Oregon Population-Based Guidelines for

Diabetes Mellitus

Fourth Edition

2006

Measuring Quality of Care in Health Systems

Oregon
Diabetes Program

2006 Oregon Population-Based Guidelines for Diabetes Mellitus

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Fourth Edition

Revised June 2006

Oregon Diabetes Coalition

Health Promotion & Chronic Disease Prevention
Oregon Public Health Services
Oregon Department of Human Services

This document is available online:
http://oregon.gov/DHS/ph/diabetes/guidelines.shtml

If you would like this information in an alternative format, please contact the Diabetes Program at the Department of Human Services, 800 NE Oregon Street, Suite 730, Portland, Oregon 97232 or call (971) 673-0984.

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Table of Contents

The Advisory Panel reviewed these guidelines between November 2005 and May 2006, and adopted the following changes:

General/Format Changes:
A new Emerging Issues section introduces three important emerging topics related to patient care: depression, the effect of a periodontal inflammation on glycemic control, and targeted screening for diabetes. Although specific guidelines on these topics are not proposed, these issues merit serious consideration by health systems involved in quality improvement efforts.

Individual adult guidelines for angiotensin converting enzyme inhibitor/angiotensin receptor blocker (ACE/ARB), blood pressure screening, lipid screening, tobacco use assessment and aspirin prophylaxis have been grouped into a new Cardiovascular Health section.

Guidelines to assess quality of care for pediatric patients have been added.

Caution statements regarding use of potentially teratogenic medications have been added where appropriate in the adult guidelines.

The phrase "medical record" has been substituted for "chart."

Levels of evidence for specific guidelines are indicated in each section, using the levels of evidence stated in the American Diabetes Association 2006 clinical practice recommendations as a guide.

References have been updated.

Specific Guideline Changes:
Angiotensin receptor blockers (ARBs) are recognized as interchangeable with ACE inhibitors for treatment of high blood pressure, microalbuminuria and overt nephropathy.

A revised adult guideline recommends that an ACE inhibitor/ARB be initiated for all people with diabetes who are $\geq$55 years of age and have at least one other cardiovascular risk factor.

The definition of microalbuminuria in adults has been changed to one early-morning albumin:creatinine ratio > 30 (µg albumin / mg creatinine).

Adult low-density lipoprotein (LDL) risk categories have been removed, and treatment with statins is recommended if LDL $\geq$130 mg/dl.

The recommended interval for HbA_{1c} testing in adults is 6 months for both type 1 and type 2 diabetes.

Patient education recommendations (now titled "Patient Education and Lifestyle Modification") include a reminder that education should include information regarding the importance of physical activity and monitoring of total carbohydrate intake and calories. An associated body mass index (BMI)-related quality measure has been added.

A revised guideline recommends that a schedule of regular foot examinations be started directly after diagnosis for adult patients with type 1 and type 2 diabetes.

For patients without retinopathy, a revised guideline recommends that eye examinations be performed or interpreted by an ophthalmologist or optometrist. New recommendations have been added for prenatal eye examination and counseling on diabetic retinopathy related to pregnancy. The definition of blindness has been updated.

Oral/dental guidelines now include a recommendation for all adults with diabetes to be referred to a dentist for comprehensive oral evaluation at diagnosis, for oral screening at least every 6 months, and for immediate treatment of an expanded list of oral/dental conditions. Patients without access to regular dental care should receive oral screening and self-care education from their primary care provider every 6 months until they can see a dentist.

Introduction

Purpose of the Guidelines

These guidelines have been developed to define appropriate measures for monitoring the quality of medical care provided to a population of people with diabetes.

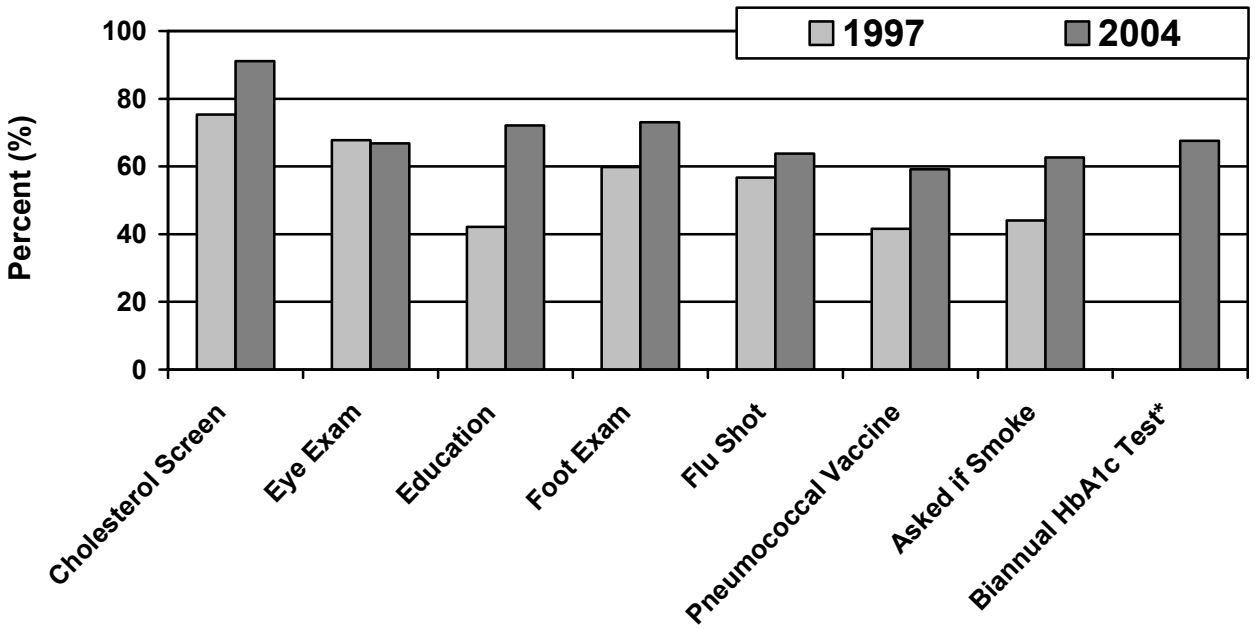
Diabetes is an expensive condition, with estimated costs of over $1.7 billion dollars in Oregon in 2002 for direct and indirect expenses. An estimated 230,000 Oregonians may be at risk of suffering from the complications of diabetes including blindness, end-stage renal disease, heart disease, stroke and lower extremity amputations. Many of the adverse outcomes associated with diabetes are preventable, or at least can be delayed. Good diabetes medical care is an essential component of a strategy to forestall the onset and reduce the severity of complications and to improve the quality of life for Oregonians with diabetes.

Many medical systems and providers are committed to improved quality of care for their patients with diabetes. These guidelines have been created to define a common means to measure the success of the effort. The guidelines do not address all the care a patient with diabetes may need; they are not therapeutic treatment guidelines. Rather, these guidelines are a set of important procedures that are measurable for defined populations and appropriate for systematic monitoring. These guidelines augment clinical practice guidelines such as those of the American Diabetes Association. The evidence for these population-based guidelines is strongest for people aged 18 to 75. The very young and very old may need care which is different from that described here. For the first time, a specific set of guidelines for measuring quality of diabetes care in people under 18 has been included in this revision.

Progress in Better Diabetes Care

The quality of care provided to people with diabetes in Oregon, as measured in these guidelines, has improved. According to statewide surveys of people with diabetes such as the Behavioral Risk Factor Surveillance System (BRFSS) shown in Figure 1, the nine guidelines addressed show improvements. Data from Medicare and from managed care plans also show improvements.

Figure 1: Receipt of Preventive Services in Oregonians with Diabetes, 1997 and 2004
Source: Oregon Behavioral Risk Factor Surveillance System.



*Data are not presented for Biannual HbA_{1c} Test for 1997 because the question used to assess this was significantly different.

How to Use the Diabetes Guidelines

Though these guidelines will find many purposes, they have been specifically designed for use in health systems that provide care to defined populations. By combining recommended procedures with population-based measures of success in delivering those procedures, the stage is set for continuous monitoring and improvement of specific processes of care. Quality improvement programs are urged to use this document to develop improvement projects and to assess their success. Health systems that have a continuous process to (a) identify the population of members who have diabetes (b) track their current status regarding procedures, (c) trigger and support provider actions in response to that information in a timely way, and (d) give aggregate information to the providers of care will be most successful in improving the quality of care described in the guidelines.

How the Guidelines Were Developed

The guidelines were developed through a collaborative effort of clinicians, educators, health plan administrators, epidemiologists, and people with diabetes. Many of the guidelines are based on the results of clinical trials that have demonstrated an effect on the development or progression of specific diabetes complications. In areas where clinical trial research is not available, expert consensus opinion guided development. This 2006 edition is the fourth revision of the guidelines, which were first released in provisional form in October 1995.

