



Complete Summary

GUIDELINE TITLE

American Association of Clinical Endocrinologists medical guidelines for clinical practice for the management of diabetes mellitus. Glycemic management.

BIBLIOGRAPHIC SOURCE(S)

AACE Diabetes Mellitus Clinical Practice Guidelines Task Force. AACE diabetes mellitus guidelines. Glycemic management. *Endocr Pract* 2007 May-Jun;13(Suppl 1):16-34. [178 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previously published version: American Association of Clinical Endocrinologists, American College of Endocrinology. Medical guidelines for the management of diabetes mellitus: the AACE system of intensive diabetes self-management--2002 update. *Endocr Pract* 2002 Jan-Feb;8(Suppl 1):40-82.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [April 10, 2008, Exubera \(insulin inhalation\)](#): Pfizer informed healthcare professionals and patients of updated safety information in the WARNINGS section of prescribing information for Exubera. This warning relates to a small number of primary lung malignancies that have been discovered in users of Exubera in clinical trials and post-marketing reports.
- [February 26, 2008, Avandia \(rosiglitazone\)](#): A new Medication Guide for Avandia must be provided with each prescription that is dispensed due to the U.S. Food and Drug Administration's (FDA's) determination that this medication could pose a serious and significant public health concern.
- [November 14, 2007, Avandia \(rosiglitazone\)](#): New information has been added to the existing boxed warning in Avandia's prescribing information about potential increased risk for heart attacks.
- [August 14, 2007, Thiazolidinedione class of antidiabetic drugs](#): Addition of a boxed warning to the updated label of the entire thiazolidinedione class of antidiabetic drugs to warn of the risks of heart failure.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

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SCOPE

DISEASE/CONDITION(S)

Diabetes mellitus, including:

- Type 1 diabetes
- Type 2 diabetes
- Gestational diabetes

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Cardiology
Endocrinology
Family Practice
Internal Medicine
Nursing
Nutrition
Obstetrics and Gynecology

INTENDED USERS

Advanced Practice Nurses
Dietitians
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide clinicians with clear and accessible guidelines to care for patients with diabetes mellitus

TARGET POPULATION

Children, adolescents, and adults with or at risk of developing diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Assessment

1. Hemoglobin A_{1c} testing
2. Blood glucose levels (fasting plasma glucose or 2-hour oral glucose tolerance test)

Treatment/Management

1. Insulin therapy (type 1)
 - Rapid acting
 - Short acting
 - Intermediate, basal
 - Long acting, basal
 - Premixed
2. Addition of pramlintide or an insulin sensitizer
3. Pharmacological therapy (type 2)
 - Sulfonylureas
 - Biguanides (metformin)
 - Alpha-glucosidase inhibitor
 - Thiazolidinediones
 - Secretagogues (glinides)
 - Pramlintide
 - Exenatide
 - Sitagliptin
 - Insulin
 - Combination therapy
4. Patient education regarding self-management
5. Lifestyle modifications (weight management, medical nutrition, physical activity)
6. Follow-up and patient monitoring to achieve glycemic goals

MAJOR OUTCOMES CONSIDERED

- Plasma glucose concentration: fasting, 2-hour post-challenge load
- Glycosylated hemoglobin (HbA_{1c}) levels
- Adverse effects of medications

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

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

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

References were obtained by performing a computerized search of the literature using PubMed and other search engines; scanning incoming journals in the medical library; and reviewing references in publications relevant to diabetes including review articles, leading textbooks, and syllabi from national and international meetings.

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

Levels of Substantiation in Evidence-Based Medicine^a

Level-of-Evidence Category ^b	Study Design or Information Type	Comments
1	Randomized controlled trials	Well-conducted, well-controlled trials at 1 or more medical centers
	Multicenter trials	Data derived from a substantial number of trials with adequate power; substantial number of subjects and outcome data
	Large meta-analyses with quality ratings	Consistent pattern of findings in the population for which the recommendation is made – generalizable results Compelling nonexperimental, clinically obvious evidence (e.g., use of insulin in diabetic ketoacidosis); "all or none" evidence
2	Randomized controlled trials	Limited number of trials, small number of subjects
	Prospective cohort studies	Well-conducted studies
	Meta-analyses of cohort studies	Inconsistent findings or results not representative for the target population

