Guideline Summary NGC-9416

Guideline Title

Management of type 2 diabetes mellitus.

Bibliographic Source(s)

University of Michigan Health System. Management of type 2 diabetes mellitus. Ann Arbor (MI): University of Michigan Health System; 2012 Sep. 27 p. [17 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: University of Michigan Health System. Management of type 2 diabetes mellitus. Ann Arbor (MI): University of Michigan Health System; 2008 Jan. 21 p. [15 references]

Scope

Disease/Condition(s)

Type 2 diabetes mellitus

Guideline Category

Diagnosis

Management

Prevention

Screening

Treatment

Clinical Specialty

Endocrinology

Family Practice

Geriatrics

Internal Medicine

Nephrology

Obstetrics and Gynecology

Preventive Medicine

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To reduce morbidity and mortality by improving adherence to important recommendations for preventing, detecting, and managing diabetic complications

Target Population

Adults seen in primary care settings including those at risk for or diagnosed with diabetes mellitus

Adults seen in primary care settings including those at risk for or diagnosed with diabetes mellitus

Interventions and Practices Considered

Prevention

Diet, exercise, and pharmacologic interventions

Screening

1. Screen for diabetes every 3 years or annually in certain circumstances
2. History for hypertension, gestational diabetes, or other risk factors
3. Routine screening for cardiovascular risk factors (hypertension, hyperlipidemia, tobacco use)

Diagnosis

1. Fasting glucose test and confirmed by second test
2. Oral glucose tolerance test (OGTT)

Treatment

1. Self-management education
2. Lifestyle interventions
3. Goal setting
4. Glycemic management
5. Pharmacologic management of hypertension and hyperlipidemia
6. Prompt treatment for cardiovascular risk factors (hypertension, hyperlipidemia, tobacco use)

Major Outcomes Considered

- Progression from impaired glucose tolerance (IGT) to diabetes
- Efficacy of treatments for diabetes and comorbidities
- Adverse effects of treatments for diabetes and comorbidities
- Incidence of co-morbid conditions, including hypertension, hyperlipidemia, smoking, use of aspirin
- Mortality rate among patient with diabetes
- Psychological status
- Incidence of end-stage outcomes of diabetes including blindness, renal failure, and amputation
- Cost of medical care
- Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The literature search for this update began with the results of the literature searches performed in 1995 to develop the guideline and in 2003 for a major update that included literature through February 2003. The literature search conducted in April 2010 for this update used keywords that were similar to those used in previous searches, with the addition of a few new topics for searches. An exception was made for topics related to the diagnosis of diabetes mellitus. For these topics the recommendations of the American Diabetes Association's guidelines for Diagnosis and Classification of Diabetes Mellitus were accepted.

The searches for treatment were performed prospectively on Medline using the major key words of diabetes mellitus; clinical guidelines, controlled clinical trials, cohort studies; adults; and English language; and published from 1/1/2003 to present. Terms for specific topic searches within the major key words included: pre-diabetes or impaired fasting glucose tolerance; glycemic goal; lifestyle modifications: diet, exercise; treatment for type I diabetes: insulin; treatment for type II diabetes: sulfonylureas, metformin, alpha-glucosidase inhibitors, thiazolidinediones, nonsulfonyluric secretagogues (repaglinide, nateglinide), new insulins (glargine, aspart, lispro), exenatide, amylin, liraglutide; sitaglipitin, saxagliptin; screening and treatment for hypertension, lipids, retinopathy, nephropathy, neuropathy, macrovascular disease; and preconception planning in pregnancy. Specific search terms and strategy available upon request.

The search was conducted in components each keyed to a specific causal link in a formal problem structure. The search was supplemented with very recent clinical trials known to expert members of the panel. Negative trials were specifically sought. The search was single cycle.

