## **Complete Summary**

#### **GUIDELINE TITLE**

Type I diabetes practice guidelines.

## **BIBLIOGRAPHIC SOURCE(S)**

International Diabetes Center. Type 1 diabetes practice guidelines. Minneapolis (MN): International Diabetes Center; 2003. 1 p.

#### **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: International Diabetes Center, Institute for Research and Education. Staged diabetes management: a systematic approach. Minneapolis (MN): Matrex, International Diabetes Center; 2000. Type 1 diabetes practice guidelines. p. 133-71.

## **COMPLETE SUMMARY CONTENT**

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## SCOPE

## DISEASE/CONDITION(S)

Type 1 diabetes mellitus

#### **GUIDELINE CATEGORY**

Diagnosis Evaluation Management Screening Treatment

#### **CLINICAL SPECIALTY**

Endocrinology
Family Practice
Internal Medicine
Pediatrics

#### **INTENDED USERS**

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Managed Care Organizations
Nurses
Pharmacists
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Social Workers

## **GUIDELINE OBJECTIVE(S)**

Staged Diabetes Management is a systematic approach to detecting and treating diabetes using practice guidelines and clinical pathways that reflects the changing responsibilities of the primary care provider and the primary care team. The purpose of Staged Diabetes Management is to:

- Provide a systematic, data-based approach for clinical decision making in the treatment of diabetes and its complications
- Provide a consistent set of scientifically based practice guidelines that can be adapted by a community according to its resources
- Identify appropriate criteria for altering therapies during three treatment phases: Start, Adjust, and Maintain
- Provide a common Master DecisionPath for the type of diabetes that both patients and providers can use to understand treatment options, to enhance communication, and to optimize therapies
- Facilitate the detection and treatment of diabetes and its complications by primary care providers, in consultation with specialists (comanagement)

#### **TARGET POPULATION**

Children, adolescents, and adults with suspected or documented type 1 diabetes mellitus

#### **INTERVENTIONS AND PRACTICES CONSIDERED**

- 1. Screening and diagnosis
  - Casual plasma glucose, oral glucose tolerance test, fasting plasma glucose
  - Assessment of signs and symptoms
  - Urinary ketones

- 2. Staged treatment
  - Medical nutrition therapy
  - Exercise interventions
  - Staged insulin therapy (insulin stages 2, 3A, 4A, 3B, or pump)
    - Lispro or Aspart
    - Regular human insulin
    - Neutral protamine Hagedorn (NPH) insulin
    - Glargine
    - Ultralente insulin
- 3. Targeting and monitoring blood glucose control
  - Blood pressure
  - Lipids
  - Self-monitored blood glucose
  - Hemoglobin A<sub>1c</sub>
  - Urinary ketones
- 4. Monitoring growth and development using anthropometric scales and growth charts
- 5. Follow-up (includes both short- and long-term assessments)
  - Blood glucose and hemoglobin A<sub>1c</sub>
  - Weight, height, growth rate
  - Complete history/physical
  - Food and exercise plan
  - Blood pressure
  - Eye and foot screen, neurologic assessment
  - Smoking cessation counseling
  - Preconception counseling
  - Diabetes/nutrition education
  - Aspirin therapy
  - Fasting lipid profile
  - Albuminuria/proteinuria screen
  - Patient satisfaction assessment
- 6. Patient education
- 7. Psychological and social assessment
- 8. Complications surveillance

#### **MAJOR OUTCOMES CONSIDERED**

#### **Intermediate Outcome Measures of Blood Glucose Control**

- Blood pressure
- Lipids
- Hemoglobin A<sub>1c</sub>
- Blood glucose, by self-monitored blood glucose and casual (random) and fasting plasma glucose
- Urinary ketones

## **Long-term Outcome Measures**

- Retinal changes
- Renal changes
- Neurological changes
- Cardiovascular disease

- Peripheral vascular disease
- Foot problems (ulcers, deformities, infections)

#### **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

Expert Consensus Subjective Review

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

#### METHODS USED TO ANALYZE THE EVIDENCE

Review

#### **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not applicable

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A team of endocrinologists, family physicians, clinical nurse specialists, and dieticians joined together in 1988 to identify the therapeutic principles that lie at the core of diabetes management. Specialists joined the team as needed, including a perinatologist, an epidemiologist, and a psychologist, among others. The team investigated current approaches to the treatment of type 1 diabetes, type 2 diabetes, and diabetes in pregnancy. At biweekly conferences over a period

of 5 months, each step in diagnosing and treating each type of diabetes was carefully delineated.

Key decisions points were placed on flow charts termed "DecisionPaths." These DecisionPaths contained the following:

- Treatment modalities
- Criteria for initiating treatment
- Criteria for changing treatment
- Key clinical decision points
- Information about establishing, monitoring, and evaluating therapeutic goals
- Recommended follow-up

Changes in the original design of Staged Diabetes Management since its initiation in 1988 have been made to reflect additional patient data collected during clinical trials and implementation studies.