Level-of-Evidence Category ^b	Study Design or Information Type	Comments
	Case-control studies	
3	Methodologically flawed randomized controlled trials Nonrandomized controlled trials Observational studies Case series or case reports	Trials with 1 or more major or 3 or more minor methodologic flaws Uncontrolled or poorly controlled trials Retrospective or observational data Conflicting data with weight of evidence unable to support a final recommendation
4	Expert consensus Expert opinion based on experience Theory-driven conclusions Unproven claims Experience-based information	Inadequate data for inclusion in level-of-evidence categories 1, 2, or 3; data necessitates an expert panel's synthesis of the literature and a consensus

^aAdapted from the American Association of Clinical Endocrinologists Protocol for the Standardized Production of Clinical Practice Guidelines.

^bLevel-of-evidence categories 1 through 3 indicate scientific substantiation or proof; level-of-evidence category 4 indicates unproven claims.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The American Association of Clinical Endocrinologists (AACE) Task force members reviewed selected reports and studies and rated the clinical evidence from these sources.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

When possible, clinical recommendations put forth in the clinical practice guideline have been assigned a letter grade (A-D) based on the level of scientific substantiation (see "Rating Scheme for the Strength of the Recommendations"). However, when task force members determined that clinical judgment regarding a recommendation outweighed study findings or a recommendation lacked supporting studies, they assigned the final grade based on their extensive clinical experience and expertise in diabetes management. An A grade is the strongest recommendation, and a D grade is the weakest recommendation. These recommendations include subjective components such as: (a) judgment regarding whether results from a particular study are conclusive; (b) the relative weighing of positive and negative conclusive study results; (c) assignment of evidence rating when certain study methodologies are controversial; (d) the impact of risk-benefit analysis; (e) the impact of cost-effectiveness; (f) assessment of geographical differences in practice standards and availability of certain technologies; (g) assessment of ethnic, racial, and genetic differences in pathophysiology; (h) incorporation of patient preferences; and (i) incorporation of physician preferences.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendation Grades in Evidence-Based Medicine^a

Grade	Description
A	<p>Homogeneous evidence from multiple well-designed randomized controlled trials with sufficient statistical power</p> <p>Homogeneous evidence from multiple well-designed cohort controlled trials with sufficient statistical power</p> <p>≥1 conclusive level of evidence category 1 publications demonstrating benefit >> outweighs risk</p>
B	<p>Evidence from at least one large well-designed clinical trial, cohort or case-controlled analytic study, or meta-analysis</p> <p>No conclusive level of evidence category 1 publication; ≥1 conclusive level of evidence category 2 publications demonstrating benefit >> risk</p>
C	<p>Evidence based on clinical experience, descriptive studies, or expert consensus opinion</p> <p>No conclusive level 1 or 2 publication; ≥1 conclusive level of evidence category 3 publications demonstrating benefit >> risk</p> <p>No conclusive risk at all and no conclusive benefit demonstrated by evidence</p>
D	<p>Not rated</p> <p>No conclusive level of evidence category 1, 2, or 3 publication demonstrating benefit >> risk</p> <p>Conclusive level of evidence category 1, 2, or 3 publication demonstrating risk >> benefit</p>

^aAdapted from the American Association of Clinical Endocrinologists Protocol for the Standardized Production of Clinical Practice Guidelines.

COST ANALYSIS

Published cost analyses were reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A separate panel composed of American Association of Clinical Endocrinologists (AACE) members with expertise in diabetes reviewed the compiled report. Final recommendations included in this clinical practice guideline represent a consensus among the task force members and have been approved by reviewers, the AACE Publications and Executive Committees, and the AACE Board of Directors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the classes (1-4) and levels of evidence (**A-D**) are provided at the end of the "Major Recommendations" field.