The Diabetes Guidelines Format

Each of the 13 adult and 5 pediatric guidelines has two parts:

(1) Quality Measures: These define the **clinical documentation** and the short-, intermediate- and long-term **population measures** that are appropriate to monitor the quality of care within a health system and the outcomes affected by that care. These are useful to organizations and providers developing systems for continuous quality improvement and are summarized in "At A Glance: Population Based Measures."

(2) Clinical Recommendations: These define the relevant **population** to receive specific **procedures** on a certain delivery **schedule**. These recommended procedures are useful to a wide variety of audiences and have been summarized in "At A Glance: Recommended Procedures."

In order to clarify the levels of evidence backing clinical recommendations in this document, evidence grades for specific guidelines are indicated after each clinical recommendation section, using the levels of evidence stated in the American Diabetes Association 2006 *Clinical Practice Recommendations* as a guide.

Table 1. American Diabetes Association Evidence Grading System

Grade	Criteria
A	Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered. Supportive evidence from well-conducted, randomized controlled trials that are adequately powered.
B	Supportive evidence from well-conducted cohort studies. Supportive evidence from well-conducted case-control studies.
C	Supportive evidence from poorly controlled or uncontrolled studies. Conflicting evidence with the weight of evidence supporting the recommendation.
E	Expert consensus or clinical experience.

Diagnostic Criteria
The International Expert Committee sponsored by the American Diabetes Association has defined and described diabetes. See Report of The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus: 25:(Supplement 1), Jan 2002, S140-147.

1. Symptoms of diabetes plus casual plasma glucose concentration $\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

2. Fasting plasma glucose (FPG) $\geq$126 mg/dl (7.0 mmol/l.) Fasting is defined as no caloric intake for at least 8 hours.

or

3. 2-hour 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 WHO,[1] using a glucose load containing the equivalent of 75g anhydrous glucose dissolved in water.

In the absence of unequivocal hyperglycemia with acute metabolic decompensation, these criteria should be confirmed by repeat testing on a different day. The third measure (OGTT) is not recommended for routine clinical use.

[1] World Health Organization: *Diabetes Mellitus: Report of a WHO Study Group.* Geneva, World Health Org., 1985 (Tech. Rep. Ser., no 727)

Emerging Issues

The following topics were discussed at length by the Guidelines Advisory Panel and considered for inclusion in the Guidelines section of this document. While they were not yet supported by the level of evidence required to justify inclusion as formal guidelines, they were felt by the Panel to be of sufficient importance to diabetes care that they warrant discussion in an Emerging Issues section. As the level of evidence grows, these topics may be addressed through formal guidelines in subsequent revisions.

Screening for Depression

Several studies suggest that people with diabetes and other chronic diseases are disproportionately affected by depression. The presence of depression as a co-morbidity impairs people's ability to self-manage their diabetes. People with both diabetes and depression also experience a higher mortality rate than do those with either condition alone.

The U.S. Preventive Services Task Force recommends screening all adults for depression in clinical practices that have systems in place to assure accurate diagnosis, effective treatment, and follow-up. Guidelines to assess extent of screening for and treatment of depression among people with diabetes are not included in this document, in part because screening practices are not standardized, and because there is little evidence in the literature from controlled studies demonstrating that early identification and treatment of depression in people with diabetes result in improved outcomes. Still, screening for depression in people with diabetes should be strongly considered, and when depression is diagnosed, affected people should be offered appropriate therapy and monitored for control of symptoms.

The Effect of Gingival Inflammation Upon Glycemic Control

The association between diabetes and periodontal disease is well recognized. In the setting of diabetes, the extent and severity of oral pathology is inversely related to the degree of glycemic control. Roughly one-third of people presenting for dental care have poor glycemic control, a situation that can jeopardize the safety and effectiveness of dental treatment.

Recent evidence suggests that control of periodontal inflammation in people with type 2 diabetes may result in improved glycemic control. In people with gingivitis in the absence of subgingival pocket formation or loss of alveolar bone, control of inflammation may be achieved with a program of home oral hygiene, including meticulous daily removal of dental plaque biofilm from the gum line. Achieving this level of self-care usually requires ongoing professional instruction. For people with more severe periodontal involvement, professional periodontal treatments are necessary.

Targeted Screening for Diabetes

Prevalence of type 2 diabetes mellitus is increasing. There is evidence that early detection and management for glycemic control decreases microvascular complications (retinopathy and nephropathy) as well as macrovascular complications of diabetes (although the latter findings have been demonstrated only in people with type 1 diabetes).

Pre-diabetes (characterized by impaired fasting glucose, impaired glucose tolerance, or both) carries with it a cumulative 5-year risk of progression to type 2 diabetes of 20-65%. Several large studies have demonstrated that modest weight loss and increases in level of physical activity can forestall or prevent onset of overt diabetes in those with pre-diabetes. Epidemiologic studies suggest that 23% of Americans who are both ≥45 years old and have a body mass index (BMI) of ≥25 have pre-diabetes.

The American Diabetes Association recommends that screening for diabetes and pre-diabetes be considered in adults aged ≥45, particularly those with a BMI ≥25, and other adults with a BMI ≥25 in the presence of other risk factors. The U.S. Preventive Services Task Force recommends screening for diabetes among adults with hypertension or hyperlipidemia.

A measure to assess extent of diabetes screening has not been included in this document for two reasons. First, there have not been randomized, controlled trials to assess the effectiveness of targeted screening programs in improving diabetes outcomes or preventing diabetes. Second, the focus of this document is on the assessment of care among people known to have diabetes, and the Panel recognizes it is unlikely at this time that health systems are routinely collecting information about the specific group of people who are aged ≥45 with a BMI of ≥25 that would be needed to assess such a measure.

Nonetheless, the evidence for benefit from targeted screening for diabetes and pre-diabetes is becoming stronger, and this practice should be strongly considered in the settings outlined above.

Population-Based Measures

Short-term

Percentage of population with newly diagnosed diabetes who have	Initial diabetes education Dental referral
Percentage of diabetes population who have	HbA_{1c} test in past 6 months Microalbuminuria screen in past year Fasting lipid panel in past 2 years Dilated eye exam in past year Visual foot inspection at each routine visit Complete foot exam in past year Blood pressure reading in past 6 months Oral screening in past 6 months Received education about oral hygiene and increased risk for periodontal inflammation Tobacco use assessment Influenza vaccine in past year Pneumococcal vaccine Diabetes education in past five years Documented self-management behavioral goals
Percentage of diabetes population with lipid levels in high-risk category who	Receive lipid-lowering therapy
Percentage of diabetes population using tobacco who receive	Tobacco cessation counseling at each clinic visit
Percentage of diabetes population with new positive findings on dilated eye exam who have	Ophthalmological referral within a week of finding
Percentage of diabetes population with microalbuminuria who have	ACE inhibitor or angiotensin receptor blocker (ARB) prescribed
Percentage of diabetes population with hypertension who have	ACE inhibitor, ARB or thiazide diuretic prescribed
Percentage of diabetes population >age 55 who have ≥1 other CV risk factor	ACE inhibitor or ARB prescribed
Percentage of diabetes population >40 OR who have vascular disease OR vascular risk factors who have	Low dose aspirin prophylaxis prescribed
Percentage of female diabetes population of childbearing potential who receive	Preconception counseling
Percentage of pregnant diabetes population who are	Not taking ACEi/ARB, aspirin therapy or statins during pregnancy and lactation Not exceeding target HbA_{1c} at conception Under prenatal care before 8 weeks gestation

	In receipt of dilated eye exam in first trimester Using oral diabetes therapies indicated as safe in preconception and pregnancy (if using oral therapy)
Percentage of diabetes population who have a preventable acute episode, new complication, or new cardiovascular risk factor who receive	Educational assessment
Percentage of diabetes population starting a new therapy who have	Education regarding the new therapy

Intermediate-term

Incidence within the diabetes population of	Overt nephropathy Oral infections Low-risk levels of HbA_{1c} (<=7.0) Low-risk categorization for fasting lipid profile Emergency room visits and hospital admissions for lower extremity infections Blood pressure <130 systolic, <80 diastolic Tobacco use Former smokers Use of recommended self-management strategies
Incidence in pregnancies complicated by diabetes of	Major congenital malformations Macrosomia (>4000 grams) Stillbirth and spontaneous abortion

Long-term

Incidence within the diabetes population of	Cardiovascular disease Myocardial infarction Cerebrovascular accidents Other tobacco-related diseases Ketoacidosis Severe hypoglycemia End-stage renal disease Blindness Lower extremity amputations Osteomyelitis Infected lower extremity ulcers Periodontal inflammation, untreated caries and tooth loss Influenza Invasive pneumococcal disease Body mass index between 18.5 and 24.9