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

#### **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### METHOD OF GUIDELINE VALIDATION

Clinical Validation-Trial Implementation Period

#### **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Since its initiation in 1988, Staged Diabetes Management has undergone clinical trials and implementation studies in more than 200 sites worldwide. The results have led to changes in the original design of Staged Diabetes Management and are reflected in the guideline text. Nevertheless, the basic principles upon which Staged Diabetes Management is founded remain intact.

To continue to refine this systematic approach to clinical decision-making, the records of randomly selected patients seen in a diabetes specialty center are periodically evaluated. These are supplemented by data on more than five thousand individuals with diabetes treated in primary care centers in accordance with Staged Diabetes Management protocols.

## **RECOMMENDATIONS**

#### **MAJOR RECOMMENDATIONS**

The following is an outline of practice guidelines for management of type 1 diabetes mellitus. A detailed management plan and accompanying DecisionPaths can be found in the original guidelines.

#### **Diagnosis**

Majority younger than 30 years old and not obese

## Plasma Blood Glucose

Casual  $\geq$ 200 mg/dL plus symptoms, fasting  $\geq$ 126 mg/dL, or oral glucose tolerance test (OGTT) 2 hour glucose value  $\geq$ 200 mg/dL; if acute metabolic decompensation (positive ketones), make diagnosis immediately; in the absence of acute metabolic decompensation, confirm with casual or fasting plasma glucose within 24 hours.

#### **Symptoms**

Common: Increased urination, thirst, and appetite; nocturia; weight loss

Occasional: Blurred vision, urinary tract infection, yeast infection, fatigue, acute abdominal pain, flu-like symptoms

#### **Urine Ketones**

Usually positive, with or without diabetic ketoacidosis

#### **Treatment Options**

Insulin Stages 2, 3A, 4A, 3B, or pump synchronized with food plan and exercise program (see Type 1: Master DecisionPath in the original guideline document.)

These patients require insulin therapy and should not be treated with an oral agent.

#### **Targets**

## Blood Pressure

Less than 130/80 mmHg

## **Lipids**

Low-density lipoprotein (LDL) less than 100 mg/dL, high-density lipoprotein (HDL) ≥40 mg/dL, Triglyceride less than 150 g/dL

#### Self-Monitored Blood Glucose

- More than 50% of self-monitored blood glucose values should be within target range
- Age younger than 6 years: 100 to 200 mg/dL pre-meal and bedtime

- Age 6 to 12 years: 80 to 180 mg/dL pre-meal and bedtime
- Age older than 12 years: 80 to 140 mg/dL pre-meal; <160 mg/dL 2 hours after start of meal; 100 to 160 mg/dL at bedtime
- No severe (assisted) or nocturnal hypoglycemia

Adjust pre-meal target upwards if hypoglycemia unawareness or repeated severe hypoglycemia occurs.

#### Hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>)

- Age younger than 6 years: Within 2.5% points of upper limit of normal (e.g., normal 6%; target <8.5%)</li>
- Age 6 to 12 years: Within 2% points of upper limit of normal (e.g., normal 6%; target <8.0%)</li>
- Age older than 12 years: Within 1.0% points of upper limit of normal (e.g., normal 6%; target <7.0%)</li>
- Use hemoglobin A1c to verify self-monitored blood glucose data or to adjust therapy when data unavailable

## Monitoring

Hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>)

Frequency: every 3 to 4 months

## Self-Monitored Blood Glucose

Minimum 4 times per day (before meals, 2 hours after start of meal, and bedtime) Check 3 a.m. as needed (AM hyperglycemia, nocturnal hypoglycemia)

#### Method

Meter and log book

#### **Urine Ketones**

Check if unexplained blood glucose >240 mg/dL on 2 consecutive occasions, or if any illness or infection present

## **Growth and Development**

Normal, as determined using anthropometric scales/growth charts

#### Follow-Up

## Weekly

During Start and early Adjust Phase

#### <u>Monthly</u>

Office visit during Adjust Phase (weekly phone contact may be necessary)

## **Every 3 Months**

Hypoglycemia, medications, weight, height, growth rate, food plan and exercise, blood pressure, self-monitored blood glucose data (download and check meter), hemoglobin  $A_{1c}$ , eye screen, foot screen, diabetes/nutrition continuing education, preconception planning for women with child bearing potential, smoking cessation counseling, aspirin therapy

#### Yearly

In addition to the 3 month follow-up, complete the following: history and physical, dental examination, fasting lipid profile within 6 months of diagnosis.

In patients older than age 12 with diabetes for 5 years, complete the following: albuminuria/proteinuria screen, dilated eye examination, neurologic assessment, complete foot examination (pulses, nerves, and inspection), patient satisfaction evaluation.