Glycemic Management

All Patients With Diabetes Mellitus

- Encourage patients to achieve glycemic levels as near normal as possible without inducing clinically significant hypoglycemia (**grade A**); glycemic targets include:
 - HbA_{1c} ≤6.5% (**grade B**)
 - Fasting plasma glucose concentration <110 mg/dL (**grade B**)
 - 2-hour postprandial glucose concentration <140 mg/dL (**grade B**)
- Refer patients for comprehensive, ongoing education in diabetes self-management skills and nutrition therapy (**grade A**); education should:
 - Be provided by a qualified health care professional
 - Focus on all aspects of diabetes self-management relevant to each patient's treatment plan
 - Promote behavioral changes to support effective and consistent application of the prescribed diabetes treatment plan and an overall healthy lifestyle
 - Be continued as an ongoing intervention to accommodate changes in the treatment plan and patient status
- Initiate self-monitoring of blood glucose levels (**grade A**)

Patients With Type 1 Diabetes Mellitus

Initiate intensive insulin therapy (**grade A**) (Table 4.1 describes the pharmacokinetics of available insulin preparations); regimen options include:

- Basal-bolus therapy, using a long-acting insulin analog in combination with a rapid-acting insulin analog or inhaled insulin at meals
- Continuous subcutaneous insulin infusion with an insulin pump; insulin pump therapy is indicated for:
 - Patients who are unable to achieve acceptable control using a regimen of multiple daily injections
 - Patients with histories of frequent hypoglycemia and/or hypoglycemia unawareness
 - Patients who are pregnant
 - Patients with extreme insulin sensitivity (pump therapy facilitates better precision than subcutaneous injections)
 - Patients with a history of dawn phenomenon (these patients can program a higher basal rate for the early morning hours to counteract the rise in blood glucose concentration)
 - Patients who require more intensive diabetes management because of complications including neuropathy, nephropathy, and retinopathy
 - Patients taking multiple daily injections who have demonstrated willingness and ability to comply with prescribed diabetes self-care behavior including frequent glucose monitoring, carbohydrate counting, and insulin adjustment
- Consider adding pramlintide to intensive insulin therapy to enhance glycemic control and to assist with weight management (**grade D**)
- Consider adding an insulin sensitizer to address insulin resistance as needed (**grade C**); exercise caution because of the potential for increased fluid retention when thiazolidinediones are used with insulin
- Instruct patients whose glycemic levels are at or above target while receiving multiple daily injections or using an insulin pump to monitor glucose levels at least 3 times daily (**grade A**)
- Instruct patients whose glycemic levels are above target or who experience frequent hypoglycemia to monitor glucose levels more frequently; monitoring should include both preprandial and 2-hour postprandial glucose levels and occasional 2:00 AM to 3:00 AM glucose levels (**grade C**)
- Instruct insulin-treated patients to always check glucose levels before administering a dose of insulin by injection or changing the rate of insulin infusion delivered by an insulin pump (**grade A**)
- Instruct patients to monitor glucose levels anytime there is a suspected (or risk of) low glucose level and/or before driving (**grade A**)
- Instruct patients to monitor glucose levels more frequently during illness and to perform a ketone test each time a measured glucose concentration is greater than 250 mg/dL (**grade C**)

Table 4.1 Pharmacokinetics of Available Insulin Preparations

Insulin, Generic Name (Brand)	Onset	Peak	Effective Duration
Rapid-acting			
Insulin aspart injection (NovoLog)	5-15 min	30-90 min	<5 h
Insulin lispro injection (Humalog)	5-15	30-90	<5 h

Insulin, Generic Name (Brand)	Onset	Peak	Effective Duration
	min	min	
Insulin glulisine injection (Apidra)	5-15 min	30-90 min	<5 h
Insulin human (rDNA origin) Inhalation Powder (Exubera)	5-15 min	30-90 min	5-8 h
Short-acting			
Regular	30-60 min	2-3 h	5-8 h
Intermediate, basal			
NPH	2-4 h	4-10 h	10-16 h
Long-acting, basal			
Insulin glargine injection (Lantus) ^{a,b}	2-4h ^c	No peak	20-24 h
Insulin detemir injection (Levemir) ^{a,b}	3-8 h	No peak	5.7-23.2 h
Premixed			
75% insulin lispro protamine suspension/25% insulin lispro injection (Humalog Mix 75/25)	5-15 min	Dual	10-16 h
50% insulin lispro protamine suspension/50% insulin lispro injection (Humalog Mix 50/50)	5-15 min	Dual	10-16 h
70% insulin aspart protamine suspension/30% insulin aspart injection (NovoLog Mix 70/30)	5-15 min	Dual	10-16 h
70% NPH/30% regular	30-60 min	Dual	10-16 h

^aMay require 2 daily injections in patients with type 1 diabetes mellitus.