Team members identified recent major evidence searches and major clinical trials. The evidence summary and clinical practice recommendations of the American Diabetes Association were the basis for screening and diagnosis recommendations. Glycemic control was based on the United Kingdom Prospective Diabetes Study (UKPDS) for control value and the American Diabetes Association (ADA) recommendations for goal. Life style modifications (diet, exercise) were based on the UKPDS and Diabetes Prevention Program (DPP) studies. The evidence summary and recommendations

were based on the UKPDS and Diabetes Prevention Program (DPP) studies. The evidence summary and recommendations of the National Standards for Diabetes Self-Management Education were the basis for self-management recommendations. Comments about treatment for type 1 diabetes and insulin use are based on the Diabetes Control and Complications Trial (DCCT). Treatment for type 2 diabetes with sulfonylureas and metformin is based on the UKPDS. Screening and treatment of hypertension and lipid levels in type 2 diabetes is based on an evidence review and recommendations performed by the American College of Physicians, which included a member of our team. Screening and treatment for retinopathy were based on a literature review performed by the U.S. Veterans Administration. Recent evidence reviews were not available for the remaining topics.

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

Level of Evidence Supporting a Diagnostic Method or an Intervention

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

Methods Used to Analyze the Evidence

Systematic Review

Description of the Methods Used to Analyze the Evidence

Conclusions were based on prospective randomized controlled trials if available, to the exclusion of other data. If randomized controlled trials were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size. The "strength of recommendation" for key aspects of care was determined by expert opinion.

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

Strength of Recommendation

I. Generally should be performed
II. May be reasonable to perform
III. Generally should not be performed

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

Peer Review

Description of Method of Guideline Validation

Drafts of this guideline were reviewed in clinical conferences and by distribution for comment within departments and divisions of the University of Michigan Medical School to which the content is most relevant: Family Medicine; General Medicine; Geriatric Medicine; and Metabolism, Endocrinology, and Diabetes. The Executive Committee for Clinical Affairs of the University of Michigan Hospitals and Health Centers endorsed the final version.

Recommendations

Major Recommendations

Note from the University of Michigan Health System (UMHS) and the National Guideline Clearinghouse (NGC): The following guidance was current as of September 2012. Because UMHS occasionally releases minor revisions to its guidance based on new information, users may wish to consult the original guideline document for the most current version.

The strength of recommendation (I-III) and levels of evidence (A-D) are defined at the end of the "Major

Recommendations" field.

Note: The following key points summarize the content of the guideline. Refer to the full text for additional information, including detailed information on dosing, possible side effects, and cost of medications for the management of type 2 diabetes.

Key Points

Prevention

In individuals at risk for type 2 diabetes (see Table 1 in the original guideline document), type 2 diabetes can be delayed or prevented through diet, exercise, and pharmacologic interventions *[IA]*.

Screening

Although little evidence is available on screening for diabetes, screening should be considered every 3 years beginning at age 45 or annually at any age if body mass index (BMI) ≥25 kg/m^2 *[IID]*, history of hypertension *[IIB]*, gestational diabetes *[IC]*, or other risk factors.

Diagnosis

A hemoglobin A1c (A1c) of 6.5% or greater, confirmed by a second test, is considered diagnostic of diabetes. Alternatively, diabetes can be diagnosed by two separate fasting glucoses ≥126 mg/dL; with symptoms, a glucose ≥200 mg/dL confirmed on a separate day by a fasting glucose ≥126 mg/dL; or 2-hour postload glucose ≥200 mg/dL during an oral glucose tolerance test *[B]*. (See Table 1 in the original guideline document. See Table 2 in the original guideline document for differential diagnosis of diabetes.)

Treatment

Essential components of the treatment for diabetes include diabetes self-management education, lifestyle interventions, and goal setting (see Table 3 in the original guideline document); glycemic management (see Tables 4-8 in the original guideline document); and pharmacologic management of hypertension (see Table 9 in the original guideline document) and hyperlipidemia.