## **Complications Surveillance**

Cardiovascular, renal, retinal, neurological, foot, oral, and dermatological

## **CLINICAL ALGORITHM(S)**

Algorithms are provided for management of type 1 diabetes mellitus in the form of a Master DecisionPath as well as separate detailed DecisionPaths for:

- Screening and Diagnosis
- Medical Nutrition Therapy
- Insulin Pump/Start
- Preconception Diabetes Management
- Multidisciplinary Approach to Management of Pregnancy
- Exercise Plan
- Insulin Administration Adherence
- Psychological and Social Assessment

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation. However, throughout the guideline document, the evidence used as the basis for the recommendations is discussed.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### **POTENTIAL BENEFITS**

- The benefits of early detection of type 1 diabetes in a general pediatric or family practice setting are based on evidence that many acute complications are directly related to the severity of persistent hyperglycemia prior to diagnosis. In particular, timely diagnosis avoids further metabolic decompensation and the risk of diabetic ketoacidosis.
- The multicenter study, Diabetes Control and Complications Trial (Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med 1993;329:977-86), showed that while any improvement in glycemic control was beneficial, near-normal levels of blood glucose afforded the best protection against the development and progression of microvascular disease.
- Insulin insufficiency, with accompanying diabetes out of control, can contribute to retarded growth, which, in turn, may contribute to developmental problems. Generally, children with diabetes treated to maintain near-normal glycemia have normal growth and development.

#### **POTENTIAL HARMS**

Insulin therapy can cause mild, moderate, or severe hypoglycemia, including unconsciousness and seizures.

#### **QUALIFYING STATEMENTS**

## **QUALIFYING STATEMENTS**

These Guidelines should not be interpreted as including all available and proper methods of diabetes care. The decision regarding any specific treatment modality should be made by the health care professional with consideration of the particular circumstances presented by the patient and the needs and resources particular to the community or institution.

#### IMPLEMENTATION OF THE GUIDELINE

#### **DESCRIPTION OF IMPLEMENTATION STRATEGY**

To fully implement Staged Diabetes Management requires participation in the Staged Diabetes Management process. This entails orientation to Staged Diabetes Management principles as well as assessing current practices, customizing elements of Staged Diabetes Management for the community, and identifying possible obstacles to implementation and follow-up.

Commitment to improving diabetes care is crucial to the success of Staged Diabetes Management in any community, and the key is building consensus. The goal of Staged Diabetes Management is to ensure consistent, high-quality diabetes care. To do this, all providers in the community need to become acquainted with and follow the same guidelines. A process based on consensus building is recommended in order to optimize the adoption of Staged Diabetes Management.

Starting and staying with successful Staged Diabetes Management requires six steps:

- · Community diabetes care needs assessment
- Group formation
- Orientation to Staged Diabetes Management
- Customization of Staged Diabetes Management
- Implementation of Staged Diabetes Management
- Evaluation of Staged Diabetes Management

Note: A detailed implementation plan can be found in the original guidelines.

#### **IMPLEMENTATION TOOLS**

Clinical Algorithm

For information about <u>availability</u>, 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

#### **IOM DOMAIN**

Effectiveness Patient-centeredness

## **IDENTIFYING INFORMATION AND AVAILABILITY**

## **BIBLIOGRAPHIC SOURCE(S)**

International Diabetes Center. Type 1 diabetes practice guidelines. Minneapolis (MN): International Diabetes Center; 2003. 1 p.

## **ADAPTATION**

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

## **DATE RELEASED**

2000 (revised 2003)

## **GUIDELINE DEVELOPER(S)**

International Diabetes Center - Private Nonprofit Organization

#### **GUIDELINE DEVELOPER COMMENT**

The International Diabetes Center is part of the Institute for Research and Education HealthSystem Minnesota. HealthSystem Minnesota, an integrated care system, also includes Methodist Hospital, Park Nicollet Clinic, and The Foundation.

The International Diabetes Center is a World Health Organization (WHO) Collaborating Center for Diabetes Education, Translation and Computer Technology.

## **SOURCE(S) OF FUNDING**

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#### **GUIDELINE COMMITTEE**

Not stated

#### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

#### **GUIDELINE STATUS**

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#### **GUIDELINE AVAILABILITY**

Print copies: Available for purchase from the International Diabetes Center, 3800 Park Nicollet Boulevard, Minneapolis, MN 55416-2699; (888) 825-6315 (U.S. only); Web site: <a href="https://www.idcdiabetes.org">www.idcdiabetes.org</a>.

## **AVAILABILITY OF COMPANION DOCUMENTS**

None available

## **PATIENT RESOURCES**

None available

#### **NGC STATUS**

This summary was completed by ECRI on May 21, 2001. This summary was updated by ECRI on February 18, 2004. The information was verified by the guideline developer on March 11, 2004.

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