^bAssumes 0.1-0.2 U/kg per injection. Onset and duration may vary significantly greatly by injection site.

^cTime to steady state.

NPH, neutral protamine Hagedorn; h, hour; min, minutes

Patients With Type 2 Diabetes Mellitus

- Aggressively implement all appropriate components of care (medical nutrition therapy, physical activity, weight management regimen, pharmacologic interventions, diabetes self-management education) at the time of diagnosis (**grade A**)
- Persistently monitor and titrate pharmacologic therapy until all glycemic goals are achieved (**grade A**)
 - First assess the patient's current HbA_{1c} level, fasting/preprandial glycemic profile, and 2-hour postprandial glycemic profile to evaluate the level of control and to identify patterns; this will require the patient to obtain comprehensive fasting, preprandial, and postprandial glucose readings over a 7-day period (**grade A**)
 - After initiating pharmacologic therapy based on the patterns identified in the profile, persistently monitor and titrate therapy over the next 2

to 3 months until all American College of Endocrinology/American Association of Clinical Endocrinologists (ACE/AACE) glycemic goals are achieved (**grade A**) (Table 4.2 below shows examples of pharmacologic regimens that are intended to serve as starting points for selecting appropriate therapies. Tables 4.3, 4.4, 4.5, and 4.6 in the original guideline document present information about new medications and currently available oral therapies.)

- If glycemic goals are not achieved at the end of 2 to 3 months of therapy, initiate a more intensive regimen and persistently monitor and titrate therapy over the next 2 to 3 months until all ACE/AACE glycemic goals are achieved (**grade A**)
- Recognize that patients currently treated with monotherapy or combination therapy who have not achieved glycemic goals will require either increased dosages of their current medications or the addition of a second or third medication (**grade A**)
- Consider insulin therapy in patients with HbA_{1c} levels greater than 8% and symptomatic hyperglycemia and in patients with elevated fasting blood glucose levels or exaggerated postprandial glucose excursions regardless of HbA_{1c} levels (**grade A**)
- Initiate insulin therapy to control hyperglycemia and to reverse glucose toxicity when the HbA_{1c} level is greater than 10%; insulin treatment can then be modified or discontinued once glucose toxicity is reversed (**grade A**)
- Consider use of continuous subcutaneous insulin infusion in insulin-treated patients (**grade C**)

Table 4.2 Examples of Pharmacologic Regimens for Treating Type 2 Diabetes Mellitus^a

Patients With Type 2 Diabetes Mellitus Naïve to Pharmacologic Therapy
<p>Initiate monotherapy when HbA_{1c} levels are 6%-7%</p> <ul style="list-style-type: none"> • Options include: <ul style="list-style-type: none"> • Metformin • Thiazolidinediones • Secretagogues • Dipeptidyl-peptidase 4 inhibitors • Alpha-glucosidase inhibitors <p>Monitor and titrate medication for 2-3 months</p> <p>Consider combination therapy if glycemic goals are not met at the end of 2-3 months</p>
<p>Initiate combination therapy when HbA_{1c} levels are 7%-8%</p> <ul style="list-style-type: none"> • Options include: <ul style="list-style-type: none"> • Secretagogue + metformin • Secretagogue + thiazolidinedione • Secretagogue + alpha-glucosidase inhibitor • Thiazolidinedione + metformin • Dipeptidyl-peptidase 4 inhibitor + metformin • Dipeptidyl-peptidase 4 inhibitor + thiazolidinedione • Secretagogue + metformin + thiazolidinedione

- Fixed-dose (single pill) therapy
 - Thiazolidinedione (pioglitazone) + metformin
 - Thiazolidinedione (rosiglitazone) + metformin
 - Thiazolidinedione (rosiglitazone) + secretagogue (glimepiride)
 - Thiazolidinedione (pioglitazone) + secretagogue (glimepiride)
 - Secretagogue (glyburide) + metformin
- Rapid-acting insulin analogs or premixed insulin analogs may be used in special situations
- Inhaled insulin may be used as monotherapy or in combination with oral agents and long-acting insulin analogs
- Insulin-oral medications; all oral medications may be used in combination with insulin; therapy combinations should be selected based on the patient's self-monitoring of blood glucose profiles

Initiate/intensify combination therapy using options listed above when HbA_{1c} levels are 8%-10% to address fasting and postprandial glucose levels