Recommended Procedures

Initial visit & when indicated	Patient education Preconception counseling Pneumococcal vaccination
Each routine visit	Visual foot inspection Tobacco assessment if under age 25 or former user Tobacco counseling and referral for users Blood pressure measurement
Semiannually	Oral screening HbA_{1c} measurement and risk assessment
Annually	Dilated eye exam Microalbuminuria/proteinuria screening and monitoring Influenza vaccination Preconception counseling assessment Self-management goal development LDL risk assessment and lipid-lowering therapy if indicated Collaborative development of self-management behavioral goals
Annually & when indicated	Complete foot exam with risk categorization, education, and metabolic assessment
Every 5 years	General diabetes continuing education and counseling Assessment of tobacco use (if age >25 and not a former user)
When HbA_{1c} >7	Behavioral/physiological assessment and glucose management plan review
When indicated by positive findings	Dental referral
When indicated by referral criteria	Referral to ophthalmologist experienced in evaluation and treatment of retinopathy
Age 40 OR at onset of vascular disease OR at onset of vascular risk factors	Aspirin prophylaxis
At onset of microalbuminuria OR onset of hypertension OR age >55 (with one other CV risk factor)	ACE inhibitor/ARB therapy

Cardiovascular Health: ACE Inhibitor / Angiotensin Receptor Blocker at Age 55

Quality Measures

Clinical Documentation	Population-based Measures
• Initiation or continuation of ACEi/ARB, or contraindication to its use is documented in the medical record.	Short-term: a successful program will show an increase in the **percentage of population with diabetes who are over age 55 and who are taking an ACE inhibitor or ARB (unless contraindicated).** Long-term: a successful program will contribute to a decrease in the **incidence of myocardial infarction (MI).**

Clinical Recommendations

Evidence for ACEi/ARB at Age 55: *Initial drug therapy for those with blood pressure >140/90 mmHg should be with a drug class demonstrated to reduce CVD events in patients with diabetes (A). All patients with diabetes and hypertension should be treated with a regimen that includes either an ACE inhibitor or an ARB (E). In patients with type 2 diabetes, hypertension, and microalbuminuria, ACE inhibitors and ARBs have been shown to delay the progression of macroalbuminuria (A).*

Category of Patient	Recommended Procedure	Schedule
Persons with type 1 or type 2 diabetes, age 55 or older, with at least one other cardiovascular risk factor. *	Start ACE inhibitor (ACEi) or angiotensin receptor blocker (ARB) unless contraindicated.**	At age 55.

*Hypertension, total cholesterol >200 mg/dl, HDL-cholesterol ≤35 mg/dl, current smoking, or known vascular disease.

** If pregnancy suspected or known, patients should be warned to stop the ACE/ARB immediately, and not restart until lactation is discontinued.

Cardiovascular Health: Blood Pressure Screening

Quality Measures

Clinical Documentation	Population-based Measures
Patient Categories A & B • The blood pressure reading must be documented in the medical record. **Patient Category B** • If the blood pressure is ≥130 systolic or ≥ 80 diastolic, ACE inhibitor/ARB prescription or a contraindication to their use must be documented in the medical record or pharmacy database.	Short-term: a successful program will show an increase in the **percentage of the population with diabetes who have had a blood pressure reading in the past six months.** Short-term: a successful program will show an increase in **ACEi/ARB or thiazide use among the population who have high blood pressure** Intermediate-term: a successful program will show an increase in the **percentage of the population who have blood pressure < 130 systolic, < 80 diastolic.** Long-term: a successful program will show a decrease in the **incidence of** **1. end-stage renal disease,** **2. cerebrovascular accidents (CVA), and** **3. cardiovascular disease.**

Clinical Recommendations

Category of Patient	Recommended Procedure	Schedule
A Persons with type 1 or type 2 diabetes.	**Blood pressure reading** (mmHg).	At each visit, minimum semiannually.
B Persons with type 1 or type 2 diabetes who have documented blood pressure of ≥130 systolic or ≥ 80 diastolic, measured on at least 3 occasions.	Type 1 and type 2: If nonpharmacologic therapy is not achieving goal within 3 months, in addition to lifestyle modifications **start ACE inhibitor, ARB* or thiazide diuretic** (unless contraindicated**) and add other anti-hypertensive as needed to achieve blood pressure control. (Also, see "Expanded Nephropathy and Hypertension Treatment Recommendations" in the Appendix.	At onset of high blood pressure.

*Clinicans may consider a thiazide diuretic as an acceptable first-line alternative for hypertension uncomplicated by microalbuminuria.

** Pre-existing renal dysfunction is not an absolute contraindication to ACEi/ARB use, but requires ongoing monitoring. If pregnancy suspected or known, patients should be warned to stop the ACE/ARB immediately, and not restart until lactation is discontinued.

Evidence for Blood Pressure Screening: *Blood pressure should be measured at every routine diabetes visit. Patients found to have systolic blood pressure ≥130 mmHg or diastolic blood pressure ≥80 mmHg should have blood pressure confirmed on a separate day (C). Patients with a systolic blood pressure of 130-139 mmHg or a diastolic blood pressure of 80-89 should be given lifestyle and behavioral therapy alone for a maximum of 3 months and then, if targets are not achieved, in addition, be treated with pharmacological agents that block the renin-angiotensin system (E).*

Cardiovascular Health: Lipid Screening

Quality Measures

Clinical Documentation	Population-based Measures
• Lab results must be documented in the medical record or in a lab database. • For LDL higher-risk categories, a lipid management plan must be documented in the medical record.	Short-term: a successful program will show an increase in the **percentage of the population with diabetes who have had a fasting lipid profile in the past two years.** Short-term: a successful program will show an increase in the **percentage of the population with lipid levels in the high-risk category who receive lipid lowering therapy.** Intermediate-term: a successful program will show an increase in the **percentage of the population who are in low-risk categories for fasting lipid profile.** Long-term: a successful program will show a decrease in the **incidence of myocardial infarction (MI).**

Clinical Recommendations

Category of Patient	Recommended Procedure	Schedule
A Persons with type 1 or type 2 diabetes, age 18 or older.	Lipid screening. LDL treatment to <100 mg/dl is recommended using pharmacologic and nonpharmacologic means.* Unless contraindicated,** treat high-risk patients aged ≥40 with statins.	Assess annually. If low risk, may decrease frequency to every 1-2 years.
B Persons with type 1 or type 2 diabetes with CAD.	Refer to **ADA and NCEP* algorithms** for risk categorization/treatment approaches.	If higher risk (> optimal) and patient under treatment, see ADA and NCEP guidelines.

NOTE: For patients with triglycerides >200 mg/dl, calculation of non-HDL cholesterol (total minus HDL) is recommended. Target range for non-HDL cholesterol is 30 mg/dl above the stated target for LDL.

*Expert panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults. (2001). Executive summary of the third report of the National Cholesterol Education Program (NCEP) expert panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). Journal of the American Medical Association 285(19), 2486-2497. AND American Diabetes Association (2006). Standards of Medical Care in Diabetes. Diabetes Care 29 (supplement 1), S18-19.

**Statin treatment should be discontinued if pregnancy is anticipated.

Evidence for Lipid Screening: *Test for lipid disorders at least annually and more often if needed to achieve goals. In adults with low-risk lipid values (LDL<100 mg/dl, HDL>50 mg/dl, and triglycerides<150 mg/dl), lipid assessments may be repeated every two years (E).*

Cardiovascular Health: Tobacco Use Assessment

Quality Measures

Clinical Documentation	Population-based Measures
Patient Categories A & B • Tobacco-use status (user/nonuser) must be documented in the medical record. Patient Category B • The type of tobacco use must be documented in the medical record. • Evidence of cessation counseling/referral must be documented in the medical record.	Short-term: a successful program will show an increase in the **percentage of population with diabetes who have been categorized as tobacco users or nonusers.** Short-term: a successful program will show an increase in the **percentage of tobacco users counseled to quit.** Intermediate-term: a successful program will show a decrease in the **percentage of the population with diabetes who use tobacco.** Intermediate-term: a successful program will show an increase in the **percentage of former smokers within the non-smoking population with diabetes.** Long-term: a successful program will contribute to a decrease in the **incidence of myocardial infarction (MI), cerebrovascular accidents (CVA), other vascular disease, and other tobacco-related diseases.**

Clinical Recommendations

Category of Patient	Recommended Procedure	Schedule
A Persons with type 1 or type 2 diabetes.	**Assessment of current tobacco use** (defined as any use, including smokeless, in past 30 days). **Categorization as a user/nonuser.**	At every visit if under 25 years old or past user. Otherwise, every 5 years.
B Persons with diabetes who are tobacco users.	1. **Counsel on tobacco cessation,** in accordance with USPHS guidelines.* 2. If patient is willing to make a quit attempt at time of assessment, **provide assistance** in accordance with USPHS guidelines.*	Each visit.