Screening for Comorbidities and Complications

Routine screening and prompt treatment for cardiovascular risk factors (hypertension, hyperlipidemia, tobacco use) and for microvascular disease (retinopathy, nephropathy, neuropathy) are recommended in the time frames below.

Treatment of Comorbidities and Complications

Management of risk factors and complications is summarized in Table 10 in the original guideline document. Diet, exercise, and pharmacologic interventions should be initiated for:

- Hypertension *[IA]*
- Cardiovascular risk reduction *[IA]*
- Hyperlipidemia *[IA]*
- Diabetes complications as indicated

Each Regular Diabetes Visit	Annually
• Blood pressure measured and controlled *[IA]*. • Check hemoglobin A1c every 3 months if on insulin; every 6 months if on oral agents or diet only and well-controlled *[II]*. Optimize glycemic control *[IA]*. • Review and reinforce diet and physical activity *[IID]*. • Check weight, calculate body mass index (BMI) *[IID]*. • Feet should be inspected at each visit if neuropathy present. Otherwise visual foot exam and neuropathy evaluation annually *[IA]*. • Smoking cessation counseling provided for patients with tobacco dependence *[IB]*. • Review and reinforce key self-management goals (See Table 8 in the original guideline document) *[IA]*.	• Dilated retinal examination by an eye care specialist every 2-3 years if good blood sugar and blood pressure control and previous eye exam was normal; otherwise annually or more frequently as recommended by the eye care provider if diabetic changes *[IB]*. Treatment of retinopathy *[IA]*. • Screen for microalbuminuria if not on an angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) *[IB]*. Prescribe an ACE inhibitor or ARB for microalbuminuria or proteinuria *[IA]*. • Serum creatinine and estimated glomerular filtration rate (eGFR) *[ID]*. • Monofilament testing of feet (see Table 11 in the original guideline document) *[IA]*. • Lipids measured *[IB]* and treated *[IA]*. • Smoking status assessed *[IB]*. • All self-management goals reviewed and reinforced. (See Table 8 in the original guideline document). • Influenza vaccination (annual) and confirm or give pneumococcal and hepatitis B vaccinations.
Special Considerations: Pregnancy. Preconception counseling and glycemic control targeting a normal A1c in women with diabetes mellitus reduces the risk of congenital malformations and results in optimal maternal and fetal outcomes *[IB]*.	

Definitions:

Levels of Evidence

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

Strength of Recommendation

I. Generally should be performed
II. May be reasonable to perform

III. Generally should not be performed

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).

Conclusions were based on prospective randomized controlled trials if available, to the exclusion of other data. If randomized controlled trials were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Improved adherence to important recommendations for preventing, detecting, and managing diabetic complications, which may lead to reduced morbidity and mortality

Potential Harms

Side Effects of Medications

Agents for Glycemic Management

- For metformin, nausea and diarrhea are seen in up to 30% of patients; gastrointestinal side effects are dose related. Metformin extended release (XR) formulation may decrease diarrhea compared to the immediate release.
- Compared to metformin, sulfonylureas have equivalent but less favorable effects on weight and increased risk of hypoglycemia. Additionally, weak evidence indicates that patients treated with sulfonylureas have higher cardiovascular mortality compared to patients treated with metformin.
- Gastrointestinal side effects of alpha-glucosidase inhibitors including abdominal pain, flatulence, and diarrhea are common. These effects usually diminish over time (4-8 weeks), but frequently lead to discontinuation of the drug.
- Due to their side effect profile, thiazolidinediones (TZDs) should be considered third tier agents. TZDs are associated with significant weight gain. The U.S. Food and Drug Administration (FDA) has issued a box warning for both available TZDs due to an increased risk of congestive heart failure (CHF). Therefore these drugs should be avoided in patients with CHF. Both TZDs are associated with fluid retention and peripheral edema, which occur in at least 15% of patients. TZDs are strongly associated with increased fracture risk in post-menopausal women. TZDs may worsen diabetic macular edema. Renal dosage adjustment is not necessary. Pioglitazone has been associated with an increased risk of bladder cancer.
- The most common side effects of incretin mimetic agents are nausea and vomiting. The FDA warns that exenatide may be associated with an increased risk for pancreatitis and subsequent acute renal failure. If pancreatitis is suspected, exenatide should be discontinued. If pancreatitis is confirmed, exenatide should not be restarted unless an alternative etiology for the pancreatitis is identified. Exenatide should be used cautiously in those with glomerular filtration rate (GFR) between 30 and 50, with careful monitoring of renal function and gastrointestinal side effects.
- Symlin is used at mealtimes to augment the effects of insulin on glycemic control. This can cause hypoglycemia which can occur within 3 hours after a symlin injection. Symlin and insulin should never be mixed in the same syringe. Symlin can also suppress appetite and lead to weight loss. Nausea is the most common side effect but improves with time in most patients.