Initiate/intensify insulin therapy when HbA_{1c} levels are >10%

- Options include:
 - Rapid-acting insulin analog or inhaled insulin with long-acting insulin analog or NPH
 - Premixed insulin analogs

Patients with Type 2 Diabetes Mellitus Currently Treated Pharmacologically

The therapeutic options for combination therapy listed for patients naïve to therapy are appropriate for patients being treated pharmacologically

Exenatide may be combined with oral therapy in patients who have not achieved glycemic goals

Approved exenatide + oral combinations:

- Exenatide + secretagogue (sulfonylurea)
- Exenatide + metformin
- Exenatide + secretagogue (sulfonylurea) + metformin
- Exenatide + thiazolidinedione

Pramlintide may be used in combination with prandial insulin

Add insulin therapy in patients on maximum combination therapy (oral-oral, oral-exenatide) whose HbA_{1c} levels are 6.5%–8.5%

Consider initiating basal-bolus insulin therapy for patients with HbA_{1c} levels >8.5%

Abbreviations: HbA_{1c}, hemoglobin A1c; NPH, neutral protamine Hagedorn.

^aThe options listed are in no order of preference.

- Instruct patients whose glycemic levels are at or above target while receiving multiple daily injections or using an insulin pump to monitor glucose levels at

least 3 times daily (**grade B**); although monitoring glucose levels at least 3 times daily is recommended, there is no supporting evidence regarding optimal frequency of glucose monitoring with or without insulin pump therapy

- Instruct insulin-treated patients to always check glucose levels before administering a dose of insulin by injection or changing the rate of insulin infusion delivered by an insulin pump (**grade B**)
- Instruct patients whose glycemic levels are above target while being treated with oral agents alone, oral agents plus once-daily insulin, or once-daily insulin alone to monitor glucose levels at least 2 times daily (**grade C**); there is no supporting evidence regarding optimal frequency of glucose monitoring in these patients
- Instruct patients who are meeting target glycemic levels (including those treated nonpharmacologically) to monitor glucose levels at least once daily (**grade D**)
- Instruct patients whose glycemic levels are above target or who experience frequent hypoglycemia to monitor glucose levels more frequently; monitoring should include both preprandial and 2-hour postprandial glucose levels and occasional 2:00 AM to 3:00 AM glucose levels (**grade B**)
- Instruct patients to obtain comprehensive preprandial and 2-hour postprandial glucose measurements to create a weekly profile periodically and before clinician visits to guide nutrition and physical activity, to detect postprandial hyperglycemia, and to prevent hypoglycemia (**grade B**)
- Instruct patients to monitor glucose levels anytime there is a suspected (or risk of) low glucose level and/or before driving (**grade A**)
- Instruct patients to monitor glucose levels more frequently during illness and to perform a ketone test each time a measured glucose concentration is greater than 250 mg/dL (**grade C**)

Definitions:

Levels of Substantiation in Evidence-Based Medicine^a

Level-of-Evidence Category ^b	Study Design or Information Type	Comments
1	Randomized controlled trials Multicenter trials Large meta-analyses with quality ratings	Well-conducted, well-controlled trials at 1 or more medical centers Data derived from a substantial number of trials with adequate power; substantial number of subjects and outcome data Consistent pattern of findings in the population for which the recommendation is made – generalizable results Compelling nonexperimental, clinically obvious evidence (e.g., use of insulin in diabetic ketoacidosis); "all or none" evidence

Level-of-Evidence Category ^b	Study Design or Information Type	Comments
2	Randomized controlled trials	Limited number of trials, small number of subjects
	Prospective cohort studies	Well-conducted studies
	Meta-analyses of cohort studies	Inconsistent findings or results not representative for the target population
	Case-control studies	
3	Methodologically flawed randomized controlled trials	Trials with 1 or more major or 3 or more minor methodologic flaws
	Nonrandomized controlled trials	Uncontrolled or poorly controlled trials
	Observational studies	Retrospective or observational data
	Case series or case reports	Conflicting data with weight of evidence unable to support a final recommendation
4	Expert consensus	Inadequate data for inclusion in level-of-evidence categories 1, 2, or 3; data necessitates an expert panel's synthesis of the literature and a consensus
	Expert opinion based on experience	
	Theory-driven conclusions	
	Unproven claims	
	Experience-based information	

^aAdapted from the American Association of Clinical Endocrinologists Protocol for the Standardized Production of Clinical Practice Guidelines.