*A Clinical Practice Guideline for Treating Tobacco Use and Dependence: A U.S. Public Health Service Report (2000). Journal of the American Medical Association 283(24):3244-54.

Evidence for Tobacco Use Assessment: *Advise all patients not to smoke (A). Include smoking cessation counseling and other forms of treatment as a routine component of diabetes care (B).*

Cardiovascular Health: Aspirin Prophylaxis

Quality Measures

Clinical Documentation	Population-based Measures
• Initiation or continuation of ASA prophylaxis, or contraindication to its use is documented in the medical record.	Short-term: a successful program will show an increase in the **percentage of population with diabetes over age 40 who receive ASA (unless contraindicated).** Short-term: a successful program will show an increase in the **percentage of population with diabetes who are under age 40 and have either vascular disease or risk factors for vascular disease who receive ASA (unless contraindicated).** Long-term: a successful program will show a decrease in the **incidence of** **1. myocardial infarction (MI) and** **2. cerebrovascular accidents (CVA)**

Clinical Recommendations

Category of Patient	Recommended Procedure	Schedule
A Persons over age 40 with type 1 or type 2 diabetes	Start **low-dose aspirin (ASA) prophylaxis** (unless contraindicated).* (ASA low-dose prophylaxis ranges from 75 mg daily to 325 mg every other day.)	At age 40.
B Persons age 40 or younger with type 1 or type 2 diabetes with coronary artery disease, cerebrovascular disease, peripheral vascular disease or vascular risk factors including hypertension, cigarette smoking, obesity (> 120% ideal body weight), hyperlipidemia, or albuminuria (>30mg/24hours).	Start **low-dose aspirin (ASA) prophylaxis** (unless contraindicated).* (ASA low-dose prophylaxis ranges from 75 mg daily to 325 mg every other day.)	At onset of coronary artery disease, cerebrovascular disease, peripheral vascular disease, or risk factors.

*Aspirin therapy should be discontinued during pregnancy and lactation. Patients without CVD should not receive combined aspirin/warfarin therapy.

Evidence for Aspirin Prophylaxis: *Use aspirin in those with diabetes and a history of CVD (A), in those with type 2 diabetes >40 years of age or who have additional risk factors (A), and in those with type 1 diabetes who are >40 years of age or have additional risk factors (C).*

Glycosylated Hemoglobin (HbA_{1c}) Monitoring

Quality Measures

Clinical Documentation	Population-based Measures
Patient Categories A & B Lab results must be documented in the medical record or in a lab database. **Patient Category B** A specific management plan with target HbA_{1c} documented in the medical record.	Short-term: a successful program will show an increase in the **percentage of the population with diabetes who had HbA_{1c} measured in the last 6 months.** Short-term: a successful program will show an increase in the **percentage of the population with diabetes who know their HbA_{1c} test results and the significance.** Intermediate-term: a successful program will show an increase in the **percentage of the population with lower risk levels of HbA_{1c} (<= 7.0%).** Long-term: a successful program will show a decrease in the **incidence of nearly all the complications of diabetes, especially the most serious ones:** **1. blindness** **2. end-stage renal disease** **3. lower extremity amputations** **4. cardiovascular events.**

Clinical Recommendations

Category of Patient	Recommended Procedure	Schedule
A Persons with type 1 or type 2 diabetes.	**HbA_{1c} (%) determination and risk categorization** of result: Lower risk: ≤ 7.0% Higher risk: > 7.0%. (see Patient Category B.) Test results and significance shared with patient.	Every 3-6 months.
B Persons with type 1 or type 2 diabetes with higher risk HbA_{1c} (> 7.0%).	1. **Assessment of behavioral and physiological reasons** for unsatisfactory control (e.g., undiagnosed infection, non-adherence, need for medication change, knowledge deficit, undiagnosed mental or physical health condition). 2. **Specific management plan** based on assessment, including a specific HbA_{1c} (or alternative) target, and a specific monitoring schedule. The A_{1c} target may be affected by age, other co-morbid conditions, and other factors.	According to the specific management plan (see #2 under Recommended Procedure).

Evidence for Glycosylated Hemoglobin (HbA_{1c}) Monitoring: *A_{1c} test at least two times a year in patients who are meeting treatment goals (E). A_{1c} test quarterly in patients whose therapy has changed or who are not meeting glycemic goals (E). A_{1c} goal of <7% (B).*

Patient Education and Lifestyle Modification

Quality Measures

Clinical Documentation	Population-based Measures
• Attendance at initial education session is documented in the medical record. • Self-management goals are documented in the medical record. These should reflect behavioral goals,* have evidence of collaborative development (i.e. patient and provider/educator), and have a follow-up plan documented. • There is documentation in the medical record of each general diabetes education session. Follow-up is documented for the above goals. This might include behavior change consistent with the goal(s), and impact on patient quality of life, functioning, or patient satisfaction • Educational assessment is documented in the medical record following development of a preventable acute episode, new onset complication, or new cardiovascular risk factor. • Education regarding new therapy is documented in the medical record following the initiation of that therapy. • Body mass index (BMI) is documented in the medical record.**	Short-term: a successful program will show an increase in the **percentage of the population with diabetes who have received initial diabetes education.** Short-term: a successful program will show an increase in the **percentage of the population with diabetes who have documented self-management goals.*** Short-term: a successful program will show an increase in the **percentage of the population with diabetes who have had general diabetes education in the past five years.** Short-term: a successful program will show an increase in the **percentage of the population with diabetes who received an educational assessment within four weeks of a preventable acute episode, developing a new-onset complication, or a new cardiovascular risk factor**. Short-term: a successful program will show an increase in the **percentage of the population with diabetes starting a new therapy who have received education regarding that therapy.** Intermediate-term: a successful program will show an **increase in the percentage of patients documented to be using recommended self-management strategies**. Long-term: a successful program will show a decrease in **all complications of diabetes, especially a decrease in the incidence of 1) ketoacidosis and 2) severe hypoglycemia.** Long-term: a successful program will show **an increase in the percentage of the population with diabetes whose BMI is between 18.5 and 24.9.**

*Self-management goals may involve targets for levels of appropriate physical activity and moderation of caloric intake.

**BMI = ((weight in pounds / (height in inches x height in inches)) x 703, or use the online BMI calculator at http://www.nhlbisupport.com/bmi/bmicalc.htm.

Clinical Recommendations

Category of Patient	Recommended Procedure	Schedule
A Persons with type 1 or type 2 diabetes.	**Initial education program*** for diabetes, taught by qualified health professional with training in diabetes education.	Type 1: Within 1 week of diagnosis. Type 2: Within 6 weeks of diagnosis.
B Persons with type 1 or type 2 diabetes who have been diagnosed and gone through the initial education program.	**Self-management behavioral goals** developed by patient, physician, and educator. **General diabetes continuing education and counseling.**	Individualized; at least annually. Individualized; at least every 5 years, starting no later than 6 months after diagnosis.
C Persons with type 1 or type 2 diabetes with the following: • Admission for DKA, hypoglycemia, or uncontrolled diabetes • New episode of a specific diabetes complication (e.g., foot problem, nephropathy; retinopathy) • Cardiovascular disease or acute cardiovascular event • New additional risk factor for cardiovascular disease (e.g., hyperlipidemia, hypertension, tobacco use). • Drug/alcohol abuse or other risk factors that could negatively affect glycemic control.	**Educational assessment,** resulting in recommendation regarding need for focused education or other intervention.*	Individualized; within one month of hospital discharge or onset of new complication.
D Persons with type 1 or type 2 diabetes with a major change in therapy (for example, initiation of intensive therapy, or change in medication.)	**Education regarding new therapy.**	At time of initiation of new therapy.

*Education should include information regarding the importance of physical activity (for glycemic control and cardiovascular risk reduction) and of monitoring total intake of carbohydrates (for glycemic control) and calories (for weight management). For specifics of curriculum content, assessment guidelines, and appropriate self-management goals, refer to:

- National Standards for Diabetes Self-Management Education, Diabetes Care 29:(Supplement 1), Jan 2006, S4-42.
- Funnell, MM, Arnold, MS, Lasichak, AJ, Barr, PA. (2002). Type 2 Diabetes: A Curriculum for Patients and Health Care Professionals. American Diabetes Association.
- Funnell, MM, Arnold, MS, Lasichak, AJ, Barr, PA. (2005). Life with Diabetes: a series of teaching outlines by the Michigan Diabetes Research and Training Center. American Diabetes Association. Third edition.
- American Diabetes Association (2006). Standards of Medical Care in Diabetes. Diabetes Care 29 (supplement 1), S11-15.
- Position Statement: Physical Activity/Exercise and Diabetes. Diabetes Care 27 (supplement 1), January 2004, S58-62.
- Position Statement: Nutrition Principles and Recommendations in Diabetes, Diabetes Care 27 (supplement 1) January 2004, S36-46.