See also, Table 6 in the original guideline document for a summary of side effects and precautions for agents for glycemic control.

Antihypertensive Agents

- The combination of angiotensin-converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs) should be avoided. Although together they reduce blood pressure and proteinuria, they also clearly increase the rate of end-stage renal disease.
- High-dose thiazide diuretics have been reported to have a variety of adverse effects including worsening of hyperlipidemia, hyperuricemia and gout flares, deterioration of glycemic control, impotence, and increased mortality, therefore thiazides should be used at low doses.
- Beta-blockers may decrease high density lipoprotein (HDL) and increase triglyceride levels. In one major trial beta-blockers led to more weight gain and higher requirements for glucose-lowering agents than angiotensin-converting enzyme (ACE) inhibitors. If a beta-blocker is used, it should be cardioselective to minimize side-effects.
- ACE inhibitors can lead to cough in up to 20% of patients. Both ACE inhibitors and angiotensin II receptor blockers (ARBs) can lead to renal insufficiency and hyperkalemia. Therefore careful monitoring of renal function and serum electrolytes is therefore warranted with these agents.

Lipid Lowering Agents

- Avoid prescribing simvastatin 80 mg because of the increased risk of myalgias.
- Careful monitoring of potential drug interactions with statins is critical; many drugs can increase the risk of myalgias

and rhabdomyolysis. See the National Guideline Clearinghouse (NGC) summary of the University of Michigan Health System (UMHS) guideline Screening and Management of Lipids for information regarding drug interactions with statins.

Agents for Treatment of Diabetic Peripheral Neuropathy (PDN)

- Non-steroidal anti-inflammatory drugs (NSAIDS) should be used cautiously for chronic neuropathic pain due to their gastrointestinal and renal side effects that are of concern in this population.
- Tricyclic antidepressants (TCAs) may be used to treat painful neuropathy and their use is supported by research. They should be used with caution in the elderly, started at low doses and titrated to maximize pain relief while minimizing side effects of dry mouth, sedation, orthostatic hypotension, and constipation. Nortriptyline is the preferred tricyclic as it has fewer anticholinergic properties.
- Sedation is a side effect of gabapentin that limits its use.
- The use of carbamazepine and valproate is limited by their side effect profiles.
- As a last option, opioids may be considered, though general use is discouraged. See the NGC summary of the UMHS guideline Managing Chronic Non-Terminal Pain in Adults Including Prescribing Controlled Substances.

Other Potential Harms

Risk of tight control: The major risk of intensive glycemic control is hypoglycemia.