^bLevel-of-evidence categories 1 through 3 indicate scientific substantiation or proof; level-of-evidence category 4 indicates unproven claims.

Recommendation Grades in Evidence-Based Medicine^a

Grade	Description
A	Homogeneous evidence from multiple well-designed randomized controlled trials with sufficient statistical power
	Homogeneous evidence from multiple well-designed cohort controlled trials with sufficient statistical power

Grade	Description
	<p>≥1 conclusive level of evidence category 1 publications demonstrating benefit >> outweighs risk</p>
B	<p>Evidence from at least one large well-designed clinical trial, cohort or case-controlled analytic study, or meta-analysis</p> <p>No conclusive level of evidence category 1 publication; ≥1 conclusive level of evidence category 2 publications demonstrating benefit >> risk</p>
C	<p>Evidence based on clinical experience, descriptive studies, or expert consensus opinion</p> <p>No conclusive level 1 or 2 publication; ≥1 conclusive level of evidence category 3 publications demonstrating benefit >> risk</p> <p>No conclusive risk at all and no conclusive benefit demonstrated by evidence</p>
D	<p>Not rated</p> <p>No conclusive level of evidence category 1, 2, or 3 publication demonstrating benefit >> risk</p> <p>Conclusive level of evidence category 1, 2, or 3 publication demonstrating risk >> benefit</p>

^aAdapted from the American Association of Clinical Endocrinologists Protocol for the Standardized Production of Clinical Practice Guidelines.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Intensive treatment of diabetes mellitus and conditions known to be risk factors can significantly decrease the development and/or progression of chronic complications.

POTENTIAL HARMS

Adverse effects of medications

CONTRAINDICATIONS

CONTRAINDICATIONS

- Pramlintide is contraindicated in patients with hypoglycemia unawareness or a diagnosis of gastroparesis
- Thiazolidinediones contraindicated in patients with:
 - Alanine aminotransferase >2.5 times the upper limit of normal
 - Hepatic disease
 - Alcohol abuse
 - New York Heart Association class III or IV cardiac disease
- Inhaled insulin is contraindicated in patients who have smoked within the previous 6 months or who have unstable or poorly controlled pulmonary disease.
- Biguanides are contraindicated in patients with:
 - Serum creatinine >1.5 mg/dL (men), >1.4 mg/dL (women)
 - Congestive heart failure drug therapy
 - Hepatic disease
 - Alcohol abuse

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Criticism that purely evidence-based clinical practice guidelines do not reflect real life because subjective input is stifled or precluded is addressed to some extent by the American Association of Clinical Endocrinologists (AACE) methodology for developing the guidelines. When the task force members judged that subjective factors influenced the grade of a recommendation to an extent that outweighed the available best evidence, this logic was explicitly described in the detailed discussion that follows each topic section's executive summary. Thus, the process of developing evidence-based recommendations and the incorporation of subjective components are transparent to the reader.
- These methods, nevertheless, have the following shortcomings: (a) reliance on some subjective measures, which compromises reproducibility; (b) dependence on the best available evidence, even if only one study is used to formulate a recommendation grade; and (c) dependence on task force primary authors to perform a comprehensive literature search. Multiple levels of review by both AACE-credentialed and non-AACE-credentialed experts from academia and clinical practice backgrounds serve to address these predicted shortcomings.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

AACE Diabetes Mellitus Clinical Practice Guidelines Task Force. AACE diabetes mellitus guidelines. Glycemic management. *Endocr Pract* 2007 May-Jun;13(Suppl 1):16-34. [178 references]

ADAPTATION

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

DATE RELEASED

2000 Jan (revised 2007)

GUIDELINE DEVELOPER(S)

American Association of Clinical Endocrinologists - Medical Specialty Society
American College of Endocrinology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Association of Clinical Endocrinologists (AACE)

GUIDELINE COMMITTEE

American Association of Clinical Endocrinologists (AACE) Diabetes Mellitus Clinical Practice Guidelines Task Force