Suggestions for Implementation:

- Use certified diabetes educators when available.
- Education is an ongoing process occurring continuously throughout care. It takes place in regular medical visits and from other education resources, including individual and group training classes, printed books and articles available in hardcopy or electronic format.
- Coverage for diabetes supplies and education may vary by insurance carrier. However, Medicare and all state-regulated health care plans are required to provide coverage for diabetes self-management training and blood glucose monitoring supplies.

Evidence for Patient Education: *Diabetes self-management education (DSME) according to national standards at diagnosis and as needed thereafter (B). DSME to be provided by individuals qualified to do so based on their professional training and continuing education (E).*

Eye Examination

Quality Measures

Clinical Documentation	Population-based Measures
Patient Category A • A dilated eye exam* **performed or interpreted** by an ophthalmologist or optometrist must be documented in the medical record. • Positive exam findings must be documented in the medical record. • For those with documented findings meeting referral criteria, a referral to a designated ophthalmologist must be documented in the medical record. **Patient Category B** • The results of the referral exam or consultation must be documented in the medical record. • A revised management plan must be documented in the medical record for patients who will no longer be followed with a routine annual dilated eye exam. • Pre-conception counseling for women of childbearing age and counseling for pregnant women must be documented in the medical record.	Short-term: a successful program will show an increase in the **percentage of the population with diabetes that has had a dilated eye exam in the past year.** Short-term: a successful program will show an increase in **referrals to ophthalmologists among the population with positive findings on a screening dilated eye exam.** Short term: a successful program will show an increase in the **percentage of diabetic women of child-bearing age with documented counseling on the risk of pregnancy causing progression of retinopathy**. Short-term: a successful program will show an increase in the **percentage of pregnant women with a dilated eye exam within the first trimester**. Intermediate-term: a successful program will show an increase in **referrals to ophthalmologists among the population of pregnant women with diabetes with positive findings on a screening dilated eye exam**. Long-term: a successful program will show a decrease in the **incidence of blindness**.

*Any alternative method of retinal screening must be as sensitive in detecting diabetic retinopathy as a dilated retinal examination performed by an optometrist or ophthalmologist.

Clinical Recommendations

Category of Patient	Recommended Procedure	Schedule
A Persons with type 1 or type 2 diabetes *without* previously identified retinal pathology.*	**Dilated eye exam**** performed or interpreted by an ophthalmologist or optometrist. **Pre-conception counseling** for women of child-bearing age.	Type 1: Start within 5 years of diagnosis, then annually. Type 2: Shortly after diagnosis and then annually.*** Pregnant women: screening within the first trimester
B Persons with type 1 or type 2 diabetes *with* positive findings on routine exam*; see "Referral Criteria for Patient Category B," below.	**Examination by ophthalmologist** who is knowledgeable and experienced in the management of diabetic retinopathy.	Exam and/or consult within 1 week after new positive findings meeting referral criteria. Follow up appointments to be determined by the designated ophthalmologist. Pre-conception: counseling on the risk of pregnancy causing progression of retinopathy Pregnancy: close follow-up throughout pregnancy and for one year post partum.

*These recommendations do not apply to women who develop gestational diabetes mellitus, because such individuals are not at risk of diabetic retinopathy.

**Any alternative method of retinal screening must be as sensitive in detecting diabetic retinopathy as a dilated retinal examination performed by an optometrist or ophthalmologist.

***Organizations that can reliably identify patients who 1) are deemed by an eye care professional to require less frequent evaluations and/or type 2 patients who have had diabetes for less than 10 years, 2) who are not on insulin, 3) who have well controlled HbA_{1c}, and 4) whose most recent exam was normal, may determine that biannual exams are sufficient for these patients.

Referral Criteria for Patient Category B:

1. A positive history of sudden, unilateral, uncorrectable vision change.
2. Any evidence of retinopathy associated with unexplained and uncorrectable vision change.
3. Dilated eye exam showing any of the following:

    a. new or abnormal blood vessels on the optic nerve or elsewhere on the retina
    b. any significant abnormality in or near the macula (e.g., hard exudates, hemorrhages beyond dot hemorrhages, or retinal edema)
    c. any other abnormality of concern to the examiner.

4. Inability to adequately visualize retina.

Suggestions for Implementation:

- Designate which providers in your system are fully trained and competent in examining the interior of the eye, for performing the routine dilated eye exam.
- Designate which ophthalmologists in your system are knowledgeable and experienced in the management and treatment of diabetic retinopathy.
- Your system will need an operational definition of blindness for measurement purposes. The legal definition of blindness is corrected vision of 20/200 or worse in the better eye or a visual field of 10 degrees or less in the better eye.

Evidence for Eye Examination: *Initial comprehensive, dilated eye examination by an ophthalmologist or optometrist shortly after diagnosis of diabetes (B). Annual dilated fundiscopic exam (B). Prompt ophthalmologic referral for macular edema, severe nonproliferative diabetic retinopathy, or any proliferative diabetic retinopathy (A).*

Foot Screening

Quality Measures

Clinical Documentation	Population-based Measures
• Results of the visual foot inspection must be documented in the medical record. • An annual risk categorization (including monofilament test, perfusion assessment and inspection for bony deformities) with appropriate screening frequency, must be documented in the medical record.	Short-term: a successful program will show an increase in the **percentage of the population with diabetes who received a visual foot inspection at each routine clinic visit in the past year.** An alternative measure is the **percentage of all diabetes patient visits that included a visual foot inspection.** Short-term: a successful program will show an increase in the **percentage of the population with diabetes who received a complete foot exam and risk categorization in the past year.** Intermediate-term: a successful program will show a decrease in the **incidence of emergency room visits and hospital admissions for lower extremity infections.** Long-term: a successful program will show a decrease in the **incidence of** **1. lower extremity amputations and** 2. **osteomyelitis.**

Clinical Recommendations

Category of Patient	Recommended Procedure	Schedule
Persons with type 1 or type 2 diabetes.	**Visual foot inspection** with shoes and socks off performed by physician, nurse, or other skilled personnel.	Each routine visit.
	1. **Complete foot exam, assessment, and risk categorization** using a specific assessment tool such as the Carville, Veterans Administration (VA), or similar system done by physician, podiatrist, or other specially trained staff. 2. **Education/re-education** for patient self-care of feet. 3. **Reassess metabolic control.** Subsequent foot care management schedule according to Carville, US Veterans Administration, or similar system risk category (see Appendix).	Annually, or when a new abnormality is noted on visual foot inspection.

Suggestions for Implementation:

- Consider adopting the following policy for diabetes clinic visits: *When ready to be examined, the patient will have shoes and socks off*. Consider training other clinic staff to perform visual foot inspections.
- Adopt a specific risk assessment and categorization tool. The Carville system is included in the Appendix; the US Veterans Administration system is available online at http://www.oregon.gov/DHS/ph/diabetes/docs/vaft.pdf.
- Ascertain which providers in your system are fully trained and competent to perform the risk assessment and categorization.

Evidence for Foot Screening: ***Comprehensive foot examination and foot self-care education annually to identify risk factors predictive of ulcers and amputations (B).***

Early Nephropathy Detection

Quality Measures

Clinical Documentation	Population-based Measures
• Screening for microalbuminuria is documented in the medical record for those without existing nephropathy. • ACE Inhibitor/ARB use or contraindication to their use is documented in the medical record among those patients with microalbuminuria.	Short-term: a successful program will show an increase in the **percentage of the population with diabetes who have been screened for urinary protein in the past year and categorized as to whether microalbuminuria or overt nephropathy exists**. Short-term: a successful program will show an increase in **ACE inhibitor/ARB use among the population who have microalbuminuria.** Intermediate-term: a successful program will show a decrease in the **incidence of overt nephropathy.** Long-term: a successful program will show a decrease in the **incidence of end-stage renal disease.**

Clinical Recommendations

Category of Patient	Recommended Procedure	Schedule
A Persons with type 1 or type 2 diabetes and no known microalbuminuria* or overt nephropathy.	**Test for microalbuminuria** using the albumin to creatinine ratio. If positive for microalbuminuria, **quantitative albuminuria measurement.** **If positive for overt nephropathy (> 300 mg/24 hr), treat appropriately.**	Type 1: annually, starting 5 years after diagnosis. Type 2: annually, including after onset of nephropathy for monitoring of progression.
B Persons with microalbuminuria.**	Type 1 and type 2: Start **ACE inhibitor (ACEi) or angiotensin receptor blocker (ARB)** unless contraindicated,*** while maintaining blood pressure control.	At onset of microalbuminuria.

