN; Melinda Maryniuk, MEd, RD, CDE; Elizabeth Mayer-Davis, MS, PhD, RD; Janet H. Silverstein, MD; Robert Toto, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American Diabetes Association (ADA). Standards of medical care in diabetes. I. Classification and diagnosis. Diabetes Care 2007 Jan;30(Suppl 1):S4-5.

GUIDELINE AVAILABILITY

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

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Introduction. Diabetes Care 31:S1-S2, 2008.
- Summary of revisions for the 2008 clinical practice recommendations. Diabetes Care 31:S3-S4, 2008.

- Executive summary: standards of medical care in diabetes. Diabetes Care 31:S5-S11, 2008.
- Strategies for improving diabetes care. Diabetes Care 31:S44, 2008.

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

The following are also available:

- Diagnosis and classification of diabetes mellitus. Diabetes Care 2008 Jan; 31 Suppl 1:S55-60. Electronic copies: Available from the American Diabetes Association (ADA) Web site.
- 2008 clinical practice recommendations standards of care. Personal digital assistant (PDA) download. Available from the American Diabetes Association (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 most recently by ECRI Institute on March 14, 2008. The updated information was verified by the guideline developer on May 15, 2008.

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Date Modified: 9/29/2008