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Dr. Lawrence Blonde reports that he has received grant/research support from Amylin Pharmaceuticals, Inc.; AstraZeneca LP; Bristol-Myers Squibb Company; Eli Lilly and Company; MannKind Corporation; Merck & Co., Inc.; Novo Nordisk Inc.; Novartis Corporation; Pfizer Inc.; and sanofi-aventis U.S. He has received speaker and consultant honoraria from Abbott Laboratories; Amylin Pharmaceuticals, Inc.; Eli Lilly and Company; GlaxoSmithKline; LifeScan, Inc.; Merck & Co., Inc.; Novartis, Novo Nordisk Inc.; Pfizer Inc.; and sanofi-aventis U.S. He has received consultant honoraria from Kos Pharmaceuticals, Inc. and U.S. Surgical. Dr. Blonde has also disclosed that his spouse is a stock shareholder of Amylin Pharmaceuticals, Inc. and Pfizer Inc., in an account that is not part of their community property.

Dr. Susan S. Braithwaite reports that she does not have any financial relationships with any commercial interests.

Dr. Elise M. Brett reports that her spouse is an employee of Novo Nordisk Inc.

Dr. Rhoda H. Cobin reports that she has received speaker honoraria from GlaxoSmithKline; Pfizer Inc.; sanofi-aventis U.S.; and Novartis and consultant honoraria from Abbott Laboratories.

Dr. Yehuda Handelsman reports that he has received speaker honoraria from Abbott Laboratories; Amylin Pharmaceuticals, Inc.; AstraZeneca LP; Bristol-Myers Squibb Company; GlaxoSmithKline; Merck & Co., Inc.; Novartis; and sanofi-aventis U.S. and consultant honoraria from Abbott Laboratories; Daiichi Sankyo, Inc.; Novartis; and sanofi-aventis U.S.

Dr. Richard Hellman reports that he has received speaker honoraria from Daiichi Sankyo, Inc. and Pfizer Inc. and research grants for his role as an independent contractor from Abbott Laboratories; Pfizer Inc.; and Medtronic, Inc.

Dr. Paul S. Jellinger reports that he has received speaker honoraria from Eli Lilly and Company; Merck & Co., Inc.; Novartis; Novo Nordisk Inc.; and Takeda Pharmaceuticals North America, Inc.

Dr. Lois G. Jovanovic reports that she has received research grants for her role as investigator from Eli Lilly and Company; DexCom Inc.; LifeScan, Inc.; Novo Nordisk Inc.; Pfizer Inc.; Roche Pharmaceuticals; sanofi-aventis U.S.; and Sensys Medical, Inc.

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Dr. Jeffrey I. Mechanick reports that he does not have any financial relationships with any commercial interests.

Dr. Helena W. Rodbard reports that she has received consultant honoraria from Ortho-McNeil, Inc.; Pfizer Inc.; sanofi-aventis U.S.; and Takeda Pharmaceuticals North America, Inc.; speaker honoraria from Abbott; GlaxoSmithKline; Merck & Co., Inc.; Novo Nordisk; Pfizer Inc.; and sanofi-aventis U.S. and research support from Bidel, Inc. and sanofi-aventis U. S.

Dr. Farhad Zangeneh reports that he has received speaker honoraria from Eli Lilly and Company; GlaxoSmithKline; Novartis; Novo Nordisk Inc.; Pfizer Inc.; Roche Pharmaceuticals; sanofi-aventis U.S.; and Takeda Pharmaceuticals North America, Inc.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previously published version: American Association of Clinical Endocrinologists, American College of Endocrinology. Medical guidelines for the management of diabetes mellitus: the AACE system of intensive diabetes self-management--2002 update. Endocr Pract 2002 Jan-Feb;8(Suppl 1):40-82.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [American Association of Clinical Endocrinologists \(AACE\) Web site](#).

Print copies: Available from the American Association of Clinical Endocrinologists (AACE), 1000 Riverside Avenue, Suite 205, Jacksonville, FL 32204.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- American Association of Clinical Endocrinologists protocol for standardized production of clinical practice guidelines. Endocrine Pract 2004 Jul-Aug; 10(4):353-61.

Electronic copies: Available in Portable Document Format (PDF) from the [American Association of Clinical Endocrinologists \(AACE\) Web site](#).

Print copies: Available from the American Association of Clinical Endocrinologists (AACE), 1000 Riverside Avenue, Suite 205, Jacksonville, FL 32204.

PATIENT RESOURCES

None available

NGC STATUS

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