Also, see "Expanded nephropathy and Hypertension Treatment Recommendations" in the Appendix.

*Microalbuminuria is defined as a single early-morning albumin:creatinine ratio >30 (µg albumin / mg creatinine).

**Continued surveillance of microalbuminuria/proteinuria to assess both response to therapy and progression of disease is recommended by some experts.

*** Pre-existing renal dysfunction is not an absolute contraindication to ACEi/ARB use, but requires ongoing monitoring. If pregnancy suspected or known, patients should be warned to stop the ACE/ARB immediately, and not restart until lactation is discontinued.

Evidence for Early Nephropathy Detection: *Annual test for microalbuminuria in type 1 diabetic patients with diabetes duration of ≥5 years and in all type 2 diabetic patients starting at diagnosis and during pregnancy (E). Treatment of micro- or macroalbuminuria with ACE inhibitors or ARBs (except during pregnancy) (A). Continued surveillance of microalbuminuria/proteinuria to assess both response to therapy and progression of disease (E).*

Oral/Dental Screening

Quality Measures

Clinical Documentation	Population-based Measures
• Oral screening and recommendation or referral to dentist is documented in the patient record. • Discussion of oral hygiene and risk of periodontal disease is documented in the patient record. • Tooth loss, caries, and periodontal disease are documented in the patient record.	Short-term: a successful program will show an increase in the **percentage of the population with diabetes who have received oral screening in the past six months.** Short-term: a successful program will **show an increase in the percentage of the population with newly diagnosed diabetes who were referred to a dentist**. Short-term: a successful program will show an increase in the **percentage of the population with diabetes who have received education about oral hygiene and the increased risk for periodontal inflammation with diabetes**. Intermediate-term: a successful program will show a decrease in the **incidence of oral infections.** Long-term: a successful program will show a decrease in the **incidence of periodontal inflammation, untreated caries and tooth loss** among the population with diabetes**.**

Clinical Recommendations

Category of Patient	Recommended Procedure	Schedule
A Newly diagnosed patients with type 1 or type 2 diabetes.	Determine if patient has ongoing dental care. Recommend that patient inform dentist of diabetic diagnosis, undergo comprehensive oral evaluation including complete periodontal exam, and take glucose meter and/or HbA_{1c} report to the dentist. Recommend treatment to eliminate periodontal inflammation, caries and other oral problems.	Within one week of diagnosis.
B Type 1 or type 2 diabetic patients presenting with acute oral problems.*	Refer to dentist.	Within one month.
C Type 1 or type 2 diabetic patients lacking access to dental providers.	**Perform screening** of oral soft tissues (gingiva, dorsal and ventral tongue, palate, floor, buccal mucosa, pharynx) and dentition. Provide patient education materials including oral hygiene instructions and the higher risk for gum inflammation in people with diabetes.	Every 6 months, until patient can visit a dentist.

***Conditions warranting immediate referral to a dental professional:**

- Difficulty chewing food
- "Burning mouth" syndrome
- Oral candida or other mucosal infections
- Gingival inflammation (erythema, edema, bleeding upon probing)
- Clinically visible caries (cavities)
- Marked xerostomia (dry mouth)
- Poor oral hygiene (calculus, dental plaque biofilm, debris)
- Mobile teeth
- Loose dentures
- Potentially cancerous lesions
- Pregnancy or intention to conceive

Suggestions for Implementation:

- Identify dental professionals inside or outside your system to whom you can refer patients. Check the Oregon Dental Association's list of community access programs (www.oregondental.org), call Oregon SAFENET (800-723-3638), or the Oregon Society of Periodontists (call 503-494-8870 for current officers' phone numbers).
- For educational resources contact the American Academy of Periodontology (www.perio.org), the American Dental Association (www.ada.org) and/or www.colgateprofessional.com.
- For technical assistance, contact OHSU School of Dentistry, Department of Periodontology (503-404-8874).

Evidence for Oral/Dental Screening: *Expert opinion (E).*

Immunizations

Immunizations: Quality Measures

Clinical Documentation	Population-based Measures
Patient Category A • Administration of influenza vaccine is documented in the medical record. Patient Category B • Pneumococcal vaccine administration, or history of it, is documented in the medical record.	Short-term: a successful program will show an increase in the **percentage of the population with diabetes who have received an influenza vaccine in the past year.** Short-term: a successful program will show an increase in the **percentage of the population with diabetes who have received a pneumococcal vaccine.** Long-term: a successful program will show a decrease in the **incidence of** **1. influenza and** **2. invasive pneumococcal disease.**

Clinical Recommendations

Category of Patient	Recommended Procedure	Schedule
A Persons with type 1 or type 2 diabetes.	**Influenza vaccine.**	Annually.
B Persons over 2 years old with type 1 or type 2 diabetes.	**23-valent pneumococcal vaccine.**	Once. Revaccinate if (1) at highest risk for illness and not vaccinated in the past 5 years or (2) at age 65 and not vaccinated in the past 5 years.*

*Centers for Disease Control and Prevention. (1997). Prevention of Pneumococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). Morbidity and Mortality Weekly Report 46(RR-08), 1-24.

Evidence for Immunization: *Annual influenza vaccine for all diabetic patients ≥6 months of age (C). Pneumococcal vaccine for adults with diabetes. One-time vaccination for individuals ≥65 years of age previously immunized when <65 years and vaccination occurred >5 years ago (C).*

Preconception Counseling

Quality Measures

Clinical Documentation	Population-based Measures
• Preconception counseling is documented in the medical record. • Documentation in the medical record of either: effective family planning method or achievement of target HbA_{1c} or equivalent.	Short-term: a successful program will show an increase in the **percentage of female patients of childbearing age with diabetes who have had preconception counseling.** Short-term: a successful program will show an increase in the **percentage of pregnant patients with diabetes who** **1. are not taking ACE inhibitors, ARBs, aspirin or statins throughout pregnancy and lactation,** **2. if using oral diabetes therapy, are using drugs indicated as safe for use during preconception and pregnancy,** **3. are not exceeding target HbA_{1c} at conception, and** **4. are under prenatal care before 8 weeks gestation.** Intermediate-term: a successful program will show a decrease in the **incidence of** **1. major congenital malformations,** **2. macrosomia (> 4000 grams), and** **3. stillbirth and spontaneous abortion.**

Clinical Recommendations

Category of Patient	Recommended Procedure	Schedule
Women with type 1 or type 2 diabetes of childbearing potential.	**Preconception counseling to include:** • education regarding importance of meeting target blood glucose control prior to pregnancy • importance of obtaining management early in pregnancy • potential risks to mother and fetus • family planning method • need to review current medications for safety in pregnancy • need to replace any use of ACE inhibitors, ARB, aspirin or statins **Assess understanding and need for additional conception counseling and reminders.**	Minimum at initial visit or upon reaching childbearing age. Additionally when patient indicates change in pregnancy probability or when annual assessment identifies need. Additionally when patient presents for pregnancy testing or requests contraception. Annually.
Women with type 1 or type 2 diabetes actively seeking, or at high risk for, pregnancy	**Preconception counseling to include:** • Active management of capillary blood glucose (CBG) • Detailed contraceptive counseling, and clear instructions to continue effective contraception until CBGs or HbA_{1c} normalized • Careful review of other risk factors (e.g., tobacco use or co-morbidities such as hypertension) • Consultation with other relevant specialists for medical management of other conditions **Consider consultation with perinatologist.**	Minimum six months prior to woman trying to conceive. Additional visits as necessary to achieve goals prior to conception.

<u>Evidence for Preconception Counseling:</u> ***Need for family planning and education about importance of good glycemic control before pregnancy in all women with diabetes and child-bearing potential (E).***

Oregon Pediatric Population-Based Diabetes Guidelines

2006 Pediatric Guidelines At a Glance

Population-Based Measures

Short-term

Percentage of pediatric diabetes population who have	HbA_{1c} test in past 6 months Blood pressure reading in past 6 months Documentation of risk of progression to hypertension and advice on lifestyle interventions
Percentage of pediatric diabetes population over age 10 years with type 1 diagnosis for >5 years	Dilated eye exam in past year Microalbuminuria screen and nephropathy risk categorization in past year
Percentage of pediatric diabetes population over age 10 years with type 2 diagnosis	Dilated eye exam in past year Microalbuminuria screen and nephropathy risk categorization in past year
Percentage of pediatric diabetes population with new positive findings on dilated eye exam who have	Ophthalmological referral within a week of finding
Percentage of pediatric diabetes population with persistent microalbuminuria who have	ACE inhibitor or ARB prescribed, and/or short-term documented periods of improved glycemic control
Percentage of pediatric diabetes population with hypertension who have	ACE inhibitor or ARB prescribed
Percentage of pediatric diabetes population with no family history of hypercholesterolemia or CV event before age 55	Fasting lipid profile at onset of puberty, repeated every five years if low risk, annually if LDL ≥ 100 mg/dl.
Percentage of pediatric diabetes population with family history of hypercholesterolemia or CV event before age 55	Fasting lipid profile at 2 years of age, repeated at puberty or every 5 years if low risk, at least annually if LDL ≥ 100 mg/dl.