Factors heightening risk of tight glycemic control:

- History of severe hypoglycemia (inability to treat without assistance)
- Hypoglycemia unawareness
- Advanced cardiovascular or cerebrovascular disease
- Autonomic neuropathy (especially cardiac)
- Comorbidities that impair the detection of hypoglycemia (e.g., alteration in mental status, alcoholism, etc.).
- Poor social support

Contraindications

Contraindications

- Metformin should be avoided in patients with reduced creatinine clearance or who are at risk for the rare complication of lactic acidosis (e.g., patients with cirrhosis or severe congestive heart failure [CHF]). It should be withheld in clinical settings such as intravenous contrast administration, surgery, or dehydration.
- Exenatide should not be used in those with glomerular filtration rate (GFR) <30.
- The U.S. Food and Drug Administration has issued a black box warning for both available thiazolidinediones due to an increased risk of CHF; therefore these drugs should be avoided in patients with significant CHF. Thiazolidinediones (TZDs) are associated with fluid retention and peripheral edema, which occur in at least 15% of patients. TZDs are strongly associated with increased fracture risk in post-menopausal women. TZDs may worsen diabetic macular edema.
- Some members of the dihydropyridine class of calcium channel blockers (e.g., nifedipine, felodipine) may increase urinary albumin excretion, and should be avoided in patients with microalbuminuria.
- For patients with any renal impairment, glipizide is preferred. Severe hypoglycemia can occur in patients with significant renal impairment.

See also, Table 6 in the original guideline document for a summary of contraindications to agents for glycemic control.

Qualifying Statements

Qualifying Statements

These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Patient Resources

Staff Training/Competency Material

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)

University of Michigan Health System. Management of type 2 diabetes mellitus. Ann Arbor (MI): University of Michigan Health System; 2012 Sep. 27 p. [17 references]

Adaptation

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

Date Released

1996 May (revised 2012 Sep)

Guideline Developer(s)

University of Michigan Health System - Academic Institution

Source(s) of Funding

University of Michigan Health System

Guideline Committee

Diabetes Mellitus Guideline Team

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Financial Disclosures/Conflicts of Interest

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Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: University of Michigan Health System. Management of type 2 diabetes mellitus. Ann Arbor (MI): University of Michigan Health System; 2008 Jan. 21 p. [15 references]

Guideline Availability

Electronic copies: Available from the University of Michigan Health System Web site

Electronic copies: Available from the University of Michigan Health System Web site.

Availability of Companion Documents

Continuing Medical Education (CME) information is available from the University of Michigan Health System Web site.

Patient Resources

Several patient education resources about diabetes are available from the University of Michigan Health System Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This summary was completed by ECRI on May 20, 1999. The information was verified by the guideline developer on June 17, 1999. This NGC summary was updated by ECRI on October 12, 2004. The updated information was verified by the guideline developer on October 22, 2004. This summary was updated on May 3, 2005 following the withdrawal of Bextra (valdecoxib) from the market and the release of heightened warnings for Celebrex (celecoxib) and other nonselective nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI on January 11, 2006 following the U.S. Food and Drug Administration advisory on rosiglitazone. This summary was updated by ECRI Institute on September 5, 2007 following the U.S. Food and Drug Administration advisory on the Thiazolidinedione class of antidiabetic drugs. This summary was updated by ECRI Institute on November 6, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs. This NGC summary was updated by ECRI Institute on January 23, 2008. The information was verified by the guideline developer on February 11, 2008. This summary was updated by ECRI Institute on March 10, 2008 following the U.S. Food and Drug Administration advisory on Avandia (rosiglitazone maleate). This summary was updated by ECRI Institute on May 1, 2009 following the U.S. Food and Drug Administration advisory on antiepileptic drugs. This summary was updated by ECRI Institute on November 18, 2009 following the U.S. Food and Drug Administration advisory on Byetta (exenatide). This summary was updated by ECRI Institute on November 8, 2010 following the U.S. Food and Drug Administration advisory on Avandia (rosiglitazone). This summary was updated by ECRI Institute on June 27, 2011 following the U.S. Food and Drug Administration advisory on Zocor (simvastatin). This summary was updated by ECRI Institute on April 13, 2012 following the U.S. Food and Drug Administration advisories on Statin Drugs and Statins and HIV or Hepatitis C drugs. This NGC summary was updated by ECRI Institute on December 12, 2012.

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