Intermediate-term

Incidence within the pediatric diabetes population of	Overt nephropathy HbA_{1c} levels in age-specific target range (< 6 years: 7.5 – 8.5%; 6-12 years: <8%, 13-19 years: <7.5%) Normalized blood pressure (successful treatment to <90th percentile for age) LDL < 100 mg/dl

Recommended Procedures

Each routine visit, minimum semiannually	Blood pressure measurement
Every 3-6 months	HbA_{1c} measurement (type 1)
Semiannually	HbA_{1c} measurement (type 2)
Annually after age 10	Microalbuminuria/proteinuria screening and monitoring (type 2) Dilated eye exam (type 2)
Annually	Fasting lipid profile and LDL risk assessment (high risk)
Annually after age 10 (and > 5 years after Type 1 diagnosis)	Dilated eye exam (type 1) Microalbuminuria/proteinuria screening and monitoring (type 1)
When indicated	Fasting lipid profile and LDL risk assessment (low risk)
When indicated by referral criteria	Referral to ophthalmologist experienced in evaluation and treatment of retinopathy

Pediatric Glycosylated Hemoglobin Monitoring

Quality Measures

Clinical Documentation	Pediatric Population-Based Measures
• Lab results must be documented in the medical record or in a lab database. • For pediatric diabetes patients with HbA_{1c} levels out of target range, a specific management plan with target HbA_{1c} must be documented in the medical record. Documented plan may include mitigation of factors that limit or preclude management of patient within target range.	Short-term: a successful program will show an increase in the **percentage of the pediatric population with diabetes who had HbA_{1c} measured in the past 6 months.** Intermediate-term: a successful program will show an increase in the **percentage of the pediatric population with diabetes whose HbA_{1c} is in the age-appropriate target range.**

Clinical Recommendations

Category of Patient	Recommended Procedure	Schedule
Type 1 Diabetes Toddlers and preschoolers (<6 yrs.) School age (6-12 yrs.) Adolescents and young adults (13-19 yrs.)	*__Target HbA_{1c} (%) goals__: 7.5 - 8.5% < 8 % < 7.5 %	Every 3 – 6 months
Type 2 Diabetes School age (6-12) and Adolescents/young adults (13-19)	Follow type 1 guidelines	Every 6 months

* HbA_{1c} goals should be higher than those listed above in children with frequent hypoglycemia or hypoglycemia unawareness.

Evidence for Pediatric Glycosylated Hemoglobin Monitoring: Expert opinion (E).

Pediatric Eye Examination

Quality Measures

Clinical Documentation	Pediatric Population-Based Measures
Patient Category A • A dilated eye exam* performed or interpreted by an ophthalmologist or optometrist must be documented in the medical record. • Positive exam findings must be documented in the medical record. • For those documented findings meeting referral criteria, a referral to a designated ophthalmologist must be documented in the medical record. **Patient Category B** • The results of the referral exam or consultation must be documented in the medical record. • A revised management plan must be documented in the medical record for patients who will no longer be followed with a routine annual dilated eye exam.	Short-term: a successful program will show an increase in the **percentage of the pediatric population over age 10 years with type 1 diabetes *and diabetes for at least 5 years* who have had a dilated eye exam in the past year.** Short-term: a successful program will show an increase in the **percentage of the pediatric population over age 10 years with type 2 diabetes who have had a dilated eye exam in the past year** Short-term: a successful program will show an increase in the **referrals to ophthalmologists among the pediatric population with diabetes with positive findings on a screening dilated eye exam.**

***Any alternative method of retinal screening must be as sensitive in detecting diabetic retinopathy as a dilated retinal examination performed by an optometrist or ophthalmologist.**

Referral Criteria for Patient Category B:

1. A positive history of sudden, unilateral, uncorrectable vision change.
2. Any evidence of retinopathy associated with unexplained and uncorrectable vision change.
3. Dilated eye exam showing any of the following:
    - a. new or abnormal blood vessels on the optic nerve or elsewhere on the retina
    - b. any significant abnormality in or near the macula (e.g., hard exudates, hemorrhages beyond dot hemorrhages, or retinal edema)
    - c. any other abnormality of concern to the examiner.
4. Inability to adequately visualize retina.

Suggestions for Implementation:

- Designate which providers in your system are fully trained and competent in examining the interior of the eye, for performing the routine dilated eye exam.
- Designate which ophthalmologists in your system are knowledgeable and experienced in the management and treatment of diabetic retinopathy.
- Your system will need an operational definition of blindness for measurement purposes. The legal definition of blindness is corrected vision of 20/200 or worse in the better eye or a visual field of 10 degrees or less in the better eye.

Clinical Recommendations

Category of Patient	Recommended Procedure	Schedule
A Persons under age 18 with type 1 or type 2 diabetes *without* previously identified retinal pathology.	**Dilated eye exam* performed or interpreted** by an ophthalmologist or optometrist	Type 1 diagnosis > 5 years: annually after age 10. Type 2: Annually after age 10.
B Persons under age 18 with type 1 or type 2 diabetes *with* positive findings on routine exam; see "Referral Criteria for Patient Category B," below.	**Examination by ophthalmologist** who is knowledgeable and experienced in the management of diabetic retinopathy.	Exam and/or consult within 1 week after new positive meeting referral criteria. Follow up appointments to be determined by the designated ophthalmologist.

*Any alternative method of retinal screening must be as sensitive in detecting diabetic retinopathy as a dilated retinal examination performed by an optometrist or ophthalmologist.

***Evidence for Pediatric Eye Examination*:** Expert opinion (E).

Pediatric Early Nephropathy Detection

Quality Measures

Clinical Documentation	Pediatric Population-Based Measures
• Screening for microalbuminuria is documented in the medical record for those without existing nephropathy. • ACE inhibitor/ARB use (or contraindication to its use) or short-term (i.e. 6 month) period of improved glycemic control is documented in the medical record among those patients with microalbuminuria.	Short-term: a successful program will show an increase in the **percentage of the pediatric population over age 10 years with type 1 diabetes *and diabetes for at least 5 years* who have been screened for urinary protein in the past year and categorized as to whether microalbuminuria or overt nephropathy exists**. Short-term: a successful program will show an increase in the **percentage of the pediatric population over age 10 years with type 2 diabetes who have been screened for urinary protein in the past year and categorized as to whether microalbuminuria or overt nephropathy exists**. Short-term: a successful program will show an increase in the percentage of **the population who have microalbuminuria with** in **ACE inhibitor/ARB use and/or short term (i.e. 6 month) periods of documented improved glycemic control.** Intermediate-term: a successful program will show a decrease in the **incidence of overt nephropathy (> 300 mg protein/24 hr) among the pediatric population with diabetes.**

Clinical Recommendations

Category of Patient	Recommended Procedure	Schedule
A People under age 18 with type 1 or type 2 diabetes and no known microalbuminuria or overt nephropathy	**Test for microalbuminuria** using the albumin to creatinine ratio on a random urine sample (positive if ratio ≥ 30 [ug microalbumin/mg creatinine]). If random positive for microalbuminuria, **obtain overnight urine sample for microalbuminuria measurement.** If overnight urine samples are persistently positive (i.e. at least two positive samples) within six months (category B), or one positive with hypertension (category C), treat appropriately as defined below.	Type 1: Annually after age 10 and has had diabetes for 5 years. Type 2: Annually after age 10.
B People under age 18 with type 1 or type 2 diabetes with persistent overnight micro-albuminuria and no hypertension (BP < 130/80 or less than 95th percentile for age, sex and height*).	Type 1 and type 2: Start **ACE inhibitor or angiotensin receptor blocker** (unless contraindicated) or a short-term (i.e. 6 month) trial period of documented improved glycemic control.	At onset of microalbuminuria.
C People under age 18 with type 1 or type 2 diabetes with persistent microalbuminuria and hypertension (controlled or uncontrolled).	Type 1 and type 2: Add or substitute **ACE inhibitor or angiotensin receptor blocker** (unless contraindicated) while maintaining blood pressure control.	At onset of microalbuminuria and hypertension.

*Normal blood pressure levels for age, sex, and height and appropriate methods for determination are available online at: www.nhlbi.nih.gov/health/prof/heart/hbp/hbp_ped.pdf

Evidence for Pediatric Early Nephropathy Detection: *Expert opinion (E).*

Pediatric Blood Pressure Screening

Quality Measures

Clinical Documentation	Pediatric Population-Based Measures
Patient Categories A, B, C • The blood pressure reading must be documented in the medical record.	Short-term: a successful program will show an increase in the **percentage of the pediatric population with diabetes who have had a blood pressure reading in the past six months.** Short-term: a successful program will show an increase in **documentation of risk of progression to hypertension and advice on lifestyle interventions among the pediatric population with diabetes.** Short-term: a successful program will show an increase in **ACE inhibitor/ARB use for pediatric patients with diabetes and hypertension.** Intermediate-term: a successful program will show an increase in the **percentage of the pediatric population with diabetes and high normal blood pressure whose pressures have normalized.** Intermediate-term: a successful program will show an increase in the **percentage of the pediatric population with diabetes and high normal blood pressures who have been considered for treatment if blood pressure has not normalized.** Intermediate-term: a successful program will show an increase in the **percentage of the pediatric population with diabetes and hypertension successfully treated to blood pressures < 90th percentile for age.**

Clinical Recommendations

Category of Patient	Recommended Procedure	Schedule
A Patients with type 1 or type 2 diabetes.	**Blood pressure reading** (mmHg). Blood pressure screening is defined as an average systolic blood pressure percentile for age, sex and height measured on at least 3 separate days.	At each visit. Minimum semi-annually.
B (High normal blood pressure) *Systolic and/or diastolic > 90^{th} but < 95^{th} percentile for age	**Treatment of high-normal blood pressure** should include dietary intervention and exercise, aimed at weight control and increased physical activity, if appropriate. If target blood pressure is not reached within 3-6 months of lifestyle intervention, pharmacologic treatment should be initiated. ACE inhibitors or angiotensin receptor blockers are initial drugs of choice.	At onset of high normal blood pressure.
C (Hypertension) * Systolic and/or diastolic $\geq 95^{th}$ % for age.	Pharmacologic treatment of persistent hypertension should be initiated as soon as the diagnosis is confirmed.	At onset of hypertension.

*Normal blood pressure levels for age, sex, and height and appropriate methods for determination are available online at: www.nhlbi.nih.gov/health/prof/heart/hbp/hbp_ped.pdf

***Evidence for Pediatric Blood Pressure Screening*:** Expert opinion (E).

Pediatric Lipid Screening

Quality Measures

Clinical Documentation	Pediatric Population-Based Measures
• Lab results must be documented in the medical record or in a lab database. • For LDL higher-risk categories, a lipid management plan must be documented in the medical record.	Short-term: a successful program will show an increase in the **percentage of the pediatric population with diabetes who have had a fasting lipid profile according to schedule listed previously.** Short-term: a successful program will show an increased **percentage of the pediatric population with diabetes in high-risk lipid categories who are receiving treatment.** Intermediate-term: a successful program will show an increase in the **percentage of the pediatric population with diabetes who are in low-risk categories for fasting lipid profile.**

Clinical Recommendations

Category of Patient	Recommended Procedure	Schedule
A Persons under age 18 with type 1 or type 2 diabetes and no family history of hypercholesterolemia or cardiovascular event before age 55.	High Risk: LDL>160 mg/dl. Consider treatment with lipid lowering agents and lifestyle change. Moderate Risk: LDL 130-160 mg/dl. Lifestyle change emphasizing decreased dietary fat and exercise. Consider lipid lowering agents if no decline in LDL in 6 months. Target LDL: <100 mg/dl	Initial fasting lipid profile at onset of puberty. • If LDL < 100 mg/dl repeat in 5 years. • If LDL $ 100 mg/dl repeat at least annually.
B Persons under age 18 with type 1 or type 2 diabetes and family history of cardiovascular event before age 55 or hypercholesterolemia.	High Risk: LDL > 130 mg/dl. Consider treatment with lipid lowering agents and lifestyle change. Target LDL: <100 mg/dl	Initial fasting lipid profile at > 2 years of age. • If LDL < 100 mg/dl: Repeat at puberty or after 5 years if already pubertal. • If LDL $ 100 mg/dl: Repeat at least annually.

Note: Safety and effectiveness of some statin medications (i.e. atorvastatin) has been established in males and females 10 to 17 years of age in doses up to 20 mg per day. Larger doses have not been studied in this population. Safety in pregnancy has not been established. Therefore adolescent females should be counseled on appropriate contraceptive methods while on statin therapy.

Note: Calculated LDL acceptable to use if triglycerides < 400 mg/dl. If triglycerides > 400 mg/dl, a direct method of measuring LDL is necessary.

Evidence for Pediatric Lipid Screening: Expert opinion (E).

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Appendix A.

Carville Foot Screen

Fill in the following blanks with a "Y" or "N" to indicate findings on the right or left foot.	**R**	**L**
Is there a foot ulcer now or history of a foot ulcer?		
Is there elevated skin temperature?		
Is there swelling or an abnormal shape in the foot?		
Are the toenails thick or ingrown?		
Is there callus build-up?		
Is there muscle weakness?		
Is there high pressure on the Harris mat test?		
Are the pulses absent? - Dorsalis Pedis / Posterior Tibialis	/	/
Can the patient see the bottom of their feet?		
Is the patient wearing improperly fitting footwear?		

Note the level of sensation in circles:

(Use this space to draw feet)

+ = Can feel 5.07 filament
- = Can't feel 5.07 filament

Draw in: Callus ☐ Pre-ulcer/ulcer ☐ (Note width/depth in cm.)

and label: Skin condition with R-redness, D-discoloration, M-maceration, Y-dryness

Risk Category:
0 No loss of protective sensation.
1 Loss of protective sensation.
2 Loss of protective sensation with high pressure (callus/deformity), or poor circulation.
3 History of plantar ulceration or neuropathic fracture (Charcot foot)

Developed by
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Carville Foot Risk Assessment

Risk Categories	Management Categories
Risk Category 0 Has a disease that leads to insensitivity Has protective sensation Has not had a plantar ulcer	Management Category 0 Examine feet at each visit or at least 4 times/year Foot clinic once a year Patient education
Risk Category 1 Does not have protective sensation Has not had a plantar ulcer Does not have a foot deformity	Management Category 1 Examine feet at each visit or at least 4 times/year Foot clinic visit every 6 months Soft insoles - Plastazote, PPT, etc. Patient education
Risk Category 2 Does not have protective sensation Has not had a plantar ulcer Does have a foot deformity	Management Category 2 Examine feet at each visit or at least 4 times/year Foot clinic visit every 3-4 months Custom molded insoles Prescription footwear Patient education
Risk Category 3 Does not have protective sensation Has a history of plantar ulcer	Management Category 3 Examine feet at each visit or at least 4 times/year Foot clinic visit every 1-2 months Custom molded insoles Prescription footwear Patient education

Appendix B.

Expanded Nephropathy and Hypertension Treatment Recommendations

Category of Patient			Recommendations	
Overt Nephropathy (macroalbuminuria)	**Hypertension (BP ≥ 130/80)**	**Microalbuminuria (µg albumin / mg creatinine > 30)**	**Type 1 Diabetes**	**Type 2 Diabetes**
Yes	Presence or absence of hypertension does not determine the recommendation.	Not applicable	1. Control BP if elevated 2. Start or continue ACEi/ARB (unless contraindicated)	1. Control BP if elevated 2. Start or continue ACEi/ARB (unless contraindicated)
No	Yes, under control	Yes	Add or substitute ACEi/ARB (unless contraindicated) while maintaining BP control	Consider adding or substituting ACEi/ARB (unless contraindicated) while maintaining BP control
No	Yes, not under treatment	Yes	Start with ACEi/ARB (unless contraindicated), add other antihypertensives as needed to achieve BP control	Start with ACEi/ARB (unless contraindicated), add other antihypertensives as needed to achieve BP control
No	Yes, under treatment, not under control	Yes	If currently taking other antihypertensives, add ACEi/ARB (unless contraindicated)	If currently taking other antihypertensives, add ACEi/ARB (unless contraindicated)
No	Yes, not under treatment	No	Start with ACEi/ARB or thiazide diuretic (unless contraindicated), add other antihypertensives as needed to achieve BP control	Start with ACEi/ARB or thiazide diuretic (unless contraindicated), add other antihypertensives as needed to achieve BP control
No	No	Yes	Start ACEi/ARB (unless contraindicated)	Start ACEi/ARB (unless contraindicated)
Note: these recommendations assume appropriate attention to glucose control, CVD risk factors and patient education.				